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ORIGINAL ARTICLE

Knowledge of Communication Disorders and The Profession of Speech-Language Therapist (SLT) Among Medical and Allied Health Sciences Students

Nur Izzah Sarno[1], Nur Hanisah Tukiran[1*], W.A Wan Aslynn[1]

[1]Department of Audiology and Speech-Language Pathology, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Communication disorders; speech-language therapists; knowledge; students

ABSTRACT

Background: Healthcare professionals, like doctors and allied health sciences professionals, are the first point of contact with patients. Their role involves identifying individuals with communication disorders and referring them to speech-language therapists (SLTs) for further evaluation and management. However, studies have shown a significant lack of awareness regarding the profession of SLTs among healthcare professionals. As medical and allied health sciences students represent the future healthcare workforce, assessing their understanding at the early stage is essential to ensure their comprehensive knowledge of these matters. This study aimed to investigate the knowledge of communication disorders and the profession of SLTs among medical and allied health sciences students, given the critical need to address gaps in understanding among future healthcare professionals. **Methods:** A cross-sectional study was conducted among 201 medical and allied health sciences students at International Islamic University Malaysia (IIUM), Pahang, Malaysia. The Knowledge and Attitude about Communication Disorders and SLT Profession among Publics (KACS-P) questionnaire was distributed using both online platforms and printed questionnaires (paper-pencil format). **Results:** Both groups of students demonstrated a moderate to high level of knowledge of communication disorders and the SLT profession. No significant difference in knowledge levels about communication disorders was observed between medical and allied health sciences students. Nonetheless, there was a significant difference in knowledge levels regarding the SLT profession between medical and allied health sciences students, with the latter demonstrating a superior level of understanding. The academic year does not seem to exert a noteworthy influence on these knowledge levels. **Conclusion:** The study provided insights into the knowledge levels of medical and allied health sciences students regarding communication disorders and the SLT profession, which is crucial for improving their curriculum content and structures to ensure comprehensive patient care in the future.

INTRODUCTION

Effective communication is the cornerstone of human interaction, influencing personal relationships, educational pursuits and professional endeavours. However, individuals facing communication impairments often encounter significant obstacles when navigating social interactions, which can significantly diminish their quality of life (Kavya et al., 2022). This is where speech-language therapists (SLTs) play a crucial role, stepping in to assist individuals in overcoming these hurdles. SLTs are responsible for assessing, diagnosing and providing tailored interventions for those with communication impairments—language impairment, speech disorders, cognitive-communication issues, as well as swallowing disorders for individuals spanning from infancy through the geriatric stage (American Speech-Language-Hearing Association [ASHA], 2017; Annitha et al., 2023).

Patients with communication challenges often interact first with doctors and allied health professionals like physiotherapists and dietitians, prioritising immediate health issues over communication difficulties (Baskaran, 2000). Consequently, they may overlook the 'treatability' of their communication problems and the potential benefits of seeking help from SLTs, leading to undiagnosed and untreated conditions (Chu et al., 2019). Addressing these challenges requires active involvement from healthcare professionals, who serve as patients' primary point of contact. However, a lack of knowledge about SLTs among healthcare professionals can lead to delayed referrals or neglect of care, impacting treatment quality (Alhamidiet al., 2021). To address this gap, it is essential to assess healthcare students' knowledge of SLTs during their training, as they represent the future workforce.

Speech-Language Therapist

SLTs serve an array of settings, including university clinics, public and private schools, and healthcare institutions

* *Corresponding author.*
E-mail address: hanisahtukiran@iium.edu.my

such as hospitals, medical rehabilitation centres, and private centres (Schurr, 2018). In healthcare institutions, SLPs work alongside other healthcare professionals such as medical doctors, audiologists, dietitians, and physiotherapists to provide holistic treatment by catering to those with communication impairments.

In Malaysia, despite having provided services for over 60 years, there still needs to be more SLTs to meet the demand (Chu et al., 2019). Malaysia has only 156 SLTs employed in the Ministry of Health (as of May 15, 2023), and approximately 201 registered with the Malaysian Association of Speech-Language & Hearing (MASH) (Department of Statistics Malaysia, 2023; MASH, 2022). However, the actual number may be higher, as MASH registration is optional. This scarcity is evident, with one SLT responsible for the care of approximately 209,615 individuals in Malaysia, compared to 59.3 SLTs per 100,000 residents in the United States (Ministry of Health of Malaysia [MOH], 2023). Currently, only three public universities in Malaysia offer undergraduate SLT certification: Universiti Kebangsaan Malaysia, Universiti Sains Malaysia, and International Islamic University Malaysia.

Knowledge of The Speech-Language Therapy Profession and Communication Disorders

Several studies have delved into the awareness and perspectives of medical and allied health sciences students regarding the scope of practice of SLTs. A study among final-year Bachelor of Medicine and Bachelor of Surgery (MBBS) students in Pakistan and another among Nepalese MBBS students both revealed a lack of awareness and knowledge about the role of SLTs in the medical field (Adhikary & Bhattarai, 2018; Tariq et al., 2020). Similarly, a cross-sectional survey in India showed that occupational therapy students had relatively higher awareness and understanding of SLTs' role in stroke rehabilitation compared to other allied health science groups (Annitha et al., 2023).

In Malaysia, no known study specifically compares the knowledge of medical and allied health sciences students regarding the SLT profession and communication disorders. Nonetheless, two studies examined public awareness of SLT. One study found that 55.5% of respondents demonstrated a high level of knowledge about the SLT profession, with higher education correlating with greater awareness (Chu et al., 2019). Another study revealed a lack of public awareness of SLT services and professionals, with only 38.5% of respondents having heard or read about SLT, revealing a concerning gap in public knowledge (Tang & Chu, 2021).

In terms of communication disorders, public and professional awareness remains insufficient despite the increasing prevalence of communication disorders globally (Mahmoud et al., 2014). For instance, approximately 10% of the U.S. population experiences communication difficulties, yet only one-fifth receive appropriate evaluation and treatment (Morris et al., 2016). This gap in awareness is also seen among healthcare professionals, raising concerns about the understanding of communication disorders and the importance of speech-language therapy. A significant issue arises as a lack of awareness may cause the adoption of a ‘wait and see’ approach by caregivers of children with speech and language difficulties that contributes to delayed diagnosis and treatment (Chu et al., 2019). This delay can lead to long-term social, emotional, behavioural, and cognitive challenges (Sunderajan & Kanhere, 2019).

While most mentioned studies focused on the public and health professionals, there remains an evident gap in understanding the knowledge of medical and allied health sciences students, who are likely to work closely with SLTs in their future professional roles.

Aims of Study

In response to the above needs, the aims of the current study are threefold. The first aim is to evaluate the knowledge level of the profession of SLT and communication disorders among medical and allied health sciences students. The second aim is to compare the knowledge level of the profession of SLT and communication disorders among medical and allied health sciences students. The final aim is to compare the level of knowledge about communication disorders and the profession of SLT between students with different years of study.

MATERIALS AND METHODS

Study Design

A cross-sectional study was conducted at the International Islamic University Malaysia (IIUM) between February and May 2023. A questionnaire was distributed among students via online platforms and printed questionnaires to assess their knowledge of the SLT profession and communication disorders among medical and allied health sciences students.

Participants

The inclusion criteria of the participants encompassed undergraduate students who are taking any allied health sciences or medical programmes from the first to the fifth year of their studies. Those enrolled in speech-language pathology and audiology courses, however, were excluded. Postgraduate students were also excluded, considering they might have had experience dealing with SLT.

Instrument

The Knowledge and Attitude about Communication Disorders and SLT Profession among Publics (KACS-P) questionnaire was used to evaluate students' knowledge levels. The questionnaire was developed by Chu et al. (2019). Permission to use the questionnaire was obtained from the original author, Chu Shin Ying [email approval, 22 January 2024]. This questionnaire consists of three sections and a total of 35 items. Section A comprises items related to participants' demographic information. Section B contains nine items on knowledge about communication disorders and SLT, presented in multiple-choice and yes/no formats. One of the items in this section consists of five case scenarios in which participants must identify whether the cases need to be seen by a SLT. The scenarios portrayed bilingual individuals and individuals with autism spectrum disorder (ASD), dementia, voice disorder and/or language delay. Section C includes 19 items related to attitudes toward individuals with communication disorders and the SLP profession. However, Section C was excluded from this study, as the focus was solely on investigating the knowledge regarding communication disorders and the SLT profession. The questionnaire has been validated by experts and the reliability of the knowledge and attitude sections was confirmed with Cronbach's alpha values of 0.70 and 0.69, respectively. For this study, the original language of the questionnaire, which was English, remained, considering that the participating students were from the IIUM, in which the primary communication medium is English.

Procedure

The research obtained ethical clearance from the IIUM Research Ethics Committee (IREC) under reference number IREC 2023-KAHS/DASLP18 before commencement. Informed consent and the KACS-P questionnaire were integrated into a Microsoft Form and distributed online and in print. The introduction section provided participants with research details, including purpose, eligibility, procedures, risks and benefits, confidentiality, and anonymity assurances. The survey was shared via platforms like WhatsApp and Telegram, and printed questionnaires were distributed in person. A poster announcing a lucky draw was circulated alongside the survey to encourage participation, and three random respondents were selected as prize recipients.

RESULTS

The total number of participants involved in this study is 201: 101 students from the allied health sciences programmes and 100 from the medical programme. Among allied health sciences students, representation was from five different courses: Dietetics (n=24, 11.9%), Biomedical Sciences (n=40, 19.9%), Physiotherapy (n=10, 5.0%), Medical Imaging (n=13, 6.5%), and Optometry (n=14, 7.0%). All participants were Malaysian. Out of the total, 28 (13.9%) were male and 173 (86.1%) were female, with ages ranging from 20 to 24 years (Mean = 22.19, SD = 1.33).

Most participants (n=138, 68.7%) had heard about communication disorders, with 63 (31.3%) reporting no prior knowledge. Among those familiar, 54 (39.1%) recognised terms like "speech delay" and "language delay or disorder," 22 (15.9%) were aware of aphasia, 18 (13.0%) knew about stuttering, and 12 (8.7%) mentioned deafness or hearing impairment. Table 1 presents further information on the participants.

Table 1: Sociodemographic data of participants.

Sociodemographic Background		**N (%)**
Gender	Male	28 (13.9)
	Female	173 (86.1)
Academic Year	Year 1	36 (17.9)
	Year 2	38 (18.9)
	Year 3	38 (18.9)
	Year 4	53 (26.4)
	Year 5	36 (17.9)
Courses	Medicine	100 (49.8)
	Dietetics	24 (11.9)
	Biomedical Sciences	40 (19.9)
	Physiotherapy	10 (5.0)
	Medical Imaging	13 (6.5)
	Optometry	14 (7.0)
Have you ever heard about communication disorders?		
	Yes	138 (68.7)
	No	63 (31.3)

N = Total number of participants

Prior to the data analyses, the data gathered were assessed for their normality assumption. The z-score for the knowledge levels of communication disorders was 1.49 while for knowledge of the SLT profession was -2.72. Thus, the assumption of normality could only be made for the knowledge of communication disorders. Due to that, analysis using parametric tests like independent t-tests and one-way Analysis of Variance (ANOVA) would only be used for the knowledge of communication disorders. Conversely, data analysis for knowledge of the SLT profession was conducted using non-parametric tests such as the Mann-Whitney U and Kruskal-Wallis test. All p-values were evaluated under the assumption of two-tailed tests.

Knowledge Level of Communication Disorders and the Speech-Language Therapist Profession

Section B was split into two parts: one delving into the knowledge regarding communication disorders and the other into the SLT profession. Each part had a total score of 11, enabling classification into low (0-3), moderate (4-7), and high (8-11) knowledge levels, as used by Chu et al. (2019). For the level of knowledge of communication disorders and the SLT profession, none of the allied health sciences students were in the low category, while 5% (n=5) of medical students did. The percentages of students in the moderate and high categories were comparable for both groups for the knowledge of communication disorders and the SLT professions. It was found that many participants encountered challenges, with only 35.3% (n=71) recognising individuals with voice disorders and 18.4% (n=37) identifying individuals with dementia as someone who may have communication disorders and thus need further evaluation or treatment by SLT. In contrast, a significantly higher percentage correctly identified language delay (n=193, 96%) and ASD (n=187, 93%) as such.

Regarding the knowledge of the SLT profession, most of the participants identified hospitals (n=198, 98.5%) and private practices (n=171, 85.1%) as the primary work settings for SLTs. However, fewer participants mentioned other settings such as schools (n=81, 40.3%) and non-governmental organizations (NGOs) (n=110, 54.7%). In addition, the percentage of students in the high knowledge category regarding the SLT profession was higher for allied health students compared to the medical students, in which the percentage is 62.4% (n=63) and 50% (n=50), respectively. The details of the knowledge level of communication disorders and the SLT profession can be found in Table 2.

Table 2: Knowledge level of communication disorders and the SLT professions among medical and allied health sciences students

Knowledge Level	Communication Disorders N %		SLT Profession N %	
	AHS	Med	AHS	Med
Low (0-3)	0	5 (5.0)	0	5 (5.0)
Moderate (4-7)	52 (51.5)	50 (50.0)	38 (37.6)	45 (45.0)
High (8-11)	49 (48.5)	45 (45.0)	63 (62.4)	50 (50.0)

Note: AHS= Allied Health Sciences; Med= Medical

Comparison of the Knowledge Level between Medical and Allied Health Sciences Students

An independent samples t-test was conducted to compare the knowledge level of communication disorders among allied health sciences and medical students. Allied health sciences students (M = 7.5, SD = 1.33) scored higher than medical students (M = 7.16, SD = 4.1). However, the difference was not significant, p = 0.14.

In addition, a Mann-Whitney U test was conducted to determine if there was a significant difference in knowledge of the SLT profession between both groups of students. Allied health sciences students had a median score of 8.00, which was higher than the medical students, with a median score of 7.50. The Mann-Whitney U test indicated a significant difference in scores between the groups, U = 3948.50, Z = -2.723, and p<0.01.

Comparison of the Knowledge Level between Students in Different Academic Years

A one-way ANOVA and Kruskal-Wallis were conducted to investigate any significant difference in the knowledge level of communication disorders and the SLT professions across students in different academic years. The means and standard deviations for knowledge level of communication disorders for each year of study were as follows: Year 1 (M = 6.86, SD = 2.03), Year 2 (M = 7.32, SD = 1.60), Year 3 (M = 7.55, SD = 1.31), Year 4 (M = 7.43, SD =1.56) and Year 5 (M = 7.33, SD = 1.44). However, the one-way ANOVA revealed no significant difference in the knowledge level across different years of study F (4, 196) = 1.87, p = 0.12.

Moreover, the median score for knowledge of the SLT profession across years of study were as follows: Year 1 (Mdn = 8.00), Year 2 (Mdn = 8.00), Year 3 (Mdn = 8.00), Year 4 (Mdn = 7.00) and Year 5 (Mdn = 8.00). Findings from

the Kruskal-Wallis test also indicate that the academic year did not significantly influence students' knowledge levels of the SLT profession H (4) = 3.73, p = 0.44.

DISCUSSION

This study aims to evaluate and compare the knowledge level of communication disorders and the SLT profession among allied health sciences and medical students. Our findings indicated that most allied health sciences and medical students possessed moderate to high knowledge of communication disorders and the SLT professions. These results align with previous research that found health professionals and students are more likely to be aware of the SLT profession and communication disorders than those in non-medical fields (Hill et al., 2018; Tang & Chu, 2021).

Nonetheless, further analysis of the current findings indicated that allied health students have higher knowledge of the SLT profession than medical students. The result was expected given that past studies have found that allied health students possessed a robust understanding of the role of SLTs (Byrne & Pettigrew, 2009) and the lack of awareness of the roles of SLTs among medical students (Adhikary & Bhattarai, 2018; Tariq et al., 2020). A possible explanation for this discrepancy is that medical education curricula may focus less on interdisciplinary collaboration than allied health sciences programmes (Adhikary & Bhattarai, 2018; Tariq et al., 2020). Due to their comparatively greater exposure to occupations such as SLT, allied health sciences students may be more able to comprehend the significance of the SLT profession in managing patients with communication problems.

Interestingly, the analysis of case scenarios suggests that regardless of participants' education programmes, many of them encountered challenges in recognising the necessities of individuals with voice disorders and dementia to meet SLTs, unlike language delay and ASD. These findings align with a study by Mahmoud et al. (2014), which revealed a significant lack of recognition among participants regarding these conditions as communication disorders. These findings emphasise the crucial role of SLTs not only in diagnosing and treating these conditions but also in raising awareness about them.

Additionally, the study revealed no significant effect of academic year on the knowledge level of communication disorders and the SLT professions, suggesting that the knowledge does not show progressive improvement throughout their academic journey. This may imply potential curriculum limitations. As they will be the future healthcare providers who play critical roles in identifying and referring those with communication disorders, this knowledge gap may contribute to the low number of referrals, delays in diagnosis and reduced interdisciplinary collaboration when they are practising, which could lead to suboptimal patient outcomes (Agbu et al., 2024; Mustaffa Kamal et al., 2012, 2015).

LIMITATIONS

The study's convenience sampling may restrict the generalizability of findings to broader populations of medical and allied health sciences students in Malaysia. Moreover, the overrepresentation of female participants might bias results, potentially overlooking male perspectives. Future research should strive for larger, more diverse samples to enhance representativeness and reliability.

CONCLUSION

The study provides insight into the knowledge of communication disorders and the SLT profession among allied health sciences and medical students in Malaysia. Although both groups of students posed a moderate to high level of knowledge, allied health sciences students have a significantly higher knowledge level than medical students, and the difference could not be seen across the academic year.

This study underscores the importance of integrating knowledge about communication disorders and the SLT profession into healthcare education to produce future health professionals with greater awareness of interdisciplinary collaboration to optimise patient outcomes. Future research should consider exploring the effectiveness of educational interventions designed to bridge these knowledge gaps.

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ORIGINAL ARTICLE

Translation and Adaptation of the *Satisfaction with Amplification in Daily Life (SADL)* Questionnaire into Malay

Nurul Syarida Mohd Sakeri[1], Afira Nadia Ramli[2], Nur 'Azzah Zakaria[1], W. A. Wan Aslynn[1*]

[1]Department of Audiology and Speech Language Pathology, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Department of Audiology, KMI Kuantan Medical Center, Kuantan, Pahang, Malaysia

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amplification; hearing aid user; quality of life; translation studies

ABSTRACT

Background: Most questionnaires designed to assess satisfaction with hearing aid (HA) and its amplification are available in English, primarily benefiting English-speaking users. This can create challenges when distributed to non-English-speaking HA users, as language barriers and culturally inappropriate items may lead to inaccurate reflections of their satisfaction levels. In response, this paper aims to translate and validate the Satisfaction with Amplification in Daily Life (SADL) questionnaire into Standard Malay to better capture the experiences of Malaysian HA users, who predominantly speak Malay. **Methods**: To achieve these aims, the original SADL questionnaire (Cox & Alexander, 1999) was translated and validated through a multi-stage process to ensure cultural relevance and linguistic appropriateness for Malay-speaking participants. The translated questionnaire then underwent content and face validation. **Results:** During translation, several linguistic modifications were made to adjust morphology and syntax for Malay. After content validation, additional revisions were implemented to enhance comprehension for the Malay-speaking population. **Conclusion:** The Malay-translated SADL questionnaire has been meticulously translated and validated, however, further studies involving hearing aid users are encouraged to enhance its test-retest reliability and validity.

INTRODUCTION

Hearing is a critical sensory domain for ensuring a high quality of life. With normal hearing, individuals can communicate effectively, socialise, recognise threats, and fully experience their environment. However, hearing impairment has become a significant global healthcare issue due to its prevalence and long-term impacts on individuals and society. In Malaysia, a survey by the Institute of Public Health found that hearing loss affects 21.57% of the population, equivalent to one-fifth of Malaysians (Cheah & Lim, 2023).

Hearing loss often impairs emotional, social, communication, and educational functions, which can negatively affect a person's quality of life (Alexander & Chen, 2022). One effective intervention for people with hearing impairment is the use of HA, which offer substantial auditory rehabilitation to improve communication. Although the technology has advanced significantly in sound processing, issues such as poor sound clarity and disruptive background noise still limit user satisfaction (Kochkin & Rogin, 2022). To address these challenges, satisfaction surveys are used to collect feedback from hearing aid users, providing manufacturers and professionals with valuable insights to improve their services.

Among the available hearing aid inventories are the Client Oriented Scale of Improvement (COSI) (Dillon, James, & Ginis, 1997), the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox et al., 1999), and the Satisfaction with Amplification in Daily Life (SADL) survey (Cox et al., 1999).

While COSI and APHAB are validated tools focusing on the benefits of hearing aid use, only SADL specifically measures user satisfaction. It has been translated into various languages, including Mandarin, Danish, Spanish, Brazilian Portuguese, and Swedish, though it has yet to be adapted for Malay-speaking users (Wong et al., 2023).

Satisfaction is an essential outcome in HA fitting, reflecting users' emotional experiences with their devices (Alexander & Chen, 2022). Wong, Hickson, & Zhang (2023) define HA satisfaction as a positive emotional response during device use, which may not always correlate directly with the device's measured performance. For example, users may report significant hearing benefits but still feel dissatisfied due to aspects like sound quality (Costanza, Simons, & Barry, 2023). Therefore, understanding the factors contributing to the satisfaction is crucial for optimising the user experience, as audiologists can use this information to help users achieve a higher level of satisfaction.

* *Corresponding author.*
E-mail address: wanaslynn@iium.edu.my

Contributing factors to satisfaction include duration of use and device-related aspects like sound clarity, reliability, and comfort in loud environments (Wong et al., 2023). Kochkin (2022) highlighted that satisfaction influences users' compliance, likelihood to recommend the device, and brand loyalty, with new users often reporting higher satisfaction than experienced users (Costanza et al., 2023). Additionally, Kochkin found that performance, relative to the cost and quality of the sound, is crucial, with satisfaction ratings in these areas sometimes falling below 80%.

Given the importance of accurately capturing social and economic indicators that reflect human needs, self-assessment surveys are valuable tools for measuring patient satisfaction (Theofilou, 2023). Evaluating the effectiveness of rehabilitative services through patient perspectives has gained global acceptance, underscoring the need for a validated Malay version of the SADL to assess satisfaction among HA users in Malaysia. SADL has yet to be adapted or validated in Bahasa Melayu. Without this validation, responses may fail to fully capture cultural nuances and language-specific interpretations, potentially impacting the accuracy and reliability of satisfaction measurements among Malay-speaking users.

Following the gap in the literature, the objectives of this study are: 1) to translate and adapt SADL into Malay and 2) to validate the translated questionnaire so that it can be used to understand the satisfaction level of Malay-speaking HA users.

MATERIALS AND METHODS

The SADL Questionnaire

With 15 items, it assesses HA user satisfaction across four key areas: *Positive Effect, Service and Cost, Negative Features, and Personal Image*. The *Positive Effect subscale* evaluates on communication and social interactions with hearing aids, indicating improvements in users' quality of life. The *Service and Cost* subscale examines satisfaction with support from providers and the affordability of HAs, impacting perceived value. *Negative Features* addresses issues like sound distortion or discomfort, identifying areas where devices may fall short. The *Personal Image* subscale captures users' feelings about how hearing aids affect their self-image and social comfort. Together, these subscales provide both individual and composite satisfaction scores, offering a comprehensive view of the user experience. The SADL questionnaire provides a Global satisfaction score and a profile of subscale scores, which are based on a 7-point scale. Higher scores generally reflect greater satisfaction with hearing aids, whereas lower scores highlight areas that may require improvement. After obtaining the permission from the author, the research group started to translate the English text.

The Translation Process

To develop the Malay version of the SADL, a structured translation process was carried out, adhering to standard translation and adaptation methodologies used in health assessments. Initially, two bilingual translators who are also audiologists translated the original English text. Their expertise in both language and audiology ensured that the specialised terminology used in the questionnaire was accurately rendered. This step is aligned with translation best practices, which recommend involving experts familiar with the subject matter to maintain conceptual and linguistic accuracy (Beaton et al., 2000; Jones et al., 2023).

In Phase 1, the translated texts were reviewed by an expert panel, which comprised a senior audiologist/ academics, a linguist and a research student, to examine potential differences in morphology, syntax, and cultural nuances. This review is crucial in identifying and addressing issues related to cultural relevance and linguistic equivalence (Maneesriwongul & Dixon, 2004). These two texts were then reconciled to achieve the best translation. Following this, the reconciled draft underwent backward translation by another bilingual translator who are not an expert in the field of Audiology. This is to ensure that the background knowledge did not interfere with the translation, which helps identify discrepancies and ensures that the translation is accurate and retains its original meaning (Brislin, 1970; Theofilou, 2023).

Phase 2 of the deliberation process involved analysing the differences found in the backward translation and refining the Malay version. The final version was then validated for both content and face validity, ensuring it was culturally appropriate and methodologically sound for the Malaysian context (Vallerand, 1989). These steps reflect a rigorous process for translation and adaptation, ensuring both linguistic and conceptual equivalence, as outlined in translation studies (WHO, 2023; Beaton et al., 2000). The overview of the process is presented in Figure 1. The linguistic analysis in phases 1 and 2 will be reported in the Results section.

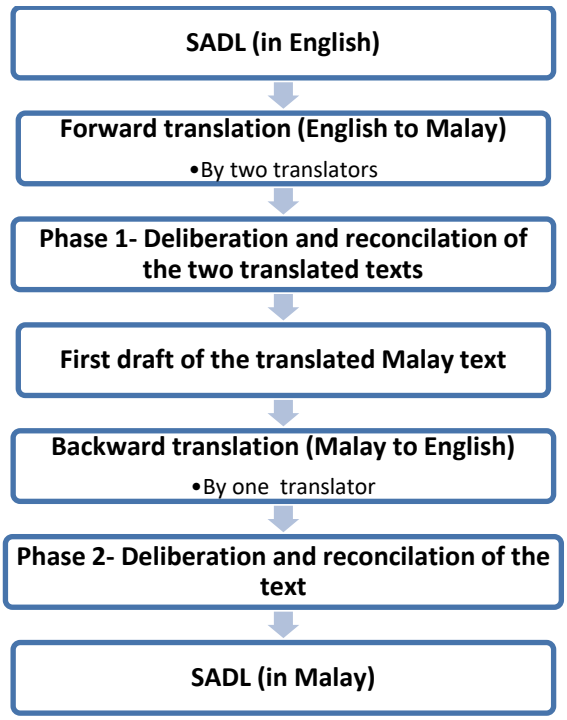

Figure 1: An overview of the translation process

The Validation Process

These newly translated questions were then undergo the content and face validation,

Content validation

The content validation was completed by three different professionals who are linguist, audiologist and speech-language pathologist who were selected for their expertise aligning with Yusoff (2019) recommendation that a minimum of two panellist is sufficient for content validation. The experts were given a set questions to review the scale items and validate whether the instrument appropriately represents the construct. The questions are: 1) Are the instructions well understood?; 2) Does the rating scale accurately measure the items?; 3) Does each item reflect the satisfaction with amplification in daily life?. The experts must rate each item either yes or no.

Face validation

Face validation assesses whether the Malay translated SADL questionnaire appears subjectively appropriate, clear, and relevant to respondents and experts. This is a preliminary validation step to ensure that the items are easy to understand and seem to measure satisfaction with hearing aid as intended. Three normal-hearing-non-experts participated in the face validity assessment to evaluate the organization, appropriateness and logical coherence. As this face validity primarily focuses on whether the instrument appears to measure its intended at face value, no strict minimum number of non-experts is required (Masuwai, 2024). During the process, validators were given time to review all the items and respond with 'Yes' or 'No' to indicate whether the items were understandable and acceptable, along with providing additional comments if necessary.

RESULTS AND DISCUSSION

The Linguistic Analysis

This section will present an analysis of the syntax, semantics and morphology involved in the translation process.

Syntax

Based on the forward translation of the questionnaire, it could be observed that both translators used a direct translation. Table 1 provides a side-by-side comparison of a sentence in English with its translation in Malay in this case. The table shows each component of the sentence broken down by parts of speech, illustrating how each part of the sentence aligns linguistically in the translation process.

The example of the sentence in English: "*Compared to using no hearing aid at all*," is segmented into parts of speech: verb "compared", preposition "to", and noun phrase "no hearing aid at all". The translation renders this as "Berbanding dengan tidak menggunakan alat pendengaran langsung…" where each part of speech in Malay aligns to create an equivalent meaning.

This table highlights both structural and lexical differences between English and Malay. For instance, the Malay translation substitutes "no" with "tidak menggunakan" (meaning "not using"), which alters the sentence structure but preserves the intended meaning. This breakdown is useful for translators to understand how different languages may require adjustments in grammar and syntax to maintain the original meaning and context.

Table 1: Examples of the equivalent of part of syntax structures of English and Malay in the questionnaire for item no. 1

English	Compared	to	using	no	hearing aid	at	all…
Parts of speech	VERB	PREPOSITION	NOUN				
Malay	Berbanding	dengan	tidak menggunakan		alat pendengaran		langsung…

This demonstrates a systematic approach to translation by first identifying parts of speech in the original language to ensure an accurate match in the target language. This process includes semantic adaptation, where phrases are adjusted to fit linguistic norms, even if they differ structurally. Structural flexibility allows certain elements to be added or removed, ensuring natural expression while maintaining the original meaning. This approach aligns the translation to the original sentence's intent, even when direct word-to-word translation is not possible.

Throughout the translation of this questionnaire, similar style of translation is noted. The semantic features were maintained in the target language.

Semantics and morphology

One of the challenges faced during the translation process was selecting Malay words that convey nuances similar to those of the original English terms. For instance, words like 'notice,' 'appearance,' 'natural,' and 'less capable' have several possible equivalents in Malay, as shown in Table 2.

Table 2: Examples of English words with multiple equivalents in Malay

English	Malay equivalents	Linguistic decision
Notice	Perasan Kenyataan	Perasan
Appearance	Penampilan Kemunculan	Penampilan
Natural	Semula jadi Bersahaja	Bersahaja
Less capable	Kurang kemampuan kurang upaya	Kurang upaya

For the word 'notice,' two Malay equivalents were considered: 'perasan' (to notice) and 'kenyataan' (a statement). After careful deliberation, 'perasan' was chosen as it better fits the questionnaire's context. For 'appearance,' two alternatives were identified: 'penampilan' (the way someone looks) and 'kemunculan' (to appear). 'Penampilan' was selected to describe how HA users feel about their appearance with the device. Similarly, the word 'natural' has multiple Malay translations, including 'semula jadi' (natural environment) and 'bersahaja' (to act naturally). For this questionnaire, 'bersahaja' was chosen as it aligns more closely with the intended meaning. Another term requiring semantic decision was 'less capable,' which could be translated as 'kurang kemampuan' (financially unable) or 'kurang upaya' (person with special abilities). After panel discussion, 'kurang upaya' was deemed more appropriate.

The linguistic analysis of the questionnaire translation reveals that translating from English to Malay requires careful consideration of syntax, semantics, and morphology to preserve meaning and ensure cultural appropriateness. The syntactic analysis demonstrates that while direct translation may sometimes be feasible, structural adjustments are often necessary to align with Malay grammatical norms. The example in Table 1 illustrates how specific English sentence components are adapted in Malay, showing how structural flexibility is employed to maintain the sentence's original intent and readability.

Overall, this translation process highlights the importance of linguistic adaptation in cross-cultural contexts, where maintaining the original meaning requires balancing direct translation with context-sensitive modifications. The analysis serves as a valuable guide for translators, underscoring the need for systematic approaches that consider both linguistic and cultural nuances in order to achieve an accurate and effective translation.

The Validation

Content validation

The expert review of the questionnaire content substantiated that the translated questionnaire is suitable for HA users and effectively captures their level of satisfaction with amplification. However, several adjustments were made to ensure the questionnaire is appropriate and relevant for the local population. These changes included refining the overall format and simplifying instructions for clearer understanding (Table 3).

Table 3: Simplification of the Malay instruction following the content validation

English	INSTRUCTIONS Listed below are questions on your opinions about your hearing aid(s). For each question, please circle the letter that is the best answer for you. The list of words on the right gives the meaning for each letter. Keep in mind that your answers should show your general opinions about the hearing aids that you are wearing now or have most recently worn.
Malay	ARAHAN: Berikut adalah soalan-soalan mengenai alat bantu pendengaran anda. Untuk setiap soalan, anda diminta untuk membulatkan huruf yang paling sesuai dengan jawapan anda. Di sebelah kanan anda disediakan panduan pemarkahan iaitu penerangan bagi setiap wakil huruf yang terlibat. Perlu diingatkan bahawa setiap jawapan anda perlu menunjukkan pendapat anda tentang alat bantu pendengaran yang sedang dipakai atau yang pernah dipakai.

Further modifications were also made to the rating scales to ensure all items were applicable (Table 4). Sentence structure revisions were recommended as well; for instance, the phrase "…yang paling kerap dipakai" was modified to "…yang pernah dipakai," and "…percakapan orang lain" was updated to "…percakapan orang yang paling kerap berkomunikasi dengan anda." These revisions aimed to make responses more specific. Another change was made to enhance comprehension: "betapa puaskah anda…" was revised to "adakah anda berpuas hati…" to improve clarity.

Table 4: Changes made to the rating scales of the SADL questionnaire

Original	First translation	Change made after content validation
Medium	Agak sederhana	Agak sedikit
Considerably	Baik	Agak sederhana
Greatly	Bagus	Sangat
Tremendously	Hebat	Amat sangat

Face validation

Face validators, who were laypeople aged 28 to 66, agreed on the organisation, appropriateness, and clarity of the translated questions. This validation group found the questionnaire easy to navigate and the language suitably adapted for the target audience. Face validation is a crucial step in questionnaire development, as it provides insight into how well the questionnaire can be understood and completed by hearing aid users, ensuring that items accurately reflect the intended constructs without ambiguity (Parsian & Dunning, 2009). Additionally, feedback from face validators helps identify potential issues with wording, cultural relevance, and layout, which are essential for optimising the questionnaire's usability and effectiveness in capturing meaningful data from respondents.

CONCLUSION

In this article, the translation and validation processes for the SADL questionnaire into Malay is presented. The meticulous procedure involved ensures that the Malay-SADL is a reliable tool for measuring satisfaction with hearing aids among the Malay-speaking population. The subscales available in this document provide both individual and composite satisfaction scores, offering a comprehensive view of the user experience. While the SADL has been widely translated and used internationally, further assessments with hearing aid users are recommended to refine its test-retest reliability and validity. These evaluations will strengthen its application and helps audiologists and providers tailor hearing aid services to better meet users' needs across diverse contexts.

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ORIGINAL ARTICLE

Clinical Supervisory Approaches That Are Perceived To Promote Or Hinder Motivation Amongst Audiology Students: A Qualitative Investigation

Saiful Adli Bin Jamaluddin[1], Nurlin Binti Ali Hanafiah[1*], Nur Filzah Hayani Binti Milatu Samsi[2]

[1]Department of Audiology and Speech-Language Pathology, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Jalan Sultan Ahmad Shah, Bandar Indera Mahkota, 25200 Kuantan, Pahang, Malaysia
[2]Kementerian Pendidikan Malaysia, SMK Mantin, Jalan Besar Mantin, 71700 Mantin, Negeri Sembilan, Malaysia

Keywords:
Clinical supervision; audiology; promote; hinder; motivation

ABSTRACT

Mentoring students in the clinics through clinical supervision is a crucial part of providing them with real-world experience, but not much is known about effective supervision techniques in the field of audiology. **Background:** The purpose of this study is to explore the characteristics of clinical supervision that motivate and demotivate students' learning during their undergraduate study. **Methods:** A qualitative descriptive study approach was applied as it enabled in-depth exploration of students' opinions on supervisory approaches based on their experiences during undergraduate study. Interviews had been carried out among ten graduating Audiology students from the International Islamic University Malaysia, Kuantan. **Results:** Seven themes emerged from the qualitative content analysis which were constructive behaviour during discussion, positive interaction between students and supervisors, constructive behaviour during testing, unconstructive behaviour during discussion, unconstructive behaviour during testing, conflicting approaches between supervisors, and negative attitude towards students. **Conclusion:** Actions that negatively affect students' motivation should be identified and addressed, while actions that positively affect students' motivation should be maintained and internalized to help students advance their audiology abilities.

INTRODUCTION

Clinical supervision plays a vital role in healthcare practices and clinical education to guarantee the safe and ethical delivery service (Cokely & Deplacido, 2012). The definition of clinical supervision can be summarized as the provision of guidance and feedback on matters of personal, professional, and educational development in the context of a trainee's experience of providing safe and appropriate patient care (Kilmnister et al., 2007). Clinical education is part of the Audiology curriculum for undergraduate students which takes place in university or hospital settings and normally being supervised by experienced clinicians that covers counselling and history-taking techniques, assessment methods, and the intervention of hearing impairment cases (Mormer et al., 2013).

Clinical supervision is a multidimensional and complicated process that involves the interaction between clinical educator and the student in which the clinical educator needs to train students and deliver the patients' services simultaneously which make them encounter the logistical and pedagogical problems (Mormer et. al., 2013 & Falender & Shafranske, 2017). Several recognized models were developed to understand the concept of clinical supervision in healthcare. Proctor's model outlines the functions of supervision in nursing to be normative, formative, and restorative while in speech pathology, the Anderson's continuum model is observed which highlights the directive, collaborative, and consultative styles of supervision. In audiology, several recognized models have been described and adopted which are Deliberate Practice, Reflective Practice, Cognitive Apprenticeship and Supervision, Questioning and Feedback Model of Clinical Teaching (Dudding et. al, 2017). These supervision models agree that the level of supervision is based on the capability of the supervisees (Dudding et. al, 2017; Winstanley & White 2003).

Several themes of clinical supervision attributes have been found as helpful and unhelpful to supervisees were highlighted in medical and health science literature. Positive aspects of clinical supervision were emphasized, including professionalism, zeal, concern, mentoring and direction, active teaching techniques, students' independence and autonomy, and providing constructive criticism (Reising et al., 2018; Naidoo & Van Wyk 2016). According to Kilminster et al. (2007), clinical supervisors'

* Corresponding author
E-mail address: nurlin@iium.edu.my

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favourable attributes—such as their ability to interact well with others, give role feedback, and having up-to-date knowledge—have a beneficial impact on students' motivation. In contrast, unhelpful qualities of clinical supervision, like the use of outdated approaches, unorganized sessions, threatening attitude, lack of practice time, and supervision in big groups were identified as potential barriers to students' motivation. (Reising et al., 2018; Killam & Heerschap, 2013). Despite the established models and recognized positive and negative supervisory attributes, there are few studies on clinical supervision in the field of audiology especially in Malaysia. Therefore, the goal of this study was to investigate the aspects of clinical supervision that both encourages and discourages undergraduate students' learning particularly amongst audiology undergraduate students at the International Islamic University Malaysia.

MATERIALS AND METHODS

Ten participants were recruited for this study consistent with the suggestion from Milne & Oberle (2005) that proposed 10 to 20 individuals for an interview. The participants were recruited through the International Islamic University Malaysia (IIUM) Audiology alumni group in the Whatsapp™ (Google Inc, California) mobile application. The target participants were graduating Audiology students from the IIUM Kuantan Campus who had just completed their clinical training within 6 months prior to the recruitment drive. This criterion was set to ensure that the participants had the most recent memory of their experience in clinical training and would be able to provide a rich description on the study topic (Bengtsson, 2016).

A brief research information about this study was posted in the Whatsapp™ group (Google Inc, California) and personal contact was made with interested candidates who met the selection criterion. During the personal contact, detailed research information was provided to the interested candidates to ensure their full understanding of what was required of them. An online consent was obtained using the Google Form™ (Google Inc, California) before arranging for an interview. A one-to-one interview was conducted over the online platform Google Meet™ (Google Inc, California) at a time convenient to each participant. Whenever clarifications on the interviews were needed, the participants were contacted within 2 weeks from their interview session for a follow-up interview. Ethical approval was obtained from the International Islamic University Malaysia (IIUM) research ethics committee (IREC).

This study applied the semi-structured interview format that used open-ended questions with probing questions (Ryan et al., 2009). The semi-structured questions were formed based on past study from Reising et. al, (2018) that questioned more towards the characters of clinical instructors that foster and hinder students' learning. After developing the question guide, it was translated from English into the Malay language to prevent language barrier during actual interview (Squires, 2009). The translation process was carried out by N.S. and then reviewed by the N.H and S.J. Pre-testing of the interview guide was conducted by N.S, who was undergoing training in qualitative investigation, on the first participant. A verbatim transcription was made upon completion of the first pre-test interview and was discussed with N.H. and S.J. who had experience in qualitative investigation. The unnecessary, redundant, inappropriate, and misleading questions from the transcription were modified accordingly. Additional probing questions were also created to ensure a thorough exploration of the participants' experiences. After the first modification, the interview guide was used for the second interview. During the second interview, the interview guide and probing questions were found to be optimised to explore the experiences of the participants. The finalised interview guide is as follows:

1) Can you begin by telling me about your experiences during your past clinical supervision?

   Probe: Can you explain further about...?

2) In your opinion, what are the factors that affect the effectiveness of clinical supervision?

   Probe: Can you talk more about that?; Can you give example about that?

3) Can you tell me about supervisory styles that you feel encourage learning during your clinical training?

   Probe: Can you elaborate further on the supervisory styles that encouraged you to learn?; How did these supervisory styles affect you?; Could you please give some examples?

4) Can you tell about supervisory styles that you feel did not encourage learning during your clinical training?

   Probe: Can you elaborate further on supervisory styles that discouraged you to learn?; How did these supervisory styles affect you?; Could you please give example?

Qualitative content analysis was carried out based on the

qualitative descriptive approach (Jameel, Shaheen & Majid, 2018; Sandelowski, 2000; Krauss SE, 2005). Firstly, the recorded interviews were transcribed verbatim by N.S. Then, a familiarization process occurred in which all authors read the transcripts word by word to get the whole idea of the transcription before breaking them down into smaller meaning units. The meaning units that produced the insights that the authors needed or a group of sentences or paragraphs that shared the same ideas or related ideas were identified. Then, the meaning units were condensed while maintaining the core of the units. The condensed meaning units were labelled with codes, which were then grouped based on similarities within the context. Then codes with shared commonality were grouped into sub-categories or categories. Finally, the themes were formulated by interpreting the underlying meaning of the categories (Graneheim & Lundman, 2004).

RESULTS & DISCUSSION

Tables 1 and 2 reveals the three themes of supervisory attributes that foster and four themes of supervisory attributes that hinder students' learning, respectively.

Table 1: Themes and categories for characteristics that foster students' learning. Number in brackets indicate the frequency of reported categories.

Themes	Categories
Constructive behaviour during discussion	Constructive behaviours that boost students' knowledge (3)
	Promote self-reflection during discussion (6)
	Providing feedback to students (6)
	Provide discussion about the sessions (7)
	Provide homework for student to learn (3)
	Informing student's mistakes after session (5)
	Suggesting the correct technique after commenting (2)
	Catching-up with students about the session (6)
Positive interaction between students and supervisors	Being approachable to students (6)
	Being casual with students (3)
	Being responsive to students' questions (5)
Constructive behaviour during testing	Remind students directly during testing (4)
	Remind students in respectful manner (7)
	Allow time for students to think during testing (6)

Characteristics That Foster Students' Learning

Constructive Behaviour During Discussion

Under this theme, seven categories were identified. Firstly, the action of Promoting Self-Reflection was perceived as helpful practices as described in the excerpt from participant S4 of this study:

S4 : "...and then, after the session ends, the supervisor will be like...we will reflect back what we have done just now. Supervisor will ask me like, okay, what did you learn today? From this session, what did you learn?..."

The questions posed by supervisors seem to encourage students to think critically about themselves and encourage introspection. Apart from Promoting Self-Reflection during Discussion , Providing Feedback to Students was also regarded as positive behaviour in which the students would be able to gauge their strength and weaknesses from their clinical sessions with supervisors. Next, majority of students viewed that Providing Discussion About the Sessions was very important for their learning as expressed below:

S4 : "...If the supervisor conducts discussion after the session, there will be many things that we can learn..."

S9 : "...Having discussion is very important for me..."

Additionally, Informing Student's Mistakes After Session was found to be useful for students' learning as described by S1:

S1 : "...Usually after the clinical sessions, we will have discussion, and the supervisor will point out our mistakes at that time. That is okay for me..."

Participants also revealed a few behaviours or actions that were motivating the students to improve themselves (Constructive Behaviours that Boost Students' Knowledge). These were represented by sub-categories Discussing the Significance of the Test during the discussion session, following-up with the students on the task given at the end of the clinic session (Follow-up on Task Given), and Encouraging Students To Learn More about certain aspects of testing or conditions related to the cases seen by the students.

Positive Interaction Between Supervisors and Students

The second theme revolves around personal interaction and communication between supervisors and supervisees. One of the behaviours that showed positive interaction between supervisors and students was identified as Being Approachable to Students. For example :

S6 : " When we are not performing well on some days during the session, they will ask for one-to-one session, discussion after the session or after the clinic day. So, they will ask if there is any wrong with us, there's one way for us to communicate on what we actually felt during the session..."

Apparently a casual persona during interaction with students (Being Casual with Students) also positively influenced students to learn as revealed by participant 2:

S2 : "...some supervisors like to tell jokes during discussion but there are not so much jokes that they share. They just want to make us feel calm and at ease..."

Constructive Behaviour During Testing

Participants reported that interaction during the audiological testing session played an important part in their training. Three categories made up the third positive theme which are 1) Remind Students Directly During Testing, 2) Remind Students in Respectful Manner and 3) Allow Students to Think During Testing. As an example, the manner on reminding students' mistakes during testing influenced students' learning positively if delivered in a respectable manner (Remind Students in Respectful Manner), as described by S4:

S4 : ...The supervisor will ask gently with a nice tone like "okay, can you check back what you have done?, "try to check back..."

Characteristics that Hinder Students' Learning.

Table 2: Themes and categories for characteristics that hinder students' learning. Number in brackets indicate the frequency of reported categories.

Themes	Categories
Unconstructive behaviour during discussion	Give unconstructive homework (3)
	Unconstructive behaviours during discussion (2)
	Poor responsiveness during discussion (4)
Unconstructive behaviour during testing	Urging students to perform the test quickly (5)
	Interrupt student's session (3)
	Takes over the session completely (6)
	Takes over the session without giving the reasons (2)
	Let students make mistakes during testing (3)
	Does not suggest ways to correct mistakes (1)
Negative attitude towards students	Criticizing behaviour (4)
	Showing anger (6)
	Show dissatisfaction in many forms (5)
	Degrading behaviour (6)
	Degrading student's performance (7)
Conflicting approaches between supervisors	Conflicting approaches between supervisors (2)

Unconstructive Behaviour During Discussion.

Supervisors' interaction style could also hinder students' motivation and as presented by the three categories under this theme. It was identified that students felt demotivated when supervisors persistently focus on students' mistakes (sub-category; *Only Highlighting Students' Mistakes During Discussions)* and not providing them constructive criticism (sub-category; *Providing No Suggestions to Students)* as described by S6.

S6 : "...but then even during the discussion after the session, they still like telling us that what we are doing is wrong, "you should not do this in front of the patient, you should not do that in front of the patient...Because they just told us what we did wrong, but they don't tell us what we can do instead of the mistakes that we've done. They just like "you should know what to do..."

Unconstructive Behaviour During Testing.

During the training session, particularly during assessments, six participants revealed that *Taking Over the Session Completely* seems to be detrimental to learning, for example:

S6 : " ... Okay so..if I'm the tester, if I like doing something not right....doing a late presentation time, and then they just like "okay, let me do this audiometer test"...

Participant S6 also reported that the supervisor did not give adequate opportunity to overcome the difficult situations independently by taking over the clinical session. Similar views were shared by Participant S4 as she could only observe the supervisor performing the test after being taken over when she was getting confused:

S4 : "... For example, like... when I do masking during PTA, there are times that I feel confused with the steps. Once my supervisor notices me in that state, he will take over the session immediately. So, I just sit beside and observe the session until finished..."

In relation to the above, *Interrupting Students' Session* was also regarded as unconstructive behaviour during testing. In contrast, some participants (n=3) regarded the action of *Letting Students Make Mistakes During Session* was also unhelpful.

Urging Students to Do Test Quickly was also considered as unconstructive behaviour in which the students would feel pressured when performing the tests as described below:

S2 : " ... Then, perhaps he is impatient, so he urges me to do the test quickly like "Quick! Quick! Quick!" sometimes he will raise his voice while pushing me..."

Negative Attitude Towards Students.

Under this theme, the most hindering behaviour that was perceived by students was *Showing Anger* with 24 codes in total. The action of showing anger like *Scolding Students in Front of the Patients* was the most unfavourable among the participants. For example:

S1 : "...or they will get extremely mad at us, it is not like the usual one, but their scolding is very harsh, like using harsh tone, plus they scold me in front of the patients...."

Participant S3 also shared when the supervisor scolded the participant in front of the patients, the participant felt that the clinical session was not successful:

S3 : "...and then, when the supervisor starts to raise her voice in front of patient. Like directly scolds me. It makes me feel like...like "I have done this terribly"...

Some participants disliked the behaviour of *Degrading Students' Performance* during testing by comparing between students of the same batch (*Comparing Students' Skills With Their Peers).* Additionally, *Comparing Students With Other Batches* was also reported to negatively influence students' motivation to learn. For instance, Participant S4 shared the experience of being compared with juniors when the participant's felt confused in doing basic tests:

S4 :"...while doing acoustic reflex, ...sometimes I feel blurred doing the test...then, my supervisor likes...comparing me with junior. He says, "your junior can do this, why are you still doing the same mistakes, the basic ones?..."

Then, *Criticizing Behaviour* was also expressed to negatively influenced the students' motivation to learn:

S1 : "...However, when the supervisor starts saying some words that can hurt us like "if you're still like this, you think you can pass the clinics?..."

Criticizing Students' Mistakes In Front of Patients was reported to also demotivate students to learn:

S6 : "...we prefer to do like one ear first and then second ear. But then the supervisor would like, "no, you can't do this, you need to do like this, you need to do this and this". So, it's like actually really like ruin the rhythm of .....my performance at that time..."

Conflicting Approaches Between the Supervisors

The supervisory style that was unfavourable to some participants was *Conflicting Approaches Between the Supervisors.* Students felt confused about which methods to utilize throughout clinical sessions because different supervisors had taught different approaches.

From these findings, primary theme of clinical supervision that highly influenced the students' motivations was the *Constructive Behaviours During Discussion.* During the discussion, the students were asked by supervisors to reflect on their actions and overall conduct of the sessions and everything that they learnt. Andrews (1996) stated that incorporating the reflection in learning activity will make the learning process become purposeful and intentional with the purpose of changing behaviour. Through practicing self-reflection, students will recognize their own strengths, weaknesses, and what they should strive for to improve themselves.

Providing room for discussion to students was found to be very meaningful for students. This is when students get the opportunity to ask supervisors and seek clarification. Because the patient's appointment time is being prioritized for service delivery, students may not have many opportunities to ask supervisors questions during testing sessions. At the same time, *providing feedback* during discussion is crucial as students will gain insight into what they performed correctly or poorly as well as the implications of their actions (Ramani & Leinster, 2008). According to Dudding et.al (2017), providing objective and non-evaluative feedback on clinical performance intend to enhance students' clinical skills. In delivering the feedback, there are certain aspects that supervisors should be aware of such as the form of feedback, intonation, and use of words. From this study, students preferred that their supervisors would first highlight their strengths before discussing their weaknesses.

Regarding the supervisors' behaviours during testing, one of the behaviours that is mostly mentioned by participants is pointing out mistakes of students. It is found to be both constructive and unconstructive behaviour for learning. While some participants preferred to be able to complete the tests without any interruptions, others preferred their mistakes to be immediately pointed out during the test. Pointing out errors during a session implies that the students will be corrected in front of clients, which some participants felt had a negative effect on their learning. Jarski et al. (1990) corroborated this, observing it as a behaviour that hinders learning. This study also showed that most students could accept if their supervisors pointed out the mistakes they made in a constructive way, including by speaking in a calm tone, avoiding interruptions, and providing a suitable form of encouragement. As mentioned by Sahl ibn Sa'd who reported that The Messenger of Allah, peace and blessings be upon him, said, "The believer is friendly, for there is no good in one who is not friendly or befriended." (Musnad Aḥmad 22840).

Lastly, the *conflicting approaches between the supervisors* may negatively affect the students' motivation to learn as it will lead students to confusion to follow the best approaches for their clinics. The differences in approaches that participants reported to be unhelpful could be similar to the theory-practice gap observed in clinical training in nursing in which there is a difference between what is taught in the classroom and what is practiced. In addition, the dissimilarity in principles or protocols and guidelines of practice in the clinical setting and those learnt by students may lead to a theory-practice gap (Kaphagawani, 2015).

CONCLUSION

In conclusion, perceived supervisory behaviours during the testing and discussion sessions can have a positive or negative effect on IIUM audiology students' motivation to study, indicating a major influence on their attitude toward learning. In addition to focusing on and correcting behaviours that hinder students' learning, supervisors should identify the qualities that would benefit students during training. Enhancing supervisory techniques can be achieved through an organized training session that includes a discussion on harmonizing opposing perspectives.

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ORIGINAL ARTICLE

Acoustic Complexity Variables Used in Adult Auditory Training: A Scoping Review

Sarah Rahmat [1*,2,3], Nadia Munira Mustafa[4], Juliana Aminah Marhaban[1]

[1]Department of Audiology and Speech-Language Pathology, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3] Children Health and Wellbeing Research Group, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[4] InnoHear, No 23A, Pusat Komersial Batu 3, Sungai Isap, 25150 Kuantan, Pahang, Malaysia

ABSTRACT

Background: Auditory training is a crucial component of aural rehabilitation for individuals with hearing loss, aiming to enhance speech perception and device satisfaction. The effectiveness of such training is influenced by various acoustic complexity variables that determine task difficulty. This scoping review aims to compile the acoustic complexity variables used in adult auditory training programs and examine effectiveness trends in programs that incorporate specific acoustic complexities. **Methodology:** A comprehensive literature search was conducted across four databases using keywords such as 'hearing loss,' 'auditory training,' 'hearing aids,' 'cochlear implants,' 'perceptual learning,' 'aural rehabilitation,' 'auditory rehabilitation,' and 'adults,' yielding 220 articles, of which 29 met the inclusion criteria. Data was extracted and analysed using descriptive and thematic analysis, following the Joanna Briggs Institute (JBI) framework. **Results:** The review identified 17 acoustic complexity categories in auditory training. All 29 studies used recorded sounds, while only 6.9% included both recorded and live sounds. Key variables linked to 100% positive outcomes were: Complexity of Utterance (Simple), Learning Style (Passive), Distance (Close), Segmental (Little or No Emphasis), and Stimulus Context (Out of Context). On the other hand, Distance and Sound Origin (Live) were linked to no significant differences in outcomes in 27% and 50% of studies, respectively. **Conclusion:** Acoustic complexity variables play a vital role in auditory training outcomes. Future research should explore a progression from least to most complex variables, enabling individuals with hearing loss to improve their auditory skills progressively, ultimately enhancing real-world speech perception and communication abilities.

Keywords:
Acoustic complexity, Auditory training; Aural rehabilitation; Adults; Hearing loss

INTRODUCTION

Individuals with hearing loss typically experience a reduction in speech audibility and quality of life. Amplification devices, such as hearing aids and cochlear implants, are designed to enhance audibility and communication while reducing perceptual handicaps. However, despite the benefits of these devices, many users continue to struggle with complex listening tasks, particularly in noisy environments (Voola et al., 2024). This difficulty arises because speech perception in noise requires cognitive abilities such as processing speed, working memory, and attention to focus on speech sounds while ignoring background noise. Unfortunately, these cognitive abilities are often diminished in individuals with hearing loss, especially among adult listeners (Maren et al., 2019).

To alleviate the listening challenges faced by adults with hearing impairment, auditory training can be implemented. This intervention has been shown to improve speech perception and device satisfaction among users (Casserly et al., 2019). Auditory training serves as a compensatory mechanism for the degradation of auditory signals experienced by individuals with hearing loss (Sweetow & Palmer, 2005). Several parameters are utilized in auditory training programs, including: 1) training activities, 2) training themes, 3) communication strategies, 4) methods, 5) approaches, 6) modes, 7) auditory skills, 8) speech stimuli, 9) sound stimuli, and 10) complexity of training components (Marhaban et al., 2023). The effectiveness of auditory training has been demonstrated

* Corresponding author
E-mail address: sarahrahmat@iium.edu.my

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by numerous researchers who report improvements in speech sound perception (Fallahnezhad et al., 2023). For example, Beier et al. (2015) conducted a systematic review that identified the effectiveness of auditory training for individuals with hearing loss. They found that hearing aid users benefit from auditory training programs, particularly from tasks that involve cognitive demands. This study suggests that the types of tasks and the acoustic complexity variables used during training can significantly influence the effectiveness of auditory training (Beier et al., 2015).

Acoustic complexity in this paper refers to the variation in sound characteristics that influence how auditory stimuli are perceived and processed. It also refers to how stimulus is being presented which can influence the audibility of speech from most audible (least complex) to least audible (most complex) (Marhaban et al., 2023). This includes factors such as the frequency, intensity, and temporal patterns of sounds, as well as the phonetic similarity between words. In auditory training, manipulating acoustic complexity can enhance or hinder the learning process by affecting the listener's ability to discriminate between sounds and recognize speech in various contexts. Training programs that incorporate a range of acoustic complexities—such as different talkers, background noise levels, and types of stimuli—can better prepare individuals with hearing loss to navigate real-world listening environments, ultimately improving their speech perception and communication skills. Many studies have been conducted to investigate the relationship between acoustic complexity variables used in auditory training programs and speech sound perception's improvement. For example, Burk et al. (2006) investigated the effectiveness of word-based auditory training and found that both young normal-hearing and older hearing-impaired listeners performed significantly better on trained word lists compared to untrained lists presented by the same speaker. Improvements in untrained words were small but significant, indicating some generalization to new words. The substantial gains in trained words persisted even with different speakers, suggesting that listeners focused more on memorizing the words rather than specific acoustic features of the speaker. Six months later, participants still showed improved performance on trained words compared to their initial scores. However, when trained words were placed in sentences, there was no improvement in recognition over untrained words, indicating that the complexity of sentences may limit generalization. This study highlights how the type of acoustic complexity used in training—such as trained versus untrained words, and single words versus sentences—can affect how well auditory training works.

To the best of the author's knowledge, no study has yet identified which acoustic complexity variables are used in adult auditory training programs. Therefore, this scoping review aims to compile the acoustic complexity variables used in adult auditory training programs and examine effectiveness trends in programs that incorporate specific acoustic complexities. Using the Joanna Briggs Institute (JBI) framework, this review will synthesize existing knowledge, address literature gaps, and offer recommendations for future research, with the goal of enhancing auditory training programs for adults with hearing difficulties.

METHODOLOGY

A scoping review was employed in this study due to its ability to map out key concepts and compile evidence from a wide range of sources. The methodological framework proposed by the Joanna Briggs Institute (JBI) was utilized, as it offers a comprehensive and structured approach to conducting scoping reviews. This process included several critical stages (1) identifying the research questions, (2) developing inclusion and exclusion criteria, (3) data searching, (4) data selection, (5) data extraction and charting, and (6) data analysis (Peters et al., 2020).

Research Questions

This study was guided by two specific questions: "What types of acoustic complexity variables are used in adult auditory training programs?" and "What are the effectiveness trends of auditory training programs that incorporate the acoustic complexity variables?"

Eligibility Criteria

Criteria of study participants

Studies were included if they involved adult participants with any degree of hearing loss using hearing aids, cochlear implants, or other listening devices, as well as normal-hearing subjects recruited for auditory training program validation. Studies involving children with hearing loss, animals as subjects, or participants with diseases or pathological conditions were excluded.

Criteria of study characteristics

Studies published in English or Malay that compared the intervention group (participants who received auditory training) with the control group, or included repeated measurements (pre- and post-comparison), were included. The review also included studies that used randomized controlled trials, non-randomized controlled trials, cohort studies, repeated measures (pre- and post-

training comparisons), case studies, reliability tests, and validity tests as study designs.

Data searching

A systematic search of four databases—PubMed (6 results), ScienceDirect (48 results), Scopus (70 results), and ProQuest (92 results)—yielded 216 articles. An additional four articles were gathered from a grey literature search, bringing the total to 220 articles for further screening and review. All articles were systematically searched using keywords such as 'hearing loss,' 'auditory training,' 'hearing aids,' 'cochlear implants,' 'perceptual learning,' 'aural rehabilitation,' 'auditory rehabilitation,' and 'adults.' The data search was conducted from November 2020 to January 2021.

Data selection

A total of 220 articles identified through the data search underwent a three-stage screening process based on the inclusion criteria. First, 19 duplicate articles were removed, leaving 201 articles for further screening. In the second stage, titles and abstracts were reviewed, resulting in the exclusion of 165 articles that did not meet the inclusion criteria. The remaining 36 full-text articles were then assessed for eligibility in the third stage. During this stage, 7 articles were excluded because they either did not meet the inclusion criteria or met the exclusion criteria. After completing all three stages of screening, 29 articles were selected for further analysis in this review. Three reviewers participated in the screening process, and any disagreements or uncertainties were resolved through discussion to reach a consensus. Figure 1 shows the flow diagram of the data search and selection process.

Data extraction and charting

Information from the selected studies was extracted and organized into a table (Table 2), categorizing the following details: authors, year of publication, research objective, study design, participant characteristics (sample size, age, hearing status—whether hearing loss or normal hearing—and type of amplification device used), auditory training background (name or description of the auditory training), training protocol (procedures), and outcome measurements, including the study's effectiveness. Data extraction was carried out by two reviewers, and any discrepancies were resolved through discussion. The extracted data was then verified by a third reviewer.

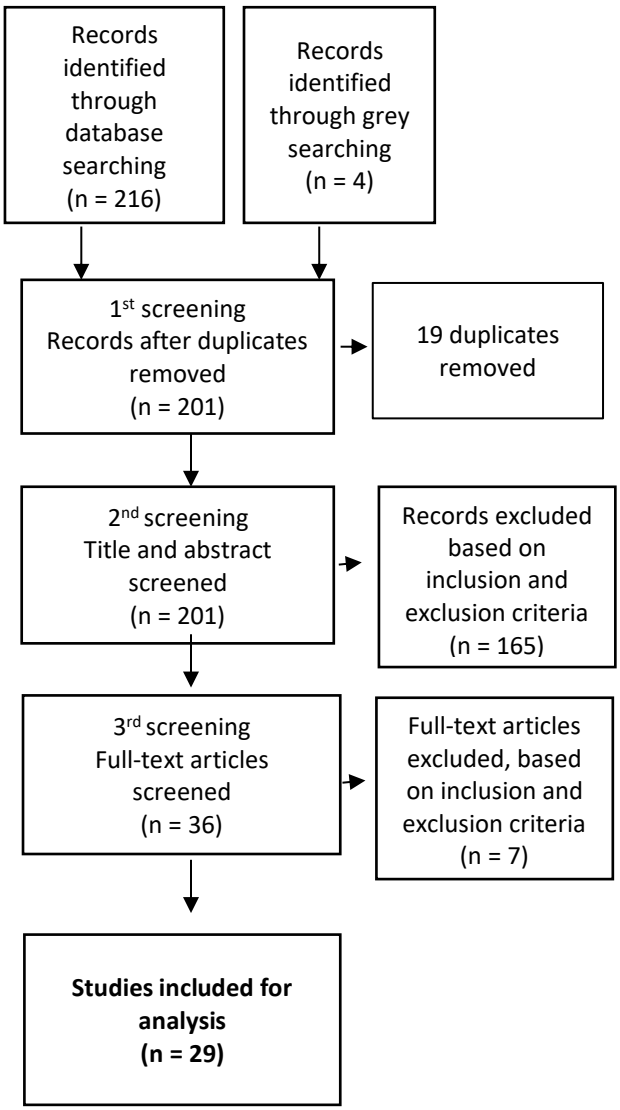

Figure 1: Flow diagram of the data search and selection process.

Data analysis

A descriptive summary table of adult auditory training programs that met the inclusion criteria was created to present the findings from the included studies (see Table 2). The effectiveness of each study was categorized as follows: positive findings (+) were assigned when a significant improvement was observed in at least one of the outcome measures after auditory training. Findings were categorized as 'no difference' (ND) when no significant improvement or difference was found between pre- and post-training measures, or between the control and training groups, across all outcome measures. If no

outcome measures were reported (e.g., studies that only described the program's development without assessing its effectiveness), the effectiveness was categorized as 'no available findings' (NA).

Thematic analysis was then employed to analyse and categorize the types of acoustic complexity variables used in auditory training programs, based on previous literature. A deductive approach was applied, with the categorization of information guided by existing concepts and frameworks. The table of definitions used to categorize the acoustic complexity variables is based on the definitions listed in Table 1 below.

Table 1: Definition of acoustic complexity variables

Acoustic Complexity	Variables	Definition
Authenticity of Sounds	Undegraded, Degraded	Refers to the quality of sound; undegraded sounds maintain their original quality, while degraded sounds have been altered to reduce redundancy.
Background Noise	Absence, Presence	Refers to ambient noise that competes with speech signals; absence indicates a quiet environment, while presence signifies the existence of competing noise.
Complexity of Utterances	Simple, Complex	Refers to the structure of utterances; simple utterances utilize straightforward language rules, while complex utterances incorporate various linguistic elements, making them harder to understand.
Distance	Close, Distance	Refers to the distance between the listener and the sound source; indicates proximity (close) or separation (distance).
Learning Effect	New, Adapted	Refers to the improvement in performance on tests due to familiarity with the testing process or items; new items are introduced, while adapted items have been modified for better understanding.
Learning Style	Passive, Active	Refers to the preferred methods of learning; passive learning involves receiving information without direct engagement, while active learning includes self-training or interactions with a trainer.
Length of Utterance	Short, Long	Refers to the length of spoken expressions; short utterances consist of brief phrases or words, while long utterances encompass complete sentences or extended discourse.
Rate of Utterances	Slow, Individual/Normal Conversation	Refers to the speed of spoken expression; slow rates indicate a measured pace, while individual or normal conversation rates reflect typical speech patterns.

Repetition	Once, Repeated	Refers to the occurrence of spoken elements; once indicates a single instance, while repeated involves multiple occurrences of the same phrase or action.
Segmental Features	Little/No Emphasis, Emphasis	Refers to Individual segment of spoken language; little or no emphasis indicates a flat delivery, while emphasis highlights certain syllables, words or phrases to convey meaning.
Suprasegmental	Little/No Emphasis, Emphasis	Refers to the prosodic aspects of speech; little or no emphasis indicates a monotone delivery, while emphasis involves variations in pitch, intensity, and rhythm to convey meaning.
Set	Closed, Open	Refers to collections of related items; closed sets contain a fixed number of known items, while open sets have no restrictions on membership, allowing for variability.
Sounds Origin	Live, Recorded	Refers to the source of sounds; live sounds occur in real-time, while recorded sounds have been captured and played back.
Speaker Familiarity	Unfamiliar, Familiar	Refers to the listener's recognition of the speaker's voice; unfamiliar indicates a lack of prior exposure, while familiar denotes previous experience with the speaker's voice.
Stimulus Context	In-Context, Out-of-Context	Refers to the circumstances surrounding a stimulus; in-context stimuli are relevant to the current situation, while out-of-context stimuli lack direct relevance.
Stimulus Presentation	In Sequence, Random	Refers to the arrangement of stimuli; in sequence indicates a structured order, while random presentation lacks a predetermined sequence.
Target Position	Initial, Middle, End	Refers to the placement of important messages within spoken language; initial indicates the beginning, middle denotes the center, and end signifies the conclusion of word, phrase, sentence, or whole message.

To determine the trend of acoustic complexity used in the auditory training program, the percentage of auditory training programs that use specific acoustic complexity variables was calculated using the following equation:

Percentage of auditory training programs that use specific acoustic complexity variables = Number of auditory

training program that use specific acoustic complexity variables / Total number of study (29) x 100

To determine effectiveness trends in programs that incorporate specific acoustic complexities, the effectiveness of auditory training programs that utilize different acoustic complexity variables was determined using the following equation:

Percentage of effectiveness for each acoustic complexity variable in auditory training programs = (a/N) × 100%

where:

- *a represents the total number of studies that report different category of effectiveness outcomes (positive, no difference, not available) for a specific acoustic complexity variable.*
- *N is the total number of studies utilizing that specific acoustic complexity variable in auditory training programs.*

RESULTS

Overview of the studies

A total of 29 studies that were included in this scoping review study have been summarised in a table of descriptive summary of auditory training programs that met the inclusion criteria as shown in Table 2.

Table 2 illustrates that all studies included participants ranging in age from young adults to older adults, with varying levels of hearing ability, from normal hearing to mild and profound hearing loss. 12 studies involved participants using hearing aids, 10 included cochlear implant recipients, two featured users of both cochlear implants and hearing aids (bimodal users), seven studies included participants without any amplification, and one study did not report amplification status. The sample sizes for the training and control groups varied significantly, ranging from 2 to 263 participants. Additionally, Table 2 summarizes the different types of auditory training programs employed in the 29 included studies, along with their findings.

Out of 20 types of auditory training programs that are used in studies, the most used auditory training programs in studies are Listening and Communication Enhancement (LACE) and ReadMyQuips (RMQ). Both programs are classified as computer-based auditory training (CBAT), which allows participants to complete training at their leisure and it is more self-directed. The LACE program consists of five tasks, where three tasks are listening to degraded speech (speech in noise, rapid speech, competing speakers) and two tasks related to auditory memory (word memory task and missing word task). Whereas, the RMQ program is the only program that combines auditory and visual information in their training. It uses an audiovisual (AV) training approach that aims to improve communication and speechreading skills by giving tasks to complete the modified crossword puzzles after listening to video recordings of quips. The results in Table 2 also show the studies that used different types of auditory training programs, including individual training and training in groups of participants. The CBAT program, however, is the most commonly used auditory training program in the literature.

Most studies measured outcomes across four subcategories: speech intelligibility, cognition, quality of life, and musical perception. They also included two additional categories of outcome measures: 1) electrophysiology, and 2) psychoacoustic tests. Speech intelligibility was assessed using a variety of speech tests that manipulated task difficulty through different acoustic complexity variables during training. Cognitive abilities were evaluated with word memory tests, while quality of life assessments aimed to determine whether participants' hearing abilities had improved. In terms of study effectiveness, the majority of the studies (75.9%, n=22) demonstrated that auditory training programs showed positive outcomes, while a smaller percentage reported no significant impact (17.2%, n=5). The other 6.9% (n=2) of the studies did not report the effectiveness of the auditory training program. This trend highlights the potential efficacy of auditory training interventions, although it also underscores the need for further investigation into the variables influencing both positive and negative outcomes.

Acoustic complexity variables used in adult auditory training programs

Table 3 presents 17 categories of acoustic complexity utilized in auditory training programs, organized into specific types of acoustic complexity variables. Based on the results in Table 3, the most commonly used acoustic complexity variable in auditory training programs is the recorded sounds presentation variable. All 29 studies (100%) employed recorded sounds during training, while only two studies (6.9%) used both recorded and live sounds. The recorded sounds are typically presented through speakers or other assistive devices, whereas live sound presentations involve one or multiple speakers delivering stimuli such as words or sentences, positioned between the speakers and listeners. In contrast, the acoustic complexity variables that were used less

Table 2: Descriptive summary of auditory training programs that met inclusion criteria

Authors (Year) [Paper ID]	Research objectives	Study design	Participants				Name of auditory training or description	Outcome measurement	Study Effectiveness +(positive)/ ND (No differences)/ NA (Not Available)
			Sample size	Age (years)	Hearing status	Hearing device			
Fu & Galvin, (2007) [1]	Developed a computer-assisted speech- training (CAST) program to provide the means to conduct auditory rehabilitation at home; CI users' adaptation to a severe spectral mismatch over an extended learning period	Experimental and case study	N=13 1) Training group= 13 2) Control group= 0	NS	HL (NS) and NH	CI	Computer-Assisted Speech Training (CAST)	1. Hearing in Noise Test (HINT) sentence recognition thresholds in steady, speech-shaped noise 2. IEEE21 sentence recognition in quiet 3. Multitalker vowel recognition in quiet 4. Multitalker consonant recognition in quiet	+
Miller et al. (2007) [2]	To provide a much more detailed assessment of the speech- perception problems encountered by hearing-impaired clients than was previously available and then, based on that assessment, to offer a training program designed improve the clients' abilities to understand speech in everyday situations	Program development	N=65 1) Training group= 65 2) Control group= 0	NS	HL (NS)	NS	Speech Perception Assessment and Training System (SPATS)	NS	NA
Sweetow & Sabes, (2007) [3]	Development of Listening and Communication Enhancement (LACE) and to assess the effects of training with LACE	Program development and pilot test	N=65 1) Training group= 65 2) Control group= 0	28 – 85 years	HL (NS)	HA	Listening & Communication Enhancement (LACE)	1. Quick Speech-in-Noise Test 2. Hearing Handicap Scale for the Elderly (HHIE) 3. Communication Scale for Older Adults (CSOA)	+

Preminger & Ziegler (2008) [4]	To determine whether auditory-only and auditory-visual speech perception could be trained in a group format	Experimental study	N=47 1) Training group >16 2) Control group ≥16	55 to 75 years	HL (NS)	HA	Audiologic Rehabilitation Classes	1. City University of New York (CUNY) AB Isophonemic Word Lists 2. CUNY Topic Related Sentences 3. Hearing Handicap Inventory (HHI) for the elderly and adults 4. World Health Organization Disability Assessment Schedule II 5. Class evaluation form: A subjective class evaluation form	ND
Shafiro (2008) [5]	To examine whether auditory training improves listeners' identification of spectrally-degraded environmental sounds	Pretest-posttest design	N=7 1) Training group= 7 2) Control group= 0	21 to 26 years	NH	None	Environmental Sounds Training	Tested using the entire stimulus set (40 sound sources, 4 exemplars each, for a total of 160 stimuli)	+
Richie & Kewley-Port (2008) [6]	To examine the effects of a computer-based, auditory–visual vowel identification training program on sentence recognition under difficult listening conditions	Experimental study	N=14 1) Training group= 7 2) Control group= 7	19 – 28 years	NH	None	Vowel identification Training	1. Closed-set vowel identification test 2. An open-set monosyllable word recognition test 3. An open-set sentence recognition test	+
Driscoll et al. (2009) [7]	1) To compare the efficacy of repetition (RE), feedback (FB), and direct instruction (DI) on the ability to acclimatize to a distorted signal 2) To recognize simulations of the signal of musical	Experimental study	N=66 1) Training group= 66 2) Control group= 0	18 to 69 years	NH	CI	Musical Instruments training	1. Music Background Questionnaire (MBQ) 2. Paired Associate Memory Test (PAT) 3. Instrumental Simulation Recognition Test	+

Loebach et al. (2009) [8]	To assess whether training on speech processed with an eight-channel noise vocoder would produce transfer of auditory perceptual learning to the recognition of	Experimental study	N=48 1) Training group= 24 2) Control group= 24	Young adult	NH	None	Speech Processed Training	1. Environmental sound identification 2. Talker- gender identification 3. Talker discrimination	+
Loebach et al. (2010) [9]	To assess whether different types of training and feedback affect perceptual learning of speech processed with a CI simulation to evaluate the efficacy of different rehabilitation methodologies for newly implanted individuals	Experimental study	N=144 1) Training group= 96 per group 2) Control group= 48	Young adults	NH	CI	Speech Processed Training	Transcribe 20 spectrally degraded meaningful sentences	+
Preminger & Meeks (2010) [10]	1. To evaluate the effectiveness of training in communication strategies and psychosocial exercises for spouse (SPs) of person with hearing loss (PHLs) 2. To determine whether PHLs of SPs had significantly improved mood, reduced stress, improved marital communication, and better HL-QOL scores	Randomized controlled study	N=72 1) Training group= 36 2) Control group= 36	1) PHLs: i.Training (mean age = 63.5) ii.Control (mean age 72.2). 2) SPs i.Training (mean age =69.1) ii.Control (mean age = 62.4)	1) PHLs: Moderate HL 2) SPs: NH	HA= 34 CI= 2	Audiological Rehabilitation (AR) classes	1. Hearing Handicap Inventory (HHI) Elderly 2. Modified HHI-Adult 3. Modified HHI-Spouse 4. 10-item Perceived Stress Scale (PSS) 5. Affect Rating Scale (ARS) 6. Communication in the Marriage Primary Communication Inventory (PCI)	+

Tyler et al. (2010) [11]	Describes the initial development of a novel approach for training hearing-impaired listeners to improve their ability, to understand speech in the presence of background noise and to also improve their ability to localize sounds	Program development and pilot test	N=12 1) Training group= 6 2) Control group= 6	57 to 77 years	Mild to profound HL	CI	The localization and speech- in-noise modules	1. Nucleus-consonant monosyllabic words (CNC) 2. CUNY sentences 3. Hearing in Noise Test (HINT) sentences 4. Everyday sounds localization test 5. Real-world listening test for localization and recognition	+
Krull et al. (2012) [12]	To compared the efficacy of talker-identification training in two groups of young normal-hearing adults, listening to either acoustic simulations of unilateral CI or bimodal (CI+HA) hearing	Experimental study	N=30 1) Training group= 24 2) Control group= 6	18 – 25 years	NH	CI or CI+HA	Talker-Identification Training	1. Sentence-recognition using two lists of sentences (in quiet and in noise) 2. Emotion-recognition performance using 100 tokens in quiet	+
Petersen et al. (2012) [13]	Investigated the effect of a 6-month one-to- one musical ear- training program on the perception of music, speech, and emotional prosody of deaf patients receiving a cochlear implant (CI)	Experimental study	N=24 1) Training group= 15 2) Control group= 9	21-73 years	Severe HL	CI + HA	The Musical Ear-Training	Musical instrument identification (MII) 1. Melodic contour identification (MCI) 2. Pitch ranking (PR) 3. Rhythmic discrimination (RD) 4. Melodic discrimination (MD) 5. The Hagerman speech perception test (HAG) 6. An emotional prosody recognition test (EPR)	+

Wayne & Johnsrude (2012) [14]	Evaluated the contribution of visual speech information to perceptual learning when it was presented concurrently with clear auditory speech as feedback	Experimental study	N=144 1) Training group= 144 2) Control group= 0	17 -28 years	NH	None	Perceptual Learning of Degraded Speech Training	Word-report task	ND
Anderso n et al. (2012) [15]	1) To compare the effects of auditory-based cognitive training on the ratio of temporal fine structure (TFS)/ envelope in individuals with and without hearing loss. 2) To evaluate changes in perceptual and cognitive function, given evidence that successful hearing in noise relies on a complex interplay of sensory and cognitive	Experimental study	N=77 1) Training group= 38 2) Control group= 39	55 to 79 years	Mild to profound HL	None	The Brain Fitness™ Cognitive Training	1. Quick Speech-in-Noise Test 2. Two subtests of the Woodcock–Johnson Tests of Cognitive Abilities 3. The Integrated Visual and Auditory Continuous Performance Test 4. Electrophysiology test	+
Miller et al. (2015) [16]	To evaluate the efficacy of two types of computerized speech-perception training for adults who use hearing aids	Experimental study	N=240 1) Training group= 240 2) Control group= 0	35 to 89 years	Mild to moderate HL	HA	Speech Perception Assessment and Training System (SPATS)	1) Non-SPATS i. Word-in-Noise-test (Win) ii. Quick Speech-in-Noise Test iii. CID Monosyllabic Word Test in Quiet and in Noise iv. Connected Speech Test (listen Only) v. Connected Speech Test (Look and Listen) vi. The abbreviated profile of hearing aid performance (APHAP) 2) SPATS–Related	NA

Shafiro et al. (2015) [17]	To investigate the effect of a short computer-based environmental sound training regimen on the perception of environmental sounds and speech in experienced cochlear implant (CI) patients	Experimental study	N=14 1) Training group= 14 2) Control group= 0	51 to 87 years	Mild HL	CI	Environmental Sound Training	1. The Familiar Environmental Sound Test (FEST) 2. Consonant-Nucleus-Consonant (CNC), monosyllabic word recognition test 3. Speech-in-Noise (SPIN-R) sentence test	+
Rishiq et al. (2016) [18]	To determine whether hearing aids in combination with computer-based auditory training improve audiovisual (AV) performance compared with the use of hearing aids alone	Experimental study	N=24 1) Training group= 12 2) Control group= 12	1) Training group: range = 51–84 years 2) Control group: range= 62-81 years	Mild to moderate HL	HA	ReadMyQuips (RMQ)	The Multimodal Lexical Sentence Test for Adults (MLST-A)	ND
Saunders et al. (2016) [19]	To examine the effectiveness of the Listening and Communication Enhancement (LACE) program as a supplement to standard-of-care hearing aid intervention in a Veteran population	Multisite randomized controlled trial	N=243 1) Training group= 206 2) Control group= 73	66 to 71 years	Mild to moderate HL	HA	Listening and Communication Enhancement (LACE)	1. Word-in-Noise-test (WIN) 2. NU-6-word lists (Wilson et al. 1994) 3. Modified NU-20 test 4. Wechsler Adult Intelligence scale 3rd Edition WAIS-II)I 5. The Low Predictability Sentences performance on the multi-SNR R-SPIN 6. Abbreviated Profile of Hearing Aid Performance (APHAP) 7. HHI for the elderly and adults	ND

Smith et al. (2016) [20]	1) To determine if patient characteristics or clinical variables could predict who benefits from individual auditory training 2) To determine if at-home AT with the LACE programs were more effective than placebo training or simply providing a single session of educational	Multisite and randomized controlled clinical trial (RCT) study	N=263 1) Training group= 193 2) Control group=70	Older Veterans (mean age = 68.6, SD= 7.7)	Mild to moderate HL	HA	Listening and Communication Enhancement (LACE)	1. Word-in-Noise-test (WIN) 2. HHI for the elderly and adults 3. The abbreviated profile of hearing aid performance (APHAP)	+
Tye-Murray et al. (2016) [21]	This study determined whether auditory training with the speech of an individual's frequent communication partner in this case their spouse, would lead to enhanced recognition of their spouse's speech	Experimental study	N=10 Training group=10	Mean age = 73.2 years	At least Mild to moderate HL	HA	Customized Learning: Exercises for Aural Rehabilitation (clEAR)	Pre- and post-training assessments included speech-in-noise tests—the Build-a-Sentence Test (BAS) and the 4 alternative forced choice (4 AFC) test and the Client Oriented Scale of Improvement (COSI) questionnaire	+

Rao et al. (2017) [22]	To investigate the effects of hearing aid use and the effectiveness of ReadMyQuips (RMQ) on speech perception performance and auditory selective attention using electrophysiological measures.	Experimental study	N=22 1) Training group= 11 2) Control group=1 1	1) Training group (range = 60–85) 2) Control group (range = 49–85)	Mild to moderate HL	HA	Read My Quips (RMQ)	1. Cortical late event-related potentials (ERPs) 2. HINT sentences	+
Tye-Murray et al. (2017) [23]	This investigation was conducted to compare the efficacy of meaning-oriented auditory training when administered with a spaced versus massed practice schedule	Experimental study	N=47 1) Spaced group= 24 2) Massed group: 23	1) Spaced group: mean = 64.6 years 2) Massed group: mean = 69.6 years	HL (NS)	HA	Customized Learning: Exercises for Aural Rehabilitation (clEAR)	1. Transfer-Appropriate Processing (TAP) 2. The Build-a-Sentence test (BAS)	+
Yu et al. (2017) [24]	Clinical case study reports functional magnetic resonance imaging (fMRI) data from two hearing- impaired patients who were first-time HA users	Case report	N=2 1) Training group= 2 2) Control group= 0	1) 68 years 2) 52 years	Mild to severe HL	HA	Read My Quips (RMQ)	1. Multimodal Lexical Sentence Test for Adults (MLST-A) 2. Functional magnetic resonance imaging (fMRI)	+

Casserly et al. (2019) [25]	This study tested the viability of such popular media interviews as training materials, comparing their effectiveness to that obtained with sentence transcription training.	Experimental study	N=60, Training group= 60	Young adult	NH	None	A new set of AT materials: excerpts of interviews from popular media.	1. Speech recognition in quiet 2. Speech recognition in multi talker babble 3. High variability sentence recognition 4. Isolated word recognition with context	+
Jiam et al. (2019) [26]	To evaluate the impact of an online, short music training intervention on pitch and timbre perception in CI users	randomized controlled crossover	N=32 1) Training group= 15 2) Control group= 17	Aged 18 or over	HL (NS) and NH	CI	Online Music Training	1. Pitch task 2. Timbre task	+
Cardin et al. (2020) [27]	To test the effect of L-DOPA on the comprehension of a simulated cochlear implant acoustic signal in hearing individuals	Pilot study	N=35 Training group= NS	Age = 38.0 ± 10.1 SD)	(PTA average) Group 1: 16.4 ± 1.8, Group 2: 14.8 ± 1.3, Group 3: 14.3 ± 1.7	CI	Spectrally-Shifted Noise-Vocoded (SSNV) Speech Training	Spectrally shifted noise vocoded speech (SSNVS) in the presence of L-DOPA or a placebo	+
Kwak et al. (2020) [28]	To introduce the developmental process and contents of a healthcare mobile application-based aural rehabilitation tool, namely, Hearing	program development	N=44 1) Training group= 44 2) Control group= 0	Older adults (mean age= 72.89 years)	NH	None	Hearing Rehabilitation for Older Adults (HeRO) Healthcare Mobile	Phase 1: Development of E-Health Technology 1. Syllable Trainings Using Consonant–Vowel Combinations 2. Sentence Trainings under Background Noise and Fast Rate of Speech	+

Moberly et al. (2020) [29]	To demonstrate that a CAR approach incorporating auditory training (AT) by a speech-language pathologist (SLP) is feasible in adults receiving CIs and to explore whether this approach results in improved outcomes.	Pilot study	N=19 1) Training group= 6 2) Control training: i.Passive =7 ii.Active = 6	49-91 years	Moderate to profound SNHL	CI and HA (Teste d preoperat ively using their HA if worn)	Comprehesive Auditory Rehabilitation (CAR) Training	1. Speech recognition: i. AzBiosentences in quiet, ii. AzBiosentences in 10-talker babble, and iii. Consonant-Nucleus-Consonant (CNC) words in quiet 2. Self-reported QoL: i. Nijmegen Cochlear Implant Questionnaire ii. Hearing Handicap Inventory for Adults/Elderly iii. Speech, Spatial and Qualities of Hearing Scale	ND

NS: Not specified, NA: Not available, ND: No difference, HL: Hearing loss, NH: Normal hearing

Table 3: The acoustic complexity variables used in auditory training programs and the effectiveness trend

Acoustic complexity	Variables	Studies that are found to use specific acoustic highlighting variables in auditory training programs	Findings on study effectiveness + (positive)/ ND (No differences)/ NA (Not Available)		
		n (%) *Paper ID*	+	ND	NA
			n (%) *Paper ID*	n (%) *Paper ID*	n (%) *Paper ID*
Authenticity of sounds	Undegraded	16 (55.2) *1,2,4,6,11,13,14,15,16,17,18, 22,23,24, 25,26*	11 (68.8) *1,6,11,13,15,17,22,23,24,25,26*	3 (18.8) *4,14,18*	2 (12.5) *2,16*
	Degraded	13 (44.8) *3,4,5,7,8,9,12,14,19,21,25,27,28*	10 (76.9) *3,5,7,8,9,12,21,25,27,28*	3 (23.0) *4,14,19*	0 (0.0)
Background noise	Absence	18 (62.1) *1,2,6,7,9,12,13,14,16,17,19,23,24,25,26,27,28,29*	13 (72.2) *1,6,7,9,12,13,17,23,24,25,26,27,28*	3 (16.7) *14,19,29*	2 (11.1) *2,16*
	Presence	21 (72.4) *1,2,3,4,5,10,11,12,13,15,16,17,18,19,20,21,22,23,25,28,29*	15 (71.4) *1,3,5,10,11,12,13,15,17,20,21,22,23,25,28*	4 (19.0) *4,18,19,29*	2 (9.5) *2,16*
Complexity of utterances	Simple	5 (17.2) *8,9,23,24,25*	5 (100.0) *8,9,23,24,25*	0 (0.0)	0 (0.0)
	Complex	20 (69.0) *1,2,3,4,10,11,13,14,15,16,17,18,19,20,21,22,23,26,27,28*	14 (70.0) *1,3,10,11,13,15,17,20,21,22,23,26,27,28*	4 (20.0) *4,14,18,19*	2 (10.0) *2,16*
Distance	Close	5 (17.2) *8,12,15,24,25*	5 (100.0) *8,12,15,24,25*	0 (0.0)	0 (0.0)
	Distance	15 (51.7) *4,5,10,11,13,16,17,18,19,22,23,26,27,28,29*	10 (66.7) *5,10,11,13,17,22,23,26,27,28*	4 (26.7) *4,18,29*	1 (6.7) *16*
Learning Effect	New	9 (31.0) *1,4,12,13,15,16,19,24,25*	6 (66.7) *1,12,13,15,24,25*	2 (22.2) *4,19*	1 (11.0) *16*
	Adapted	20 (69.0) *1,2,3,5,6,7,8,9,11,14,17,18,20,21,22,23,26,27,28,29*	16 (80,0) *1,3,5,6,7,8,9,11,17,20,21,22,23,26,27,28*	3 (15.0) *14,18,29*	1 (5.0) *2*
Learning Style	Passive	7 (24.1) *1,5,10,12,13,15,24*	7 (100.0) *1,5,10,12,13,15,24*	0 (0.0)	0 (0.0)
	Active	26 (89.7) *1,2,3,4,5,6,7,8,9,10,11,12,13,14,16,17,18,19,20,22,23,25,26,27,28,29*	19 (73.0) *1,3,5,6,7,8,9,10,11,12,13,17,20,22,23,25,26,27,28*	5 (19.2) *4,14,18,19,29*	2 (7.7) *2,16*
Length of Utterance	Short	18 (62.1) *3,4,5,8,11,13,15,17,18,19,20,21,22,24,25,26,28,29*	14 (77.8) 3,5,8,11,13,15,17,20,21,22,24,25,26,28	4 (22.2) *4,18,19,29*	0 (0.0)
	Long	15 (51.7) *2,3,4,5,9,10,12,13,14,16,22,23,27,28,29*	10 (66.7) *3,5,9,10,12,13,22,23,27,28*	3 (20.0) *4,14,29*	2 (13.3) *2,16*
Rate of utterances	Slow	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Individual/ normal conversation	17 (58.6) *2,3,4,5,8,13,14,16,18,19,22,23,24,25,26,27,28*	11 (64.7) *3,5,8,13,22,23,24,25,26,27,28*	4 (23.5) *4,14,18,19*	2 (11.8) *2,16*
Repetition	Once	14 (48.3) *3,5,7,8,9,16,18,19,21,24,25,26,27,28*	11 (78.6) *3,5,7,8,9,21,24,25,26,27,28*	2 (14.3) *18,19*	1 (7.1) *16*

	Repeated	13 (44.8) *2,4,6,7,10,11,12,13,14,15,17,22,23*	10 (76.9) *6,7,10,11,12,13,15,17,22,23*	2 (15.4) *4,14*	1 (7.7) *2*
Segmental	Little/no emphasis	4 (13.8) *6,7,8,26*	4 (100.0) *6,7,8,26*	0 (0.0)	0 (0.0)
	Emphasis	25 (86.2) *1,2,3,4,5,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,27,28,29*	18 (72.0) *1,3,5,9,10,11,12,13,15,17,20,21,22,23,24,25,27,28*	5 (20.0) *4,14,18,19,29*	2 (8.0) *2,16*
Set	Close	22 (75.9) *2,3,4,5,6,7,8,11,12,13,15,16,17,18,21,22,23,24,25,26,27,28*	18 (81.8) *3,5,6,7,8,11,12,13,15,17,21,22,23,24,25,26,27,28*	2 (9.1) *4,18*	2 (9.1) *2,16*
	Open	9 (31.0) *5,9,10,12,13,14,16,19,28*	6 (66.7) *5,9,10,12,13,28*	2 (22.2) *14,19*	1 (11.1) *16*
Sounds Origin	Live	2 (6.9) *23,29*	1 (50.0) *23*	1 (50.0) *29*	0 (0.0)
	Recorded	29 (100.0) *1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29*	22 (75.9) *1,3,5,6,7,8,9,10,11,12,13,15,17,20,21,22,23,24,25,26,27,28*	5 (17.2) *4,14,18,19,29*	2 (6.9) *2,16*
Speaker Familiarity	Unfamiliar	20 (69.0) *1,2,3,4,5,9,11,12,13,14,15,16,18,19,22,23,24,25,27,28*	14 (70.0) *1,3,5,9,11,12,13,15,22,23,24,25,27,28*	4 (20.0) *4,14,18,19*	2 (10.0) *2,16*
	Familiar	9 (31.0) *4,5,6,7,8,9,12,21,26*	8 (88.9) *5,6,7,8,9,12,21,26*	1 (11.0) *4*	0 (0.0)
Stimulus Context	In-context	22 (75.9) *1,2,3,4,5,6,7,8,9,11,12,14,16,17,18,19,21,22,23,25,27,28*	16 (72.7) *1,3,5,6,7,8,9,11,12,17,21,22,23,25,27,28*	4 (18.2) *4,14,18,19*	2 (9.1) *2,16*
	Out-of-context	5 (17.2) *5,9,15,24,26*	5 (100.0) *5,9,15,24,26*	0 (0.0)	0 (0.0)
Stimulus Presentation	In sequence	9 (31.0) *5,6,7,8,14,15,19,22,25*	7 (77.8) *5,6,7,8,15,22,25*	2 (22.2) *14,19*	0 (0.0)
	Random	15 (51.7) *2,3,4,5,6,11,12,13,17,18,23,24,26,27,28*	12 (80.0) *3,5,6,11,12,13,17,23,24,26,27,28*	2 (13.3) *4,18*	1 (6.7) *2*
Suprasegmental	Little/no emphasis	15 (51.7) *4,9,10,16,17,18,19,20,21,22,23,24,25,27,29*	10 (66.7) *9,10,17,20,21,22,23,24,25,27*	4 (26.7) *4,18,19,29*	1 (6.7) *16*
	Emphasis	14 (48.3) *1,2,3,5,6,7,8,11,12,13,14,15,26,28*	12 (85.7) *1,3,5,6,7,8,11,12,13,15,26,28*	1 (7.1) *14*	1 (7.1) *2*
Target Position	Initial	8 (27.6) *2,3,9,10,16,18,21,27*	5 (62.5) *3,9,10,21,27*	1 (12.5) *18*	2 (25.0) *2,16*
	Middle	8 (27.6) *2,3,9,10,16,18,21,27*	5 (62.5) *3,9,10,21,27*	1 (12.5) *18*	2 (25.0) *2,16*
	End	9 (31.0) *2,3,9,10,16,18,21,23,27*	6 (66.7) *3,9,10,21,23,27*	1 (11.1) *18*	2 (22.2) *2,16*

frequently include Rate of Utterance—Slow (0%), Segmental—Little/No Emphasis (13.8%), and Sound Origin—Live (6.9%).

Interestingly, only 10 out of the 29 studies [Paper ID: 1, 2, 4, 5, 13, 14, 19, 23, 28, 29] incorporated both the least complex and most complex variables for at least one type of acoustic complexity. For example, for background noise complexity, the study included both the absence (least complex) and presence (most complex) variables in the auditory training. In contrast, the other studies included either only the least complex or only the most complex variables in their auditory training programs.

The effectiveness trends of auditory training programs that incorporate specific acoustic complexity variables

Overall, for each category of acoustic complexity, both the least complex and most complex variables demonstrated more than 50% positive findings when utilized. As illustrated in Table 3, several specific acoustic complexity variables were associated with effective outcomes in the studies. Notably, the following variables were associated with 100% positive outcomes in the studies:

- Complexity of Utterance - Simple
- Learning Style - Passive
- Distance - Close
- Segmental - Little or No Emphasis
- Stimulus Context - Out of Context

This trend highlights the acoustic complexity variables that consistently appeared in studies demonstrating effectiveness. The consistent positive findings across these variables indicate their potential importance in optimizing training outcomes for participants.

In contrast, certain acoustic complexity variables were associated with a high percentage of studies reporting no significant differences in outcomes. Specifically, the variables of Distance and Sound Origin (Live) yielded no difference results in 27% and 50% of studies, respectively. As these findings cannot imply a causal relationship, these findings should be interpreted with cautions.

DISCUSSION

The findings from this scoping review highlight the diverse landscape of adult auditory training programs, which cater to a broad age range and varying levels of hearing ability. The studies analyzed demonstrate that auditory training can enhance auditory skills among individuals with hearing loss (Dubno, 2013; Stacey et al., 2010; Casserly et al., 2019; Maren et al., 2019). Notably, the majority of studies (75.9%) indicated that these training programs are beneficial, underscoring the potential efficacy of auditory training interventions.

This trend emphasizes the positive impact that auditory training can have, yet it also reveals the necessity for further exploration into the variables that influence both successful and less favorable outcomes. The effectiveness of auditory training programs is closely linked to the acoustic complexity variables employed during training, which have been shown to affect training outcomes and participants' speech performance (Burk et al., 2006).

Adult auditory training programs available in literature

Based on the findings, the predominant type of auditory training program in the literature is computer-based auditory training (CBAT). While other studies also explored individual and group training with clinicians, Table 2 indicates that CBAT was the most widely used approach.

Preminger and Ziegler (2008) found that group training did not improve speech perception, as it was challenging to personalize training for individual needs. In contrast, CBAT allows for tailored training, enhancing its effectiveness.

The advantages of structured CBAT programs include flexibility, cost-efficiency, and easy accessibility, enabling users to train at home while clinicians monitor progress remotely (Henshaw et al., 2012). Consequently, CBAT programs are preferred for their adaptability to individual needs compared to other training methods.

Acoustic complexity variables used in adult auditory training programs

The study also explored the range of acoustic complexity variables used in these programs. The recorded sounds variable was the most frequently utilized, allowing for easier implementation and greater exposure to training stimuli compared to live sound presentations (Mendel & Owen, 2011). A comparison of performance between recorded and live sound presentation was conducted by Faulkner et al. (2012), who examined the perception of spectrally shifted noise-vocoded speech. In this study, participants were trained with both live and recorded speech, and the results suggested that training with recorded speech was as effective as live speech in improving spectrally shifted noise-vocoded speech perception. However, the researchers found that the recorded presentation allowed for greater exposure to training phrases than live sounds, which may have contributed to its effectiveness. Therefore, the recorded sound variable is preferable in auditory training, as it is easier to implement, more time-efficient, and provides greater exposure to training stimuli compared to live sound presentations.

The findings indicate that certain acoustic complexity variables were notably underutilized in the auditory training programs reviewed. Specifically, the Rate of Utterance—Slow was not employed in any of the studies, while Segmental—Little/No Emphasis was used in only 13.8% of them, and Sound Origin—Live was included in just 6.9% of the programs.

The low utilization of certain variables may indicate a preference for training methods that provide clearer and more structured environments, such as recorded sounds, which allow for better control over acoustic conditions. The lack of emphasis on a Slow Rate of Utterance suggests that researchers may not prioritize pacing adjustments, even though these adjustments are crucial for improving comprehension in individuals with hearing loss. Research has shown that a slower speech rate can reduce listening effort for individuals with cochlear implants (Winn & Teece, 2021). Therefore, adjusting the rate of speech is essential in training hearing-impaired individuals, allowing them to progress from tasks that require less listening effort (slow rate) to faster rates as they improve.

Moreover, the limited use of Segmental—Little/No Emphasis suggests that many studies focus on dynamic training approaches while potentially overlooking the benefits of incorporating less emphasis on specific phonetic elements in auditory training. Although previous research indicates that speech intelligibility improves for learners who receive segmental training followed by production-focused practice (Yenkimaleki & van Heuven, 2021), it is important to include the little/no emphasis variable. This addition can better mimic normal speech conversations, where emphasis on segmental elements is often absent. Similarly, the infrequent use of live sound presentations may highlight challenges in maintaining consistency and clarity in real-time training settings. Future auditory training programs should incorporate live voice and real-world listening scenarios, as these elements reflect more accurately the complexities of everyday communication.

In addition, only 10 out of the 29 studies [Paper ID:1, 2, 4, 5, 13, 14, 19, 23, 28, 29] incorporated both the least complex and most complex variables for at least one type of acoustic complexity. Future research should include a variety of acoustic complexity variables, ranging from least complex to most complex. The least complex variables may be beneficial for individuals who are just beginning their auditory training or those with significant hearing challenges. These simpler tasks can help build foundational skills without overwhelming participants. On the other hand, the most complex variables suggest that, as individuals progress, exposure to more challenging tasks can further enhance their auditory skills, preparing them for real-world listening situations. This approach can better prepare individuals with hearing loss to navigate real-world listening environments, ultimately enhancing their speech perception and communication skills.

Effectiveness of adult auditory training programs according to different use of acoustic complexity variables

The findings indicate that both the least complex and most complex acoustic complexity variables yielded over 50% positive outcomes across all categories. This suggests that a wide range of acoustic complexity can be effective in auditory training programs. The presence of positive results for both ends of the complexity spectrum highlights the adaptability of these training programs to different learning needs and contexts.

The results presented in Table 3 indicate that several acoustic complexity variables were linked to effective outcomes in the studies reviewed. Variables such as Complexity of Utterance - Simple, Learning Style - Passive, Distance - Close, Segmental - Little or No Emphasis, and Stimulus Context - Out of Context all achieved 100% positive outcomes.

While these findings are promising, it is important to note that they do not establish a causal relationship. The observed effectiveness may be influenced by various factors beyond the acoustic complexity variables themselves. For instance, participant characteristics, the specific design of the training programs, or external environmental factors could also contribute to the outcomes.

Despite this limitation, the consistent positive results associated with these variables suggest they play a significant role in enhancing the effectiveness of auditory training programs. This trend underscores the importance of incorporating these specific variables into training curricula to optimize participant outcomes.

For example, out-of-context stimulus has been used in a study by Loebach and Pisoni (2010) where the stimulus being transferred from meaningful sentences into semantically anomalous by replacing keywords with unrelated or out-of-context words. Their results show that participants trained with out-of-context sentences have more generalization compared to meaningful sentences. According to the findings, out-of-context sentences are more analytical in nature because they allow listeners to focus more on the acoustic elements of sounds as opposed to meaningful sentences, which force listeners into interpretive mode (synthetic approach).

Analytic training is a 'bottom-up' approach as it stresses on acoustic elements to receive the meaning of speech signals (Leo et al., 2012; Tye-Murray, 2009). Whereas synthetic training typically progresses from focusing on acoustic element recognition to understanding sentences. It is referred to as a 'top-down' approach because listeners must fill in the perceptual or acoustic gaps in the message by using their language knowledge and contextual understanding (Bentler et al., 2016). According to Leo et al., (2012), the recognition of acoustic elements of sounds enables listeners to have better understanding and comprehending words or sentences.

In contrast, certain acoustic complexity variables were associated with a high percentage of studies reporting no significant differences in outcomes. Specifically, the variables of Distance and Sound Origin (Live) showed no difference results in 27% and 50% of studies, respectively. Since these findings do not imply a causal relationship, they should be interpreted with caution. For instance, regarding Sound Origin (Live), only two studies utilized live voice, and of those, one reported no difference in effectiveness. Generalizing conclusions based on just two studies should be avoided.

Despite this negative trend, future research should incorporate these two variables (Distance and Sound Origin-Live), as they reflect real listening environments where sound may originate from a distance and from live sources. Including these variables could provide valuable insights into how individuals with hearing loss navigate complex auditory situations in everyday life.

STUDY LIMITATION AND RECOMMENDATION

Throughout this study, we identified various acoustic complexity variables used in auditory training programs that can influence effectiveness. However, certain limitations must be acknowledged. The effectiveness of these programs may also be impacted by other factors, such as the types of training, stimulus materials, and methods employed in the auditory training process. Therefore, future research should consider a comprehensive examination of all components of auditory training that may contribute to its overall effectiveness.

Additionally, our analysis was limited to the acoustic complexity variables reported in the studies reviewed. As a result, we may have overlooked other relevant variables that were not explicitly mentioned in the studies due to the brief descriptions of the auditory training programs provided by the authors. This limitation suggests the need for more detailed reporting in future studies to ensure a complete understanding of the factors influencing auditory training outcomes.

CONCLUSION

This scoping review demonstrates the influence of acoustic complexity variables on the effectiveness of adult auditory training programs, identifying key variables that are associated with positive outcomes. Future research should aim to incorporate a spectrum of acoustic complexities, from the least complex for beginners to the most complex for advanced learners, to provide a structured progression that enhances foundational skills and prepares individuals with hearing loss for real-world listening challenges. This approach may ultimately improve speech perception, communication skills, and overall satisfaction with auditory training outcomes.

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ORIGINAL ARTICLE

Parental perception and knowledge of sound and noise pollution in learning environment at home.

Anis Syuhada Mohd Sabidi[1], Noraidah Ismail[1,*]

[1]Department of Audiology and Speech-Language Pathology, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
noise pollution; parental awareness; home learning environment; noise at home; educational intervention.

ABSTRACT

Background: Noise pollution poses increasing concerns for health and learning, with parental knowledge playing a critical role in managing noise levels in children's home learning environments. **Objective**: This study evaluates parents' perceptions and knowledge of noise pollution in their children's study spaces. **Method**: A cross-sectional design was employed, and convenience sampling was used to select 144 Malaysian parents of school-aged children. A questionnaire was administered to assess their views on noise sources and management practices in home learning environments. All data were analysed via SPSS (Version 20). **Results**: While 87.5% of parents enforced sound-level rules, only 44.4% recognised noise as a health risk, indicating limited awareness. Mann-Whitney U test showed no significant difference in noise awareness between parents of different educational levels (p=0.247). **Conclusion**: The findings reveal critical gaps in parental awareness regarding noise's health impacts, highlighting the need for educational programs to help parents create quieter, more supportive learning environments for children.

INTRODUCTION

Noise pollution refers to any unwanted or intrusive sounds within communities, including disturbances caused by loud music or television from neighbours, nighttime traffic, and outdated household appliances, while excluding workplace-related or occupational noise exposure (Petric, 2022; Rusticus et al, 2023). It has emerged as a pressing concern due to the profound impacts on human health and overall well-being.

Noise pollution can significantly impair the learning environment, whether in schools or at home (Abdullah et al., 2021). It can be highly distracting, making it difficult for students to focus on their studies (Bulunuz & Özgür, 2021). This distraction can reduce concentration, lower productivity, and ultimately hinder the learning process (Shield & Dockrell, 2003; Diaco, 2014). The learning environment encompasses physical, social, psychological, and emotional factors that contribute to the educational experience, whether in formal or informal settings (Rusticus et al., 2023). A well-designed, positive learning environment is crucial for promoting effective learning and fostering personal development (Tavşanlı et al., 2017).

In Malaysia, traffic noise is the predominant source of noise pollution, largely driven by the increasing number of vehicles on the road (Isa et al., 2018). The persistent noise from road traffic has had a considerable impact on residential areas and their surroundings. Previous studies found that none of the surveyed schools complied with the World Health Organization's (WHO) recommended noise levels, which specify a maximum of 35 dB(A) for unoccupied classrooms and 55 dB(A) for occupied classrooms (Ismail et al., 2020; Nayan et al., 2022). These findings underline the widespread issue of elevated noise levels in educational settings across Malaysia, which may negatively affect the learning environment.

Despite growing awareness of noise pollution as a critical issue in home learning, many parents remain unaware of its impact on children's cognitive, emotional development concentration, academic performance, and well-being (Klate et al., 2013; Buchari & Matondang, 2017). Past studies indicate that chronic exposure to household and environmental noise disrupts memory and attention processes, which are foundational to effective learning (Chere & Kirkham, 2021; Dohmen et al., 2022). Though parents may value noise reduction, few consistently apply noise control measures at home (Bulunuz & Özgür (2021).

* *Corresponding author.*
E-mail address: noraidah@iium.edu.my

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Socioeconomic status, education, and cultural views shape parents' perceptions and actions regarding noise pollution. Studies showed that higher-educated parents tend to limit noise more effectively, thus reducing children's exposure to loud sounds (Knobel & Lima, 2014; Đurišić & Bunijevac, 2017). This indicates that parents have a significant influence on their children's environment whether at home or outside the home. Understanding this dynamic is essential for addressing parental behaviours and increasing awareness about noise pollution and its effects.

This study examines parents' awareness, perspectives, and behaviours regarding household noise, highlighting their critical role in fostering optimal learning conditions. By assessing parents' knowledge of noise pollution within Malaysian home learning environments, the study explores sources of noise, parents' views on its impact on children's learning and well-being, and attitudes toward noise management practices. It also compares noise awareness among parents with different educational backgrounds.

METHODOLOGY

This cross-sectional study assessed parents' knowledge and opinions on noise in home learning environments. Convenience sampling was used to select the participants based on accessibility and proximity while adhering to several inclusion and exclusion criteria. The inclusion and exclusion criteria are designed to focus the study on a specific population that is most relevant to the research objectives. By selecting only parents of school-aged children (7–17 years old) and requiring proficiency in Malay, the study ensures it captures the experiences of a demographic that reflects the cultural and linguistic context of the research. Using the Malay language for the questionnaire avoids issues of misinterpretation or translation errors, ensuring the responses are accurate and meaningful.

Excluding non-primary caregivers further strengthens the study's validity by ensuring that responses come from individuals who are directly involved in the child's home learning environment and responsible for managing noise. Primary caregivers are more likely to have detailed knowledge of and influence over the child's surroundings, making their input particularly valuable to the research.

A total of 144 parents meeting these criteria participated in the study. The sample size was determined through power calculations for adequate representation. The data were collected using the translated version of the "*Pandangan ibu bapa mengenai bunyi dan pencemaran bunyi dalam persekitaran belajar*" questionnaire by Hazaha and Ismail (2022). The questionnaire consists of 36 questions across four sections: demographics information, domestic noise (5 questions), external noise sources (4 questions), and parents' knowledge of noise management at home (15 questions).

Procedures

The data collection process spanned a two-month period. All participants voluntarily completed the questionnaire via a Google Form, which was distributed through social media platforms including email, Facebook, and WhatsApp. The first page of the form contained an informed consent section, providing participants with detailed information about the study. The participants were required to read and electronically sign the consent form before proceeding to the questionnaire. Clear instructions were provided to guide them in accurately completing the form. All data were analysed using the SPSS software (Version 20).

RESULTS

Parents' Demographic Characteristics

Table 1 summarises the demographic characteristics of the parents who participated in this study. It provides a clear breakdown of the demographic variables, specifically focusing on gender, age, number of children, educational background, and employment status. A vast majority of the participants were female, accounting for 86.8% of the sample while only 13.2% were male. Most parents fell into the 46-55 age group (52.8%), followed by those aged 36-45 (33.3%). Regarding the number of children, 34.7% of parents had three children while 28.5% had five or more. The educational background showed that 59.7% of parents completed tertiary education while only 1.4% had primary school education. Regarding employment, more than half (51.4%) of the parents were employed in the government sector, followed by those in the private sector (15.3%) and self-employed (11.8%).

Table 1: *Demographic Variables Regarding Parents*

Variables	Options	n	%
Gender	Female	125	86.8
	Male	19	13.2
Age (Year)	26-35	9	6.30
	36-45	48	33.3

	46-55	76	52.8
	56-65	11	7.60
Number of children	1	13	9.00
	2	12	8.30
	3	50	34.7
	4	28	19.4
	≥ 5	41	28.5
Educational status	Primary school	2	1.40
	Secondary school	26	18.1
	Diploma	30	20.8
	Tertiary education	86	59.7
Working status	Self-employment	17	11.8
	Government sector	74	51.4
	Private sector	22	15.3
	Housewife	23	16.0
	Other	8	5.60

Household Noise Management and Parental Perception of Noise

Table 2 shows the participants' responses to the general information questions regarding household noise management and parents' perception of noise.

Table 2: Household Noise and Parental Perception

Variables	Options	n	%
Rule on sound level in the family	Yes	121	84.0
	No	23	16.0
Who sets the rules at home	None	23	16.0
	I	22	15.3
	My partner	19	13.2
	My partner and I	61	42.3
	Kids, partner, and I	18	12.5
	Other individuals	1	0.7
Obedience to household rules	Yes	117	81.3
	No	27	18.8
Child has own room	Yes	131	91.0
	No	13	9.0
Suitable study environment at home	Yes	129	89.6
	No	15	10.4
"Noise disturbs but does not harm health"	Agree	64	44.4
	Undecided	16	11.1
	Disagree	64	44.4

Table 2 outlines the household noise rules and parents' awareness of noise impacts, pointing towards possible gaps in understanding the health effects of noise pollution. Most parents (84.0%) reported having sound-level rules for family interactions while the others (16.0%) did not. Nearly half of them (42.3%) established these rules jointly with their partners and a vast majority (81.3%) indicated that all family members adhered to these rules. Additionally, 91.0% of parents said that their children had a dedicated room and 89.6% ensured a suitable study environment at home. However, the parents' opinions on the health impact of noise were mixed: 44.4% believed noise "disturbs but does not harm", an equal 44.4% disagreed, while 11.1% were undecided. This highlights a possible knowledge gap on noise's health risks.

Parents' Views on the Level and Causes of Noise at Home

Table 3 summarises the parents' perspectives on household noise sources. Nearly half of them (46.5%) reported noise issues while 53.5% did not. Children were noted as occasional noise sources by 70.1% of parents, with 6.9% indicating frequent disruptions. The most bothersome noise was attributed to children (42.4%), followed by televisions (TVs), computers, and other devices (34.7%) and domestic appliances (20.2%). Only 2.8% of parents reported no disruptive noises. Additionally, 36.8% of parents found household noise somewhat distracting during activities like reading or studying while 7.6% reported it as highly disruptive.

Table 3: Parents' Views on the Causes of Noise at Home

Variables	Options	n	%
Problems caused by noise in the house	Yes	67	46.5
	No	77	53.5
Proportion of noise made by children	Never	5	3.5
	Rarely	28	19.4
	Sometimes	101	70.1

	Often		10	6.9
Most annoying noise	Noise made by children		61	42.4
	Refrigerator/air conditioner		6	4.2
	Washing machine/ dishwasher		23	16.0
	TV/computer/ aquarium/clock		50	34.7
	None		4	2.8
The extent to which noises at home distract someone reading or studying	Not at all	1	26	18.1
	Rarely	2	30	20.8
	Sometimes	3	53	36.8
	Often	4	24	16.7
	A lot	5	11	7.6

Table 3 provides a clear overview of the sources of household noise and its impact on daily activities, underscoring the prevalence of child-related and domestic appliance noise in the home environment.

Parents' Views on External Noise Sources

Table 4 summarises the parents' views on external noise sources affecting their homes. Approximately half of them (52.8%) reported issues with external noise, with traffic noise being the most common source, impacting 66.7% of parents. Neighbour noise (34.7%) and playground sounds (15.3%) also contributed to external noise sources while only 4.9% of parents noted no issues. When asked about the most bothersome noise, 64.6% cited traffic, followed by neighbour noise (22.9%) and playground noise (7.6%). Regarding its effect on activities like reading or studying, 35.4% reported some distraction and 7.6% experienced significant disruption.

Table 4: Parents' Views on External Noise Sources

Variables	Options	n	%
Problems with outside noise	Yes	76	52.8
	No	68	47.2
Sources of external noise	Traffic noise	96	66.7
	Noise from neighbours	50	34.7
	Noise of children in the playground	22	15.3
	None	7	4.90
Most annoying external noise	Traffic noise	93	64.6
	Noise from neighbours	33	22.9
	Noise of children in the playground	11	7.60
	None	7	4.9
The extent to which noises from outside home distract someone reading or studying	Not at all 1	22	15.3
	Rarely 2	22	15.3
	Sometimes 3	52	35.4
	Often 4	38	26.4
	A lot 5	11	7.6

These findings highlight the significant impact of traffic noise on families and the effect of neighbourhood activities on the home environment, particularly in terms of disrupting focus and concentration for activities like reading and studying.

Parents' Views on Noise Management at Home

Table 5 highlights the parents' perspectives on noise management for supporting children's learning at home. Nearly a quarter (23.6%) of parents considered reducing noise critically important while 42.4% deemed it important. In reducing noise at home, 43.8% of parents limit loud TVs and music, and 32.6% enforce speaking in low tones. Although 71.5% noted that appliance sounds like vacuums are "a little audible" during study time, 72.2% said they "rarely" use them, indicating the awareness of noise as a distraction to some extent. Additionally, 36.8% of parents occasionally lower their voices when conversing during study time, though most do not do this regularly. Nevertheless, 73.6% enforced a no-loud-talking rule and 62.5% required others to stay quiet or whisper. Most parents (59.7%) rarely permitted study sessions with music or TVs while others (28.5%) perceived music to negatively impact learning. 51.4% of parents believed that sounds like TVs, radios, or appliances are considered noise that could interfere with learning.

Table 5: Parents' Views on Noise Management at Home

Variables	Options	n	%
Importance of reducing noise for children	A little important	42	29.2
	Important	61	42.4
	Very important	34	23.6
	Insignificant	7	4.9
Most disturbing noise	Noises in the house	35	24.3
	Noises from outside the house	94	65.3
	Noise is not a problem	15	10.4

What do you do to deal with or reduce noise at home?	Speak loudly to be heard	4	2.8
	Prefer low-noise appliances	6	4.2
	Limit listening to loud TV/music	63	43.8
	Speak in low tone	47	32.6
	Do not do much	19	13.2
	Other	5	3.5
How audible are household appliances from child's room?	It is never heard	16	11.1
	A little audible	103	71.5
	It can be heard easily	25	17.4
Frequency of using appliances during study time	Never	26	18.1
	Rarely	104	72.2
	Sometimes	14	9.70
	Often	0	0.00
How often are conversations/phone calls heard in child's room?	It is never heard	43	29.9
	A little audible	96	66.7
	It can be heard easily	5	3.50
Do you lower your tone when talking in child's room?	Never	24	16.7
	Rarely	51	35.4
	Sometimes	53	36.8
	Often	16	11.1
Rule against loud speaking in family communication	Yes	106	73.6
	No	38	26.4
Rule for maintaining quiet while child studies	Yes	90	62.5
	No	54	37.5
Allow child to study with music or TV on	Never	31	21.5
	Rarely	86	59.7
	Sometimes	25	17.4
	Often	2	1.40
Studying at home with music negatively affects learning	I strongly disagree	4	2.80
	I disagree	51	35.4
	I'm undecided	34	23.6
	I agree	41	28.5
	I strongly agree	14	9.7
All kind of sounds from appliances and conversations that can be heard from the room	I strongly disagree	3	2.1
	I disagree	36	25.0
	I'm undecided	14	9.7
while children are studying are considered noise	I agree	74	51.4
	I strongly agree	17	11.8

These findings suggest that parents are generally aware of the importance of managing household noise, although the level of action taken varies. While most parents recognise the disruptive nature of both internal and external noise, there are differing opinions on how significantly these noises affect learning, reflecting a need for greater awareness and possibly stricter household noise management strategies. A Spearman correlation analysis was conducted to examine the relationship between parental awareness of noise pollution and noise mitigation behaviors. The results indicated no significant relationship ($p = 0.095$, $r = -0.140$), with a weak negative correlation suggesting that increased awareness does not consistently translate into noise mitigation actions at home.

Parents' Noise Awareness Based on Education Level

A Shapiro-Wilk test was performed to evaluate data normality, revealing a non-normal distribution ($p< 0.05$). Thus, the Mann-Whitney U test was applied to compare the groups based on education level (low vs. high). "Low education" includes primary through secondary schooling while "high education" encompasses diploma and tertiary levels. The Mann-Whitney U test results indicate no significant difference in awareness regarding the negative effects of noise between parents with low and high education levels ($U=1832$, $p=0.247$). Despite a slightly higher mean rank in the high-education group (74.29) compared to the low-education group (65.07), the p-value (0.247) exceeds the conventional threshold of 0.05. This suggests that the difference in awareness levels between the two groups is not statistically significant, indicating that parents across education levels may have similar awareness of noise's negative effects.

DISCUSSION

This study assesses parents' knowledge and perceptions of noise pollution in the home learning environment. The findings reveal that while most parents recognise the importance of reducing noise, many are unaware of specific sources and effects of noise pollution. Some parents admitted to behaviours that contribute to noise pollution, such as using household appliances or allowing background noise from TVs or radios while their children are studying as shown in Table 5. This result is consistent with the findings of Bulunuz and Özgür (2021) who noted that parents often exhibit noisy behaviours like loud chatting or making phone calls even when their children

are studying. However, many parents also reported taking steps to create a quieter environment, indicating an overall awareness of the need for noise reduction.

Despite awareness of the negative impacts of noise, a noticeable gap persists between parental understanding and the consistent implementation of noise reduction strategies. Many parents acknowledge the harmful effects of noise but rarely take consistent actions, such as lowering their voices or avoiding noisy appliances during study times. This disconnect between awareness and behavior suggests that factors such as limited resources or environmental constraints may hinder parents from effectively managing noise. These findings emphasize the need for further research to explore the barriers influencing parental noise management behaviors. Future studies involving larger and more diverse samples could provide valuable insights and inform the development of targeted interventions to bridge this gap. Addressing this disconnect remains a critical area for future attention.

This study highlights that nearly half of parents experience significant external noise disruptions, particularly from traffic, neighbours, and playgrounds, which interfere with home learning. To effectively mitigate external noise in home learning environments, various acoustic strategies should be recommended to parents such as soundproofing windows and doors by installing double-glazed glass and adding weather stripping, which can significantly reduce incoming noise levels (Scannell et al., 2016; Gheller et al., 2020). Noise levels could be reduced by approximately 4 dB(A), translating to a 40% decrease in acoustic energy by installing sound barriers and planting dense vegetation along roadsides (Sonnadara et al. (2009). Apart from that, installing carpets and heavy curtains could provide further noise reduction as these materials absorb and dampen sound while curtains serve as barriers to outside noise (Shield & Dockrell, 2003; Mealings, 2023). These measures will foster an optimal acoustic environment, which is beneficial for both homes and educational settings while supporting a quieter, more focused learning atmosphere. Parents can also establish dedicated study spaces in quieter parts of the home, ideally away from external noise sources.

Enhancing parental knowledge and offering practical solutions can help create a more conducive learning environment at home. This may include community workshops, informational campaigns, and collaboration with schools to ensure that parents are well-equipped to support their children's educational needs effectively (Đurišić & Bunijevac, 2017). The survey revealed an equal split on the statement "Noise disturbs but does not harm human health", with 64 parents (44.4%) agreeing, 64 (44.4%) disagreeing, and 16 parents (11.1%) undecided. The findings suggest a common misconception that while noise can be annoying or disruptive, it does not have lasting or serious health consequences. It reflects a limited awareness of the noise risks which highlights the need for broader public education on how "harmless" noise levels can impact health and well-being over time (Klatte et al., 2013; Tavsanli et al., 2017; Dohmen et al., 2022).

The Mann-Whitney U test revealed no significant differences in noise-related health awareness between parents with low and high education levels. Although parents with higher education showed a slightly higher mean rank in awareness, this difference is not statistically significant. These findings contrast with earlier research by Knobel and Lima (2014), which suggested that parents with lower educational attainment were less concerned about their children’s exposure to noise than those with higher education levels. This discrepancy may indicate that awareness of noise pollution’s health effects transcends formal education, possibly influenced by community awareness campaigns or media initiatives. However, it is noteworthy to highlight that the sample size disparity between the groups could influence the study's statistical power and affect the generalisability of these findings. This could affect the reliability and generalisability of the findings, leading to greater variability and possibly not representing the broader population of parents with lower education levels (Slavin & Smith, 2009). Therefore, the observed difference might reflect the specific sample rather than a true population-wide phenomenon.

Based on the findings, several avenues for future research are recommended. First, it is crucial to investigate the unexpected result that parents with lower education levels exhibit greater awareness regarding the negative effects of noise. Qualitative studies could offer valuable insights into the underlying factors driving this awareness. Additionally, larger and more diverse studies are needed to validate and further explore this phenomenon, ensuring that the findings are representative of the broader population. Our data did not capture the extent of joint decision-making within households, which limits our ability to analyze this relationship. Future research could explore this aspect, as it may influence noise awareness and management behaviors. Furthermore, future studies should examine the long-term impact of noise pollution on children's academic performance, considering demographic variables such as socioeconomic status, urban versus rural environments, and age groups. This would provide a more comprehensive understanding of how noise pollution affects children's learning and development over time.

CONCLUSION

The findings of the current study highlight significant gaps in parental awareness of the health risks and cognitive impacts of noise pollution. Many parents underestimate noise's harmful effects, as reflected in mixed perceptions of its health impact and inconsistencies in noise management practices. Efforts should prioritize educating parents on the long-term effects of noise on cognitive and emotional health, particularly in households without noise management rules. Educational programs addressing these gaps can equip parents with effective strategies for managing household and external noise. Public policies and collaborative efforts with authorities, such as the Department of Environment should focus on implementing noise reduction measures like soundproofing and improving room acoustics. By addressing these issues, parents can create quieter, more supportive environments that enhance their children's focus and academic performance.

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ORIGINAL ARTICLE

Baseline Study on Knowledge, Attitude and Practice Assessments on Covid-19 Transmission and Preventive Actions Among Ecotourism Operators in Kuala Tahan and Kuala Gandah

Nur Fasihah Mat Puat[1], Shahidatulmunirah Ahmad Azam[1], Nurulwahida Saad[1], Norafiza Zainuddin[1], Mohd Arifin Kaderi[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
COVID-19, ecotourism operators, public health, preventive measures

ABSTRACT

Background: The SARS-CoV-2 virus that caused COVID-19 led to a global pandemic with widespread impacts on economies, particularly the tourism sector. This study assesses COVID-19-related knowledge, attitudes, and practices (KAP) among ecotourism operators in Kuala Tahan and Kuala Gandah by exploring demographic factors influencing these variables. **Methods:** A cross-sectional design was employed, surveying 96 ecotourism operators using a structured and validated KAP questionnaire. The survey captured detailed demographic data and assessed COVID-19 knowledge, awareness, and preventive practices. **Results:** Overall, respondents demonstrated high knowledge of COVID-19 (mean score: 12.76, SD: 1.8) likely influenced by public health campaigns. Knowledge scores were significantly associated with gender and education background ($p<0.05$). Attitude and practice scores were also positively correlated with knowledge scores, showing mean scores of 4.20 (SD: 0.59) and 9.61 (SD: 0.91) respectively and there were weak positive correlations between KAP variables ($p<0.01$). **Conclusion**:These findings highlight the importance of targeted, demographic-specific education and the integration of technology to enhance health literacy and promote adherence to COVID-19 prevention measures in rural communities.

INTRODUCTION

The novel coronavirus pandemic caused by the widespread impacts of the SARS-Cov-2 virus has drastically affected health, economics, and rural ecotourism operators (Marinov & Todorova 2020). According to The World Tourism Organization (UN Tourism 2020), the pandemic led to a decline in tourist arrivals, the closure of ecotourism destinations, and reduced activity in associated businesses such as travel agencies, tours, and hospitality. The World Economic Forum highlights how the pandemic disrupted the tourism industry globally particularly ecotourism, as it relies heavily on face-to-face engagement and international mobility making it less resilient to such shocks. This fragility was evident in the closure of destinations, loss of income, and the challenge of adapting to virtual or alternative tourism models (Al-Khateeb, 2021). The decline in tourist numbers and rising unemployment have significantly reduced both local and international visits, leading to a marked decrease in financial income for operators in the ecotourism sector. This decline has been particularly severe in Malaysia, where rural ecotourism areas have been hit hard due to the pandemic's extensive reach and the resulting movement control orders (MCO) that halted operations completely (Hussin et al., 2022).Despite these challenges, there is a notable lack of research specifically addressing the impact of COVID-19 on rural ecotourism operators in Pahang and Malaysia in general, as well as insufficient documentation of the effectiveness of countermeasures implemented to mitigate the adverse effects of the endemic on this sector. According to Yousufuddin (2024), rural health systems are less equipped to manage outbreaks due to lack of resources, trained personnel, and facilities. Hence, the increasing influx of tourists to rural ecotourism sites poses a significant threat of COVID-19 outbreaks, especially in areas where healthcare services may be limited. Besides, a collaborative frameworks that involve stakeholders from various disciplines, including infectious disease experts and tourism professionals are essential for controlling and managing COVID-19 transmission in rural ecotourism areas such as Kuala Tahan and Kuala Gandah. Engagement with health authorities, local governments, and ecotourism operators in designing health and safety protocols to mitigate transmission risks and maintain economic viability is therefore highly recommended (Gössling et al., 2020).

Hence, implementing effective surveillance and disease control measures is crucial for monitoring and managing health and well-being in these vulnerable populations (Suttiporn et al., 2021; Piyoosh et al., 2022). Conducting a KAP assessment in this context is crucial within the rural ecotourism operators in Malaysia's tourism sector particularly in Pahang as these communities face increased vulnerability to COVID-19 outbreaks due to limited healthcare resources and a high influx of tourists (Naz et al., 2022). This study aim to assess the knowledge,

* *Corresponding author.*
E-mail address: ariffink@iium.edu.my

attitudes, and Practices (KAP) related to COVID-19 transmission and preventive measures among ecotourism operators in Kuala Tahan and Kuala Gandah, Pahang and to identify how socio-demographic factors such as age, gender, and education level influence these variables.

MATERIALS AND METHODS

Study Design and Setting

This cross-sectional study targeted ecotourism operators and their employees specifically in Kuala Tahan and Kuala Gandah, Pahang. A convenience sampling was employed to select participants based on their availability and willingness to participate and snowball sampling was used to identify additional participants through referrals from initial respondents.

Ethics

This study was conducted upon ethical approval that was granted by the Kulliyyah Postgraduate and Research Committee (KPGRC) of the Kulliyyah of Allied Health Sciences, IIUM Kuantan Campus (Reference no: IIUM/310/14/11/2) to ensure minimal risks and benefits for human subjects. In addition, the study also received ethical clearance from the IIUM Research Ethics Committee (Reference no: IREC-2023 199).

Tools

The survey was conducted from February to March 2024, used a questionnaire adapted from Kaderi et al. (2024) and translated into English and Bahasa Melayu. The content was based on Conceptual Framework Figure 1 which outlines the key variables influencing KAP towards COVID-19 and preventive measures. The survey was administered through face-to-face interviews to ensure clarity and to allow the interviewer to provide explanations if any questions were unclear. The questionnaire included six sociodemographic items and 34 KAP items to assess COVID-19 knowledge, attitudes, and practices. The scoring system for the attitude items was a likert scale on a scale from "strongly disagree" (1) to "strongly agree" (5). However, the scoring system for knowledge items and practice items were dichotomous scale; "yes" and "no". Inclusion criteria required participants to work at least 12 hours per week in ecotourism within the Kuantan District and be proficient in English or Malay. Exclusion criteria included premises not directly related to ecotourism. A pilot study with 30 respondents from the Royale Chulan Cherating staff evaluated the questionnaire's clarity, reliability, and validity. Data from the pilot study were analyzed using SPSS Version 26.0 to assess internal consistency with Cronbach's alpha. The results showed alpha coefficients of 0.866, 0.960, and 0.825 for knowledge, attitude, and practice items, respectively, indicating good reliability. The study followed Roscoe's (1975) sample size standards, suggesting 30 to 500 respondents to balance statistical significance and avoid errors.

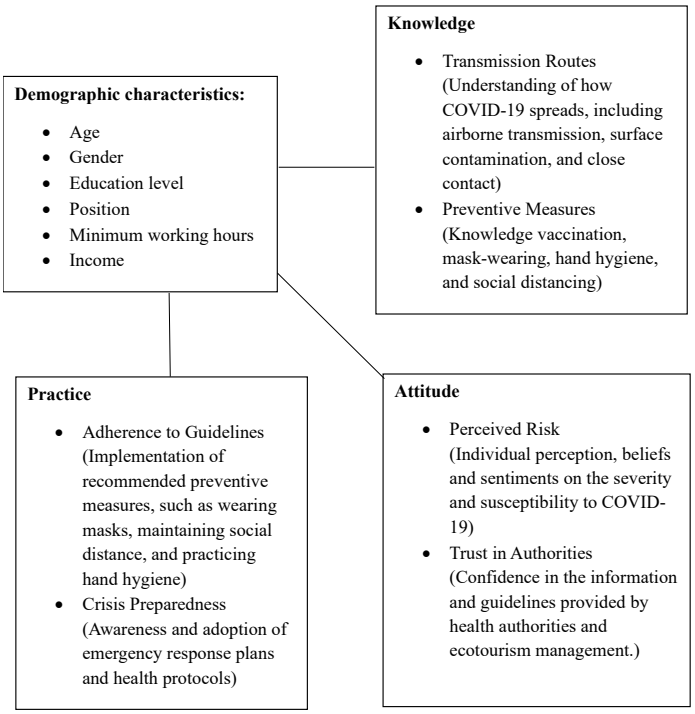

Figure 1: Conceptual Framework of Knowledge, Attitude and Practice of COVID-19 Transmission and Preventive Actions Among Operators Of International Attraction Ecotourism Areas In Rural Pahang

Analysis

Descriptive analysis was applied to the sociodemographic data to provide a clear summary of the characteristics of the respondents, such as age, gender, education level, and occupation. To investigate potential associations between demographic factors and KAP (knowledge, attitudes, and practices) levels, non-parametric statistical tests were utilized. The Mann-Whitney U test was used to compare the KAP scores between two independent groups, such as gender or educational background, to determine if there were significant differences between these groups. For assessing relationships between continuous variables, the Spearman's rank correlation coefficient was employed, as it is suitable for measuring the strength and direction of relationships between variables. These statistical methods allowed for a comprehensive analysis of the associations and correlations within the study to provide insights into how sociodemographic factors might influence the knowledge, attitudes, and practices towards COVID-19 among ecotourism operators.

RESULTS

A total of 96 ecotourism operators participated in the study. Majority of the participants were male (65.6%), aged between 21 to 30 years old (37.3%), obtained their secondary education level (59.4%), working for more than 24 hours per week (55.2%) and earn within RM1001 to RM3000 monthly (66.7%) (Table 1).

Table 1: Socio-demographic characteristics of the study participants

Variables	Frequency (n)	Percentage (%)
Gender		
Male	63	65.6
Female	33	34.4
Age		
<20	4	4.2
21-30	32	33.3
31-40	26	27.1
41-50	22	22.9
51-60	9	9.4
61-70	3	3.1
Education Level		
Primary	13	13.5
Secondary	57	59.4
Tertiary	26	27.1
Position		
Employer	17	17.7
Employee	79	82.3
Min working hour/week		
12-16 hours	28	29.2
17-21 hours	10	10.4
22-24 hours	5	5.20
>24 hours	53	55.2
Income		
<RM1k	21	21.90
RM1.1-3k	64	66.70
RM3.1-5k	5	5.20
>RM5k	6	6.30

Table 2 provides descriptive data summarizing the levels of knowledge, attitude, and practice (KAP) among respondents regarding COVID-19, along with the percentage distribution and mean scores.

Table 3 illustrates the knowledge levels categorized as poor, moderate, and good among respondents, along with the corresponding p-values to indicate statistical significance. Result show that there are association between gender and education level with p-value of 0.028 and 0.042 respectively proven by statistically significance ($p < 0.05$).

Table 4 presents attitude levels of respondents. Most respondents demonstrated a "good" attitude level across all demographic categories.

Table 2: The association between sociodemographic variable and knowledge scores

Category	n	%	Mean score	S.D
Knowledge Level				
Poor	15	15.6		
Moderate	13	13.5	12.76	1.80
Good	68	70.8		
Attitude Level				
Poor	1	1.0		
Moderate	9	9.4	4.20	0.59
Good	86	89.6		
Practice Level				
Poor	2	2.1		
Moderate	8	8.3	9.61	0.91
Good	86	89.6		

n = number of respondents, % = percentage of respondents, S.D = standard deviations

Table 3: The knowledge level and association between sociodemographic variable and knowledge score

Categories	Knowledge level			p-value
	Poor	Moderate	Good	
Gender				
Male	13	11	39	**0.028**
Female	2	2	29	
Age				
<20	2	1	1	0.129
21-30	4	3	25	
31-40	1	5	20	
41-50	3	2	17	
51-60	3	2	4	
61-70	2	0	1	
Education Level				
Primary	5	2	6	
Secondary	7	8	42	**0.042**
Tertiary	3	3	20	
Job Category				
Employer	5	2	10	0.089
Employee	10	11	58	
Mini working hours per week				
12-16 hours	5	2	21	0.658
17-21 hours	2	2	6	
22-24 hours	1	1	3	
> 24 hours	7	8	38	
Income				
< RM1000	7	2	12	0.066
RM1001-RM3000	5	10	49	
RM3001-RM5000	1	0	4	
> RM5000	2	1	3	

Table 5 presents practice levels among all the respondents and only age has a statistically significant association with practice levels.

Table 4: The attitude level and association between sociodemographic variable and knowledge score

Categories	Attitude level			p-value
	Poor	Moderate	Good	
Gender				
Male	1	6	56	0.055
Female	0	3	30	
Age				
<20	0	1	3	0.141
21-30	0	3	29	
31-40	1	3	22	
41-50	0	2	20	
51-60	0	0	9	
61-70	0	0	3	
Education Level				
Primary	0	2	11	0.506
Secondary	1	6	50	
Tertiary	0	1	25	
Job Category				0.640
Employer	0	2	15	
Employee	1	7	71	
Mini working hours per week				
12-16 hours	0	1	27	0.919
17-21 hours	1	2	7	
22-24 hours	0	0	5	
> 24 hours	0	6	47	
Income				
< RM1000	0	1	20	0.574
RM1001-RM3000	1	8	55	
RM3001-RM5000	0	0	5	
> RM5000	0	0	6	

Table 5: The association between sociodemographic variable and practice scores

Categories	Practice level			p-value
	Poor	Moderate	Good	
Gender				
Male	1	5	57	0.837
Female	1	3	29	
Age				
<20	0	2	2	**0.003**
21-30	1	2	29	
31-40	0	2	24	
41-50	1	0	21	
51-60	0	1	8	
61-70	0	1	2	
Education Level				
Primary	1	0	12	0.10
Secondary	1	7	49	
Tertiary	0	1	25	
Job Category				
Employer	0	2	15	0.704
Employee	2	6	71	
Mini working hours per week				
12-16 hours	2	4	22	0.409
17-21 hours	0	2	8	
22-24 hours	0	0	5	
> 24 hours	0	2	51	
Income				
< RM1000	0	2	19	0.820
RM1001-RM3000	2	5	57	
RM3001-RM5000	0	1	4	
> RM5000	0	0	6	

As shown in Table 6, results of the correlation analysis indicated that there is a weak positive correlation between knowledge and attitude scores (r = 0.260, p=0.01), knowledge and practice scores (r = 0.267, p=0.009), attitude and practice scores (r = 0.325, p=0.001).

Table 6 : Correlation between Knowledge, Attitude and Practice Scores

Variable	Correlation Coefficient, r	p-value
Knowledge-Attitude	0.260	0.01
Knowledge-Practice	0.267	0.009
Attitude-Practice	0.325	0.001

*Correlation is significant at 0.01 level (2-tailed)

DISCUSSION

The study reveals a statistically significant association between knowledge scores and gender with a p-value of 0.028, whereby female have better knowledge scores compared to males. This aligns with broader research indicating gender differences in COVID-19 knowledge, where women often show higher awareness and knowledge levels about the virus than men (Loleka & Ogawa 2022; Tan et al., 2022). In many settings, women are more likely to be involved in housekeeping and facility management. These roles may require them to stay informed about health and hygiene practices to maintain a safe and clean environment, thereby increasing their knowledge about COVID-19 (McInnes et al., 2020). Hence, understanding these gender-based disparities is crucial for tailoring public health interventions to ensure both men and women are equally informed and capable of adopting preventive measures.

Furthermore, the association between education level and knowledge scores is also statistically significant with a p-value of 0.042. This indicates that individuals with higher educational attainment tend to have better knowledge about COVID-19. A study conducted by Tao et al (2023) informs that high health literacy is associated with better understanding of COVID-19 symptoms and preventive behaviour. These findings emphasize that enhancing access to education and health literacy can play a critical role in improving public health outcomes during epidemics. Besides, the significant association between practice scores and age groups indicated by a p-value of 0.003 highlights the differences in how individuals across various age categories adopt preventive measures against the virus. Younger individuals are often more proficient in leveraging digital platforms and social media to gather information which can influence their adherence to preventive practices during public health crises like COVID-19 (Hauer & Sood, 2020).

The results imply that individual knowledge about COVID-19 seems to enhance their attitudes towards the disease transmission and preventive measures. This is consistent with the Knowledge-Attitude-Practice (KAP) model which emphasizes that accurate health-related knowledge can foster positive attitudes and drive adherence to preventive behaviors. For instance, a study by Zhong et al. (2020) found that Chinese residents with higher knowledge levels exhibited more proactive attitudes and better compliance with COVID-19 prevention guidelines, such as social distancing and mask-wearing. In addition, similar observations were also reported on acceptance and compliance to vaccination programs (Liu et al., 2022). The current study demonstrates a positive correlation between knowledge and practice regarding COVID-19 preventive measures. Similar findings were observed in a study by Srichan et al. (2020) which assessed knowledge, attitudes, and practices (KAP) among the Thai population during the COVID-19 pandemic showed that individuals with better knowledge were more likely to adopt preventive measures such as wearing masks and frequent handwashing. This highlights the critical role of health education in fostering better practices in disease prevention. Moreover, the correlation between attitude and practice in public health studies has been proven showing that positive attitudes often lead to better health practices (Jenny et al., 2022). For example, a study among university students in Pakistan found a significant positive correlation between attitude and preventive behaviors toward COVID-19 with individuals that have positive attitudes being more likely to adopt recommended preventive measures such as handwashing, wearing masks, and social distancing (Rehman et al., 2021). Similar association was also reported elsewhere (Wassif & Ahmed 2022)

CONCLUSION

This study highlights the significant role of knowledge, attitudes, and practices (KAP) in controlling and preventing COVID-19 among ecotourism operators. The findings demonstrate a high level of knowledge and positive attitudes toward COVID-19 preventive measures, reflecting the effectiveness of public health interventions and education campaigns by health authorities and tourism organizations. However, socioeconomic factors such as educational background remain critical for enhancing compliance with recommended practices. Thus, continued engagement between health authorities and the ecotourism community is vital for maintaining and improving preventive behaviors. Investing in targeted education programs tailored to the specific needs of ecotourism operators can further enhance their ability to

adapt to any evolving health challenges and ensure that the ecotourism sector remains resilient to future public health crises while promoting safer tourism practices in Malaysia. However, the study's findings are limited by a small sample size due to the absence of precise data on ecotourism premises in Pahang hence restricting the broader applicability of the results. This limited sample may not fully capture the diverse demographics and behaviors within Pahang's ecotourism sector or similar regions. In this context, the results reflect only a subset of surveyed operators as they may not represent the entire ecotourism sector.

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ORIGINAL ARTICLE

Fatigue Dynamics in Healthcare Workers in Kuantan, Pahang: A Cross-Sectional Study

Sinar Arina Mansor[1], Mohd Zubairy Shamsudin[1]*

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Occupational fatigue; Healthcare workers; Intershift recovery; Fatigue management

ABSTRACT

Background: This study investigates the prevalence and factors contributing to chronic and acute fatigue, as well as intershift recovery among healthcare workers in a private hospital in Kuantan, Malaysia. **Methods**: Using a cross-sectional design, data were collected from 182 healthcare professionals through a structured questionnaire, including the Occupational Fatigue Exhaustion Recovery (OFER) Scale. **Results:** Results indicate that a significant proportion of participants experience moderate to high levels of chronic fatigue and low to moderate acute fatigue, with intershift recovery also rated similarly. Key sociodemographic factors such as age, gender, job profession, and sleep quality were found to significantly influence fatigue levels. Notably, younger healthcare workers reported higher chronic fatigue, while female workers exhibited greater acute fatigue compared to males. **Conclusion:** The findings highlight the urgent need for effective fatigue management strategies within healthcare settings to enhance worker well-being and patient safety. This research provides valuable insights into the challenges faced by healthcare workers in Malaysia and underscores the importance of addressing fatigue-related issues in the healthcare sector.

INTRODUCTION

Healthcare workers, including doctors and nurses, face immense mental and physical stress, leading to high fatigue levels. Research indicates that over half of Emergency Medical Services (EMS) personnel report fatigue during shifts, increasing the risk of work-related incidents (Patterson et al., 2014). Factors such as inadequate social support, age, and irregular shift schedules contribute to this issue. In Malaysia, night shifts and on-call duties have been linked to severe consequences like needlestick injuries and prescription errors. Despite its importance for patient safety, research on fatigue management in Malaysia is limited. This study aims to assess chronic and acute fatigue levels among healthcare workers at a private hospital in Kuantan.

MATERIALS AND METHODS

Study Design

A cross-sectional study was conducted among healthcare workers at a private hospital in Pahang. Data were collected using a structured survey with questionnaires distributed to participants across various departments, including clinical and administrative staff.

Sample Size Calculation

The sample size was determined using Charan and Biswas' (2013) formula, targeting a 95% confidence level and 5% precision, with a prevalence estimate of p = 0.887 from Abdalgeleel *et al.* (2023). Considering a 10% dropout rate, the final required sample size was 182 participants.

Sampling Method

Participants were selected through non-random convenience sampling based on their accessibility and availability (Etikan *et al*., 2016). This approach allowed for the efficient recruitment of healthcare workers from various departments.

Data Collection Instrument

The self-administered questionnaire comprised two main sections:

1. **Sociodemographic Characteristics:** This section assessed factors such as job profession, department, gender, age, education level, marital status, work experience, sleep issues, average sleep hours, exercise frequency, meal frequency, shift details, health conditions, and body mass index (BMI).

2. **Occupational Fatigue Exhaustion Recovery (OFER) Scale:** Adapted from Winwood et al. (2005), the OFER scale evaluates three dimensions of fatigue: chronic fatigue (Items 1–5), acute fatigue (Items 6–10), and inter-shift recovery (Items 11–15). Responses are measured on a 7-point Likert scale ranging from 0 (strongly disagree) to 6 (strongly agree). The OFER

* *Corresponding author.*
E-mail address: mohdzubairyshamsudin@iium.edu.my

scale demonstrated strong reliability with Cronbach's alpha coefficients ranging from 0.83 to 0.89.

PILOT STUDY

A pilot study involving 36 healthcare workers was conducted to assess the validity and reliability of the questionnaire using Cronbach's alpha. The subscales of the OFER scale showed acceptable to good reliability (Cronbach's alpha between 0.70 and 0.89) show in Table 1, confirming the instrument's suitability for the main study. This revised methods provides clearer organisation and detail while ensuring that all critical information is retained.

Table 1: Cronbach's Alpha for all variables tested

Items	Cronbach's Alpha	Cronbach's Alpha Based on Standardised Items	n of items
Chronic Fatigue	0.866	0.868	5
Acute Fatigue	0.731	0.728	5
Inter-shift Recovery	0.710	0.730	5

RESULTS

Sociodemographic Characteristics

Sociodemographic data were collected from 182 respondents, focusing on factors such as age, gender, department, job profession, education level, marital status, work experience, sleep issues, sleep hours, exercise frequency, general health, meals per day, shift work, and BMI. Key findings are summarised in Table 2.

The sample was predominantly female (79.1%), with males comprising 20.9%. Most participants held clinical roles (67.7%), while administrative and operations staff represented 15.9%. Nursing staff accounted for 47.3%, followed by allied health professionals at 25.3%. The majority were 30-40 years old (42.9%), and over half of the healthcare workers had a diploma (52.7%).

Regarding marital status, 69.2% were married, 67.0% had over five years of work experience. Most participants had no sleep problems (77.5%) and an average of five hours of sleep per night (57.7%). Among healthcare workers, 47.8% reported exercising 1-3 times per week, and 53.3% reported consuming three meals daily. The majority (83.5%) worked shifts of less than 12 hours, and 54.9% had a body mass index (BMI) within the normal range.

Table 2: Sociodemographic characteristics of healthcare workers

Sociodemographic Characteristics	Frequency (n)	Percentage (%)
Department		
Clinical	**123**	**67.6**
Clinical Support	30	16.5
Non-Clinical	29	15.9
Job Profession		
Nursing	**86**	**47.3**
Allied Health	46	25.3
Administration and Operations	50	27.5
Gender		
Male	38	20.9
Female	**144**	**79.1**
Age		
<30 Years Old	77	42.3
30-40 Years Old	**78**	**42.9**
>40 Years Old	27	14.8
Educational Level		
Higher Secondary School	32	17.6
Diploma	**96**	**52.7**
Degree	34	18.7
Postgraduate	20	11.0
Marital Status		
Married	**126**	**69.2**
Single/Divorce/Widow	56	30.8
Years of Working Experience		
>6 Months - <1 Year	17	9.3
1-5 Years	43	23.6
>5 Years	**122**	**67.0**
Sleep Problems		
Yes	41	22.5
No	**141**	**77.5**
Sleep Hours Per Day		
5 Hours	**105**	**57.7**
More than 7 Hours	76	41.8
Less than 3 Hours	1	0.5
Exercise Frequency in a Week		
Never	77	42.3
1-3 Times Per Week	**87**	**47.8**
More than 3 Times Per Week	18	9.9
Meals Per Day		
1	3	1.6
2	68	37.4
3	**97**	**53.3**
4	11	6.0
5	3	1.6
Common Shift Length		
Less than 12 Hours	**152**	**83.5**
More than 12 Hours	30	16.5
General Health		
Good	**143**	**67.6**
Excellent	42	23.1

Fair/Poor	17	9.3
Body Mass Index (BMI)		
Underweight	0	0.0
Normal	**100**	**54.9**
Overweight	62	34.1
Obese	20	11.0

Note: Highlighted in bold is the highest frequency of the sociodemographic characteristics recorded

Occupational-Related Fatigue Levels

Chronic Fatigue

In assessing chronic fatigue (Table 3), approximately 39% of respondents expressed neutrality regarding feelings of being "*at the end of my rope*" with work. Neutral responses were also prevalent for statements such as "*I often dread waking up to another day of work*" (35.2%) and "*Too much is expected of me at work*" (32.4%).

Acute Fatigue

For acute fatigue (Table 4), 26.9% agreed with the statement, "*After a typical work period I have little energy left*" while 28.6% somewhat agreed with "*I usually feel exhausted when I get home from work*" Neutral responses dominated for other items, including "*My work drains my energy completely every day*" (29.7%).

Intershift Recovery

Intershift recovery (Table 5) responses showed a trend towards neutrality: 34.1% felt neutral about lacking recovery time, and 36.8% felt refreshed for the next shift.

Table 3: Distribution of responses on chronic fatigue statements among healthcare workers

Statements	Strongly Disagree (%)	Disagree (%)	Somewhat Disagree (%)	Neutral (%)	Somewhat Agree (%)	Agree (%)	Strongly Agree (%)
I often feel 'at the end of my rope' with my work	16(8.8)	17(9.3)	8(4.4)	**71(39.0)**	44(24.2)	17(9.3)	9(4.9)
I often dread waking up to another day of my work.	20(11.0)	27(14.8)	9(4.9)	**64(35.2)**	31(17.0)	20(11.0)	11(6.0)
I often wonder how long I can keep going at my work.	14(7.7)	15(8.2)	11(6.0)	**59(32.4)**	46(25.3)	27(14.8)	10(5.5)
I feel that most of the time I'm "living to work".	9(4.9)	23(12.6)	9(4.9)	**58(31.9)**	37(20.3)	36(19.8)	10(5.5)
Too much is expected of me at work.	8(4.4)	14(7.7)	13(7.1)	**59(32.4)**	41(22.5)	36(19.8)	11(6.0)

Note: Highlighted in bold is the highest frequency recorded

Table 4: Distribution of responses on acute fatigue statements among healthcare workers

Statements	Strongly Disagree (%)	Disagree (%)	Somewhat Disagree (%)	Neutral (%)	Somewhat Agree (%)	Agree (%)	Strongly Agree (%)
After a typical work period I have little energy left	6(3.3)	14(7.7)	17(9.3)	46(25.3)	35(19.2)	**49(26.9)**	15(8.2)
I usually feel exhausted when I get home from work	6(3.3)	9(4.9)	11(6.0)	40(22.0)	**52(28.6)**	38(20.9)	26(14.3)
My work drains my energy completely every day.	10(5.5)	22(12.1)	18(9.9)	**54(29.7)**	37(20.3)	21(11.5)	20(11.0)
I usually have lots of energy to give my family or friends.	15(8.2)	37(20.3)	48(26.4)	**64(35.2)**	9(4.9)	6(3.3)	3(1.6)
I usually have plenty of energy left for my hobbies and other activities after I finish work.	12(6.6)	33(18.1)	49(26.9)	**57(31.3)**	16(8.8)	10(5.5)	5(2.7)

Note: Highlighted in bold is the highest frequency recorded

Table 5: Distribution of responses on intershift recovery statements among healthcare workers

Statements	Strongly Disagree (%)	Disagree (%)	Somewhat Disagree (%)	Neutral (%)	Somewhat Agree (%)	Agree (%)	Strongly Agree (%)
I never have enough time between work shifts to recover my energy completely	13(7.1)	20(11.0)	43(23.6)	**62(34.1)**	15(8.2)	23(12.6)	6(3.3)
Even if I'm tired from one shift, I'm usually refreshed by the start of the next shift.	9(4.9)	7(3.8)	7(3.8)	**67(36.8)**	58(31.9)	26(14.3)	8(4.4)
I rarely recover my strength fully between work shifts.	7(3.8)	20(11.0)	46(25.3)	**68(37.4)**	19(10.4)	17(9.3)	5(2.7)
Recovering from work shifts isn't a problem for me.	5(2.7)	11(6.0)	18(9.9)	**73(40.1)**	49(26.9)	22(12.2)	4(2.2)
I'm often still feeling fatigued from one shift by the time I start a new one.	9(4.9)	28(15.4)	56(30.8)	**57(31.3)**	13(7.1)	13(7.1)	6(3.3)

Note: Highlighted in bold is the highest frequency recorded

Level of Chronic Fatigue, Acute Fatigue and Intershift Recovery Among Healthcare Workers

Table 6 summarises the levels of fatigue and recovery among healthcare workers:

a) Chronic Fatigue: Moderate to high levels were reported by 38.5%.
b) Acute Fatigue: Low to moderate levels were observed in 43.4%.
c) Intershift Recovery: Low to moderate recovery levels were noted in 65.4%.

Table 6: Category of Occupational Fatigue Exhaustion/ Recovery scale among healthcare workers

Category	Frequency (n)	Percentage (%)
Chronic fatigue		
Low	24	13.2
Low/Moderate	64	35.2
Moderate/High	**70**	**38.5**
High	24	13.2
Acute fatigue		
Low	11	6.0
Low/Moderate	**79**	**43.4**
Moderate/High	78	42.9
High	14	7.7
Intershift recovery		
Low	6	3.3
Low/Moderate	**119**	**65.4**
Moderate/High	49	26.9
High	8	4.4

Note: Highlighted in bold is the highest frequency recorded

Correlation Between Chronic Fatigue, Acute Fatigue and Intershift Recovery of Occupational-Related Fatigue Among Healthcare Workers

Pearson correlation analysis revealed significant relationships among chronic fatigue, acute fatigue, and intershift recovery (Figures 1, 2, and 3):

a) A positive correlation between chronic and acute fatigue ($r = +0.553$, $p<0.001$).
b) Negative correlations between chronic fatigue and intershift recovery ($r = -0.511$, $p<0.001$) and between acute fatigue and intershift recovery ($r = -0.437$, $p<0.001$).

Associations with Sociodemographic Factors

Department

The Kruskal-Wallis test (Table 7) showed no significant association between department types and chronic fatigue scores ($p=0.531$). However, significant associations were found for acute fatigue scores ($p=0.034$) and intershift recovery scores ($p=0.001$), with *post-hoc* tests revealing significant differences between clinical support and non-clinical staff.

Post-hoc tests (Table 8) found significant associations for acute fatigue scores between Clinical and Clinical Support ($p=0.014$), and Clinical Support vs. Non-Clinical ($p=0.035$). For intershift recovery scores, significant associations were found between Clinical and Clinical Support ($p<0.001$), and Clinical and Non-Clinical ($p<0.001$).

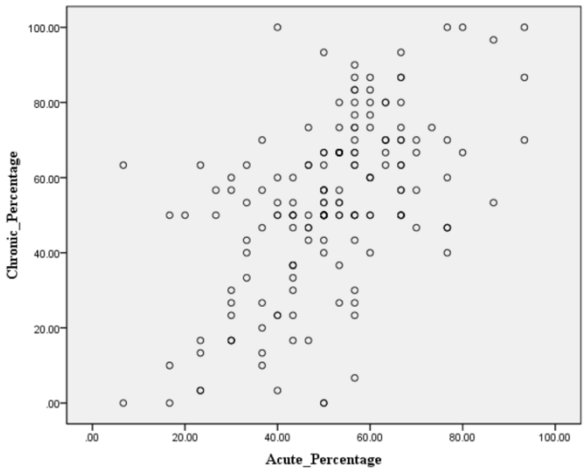

Figure 1: Scatter plot of chronic fatigue and acute fatigue

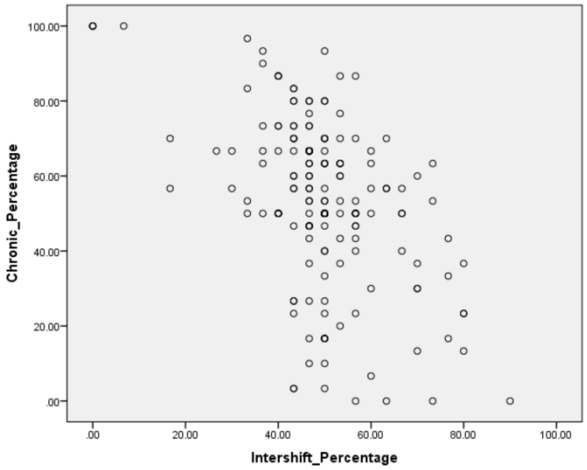

Figure 2: Scatter plot of chronic fatigue and intershift recovery score

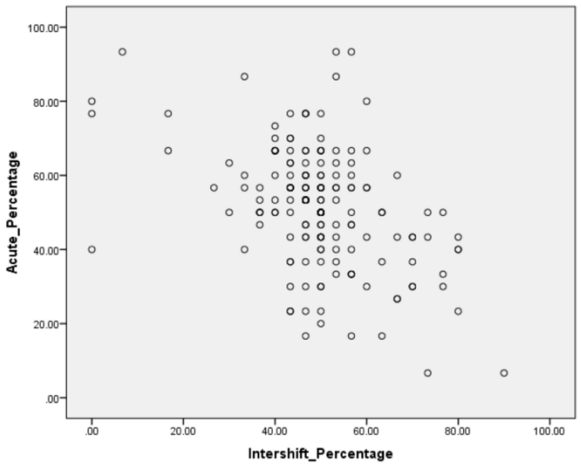

Figure 3: Scatter plot of acute fatigue score and intershift recovery score

Job profession

ANOVA results (Table 9) showed significant associations between job profession and chronic fatigue (p=0.003) and intershift recovery (*p*=0.034), but not acute fatigue (*p*=0.487). Allied Health professionals reported the highest chronic fatigue levels.

Table 7: Association between different types of departments with chronic fatigue, acute fatigue and intershift recovery scores (n= 182)

Variable	Department	n	Median	IQR	*p*-value
Chronic fatigue	Clinical	123	53.33	26.67	0.531
	Clinical Support	30	56.67	13.33	
	Non-Clinical	29	50.00	23.33	
Acute fatigue	Clinical	123	53.33	20.00	***0.034**
	Clinical Support	30	43.33	21.67	
	Non-Clinical	29	53.33	6.67	
Intershift recovery	Clinical	123	46.67	6.67	
	Clinical Support	30	55.00	17.50	****0.001**
	Non-Clinical	29	50.00	6.67	

** Significant in <0.05, ** Significant in <0.001*

Table 8: Multiple comparison of acute fatigue and intershift recovery score between different types of departments

Variable	Departments		*p*-value
Acute fatigue score	Clinical	Clinical support	**0.014**
		Non-Clinical	0.548
	Non-Clinical	Clinical support	**0.035**
Intershift recovery score	Clinical	Clinical support	****0.001**
		Non-Clinical	****0.001**
	Non-Clinical	Clinical support	0.530

** Significant in <0.05, ** Significant in <0.001*

Post-hoc analysis (Table 10) showed significant chronic fatigue differences between Nursing and Allied Health (*p*=0.037), and Allied Health versus Administration and Operations (*p*=0.003), with Allied Health reporting greater chronic fatigue. The lowest intershift recovery *p*-value was Nursing versus Administration and Operations (*p*=0.054).

Table 10: Multiple comparison (Post Hoc) of chronic fatigue and intershift recovery score between different types of job profession

Variables	Job professions		*p*-value
Chronic fatigue score	Nursing	Allied Health	***0.037**
		Administration and Operation	
	Administration and Operation	Allied Health	
Intershift recovery score	Nursing	Allied Health	1.000
		Administration and Operation	
	Administration and Operation	Allied Health	

** Significant in <0.05*

Table 9: Association between different types of job profession with acute fatigue score (n= 182)

Variable	Job Profession	n	Mean	SD	*p*-value
Chronic fatigue score	Nursing	86	52.17	21.16	****0.003**
	Allied Health	46	62.10	20.36	
	Administration and Operation	50	47.20	23.21	
Acute fatigue score	Nursing	86	52.98	15.06	**0.487**
	Allied Health	46	50.65	19.21	
	Administration and Operation	50	49.87	12.97	
Intershift recovery score	Nursing	86	48.06	10.79	**0.034**
	Allied Health	46	47.68	17.58	
	Administration and Operation	50	53.60	11.60	

*SD = standard deviation, ** Significant in <0.001*

Table 11: Comparison of chronic fatigue, acute fatigue and intershift recovery score between gender of healthcare workers (n= 182)

Variable	Male (n= 38)		Female (n= 144)		Mean differences (95% CI)	*p-value*
	Mean	SD	Mean	SD		
Chronic fatigue	49.56	18.51	54.31	22.95	-4.74 (-12.69,3.21)	0.241
Acute Fatigue	46.84	17.24	52.78	15.06	-5.94 (-11.52, -0.35)	***0.038**
Intershift Recovery	52.11	9.25	48.79	14.01	3.31 (-1.43,8.05)	0.170

*SD = standard deviation, * Significant in <0.05*

Gender

Independent t-tests (Table 11) indicated a significant association between gender and acute fatigue (p=0.038), with females experiencing higher levels compared to males.

Age

Significant differences (Table 12) were found across age groups for chronic fatigue (*p*=0.001), acute fatigue (p= 0.021), and intershift recovery (*p*=0.022). Workers under age 30 reported higher levels of chronic and acute fatigue.

Mann-Whitney *post-hoc* analysis indicated significant age-related differences in fatigue levels (Table 13). For chronic fatigue, significant pairs were: <30 vs. 30-40 years (*p*=0.043), <30 vs. >40 years (*p*<0.001), and 30-40 vs. >40 years (*p*=0.020). For acute fatigue, a significant difference was found between <30 and 30-40 years (*p*=0.011). In intershift recovery, significant pairs were <30 vs. >40 years (*p*=0.007) and 30-40 vs. >40 years (*p*=0.003).

Table 12: Association between age with chronic fatigue, acute fatigue and intershift recovery score

Variables	Age	n	Median	IQR	*p*-value
Chronic fatigue	<30	77	60.00	23.33	****0.001**
	30-40	78	50.99	17.50	
	>40	27	43.33	53.33	
Acute fatigue	<30	77	56.67	16.67	***0.021**
	30-40	78	50.00	14.17	
	>40	27	50.00	23.33	
Intershift recovery	<30	77	46.67	10.00	***0.022**
	30-40	78	50.00	7.50	
	>40	27	50.00	20.00	

** Significant in <0.05, ** Significant in <0.001*

Marital status

Marital status (Table 14) was significantly associated with chronic fatigue (*p*=0.030), with single or divorced workers reporting higher levels compared to married individuals.

Table 13: Multiple comparison (*Post Hoc*) of chronic fatigue, acute fatigue and intershift recovery score (Age)

Variable	Ages		*p*-value
Chronic fatigue	<30	30-40	***0.043**
		>40	****0.001**
	30-40	>40	***0.020**
Acute fatigue	<30	30-40	***0.011**
		>40	0.052
	30-40	>40	0.596
Inteshift recovery	<30	30-40	0.322
		>40	****0.007**
	30-40	>40	***0.033**

** Significant in <0.05, ** Significant in <0.001*

Table 16: Association between general health with chronic fatigue, acute fatigue and intershift recovery score (n= 182)

Variables	General Health	n	Median	IQR	*p*-value
Chronic fatigue	Excellent	42	50.00	26.67	***0.003**
	Good	123	53.33	23.33	
	Poor/Fair	17	63.33	35.00	
Acute fatigue	Excellent	42	50.00	20.83	***0.041**
	Good	123	53.33	16.67	
	Poor/Fair	17	56.67	35.00	
Intershift recovery	Excellent	42	50.00	10.00	***0.035**
	Good	123	50.00	10.00	
	Poor/Fair	17	43.33	25.00	

** Significant in <0.05*

Table 14: Association between marital status with chronic fatigue, acute fatigue and intershift recovery score (n= 182)

Variable	Single/Divorce/Widow (n= 56)		Married		(95% CI)	*p*-value
	Mean	SD	Mean	SD		
Chronic Fatigue	58.63	20.08	50.95	22.67	7.68 (0.74, 14.62)	***0.030**
Acute Fatigue	51.73	14.11	51.46	16.38	0.27 (-4.71, 5.25)	0.915
Intershift recovery	48.27	13.33	50.03	13.17	-1.75 (-5.94, 2.44)	0.410

*SD = standard deviation, * Significant in <0.05*

Table 15: Comparison of chronic fatigue, acute fatigue and intershift recovery score regarding sleep problem of healthcare workers (n= 182)

Variable	Yes (n= 41)		No (n= 141)		Mean differences (95% CI)	*p*-value
	Mean	SD	Mean	SD		
Chronic fatigue	64.63	16.49	50.02	22.51	14.61 (7.14,22.08)	****0.001**
Acute Fatigue	16.41	2.56	49.91	15.13	7.25 (1.85,12.65)	***0.009**
Intershift Recovery	44.15	9.85	51.04	13.68	-6.89 (-11.42,-2.37)	***0.003**

Note. SD: standard deviation, CI: confidence interval, Significant in <0.05, ** Significant in <0.001*

Sleep problem

Significant associations (Table 15) were found for chronic fatigue (*p*=0.001), acute fatigue (*p*=0.009), and intershift recovery (*p*=0.003). Workers with sleep problems reported higher chronic fatigue but lower acute fatigue.

General health

Statistically significant differences (Table 16) were found for chronic fatigue (*p*=0.003), acute fatigue (p=0.041), and intershift recovery (*p*=0.035), indicating that those in excellent health experienced lower fatigue levels.

Post-hoc Mann-Whitney tests (Table 17) found chronic fatigue differences between excellent and fair/poor health (p=0.001), and good and fair/poor (p=0.009). For acute fatigue, significant pairs were excellent and good (p=0.042), excellent and fair/poor (p=0.031). For intershift recovery, significant differences were excellent and fair/poor (p=0.014), good and fair/poor (p=0.036).

Table 17: Multiple comparison (*Post Hoc*) of chronic fatigue, acute fatigue and intershift recovery score (n= 182)

Variables	General Health		*p*-value
Chronic fatigue	Excellent	Good	0.098
		Fair/Poor	****0.001**
	Fair/Poor	Good	***0.009**
Acute fatigue	Excellent	Good	***0.042**
		Fair/Poor	***0.031**
	Fair/Poor	Good	0.227
Intershift recovery	Excellent	Good	0.222
		Fair/Poor	***0.014**
	Fair/Poor	Good	***0.036**

** Significant in <0.05, ** Significant in <0.001*

DISCUSSIONS

Level of Chronic Fatigue, Acute Fatigue, and Intershift Recovery

The study conducted in a private hospital in Kuantan indicates that healthcare workers experience moderate to high levels of chronic and acute fatigue, accompanied by low to moderate levels of intershift recovery. This pattern aligns with findings from Alsayed *et al.* (2022) and Mohd Fauzi *et al.* (2020), who reported similar fatigue levels among healthcare professionals. Notably, chronic fatigue levels surpassed acute fatigue, contrasting with previous research indicating an inverse relationship (Alsayed *et al.,* 2022; Ismail et al., 2021).The elevated fatigue levels may be due to inadequate intershift recovery, essential for preventing fatigue accumulation. Contributing factors include staffing, workload, psychosocial influences like leadership and motivation, and personal factors such as gender and health conditions. Research by Cai *et al.* (2023) highlights the progression of untreated acute fatigue into chronic fatigue, underscoring the need for effective recovery protocols.

Correlation Between Chronic Fatigue, Acute Fatigue, and Intershift Recovery

This study reveals insights into the relationship between intershift recovery and fatigue among healthcare workers. Moderate negative correlations between intershift recovery and both chronic fatigue and acute fatigue suggest that elevated fatigue levels hinder effective recovery. This aligns with Alsayed *et al.* (2022), emphasising the role of recovery in mitigating fatigue. Additionally, the moderate positive correlation between chronic and acute fatigue raises concerns about the potential progression of acute fatigue into chronic fatigue if not addressed promptly. This notion is supported by previous research from Winwood *et al.* (2005), Sagherian *et al.* (2016), and Min *et al.* (2021), highlighting the necessity for early intervention.

Work-Related Factors Associated with Chronic Fatigue, Acute Fatigue, and Intershift Recovery

The study highlights that healthcare workers in clinical departments experience significantly higher levels of acute fatigue compared to those in support roles. Key factors contributing to this include job stress, workload, and patient-facing responsibilities, as noted by Han *et al.* (2014). This finding aligns with Ross *et al.* (2021), who observed greater fatigue levels among nurses than those engaged in indirect care roles. Moreover, Allied health professionals reported higher chronic fatigue than nurses and non-clinical staff due to the physical demands associated with patient handling. Clinical staff in high-demand environments often face limited opportunities for intershift recovery, exacerbating their fatigue levels.

Individual-Related Factors Associated with Chronic Fatigue, Acute Fatigue, and Intershift Recovery

The study identifies significant associations between occupational fatigue and factors such as age, sleep quality, marital status, gender, and general health. Notably, younger healthcare workers reported higher levels of fatigue and poorer recovery compared to older colleagues, suggesting they may be more susceptible to greater physical workloads. Poor sleep quality emerged as a critical factor among high-acuity staff working irregular hours who experienced notably higher fatigue levels. Additionally, single or divorced workers reported increased fatigue while married women—especially those with family responsibilities—faced heightened fatigue levels. Data revealed that female workers generally reported more acute fatigue than males; interestingly, those in excellent health exhibited lower fatigue levels and better recovery outcomes due to greater energy reserves to meet job demands.

Limitations

This study acknowledges several methodological considerations that require careful interpretation of the findings. First, the sampling approach utilised a convenience sampling method, which potentially introduces selection bias. This non-probabilistic sampling technique means participants were selected based on accessibility rather than through a randomised process, potentially limiting the sample's representativeness of the broader healthcare worker population.

The questionnaire's administration exclusively in English

might have presented significant language-related challenges for participants from diverse linguistic backgrounds. Non-native English speakers may have experienced difficulties in fully comprehending complex questions, potentially leading to misinterpretation of survey items or incomplete responses. This linguistic barrier could compromise the accuracy and depth of data collected, particularly in a multicultural healthcare environment.

Moreover, the sample composition reveals certain variations in professional representation, which could significantly influence the comprehensive understanding of findings across different healthcare roles. Specifically, the uneven distribution of participants from various healthcare professions may introduce sampling bias, potentially overemphasizing the perspectives of certain job roles while understating others.

These methodological implications underscore the importance of considering contextual factors when interpreting the study's outcomes. Future research should address these limitations by implementing more diverse sampling strategies, providing multilingual survey options, and ensuring a more balanced representation of healthcare professionals.

CONCLUSION

This study highlights significant levels of chronic and acute fatigue among healthcare workers at a private hospital in Kuantan, with inadequate intershift recovery exacerbating these issues. Factors such as job roles, age, gender, and sleep quality were found to influence fatigue experiences, with younger workers and females reporting higher levels of fatigue. Addressing these challenges is crucial for enhancing worker well-being and ensuring safe patient care. Future research should explore the long-term impacts of fatigue and recovery practices in this population.

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ORIGINAL ARTICLE

Effects of Different Hijab Fabrics on Image Quality in Skull X-Ray using Computed Radiography

Nuramisha Diana Tamson[1], Iqbal Jamaludin[1,2,3,*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Children Health and Wellbeing Research Group, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Background: Covering the aurah in Islam is considered a sign of respect, dignity, and privacy. In skull x-ray examination, female patients often feel uncomfortable when being requested to remove their hijab for skull x-ray examination. Therefore, this study aims to evaluate the effects on radiographic image quality in PA (0°) skull x-ray examination when using different types of hijab materials. **Methods:** This study is conducted by using the skull part of Kyoto Kagaku phantom, with the help of immobilisation aids. The phantom is exposed without hijab at optimum exposure factor that is used as a reference image and been compared with the image quality produced by the x-ray examination using three different hijab materials. Each hijab materials (Premium Chiffon Georgette, Premium Valencia Satin and Premium Cotton Rayon) then been exposed together with phantom using three different exposure factors: low (61.5 kVp, 20 mAs), optimum (73 kVp, 10 mAs) and high (83 kVp, 5 mAs). Four experienced observers blindly graded the image quality using Visual Grading Analysis (VGA). The results were analysed by using Kruskal-Wallis to find the effect of different hijab materials on optimum exposure, while Friedman test was used to find any significant findings between different hijab materials and three different exposure factors: low, optimum and high. **Results:** From the Kruskal-Wallis test, the radiographic image quality of all three hijab materials produce no significant difference when compared with skull x-ray image without hijab. Friedman test found only hijab material of Premium Valencia Satin when exposed with 61.5 kVp 20 mAs (low), 73 kVp 10 mAs (optimum) and 83 kVp 5 mAs (high) to be significant (p-value=0.022). **Conclusion:** It can be concluded that Premium Chiffon Georgette and Premium Cotton Rayon are suitable to be used in skull x-ray examination as they did not produce any notable artifacts on skull x-ray radiograph, while special consideration must be made for patient wearing hijab material of Premium Valencia Satin that will undergo skull x-ray examination.

Keywords:
image quality; skull x-ray; hijab; computed radiography

INTRODUCTION

In medical imaging practice, different types of examinations require different patient preparation. Generally, some x-ray procedures involve the removal of clothing and materials from the region of interest (ROI) to avoid any presence of artifacts. Since the purpose of doing skull examination is to help doctors to detect any injuries of the bone surrounding the brain, therefore it is necessary to remove hijab before undergoing the examination. The presence of hijab material during skull X-ray examinations needs special consideration, as it has the potential to introduce artifacts into the radiographic image, consequently degrading image quality. However, for female Muslim patients, the prospect of removing the hijab during the examination may lead to discomfort, as it is considered part of the aurah, which should not be exposed to non- mahram individuals. The hijab may be removed in the presence of healthcare workers when the patient is seeking treatment for relevant medical conditions. However, privacy concerns might cause discomfort for patients and potentially hinder the care they receive (Rehman et al., 2022). Due to that, not emphasizing aurah in radiography may results in dissatisfaction among female Muslim patients. However, the act of removing the hijab to avoid artifacts for skull x-ray can be considered as violating their privacy when it is not well-informed. The presence of artifacts in radiographs may impair image quality, obscure abnormalities and also can mimic clinical features (Drost et al., 2008). An X-ray

* *Corresponding author.*
E-mail address: iqbaljamaludin@iium.edu.my

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artifact is an imperfection in image quality that can obscure the intended subject, potentially leading to a misdiagnosis if it is mistaken for a foreign body (Sheen, 2024). This can lead to misinterpretation due to the hindered visualisation of the object of interest.

Nevertheless, only few studies have been conducted to investigate the real effect of hijab materials on plain radiographs and to show medical imaging acceptability. In the study by Amran (2016) of jubah dress materials and image quality on knee examination, it has been reported that the radiographs are still deemed acceptable by radiologists even though there is presence of artifacts on the image. Additionally, Johari (2014) has noted in his study that the presence of sport trousers leads to artifacts on image although the images remain deemed acceptable. Therefore, this study aims to tackle the issue of preserving aurah for female Muslim in skull examination as discussed above by evaluating the three different hijab materials (Premium Chiffon Georgette, Premium Valencia Satin and Premium Cotton Rayon) and its effect on radiographic image quality.

MATERIALS AND METHODS

This study was conducted at the Diagnostic Imaging Laboratory, Department of Diagnostic Imaging and Radiotherapy (DDIR), Kulliyyah of Allied Health Sciences (KAHS), International Islamic University Malaysia (IIUM), Bandar Indera Mahkota, Kuantan, Pahang by using a Computed Radiography (CR) system.

Materials Used

The study was conducted by using a PBU-31 head phantom that is available at the laboratory. The head phantom mimics the features and characteristics of human tissue, especially the head part, offering an accurate simulation for experimental purposes. Images were evaluated by four assessors: two academicians and two radiographers of DDIR, KAHS, IIUM Kuantan by using Visual Grading Analysis (VGA) score and analysed using SPSS test.

This study used three different types of hijabs that are commonly used by people nowadays which were Premium Chiffon Georgette, Premium Valencia Satin and Premium Cotton Rayon. The reason these materials were chosen is that they are widely popular among women for contemporary fashion and daily wear.

Image Acquisition

Head phantom was positioned in posteroanterior (PA) position with the use of immobilisation devices to securely hold it in place. The CR tube was positioned perpendicular to the IR and directed to the head phantom by using a horizontal beam, as shown in Figure 1. The procedure started with control study (without hijab) with 73 kVp and 10 mAs which represents the optimum exposure settings commonly employed in hospital practice. Each of the three types of hijab materials; Chiffon (Figure 2), Cotton (Figure 3) and Satin (Figure 4), were then applied to the phantom. Each material then was exposed with three different kilovoltage peak (kVp) and milliampere-seconds (mAs).

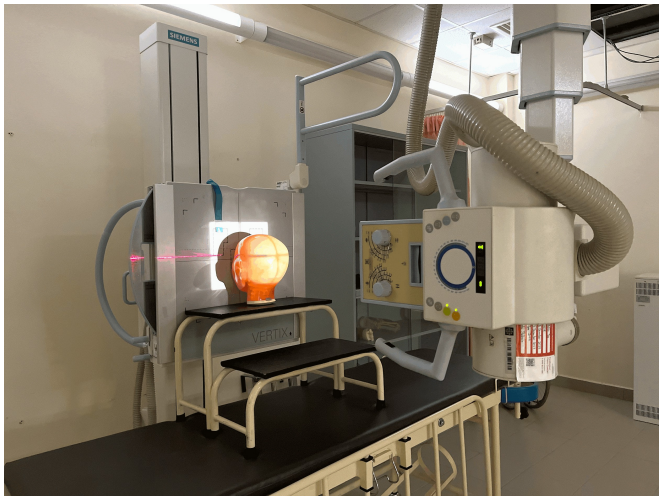

Figure 1: Position of the Head Phantom Without Hijab in PA (0^0) Skull Examination

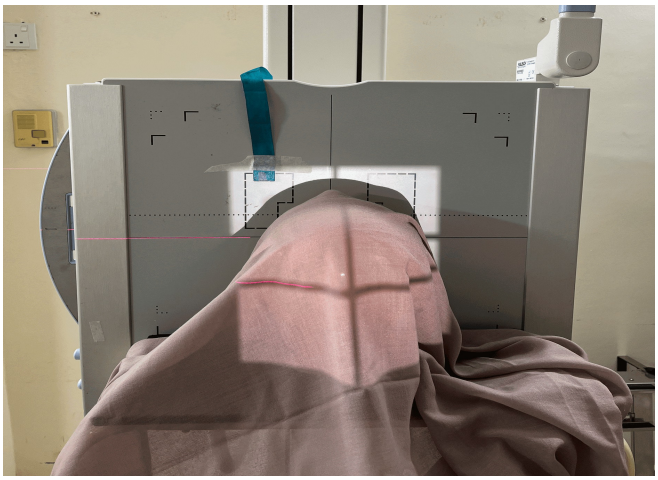

Figure 2: Head Phantom with Premium Chiffon Georgette Hijab in PA (0^0) Skull Examination

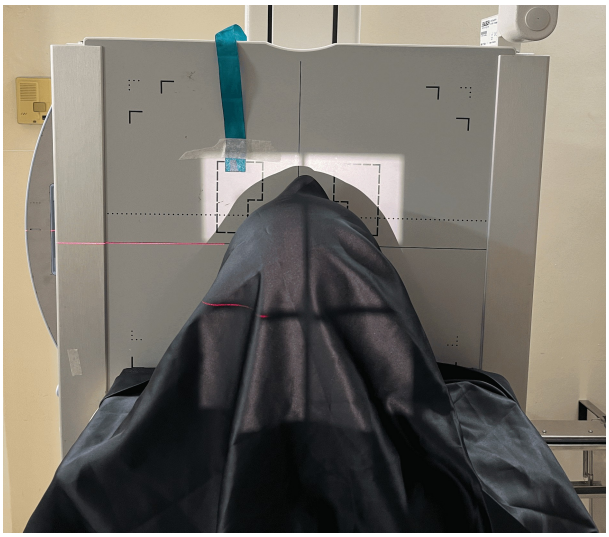

Figure 3: Head Phantom with Premium Cotton Rayon Hijab in PA (0^0) Skull Examination

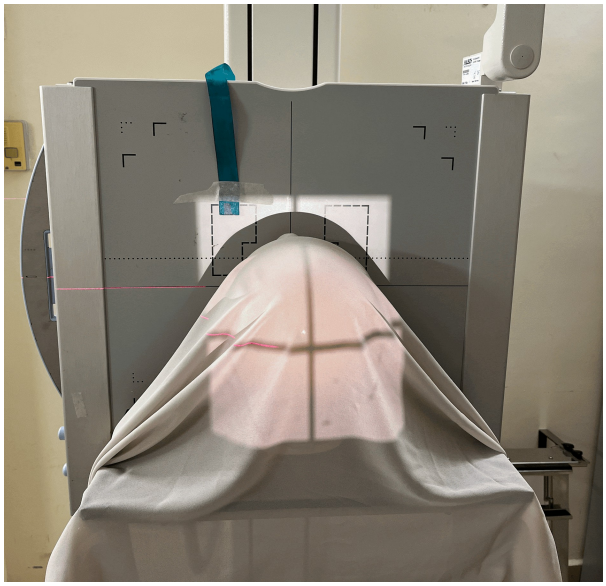

Figure 4: Head Phantom with Premium Valencia Satin Hijab in PA (0^0) Skull Examination

Imaging Parameters

15% kVp rule was used to optimise the image quality of x-ray. According to the rule, changing the kVp by 15% can affect image contrast in a way that is comparable to doubling or halving the mAs while keeping the exposure same. This technique is needed to evaluate which exposure factor is compatible with the materials. According to McQuillen (2011), the 15% kVp rule is used to adjust the kVp to correct for over or under penetration in imaging. The rule states that reducing kVp by 15% can improve image quality. Conversely, increasing kVp by 15% can increase film density, similar to doubling the mAs. Following this principle allows modifications to improve contrast and ensure accurate visualisation of anatomical structures, particularly when contrast is insufficient despite adequate density levels. Additionally, adhering to this rule may reduce radiation exposure, as increasing kVp often decreases required mAs, thereby minimizing patient radiation absorption (Yaakob et al., 2007).

Image Processing

All images were processed by the image reader and displayed on the monitor, after all the exposures were completed. No image manipulation was performed at the monitor. Each image was labelled and saved on the monitor according to the material and exposure level (low kVp, optimal, and high kVp) using a coding system. The initial image was the control image, followed by chiffon, cotton, and satin images. The images were saved in separate folders in the computer system.

Radiographic image quality was evaluated by using VGA. In the VGA study, the radiographic images were graded by four assessors, two academicians and two radiographers from DDIR, KAHS. The gradings took into account how well-defined anatomical structures appear in the image. The image criteria were taken from European Guidelines for diagnostic images from European Commission (European Commission, 1996). For VGA study, image quality criteria were scored on a scoring scale, involving observers for assessing images on a display platform within a suitable environment, followed by statistical analysis (Precht et al., 2019). In this study, the VGA score for reference image was assumed to have a neutral value which is equal to zero for all visualised structures. The reference image was used as a control study which the observer will visually compare the target structure in the test images with the reference image to determine whether they meet specified criteria (Ludewig et al., 2010). There was a total of 10 images including reference images. The score given by the observers were calculated using the equation from the study of Kheddache et al. (2004).

RESULTS

Comparison Of the Radiographic Image Quality Between Three Different Types Of Hijab Materials For Optimum Exposure Factor

Table 1 shows the VGA score obtained from each criterion at optimum exposure; 73 kVp and 10 mAs by all hijab materials. The VGA scores for all materials were slightly lower than the reference image, indicating that the visualisation of the temporal bone was poorer when wearing a hijab. Moreover, both Premium Chiffon Georgette and Premium Valencia Satin have the same

VGA score of -0.0833 for the visualisation of the floor of the sella which indicates a decrease in image quality as the VGA score was slightly inferior to the reference image. Meanwhile for Premium Chiffon Georgette showed a decrease in visualisation of outer and inner lamina of cranial vault while the other two hijab materials maintained the same image quality as reference image, with VGA scores of 0.

Table 1: The VGA criteria and score obtained at optimum exposure for Premium Chiffon Georgette, Premium Cotton Rayon and Premium Valencia Satin compared to reference image

No	Criteria	VGA Scores		
		Premium Chiffon Georgette	Premium Cotton Rayon	Premium Valencia Satin
1	Visually sharp reproduction of the outer and inner lamina of the cranial vault	-0.0833	0	0
2	Visually sharp reproduction of the floor of the sella	-0.0833	0	-0.0833
3	Visually sharp reproduction of the apex of the petrous temporal bone	-0.1667	-0.25	-0.1667

Optimum exposure factor of 73 kVp, 10 mAs

VGA Score for Premium Chiffon Georgette At Different Tube Potentials For PA (0^0) Skull X-Ray Examination

Table 2 shows that low exposure factor results in better image quality for Premium Chiffon Georgette across all criteria. This indicates that the image is slightly better than the reference image compared to other exposure factors. Meanwhile 73 kVp with 10 mAs and 83 kVp with 5 mAs have lower VGA scores which indicate poor visualisations for all listed criteria when exposed with Premium Chiffon Georgette hijab. It results in overexposed images with reduced contrast and detail across the listed criteria.

VGA Score for Premium Cotton Rayon at Different Tube Potentials Energy For PA (0^0) Skull X-Ray Examination

Table 3 shows that 61.5 kVp with 20 mAs have an increase in VGA score when compared to reference image. The VGA score for visualisation of floor of the sella was more than 0 indicating superior radiographic image quality compared to images taken at 73 kVp and 83 kVp. At 73 kVp and 20 mAs, the image was slightly inferior for visualizing the apex of the petrous temporal bone, with a VGA score of - 0.25, while the visualisation of other structures remains similar to the reference image, with VGA scores of 0. Meanwhile, high exposure factor (83 kVp and 5 mAs) gives negative results with VGA score less than 0 for visualisation of all listed structures.

Table 2: The VGA criteria and score obtained by Premium Chiffon Georgette with varying exposure factors compared to the reference image of PA Skull (0^0) projection

No	Criteria	VGA for Premium Chiffon Georgette		
		61.5 kVp, 20 mAs	73 kVp, 10 mAs	83 kVp, 5 mAs
1	Visually sharp reproduction of the outer and inner lamina of the cranial vault	+0.0833	-0.0833	-0.25
2	Visually sharp reproduction of the floor of the sella	+0.1667	-0.0833	-0.25
3	Visually sharp reproduction of the apex of the petrous temporal bone	+0.0833	-0.1667	-0.3333

Table 3: The VGA criteria and score obtained by Premium Cotton Rayon with varying exposure factors compared to the reference image of PA Skull (0^0) projection

No	Criteria	VGA for Premium Cotton Rayon		
		61.5 kVp, 20 mAs	73 kVp, 10 mAs	83 kVp, 5 mAs
1	Visually sharp reproduction of the outer and inner lamina of the cranial vault	0	0	-0.0833
2	Visually sharp reproduction of the floor of the sella	+0.0833	0	-0.3333
3	Visually sharp reproduction of the apex of the petrous temporal bone	0	-0.25	-0.4167

VGA Score for Premium Valencia Satin At Different Tube Potentials For PA (0^0) Skull X-Ray Examination

Table 4 shows average score for low exposure factor was increased for visualising floor of the sella compared to reference image. However, it showed poor visualisation of apex of the petrous temporal bone as the VGA score was less than 0. In the meantime, 83 kVp 5 mAs represents worsened radiographic image quality with VGA scores below 0 for all criteria. This indicates that with high exposure factors, Premium Valencia Satin results in low visualisation of the structures. At 73 kVp, the score was not significantly worse compared to 83 kVp, but it still contributes to the overall descending pattern.

Table 4: The VGA criteria and score obtained by Premium Valencia Satin with varying exposure factors compared to the reference image of PA Skull (0^0) projection

No	Criteria	VGA for Premium Cotton Rayon		
		61.5 kVp, 20 mAs	73 kVp, 10 mAs	83 kVp, 5 mAs
1	Visually sharp reproduction of the outer and inner lamina of the cranial vault	0	0	-0.25
2	Visually sharp reproduction of the floor of the sella	+0.1667	-0.0833	-0.5
3	Visually sharp reproduction of the apex of the petrous temporal bone	-0.0833	-0.1667	-0.5833

The result of the Friedman test found that the p-value is 0.038 which indicates there was significant difference in Premium Valencia Satin when exposed with 61.5 kVp 20 mAs, 73 kVp 10 mAs, and 83 kVp 5 mAs. Therefore, Dunn-Bonferroni post hoc analysis was conducted as shown in Table 5 to determine which pairs of conditions differed significantly. According to the result, there was a statistically significant difference between the pair of Premium Valencia Satin in low exposure and Premium Valencia Satin in high exposure, as indicated by a p-value of 0.022. This suggested that the choice of exposure settings significantly affects the image quality when comparing satin under low and high exposure conditions. Therefore, it can be stated that Premium Valencia Satin at high exposure factor resulted in poor image quality compared to low exposure factor. Conversely, there was no significant difference observed between the pair of Premium Valencia Satin in optimum exposure and low exposure, as well as between Premium Valencia Satin in high exposure and medium exposure as the p-values are 0.052 and 0.724, respectively.

Table 5: Pairwise Comparison for Premium Valencia Satin in Dunn-Bonferroni Post-Hoc Test Analysis

Sample 1 – Sample 2	Test statistic	Std. Error	Std. Test Statistic	p-value	Adj. Sig.
Satin_high-Satin_opt	1.375	0.707	1.945	0.052	0.155
Satin_high-Satin_low	1.625	0.707	2.298	0.022	0.065
Satin_opt-Satin_low	0.250	0.707	0.354	0.724	1.000

CONCLUSION

Comparison Of the Radiographic Image Quality Between Three Different Types Of Hijab Materials (Premium Chiffon Georgette, Premium Cotton Rayon and Premium Valencia Satin) For Optimum Exposure Factor

This study was conducted to evaluate the effects of different hijab materials when exposed to the optimum exposure factor which is 73 kVp and 10 mAs. Throughout this study, the Premium Chiffon Georgette hijab has the lowest VGA score among three different materials. It can be concluded that the presence of Premium Chiffon Georgette hijab gives low image quality to the skull examination. This can be seen from the VGA score of Premium Chiffon Georgette, which is less than 0, while the scores for the other two materials are higher. However, it could be due to the lower kVp used that was insufficient to penetrate the material.

According to Yaakob et al. (2007), decreasing the kVp by 15% leads to a reduction of x-rays energy and penetration power. It means that, there was a decrease in the intensity of X-rays that penetrate patients resulting in lower energy levels of the X-rays and reducing the penetration power of the X-ray beam. As a result, 73 kVp and 10 mAs was insufficient to penetrate Premium Chiffon Georgette which results in underexposed image.

Meanwhile, Premium Cotton Rayon has a better VGA score and most of the score seems to be equal to the reference image compared to Premium Chiffon Georgette and Premium Valencia Satin. It can be seen that most of the scores for Premium Cotton Rayon are equal to 0 indicating there were no difference in image quality with

the reference image. Even though the visualisation of the apex of the petrous temporal bone was not clearly be visualised from observers' point of view, the score was still near to the reference image. Thus, it can be said that the radiograph can be still acceptable and Premium Cotton Rayon gives adequate image quality to the skull radiograph. The exposure and penetration are adequate even when Premium Cotton Rayon was placed on the head phantom. It indicates that the combination of 73 kVp and 10 mAs for Premium Cotton Rayon is sufficient to allow the x-ray beam to pass through the material effectively to produce detailed structures except apex of the petrous temporal bone.

Other material which is Premium Valencia Satin has a similar VGA score with Premium Cotton Rayon. However, the visualisation of the listed structures from both materials differs from the observers' view. The image of Premium Valencia Satin has the optimum exposure to visualise outer and inner lamina of cranial vault. However, the exposure was insufficient to visualise the floor of the sella and apex of the petrous temporal bone as the scores were inferior to the reference image. It means that Premium Valencia Satin causes inadequate penetration into the structures of interest. This finding showed that this material has some influence on visualising a few structures in PA (0^0) skull radiograph.

Even though from observers' point of view there were few images that have degradation and improvement of image quality, the statistical test indicates there was no significant difference between each material when compared to reference image for optimum exposure. This is due to the differing perspectives of each observer, which include variations in eyesight, experience, and other factors (Johari, 2014). Individual differences such as the acuity of vision, familiarity with image quality assessment, and subjective interpretation of image details all contribute to the varied perceptions. The inconsistency may result from the assessors and the factors that mentioned above may effect on how the assessors evaluate the images (Sharipudin, 2015).

Consequently, while some observers might perceive an improvement in image quality, others might see degradation, leading to inconsistent evaluations. Therefore, it can be concluded that the presence of Premium Chiffon Georgette, Premium Cotton Rayon and Premium Valencia Satin on a phantom in PA (0^0) skull examination does not have any effects on radiographic image quality. In other words, patients should be allowed to wear a hijab of these three materials during skull examinations without compromising the accuracy of diagnosing pathologies.

Comparison Of the Radiographic Image Quality For Each Hijab Materials (Premium Chiffon Georgette, Premium Cotton Rayon and Premium Valencia Satin) Using Different Tube Potentials Energy

When exposed with various exposure factors (low, optimum and high), there are some effects between Premium Valencia Satin at optimum exposure and Premium Valencia Satin at high exposure factors. It can be due to the different penetration power when the exposure factors are increased. In contrast, Premium Chiffon Georgette and Premium Cotton Rayon does not have any effects in radiographic image quality when exposed with various exposure factors. It means that patients wearing this kind of materials are not required to remove the hijab during the examination. Based on the findings, 61.5 kVp and 20 mAs is optimal for PA (0^0) skull examination as most of the radiographic images have high image quality compared to other exposure factors.

There are few limitations in this study. First of all, Kyoto Kagaku phantom does not have any vascular channels. Therefore, assessors were having difficulty when giving the scores for the visualisation of vascular channels as outlined in the VGA form. The phantom only shows the bony cortical outline which is not listed in the form. Hence, for future recommendation, it is suggested to do it on the real patient and human skull. It is because phantom usage is limited to visualise certain structures and lacks pure soft tissues and bony structure. Therefore, it is recommended to conduct this research on structures that have similar characteristics to the human skull in order to get accurate data such as bovine skull.

Moreover, there is no previous study about the effects of image quality for different hijab materials in skull examination. Researcher can just review related journals in order to have an understanding of the predicted outcomes. It appears to have numerous uncertainties and contributed to several limitations and have also led to new findings and discoveries. Additionally, there are limited studies on the attenuation coefficients of various materials, making it challenging to determine which materials have high attenuation and which have low attenuation.

This study was conducted using various kVp and mAs settings. Therefore, for future recommendations, it is suggested to keep the mAs constant rather than varying its value. With a fixed mAs, any changes in image quality can be attributed to variations in other parameters, such as kVp or the type of material being imaged, allowing for

more accurate and reliable comparisons. If the kVp is changed while the mAs remains constant, the effects on image quality will be more accurate and assessable.

Overall, this study successfully achieved the primary objectives of investigating image quality by wearing different types of hijabs. By demonstrating that the three hijabs used did not affect image quality, this study supports the practice of allowing patients to maintain their modesty without compromising the quality of radiographic images. This also can preserve the aurah of female patients during skull examinations and fulfilling Allah's obligation. This is consistent with the concepts of dignity and respect in medical practice, ensuring both religious observance and excellent patient care. Both men and women should conceal their aurah from being seen by others. Hence, it is recommended that radiographers should not ask patients to remove their hijabs before the examination, as the hijab does not affect image quality. Radiographers should preserve the patient's privacy such as aurah, especially for female Muslim patients, while also ensuring excellent radiological practices to optimise image quality.

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ORIGINAL ARTICLE

Survey on Radiation Awareness and Knowledge Among Malaysians in Johor, Malaysia

Zurain Mohd Azhar[1], Norhanna Sohaimi[1,*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
radiation; awareness; knowledge; public

ABSTRACT

Background: Members of public in Malaysia need to have knowledge and awareness regarding radiation and its associated risks to prevent misconception and misunderstanding about the information. Despite the safety of low-level radiation in medical contexts, many Malaysians perceive all radiation as harmful, influenced by historical events like the Hiroshima and Nagasaki bombings and limited public awareness. This study aims to determine the existing level of radiation knowledge and awareness among Malaysians in Johor and to assess the public's source of knowledge and information regarding radiation. By addressing these gaps, the research seeks to guide educational and healthcare practices, encouraging the development of curricula and communication strategies that promote accurate understanding of radiation, ultimately fostering a more informed and confident public. **Methods:** A total of 384 respondents took part in this study. A set of questionnaires with a total of 21 questions and consists of two parts which are demographic data and radiation knowledge, and awareness was distributed online by using Google forms. It was distributed through all online platforms including social media to reach out the respondents that lives in Johor. **Results:** The survey data was collected and analysed by using non-parametric tests which are Pearson chi-square and Kruskal-Wallis to see the relationship between demographic characteristics with the level of radiation knowledge and awareness. Based on the results, it demonstrates significant gaps in radiation awareness among Johor residents and identified demographics (e.g., health-related fields, workplace environment) associated with higher knowledge levels. The results underscore the importance of targeted educational outreach, especially through credible sources, to improve public understanding of radiation. **Conclusion:** The public needs more disclosure towards the correct facts about radiation and its associated information. It is recommended that the general public obtain the correct information from reliable source to avoid misconception regarding radiation.

INTRODUCTION

This study addresses misconceptions about radiation among the general public in Malaysia, particularly in Johor. Many people mistakenly view all radiation as dangerous due to misinformation, often from sources with inadequate understanding. Such misconceptions contribute to public fear and anxiety. Knowledge and awareness are critical for countering these fears, enabling individuals to distinguish between harmful and non-harmful radiation. Awareness, coupled with accurate knowledge, can help the public understand both the risks and benefits of radiation.

In Malaysia, radiation misconceptions are prevalent. According to the Maulana et al. (2018), many Malaysians believe there is no safe radiation dose, despite low-level exposures in medical settings being non-hazardous when managed by trained professionals. Historic events, like the Hiroshima and Nagasaki bombings, have also influenced public perception, associating radiation with catastrophic harm, which fuels these misconceptions. Studies from 1994 to 2014 examined natural radioactivity in Malaysia but found limited awareness and understanding among the public about radiation.

The study's objectives include assessing the level of radiation awareness and knowledge among Johor residents and understanding the factors and sources influencing public knowledge. It seeks to determine whether misinformation is linked to specific sociodemographic factors and whether sources of information significantly affect public perception. Key research questions focus on evaluating current knowledge levels, identifying factors that cause varied awareness, and

* *Corresponding author.*
E-mail address: norhanna@iium.edu.my

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analysing the impact of information sources on public perception.

The significance of this research lies in its potential to inform educational and healthcare practices. Findings could aid educational providers across Malaysia in crafting curricula that enhance radiation awareness. For healthcare providers, particularly in medical imaging, the study highlights the importance of providing clear, factual information about radiation exposure to patients. This can help alleviate unfounded fears and enable informed decision-making among the public, ultimately contributing to a more informed and less fearful society regarding radiation.

MATERIALS AND METHODS

This methodology ensures a robust approach to gathering, validating, and analysing data on public radiation knowledge and awareness. The study design allows for generalizable results within Johor, while the questionnaire's structured format and careful validation enhance data accuracy and reliability.

Research Design

A quantitative approach was used, employing a questionnaire to measure correlations between demographic factors (e.g., age, education) and radiation knowledge and awareness. The conceptual framework in this study highlights the relationships between demographic factors (age, gender, education level, study field, and workplace) and radiation awareness. This study has obtained approval from the Kulliyyah Postgraduate and Research Committee (KPGRC) KAHS 55-18 and IIUM Research Ethics Committee (IREC) IREC 2018-235.

Population and Sampling Design

The study targets Malaysian residents of Johor aged 20 years and above. Probability sampling was used, allowing each person an equal chance of selection and ensuring the results could be generalized to the broader population of Johor. The sample size calculation was performed using Cochran's formula based on a confidence level of 95% and a 5% margin of error (Eq. 1). The calculation assumes maximum variability (p = 0.5) and results in a required sample size of 384 respondents, which is appropriate for Johor's population.

$$n_0 = z^2 pq / e^2 \qquad (1)$$

where,

n_0 = sample size
z = selected critical value of desired confidence level
p = the estimated proportion of an attribute that is present in the population
q = 1- p
e = desired level of precision

The inclusion criteria for this study were residents of Johor, aged 20 and above, and literate. While the exclusion criteria were residents outside Johor and those who are illiterate.

Questionnaire Development

A self-administered, bilingual questionnaire (in English and Bahasa Malaysia) was created to gather data on demographics and knowledge and awareness of radiation. The questionnaire was designed to include multiple-choice, dichotomous (yes/no), and open-ended questions, allowing for a comprehensive assessment of participants' knowledge and perceptions. An informed consent section was included at the beginning of the questionnaire, ensuring ethical compliance and participants' consent.

Questionnaire structure in this study comprises two parts; Part I: Socio-Demographic Data which captures respondents' gender, age, education level, field of study, and workplace environment, and Part II: Radiation Awareness and Knowledge comprises 14 questions on topics such as sources of radiation, benefits, risks, radiation symbols, and permissible exposure limits.

To ensure content validity, the questionnaire was reviewed by eight content experts from the Kulliyyah of Allied Health Sciences at the International Islamic University Malaysia (IIUM). Validation was based on criteria for relevance, clarity, simplicity, and ambiguity using Lawshe's Content Validity Ratio (CVR) with a minimum threshold of 0.75, and Content Validity Index (CVI) developed by Waltz and Bausell's (Yaghmaie, 2003). The pilot study involved 40 respondents to test reliability, yielding a Cronbach's alpha of 0.887, indicating high internal consistency.

Via this questionnaire, knowledge and awareness scores were based on modified Bloom's taxonomy. Correct answers scored 1 point; incorrect answers scored 0. Scores were categorized as Low (<58%), Moderate (59-78%), or High (>79%) to reflect varying levels of knowledge and awareness.

Data were analysed using the Statistical Package for the Social Sciences (SPSS) version 21.0. Given the non-normal

distribution of demographic variables (p-value > 0.05 in Kolmogorov-Smirnov tests), non-parametric tests were selected; Pearson Chi-Square Test and Kruskal-Wallis Test. Each demographic factor was examined for significant correlations with radiation awareness. The threshold for statistical significance was set at p<0.05.

RESULTS

Radiation Knowledge and Awareness based on Socio-Demographic Data

Demographic information, including gender, age, education level, field of study, and workplace environment, was analysed to assess how these factors influence radiation knowledge and awareness.

Out of 384 respondents, 27% were male and 73% female. Statistical analysis (Pearson chi-square) in Table 1 revealed no significant relationship between gender and radiation awareness, indicating that awareness levels do not differ by gender.

Table 1: Association of level of knowledge and awareness based on gender

Level of knowledge and awareness	Gender		Chi-square statistics (df)	*p*-value
	Male, n (%)	Female, n (%)		
Low	77 (20.1)	227 (59.1)	3.158 (2)	0.206
Moderate	21 (5.5)	41 (10.7)		
High	7 (1.8)	11 (2.9)		

Most respondents were aged 20-29 (73%), with smaller numbers in older age groups. Analysis (Kruskal-Wallis test) in Table 2, found no significant differences in awareness across age groups, suggesting age is not a major factor influencing radiation knowledge.

Table 2: Significant difference between age and level of knowledge and awareness

Age group	n	Mean rank	F stat, (df)	*p*-value
20-29	282	194.58	5.127 (4)	0.275
30-39	29	179.12		
40-49	39	181.68		
50-59	30	190.43		
60-69	4	264.00		

Based on education level, most of respondents held a bachelor's degree (58%), followed by diploma/equivalent qualifications (20%). Statistical analysis showed in Table 3, no significant association between education level and radiation awareness, indicating that higher education does not necessarily correlate with better understanding of radiation.

Table 3: Differences between education level and level of knowledge and awareness

Highest education level	n	Mean rank	F stat, (df)	*p*-value
Primary school/PMR	5	262.30	7.780 (5)	0.169
SPM/SPMV/equivalent	38	173.87		
STPM	11	169.14		
Diploma or equivalent	76	192.61		
Bachelors degree/equivalent	228	193.76		
Master or higher or equivalent	26	204.85		

Participants were categorized as having field of study either a health-related background (17%) or non-health background (83%). Analysis found a significant relationship between field of study and awareness levels, with those in health-related fields demonstrating higher knowledge of radiation, likely due to more direct exposure to radiation topics (Table 4).

Table 4: Relationship between major field of study and level of knowledge and awareness

Level of knowledge and awareness	Major field of study		Chi-square statistics (df)	*p*-value
	Non-health, n (%)	Health, n (%)		
Low	268 (69.8)	36 (9.4)	32.36 (2)	<0.001
Moderate	39 (10.2)	23 (6.0)		
High	10 (2.6)	8 (2.1)		

Around 38% of respondents worked in radiation-related environments and others were not related to radiation-related field. Statistical analysis revealed a significant association between workplace environment and radiation awareness, with those in radiation-exposed workplaces showing higher awareness, likely due to greater exposure to radiation safety practices and information (Table 5).

Table 5: Association between workplace environment and level of knowledge and awareness

Level of knowledge and awareness	Workplace surrounded by radiation		Chi-square statistics (df)	*p*-value
	No, n (%)	Yes, n (%)		
Low	203 (52.9)	101 (79.2)	17.91 (2)	<0.001
Moderate	32 (8.3)	30 (7.8)		
High	4 (1.0)	14 (3.6)		

Level of Radiation Knowledge and Awareness

Knowledge and awareness levels were categorized into three groups; low, moderate, and high, using a scoring system aligned with Bloom's taxonomy. The results reveal a significant gap (Table 6) in understanding among the public, echoing findings in similar studies on radiation awareness (Maulana et al., 2018; Jin et al., 2016).

Table 6: Distribution of level of knowledge and awareness

	Characteristic	n (%)	Mean (SD)
Level of knowledge and awareness	Low	304 (78.8)	0.26 (0.53)
	Moderate	62 (16.1)	
	High	18 (4.7)	

A large majority of respondents, comprising 304 out of 384 participants (78.8%), scored in the low category, indicating limited knowledge about radiation. These participants struggled to accurately identify basic information, such as sources of radiation, appropriate safety protocols, and permissible exposure limits. Many respondents, for example, mistakenly categorized non-ionizing sources like mobile phones and microwaves as ionizing radiation sources—a misconception noted in studies by Iqbal et al. (2014) and Yurt et al. (2014), who found that the public often confuses everyday electronic devices with sources of harmful radiation. Furthermore, misunderstandings about radiation risks were common in this group, with many unaware of the low-risk nature of controlled medical exposures, as reported by Kada (2017). The prevalence of low scores highlights the urgent need for accessible, accurate information on radiation basics.

Approximately 62 respondents (16.1%) fell within the moderate category, demonstrating partial understanding of radiation-related topics. While this group was somewhat familiar with radiation sources and applications, gaps remained in more specific areas, such as distinguishing between ionizing and non-ionizing types and understanding permissible exposure levels. Studies by Evans et al. (2015) suggest that such partial knowledge often results from limited exposure to structured education on radiation or reliance on general media sources, which may lack technical accuracy. Respondents in this category generally recognized some risks associated with radiation but lacked a nuanced understanding of its benefits, especially in medical imaging and cancer treatment, as found by Dauer et al. (2011). This level of awareness indicates that, although some foundational knowledge exists, more comprehensive education could greatly enhance understanding.

Only a small fraction of respondents, 18 in total (4.7%), achieved a high level of awareness, indicating a strong understanding of radiation concepts. These individuals were able to accurately identify various radiation sources, distinguish ionizing from non-ionizing types, and understand both risks and benefits of radiation use. Their familiarity with permissible exposure limits and safety measures suggested practical knowledge, likely due to backgrounds in healthcare, radiation safety, or related fields (Zhou et al., 2010). Studies such as those by Ricketts et al. (2013) have shown that individuals with professional or educational exposure to radiation topics exhibit significantly higher levels of understanding and awareness, consistent with findings in this study.

The findings indicate that nearly 80% of respondents possess low radiation knowledge levels, while fewer than 5% achieved high scores. This significant gap in public awareness is consistent with other research highlighting a lack of reliable information and prevalent misconceptions in the general population (Hauri et al., 2013; Maulana et al., 2018). The results suggest that the low knowledge levels could stem from limited access to accurate sources and reliance on informal information, as supported by Acar and Ince (2010), who found that misconceptions are often fuelled by unreliable online content. Given the findings, there is a clear need for educational interventions to provide foundational information on radiation safety, benefits, and risks.

The data underscore the importance of improving public education on radiation to address the pervasive misconceptions and alleviate unnecessary fears, particularly concerning medical applications (Allison, 2009; Lumbreras et al., 2017). Enhancing awareness through government-supported campaigns or healthcare provider resources could significantly improve public understanding and confidence regarding radiation exposure in controlled settings. This study's results reinforce previous recommendations for outreach efforts to counter misinformation and promote informed decision-making regarding radiation exposure (Evans et al., 2015; Jin et al., 2016).

CONCLUSION

In summary, the results indicate that the public in Johor lacks adequate knowledge and awareness of radiation, with a strong need for reliable educational resources and targeted awareness efforts. The results suggest that enhancing public understanding could help mitigate fears and misconceptions, potentially reducing anxiety related to radiation exposure in medical and environmental contexts.

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ORIGINAL ARTICLE

The Scope of Practices and Challenges of Sonographers as a Recognized Allied Health Professional in Malaysia

Nur Syafii Rahayu Mohd Khairurazi [1], Suraya Sulaiman Khan[2], Farah Wahida Ahmad Zaiki[1,3*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2] Mysonoworld Training Centre, [3] Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
sonography; sonography profession; sonographer; perspectives; practice; challenges

ABSTRACT

Background: Sonography profession in Malaysia is as a crucial component of allied health services. This study aimed to assess the current scope of practices and challenges of sonographers as recognized allied health professional in Malaysia and determined the association between the scope practices and the challenges encountered. **Methods:** A cross-sectional study was conducted among sonographers in Malaysia registered under Malaysian Sonographers Association (MASA) indicated that they are bounded to a professional organization. A total of 131 respondents were surveyed following the inclusion and exclusion criteria. An online questionnaire was distributed, comprising three sections: demographic, scope of practices and challenges of sonographers in Malaysia. Data was analyzed using the Statistical Packages for Social Sciences (SPSS), utilizing the descriptive analysis and Spearman Correlation test. **Results:** The scope of practices of sonographer yielded almost 99.2% respondents that agreed to the statement of sonographers in Malaysia should possess a thorough understanding and adhere to their workplace's standard operating procedures (SOP). The most encountered challenges of sonographers (93.1%) are obtaining a graduate certificate, graduate diploma, master's degree, or doctoral degree in sonography is necessary for employment in Malaysia. Spearman correlation test yielded p-value <0.01, correlation coefficient, (r) was 0.37, indicating a statistically significant moderate positive correlation between the scope of practices and challenges encountered by sonographers in Malaysia. **Conclusion:** As a conclusion, the scope of practices of sonographers in Malaysia has expanded, strengthening the need for enhanced recognition, education and support for their profession. Significant correlation was found suggested that as the scope of practices increase, the challenges of sonographers encountered also tend to increase. Future recommendations include establishing comprehensive training programs, improving workplace ergonomics, and conducting further longitudinal research.

INTRODUCTION

Conventional diagnostic ultrasonography, often referred to ultrasound that is commonly utilized in various medical specialties, including obstetrics and gynaecology, cardiology, urology, and musculoskeletal imaging. The global demand for ultrasound services is on the rise due to the acknowledged benefits and continuous technological advancements in ultrasound. This demand indicated the crucial role of sonographers in healthcare system, primarily because ultrasound technology is an operator dependent (Reeve et al.,2022).

The primary duty of sonographers in the beginning was to utilize physics and instrumentation to generate images while the task of interpreting and extracting information from these images remained the responsibility of physicians (Pessin, 2023). Nevertheless, sonographers nowadays need to be well-equipped with knowledge, training and expertise on the anatomy, physiology, pathology, and sonographic physics particularly for specialized procedure. Sonographers' expertise extends beyond technical proficiency with; it also includes a comprehensive understanding of numerous knowledge in delivering a high-quality patient care.

In Malaysia, the practices and responsibilities of sonographers has expanded to a wider range within healthcare system. The core responsibility of sonographers also plays a pivotal role in patient care, working closely with multidisciplinary teams including radiologists, physicians, and other healthcare providers to ensure accurate and timely diagnosis. According to the Medical Radiation Surveillance Division Ministry of Health Malaysia (2022), there are four major scopes of ultrasound currently practised by sonographers which are Obstetrics and Gynaecology, Radiology, Point-of-Care Ultrasound (PoCUS) and Echocardiography. Notwithstanding, sonographers stand to gain significant advantages from that international scope of practice, notably through

* *Corresponding author.*
E-mail address: farahzaiki@iium.edu.my

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standardized educational requirements and enhanced professional flexibility (Miles et al., 2022). Despite the significant contributions of sonographers in healthcare system, whether in Malaysia or globally, they experienced variety of challenges in light of their professional practices.

Therefore, this research is aimed to investigate the scope of practices of sonographers in Malaysia and challenges faced by sonographers as a recognized allied health profession in Malaysia. Hence, assessing the relationship between the scope of practices and challenges encountered by sonographers in Malaysia.

MATERIALS AND METHODS

Ethical approval

This cross-sectional study is aimed to assess the current scope of practices and challenges of sonographers as a recognized allied health professionals in Malaysia. The study obtained ethical approval IIUM Research Ethical Committee (IREC) IIUM/504/14/11/2/IREC 2024-KAHS/DDIR.

Study Population

The study focused on sonographers registered with Malaysian Sonographers Association (MASA) as the research participants indicated that they are bounded to the professional organization, in order to be a recognized allied health profession. The inclusion criteria were sonographers practiced in Malaysia and are active sonographers while the exclusion criteria are sonographers practiced outside Malaysia and are inactive or retired sonographers. All participants were consented, fully informed about the study and voluntarily agreed to participate.

Sample Size Calculation

The sample size was determined by using the Slovin's formula. The sample size was calculated at a 95% confidence interval (CI) where the z value is 1.96. The margin of error is 5% and the population size is 168 which are the amount of MASA registered member. Thus, the sample size for this study is about 118 participants. However, final sample size is 131 participants.

Questionnaires and Data Collection

A questionnaire was designed to evaluate the diverse viewpoints and perspectives of sonographers in Malaysia regarding their scope of practice and the challenges they encountered. The Likert-scale questionnaires consist of range of responses from "Strongly Disagree" to "Strongly Agree."

The validated questionnaire undergone a reliability test for the internal consistency of the questionnaires. The results of Cronbach's Alpha for the scope of practices was 0.86 whilst the challenges encountered by sonographers was 0.74, indicating a relatively high reliability.

Demographic Questionnaire

The first part of the questionnaire was demographic characteristics. This part involved the collection of information pertaining to age, gender, years of experience and employment setting.

Scope of Practices and Challenges of Sonographers Questionnaire

The next parts of the questionnaire were the sonographers' scope of practices and challenges. The constructed questionnaire used adapt and adopt method from several resources including previous research (Pessin, 2023, Hardicre et al., 2021. Hagen-Ansert & Baker 2007). Fifteen items were developed to examine the scope of practices for sonographers in Malaysia were shown in Table 1 while 7 items were developed to investigate the challenges of sonographers in Malaysia were shown in Table 2.

Table 1: Scope of practices for sonographers in Malaysia

No.	Item
1.	Sonographers should possess a thorough understanding and adhere to their workplace's standard operating procedures (SOP).
2.	Sonographers play a role in verifying patient identification and ensuring that the requested examination matches the patient's clinical history and symptoms.
3.	Sonographers play a role in assessing limitations and preparing the patient before the examination. (e.g.: thick abdomen, non-cooperative paediatrics patients)
4.	Sonographers should effectively communicate with different aspects of patients (e.g.: age, gender, educational background, and physical ability).
5.	Sonographers play a role in directing medical questions about diagnosis to the physicians or specialists.
6.	Sonographers play a role in integrating medical history and clinical symptoms to decide on appropriate diagnostic methods to fulfil the patient's needs.
7.	Sonographers play a role in identifying normal and abnormal features in ultrasound images to decide the necessary adjustments to the scanning techniques.

8.	Sonographers play a role in primary analysis of the sonographic findings to ensure that the physician or specialist has sufficient data to interpret the results.
9.	Sonographers play a role in providing the utmost patient care during the ultrasound procedure.
10.	Sonographers are expected to be able to perform all types of ultrasound imaging including Abdominal, Obstetrics and gynaecology, Echocardiography, Vascular sonography, Musculoskeletal sonography and small parts sonography
11.	Sonographers play a role in generating formal reports of ultrasound findings.
12.	Sonographers play a role to ensure the equipment is well-functioning and take immediate action in the case of equipment malfunctions.
13.	Sonographers play a role in utilizing problem-solving skills to make decisions during ultrasound procedures.
14.	Sonographers are involved in research activities to enhance their career's ethical and professionalism.
15.	Sonographers are involved in continuous medical education (CME) to update the current knowledge and enhance competency in their career.

Table 2: Challenges of sonographers in Malaysia

No.	Item
1.	Sonographers' job opportunities are limited.
2.	Sonographers' jobs are underpaid.
3.	Sonographers might encounter difficulty in handling patients' emotional situations when delivering bad news to patients.
4.	Sonographers are prone to have work-related musculoskeletal diseases (WRMSD).
5.	Sonographers are not provided with ergonomic workstations to meet individual postural needs.
6.	Sonographers are required to have a graduate certificate/graduate diploma/masters in sonography/doctoral degree in sonography to be employed in Malaysia.
7.	Sonographers often work extended hours beyond office hours due to:
	i) producing paperwork.
	ii) increased number of patients.
	iii) attending to the urgent cases.
	iv) research activities.
	v) Continuous medical education (CME) or professional bodies activities.
	vi) other reasons.

Data Analysis

The data collected were analyzed using the Statistical Packages for Social Sciences (SPSS) version 20 (IBM Corporation, New York, USA). The demographic characteristics, scope of practices and challenges encountered by sonographers were analyzed using descriptive analysis. Normality test was performed to check for the data distribution. The Spearman's test was used to assess the association between the scope of practices and challenges encountered by sonographers in Malaysia as the data obtained was not normally distributed.

RESULTS

Demographic Characteristics

Table 3 outlines the demographic characteristics of the respondents, comprising 131 respondents, 19 (14.5%) were from male respondents and 112 (85.5%) female respondents. Nearly half of the respondents (48.9%) fell within the age of 20 to 30 years. In terms of professional experience, 45.8% of respondents reported a tenure ranging from one to five years, while a smaller fraction (17.6%) had less than a year of work experience. A significant portion (96.9%) of respondents indicated employment within a private setting.

Table 3: Demographic Characteristics of the Respondents

Item	Characteristics	Frequency (n)	Percentage (%)
Gender	Male	19	14.5
	Female	112	85.5
Age	20 to 30 years	64	48.9
	31 to 40 years	58	44.3
	41 to 50 years	7	5.3
	51 to 60 years	1	0.8
	61 years and above	1	0.8
Years of experience	Less than 1 year	23	17.6
	1 to 5 years	60	45.8
	5 to 10 years	24	18.3
	10 years and above	24	18.3
Employment setting	Government	4	3.1
	Private	127	96.9

Throughout the study, the findings showed that sonographers responding to this survey were more likely to be female, similar with the current study by Pessin (2023). These findings suggest a demographic trend within the sonography profession that warrants further investigation. Moreover, the average age and years of experience of sonographers responding to this survey was lower than the previous study, which they reported an average age as 55-64 years with 23 years of sonography experience on average. As compared to this recent study, most responses came from the 20-30 age group, and they had 1-5 years of sonography experience, on average. This

disparity can be attributed to the varying demographics of participants.

Scope of Practices of Sonographers in Malaysia

Table 4 shows almost all items addressing the scope of practices of sonographers had the agreement that reached almost 90% and above except for the item number 5, 6, 10, 11 and 14 yielded 83.2%, 77.9%, 38.9%, 71.8% and 79.4%, respectively. Most respondents approximately 99.2% agreed to item number 1 in which sonographers in Malaysia should possess a thorough understanding of and adhere to their workplace's standard operating procedures (SOP). Interestingly, the statement to the item number 10 stated that sonographers are expected to be able to perform all types of ultrasound imaging, such as abdominal sonography, obstetric and gynaecological sonography, echocardiography, vascular sonography, musculoskeletal sonography, and small parts sonography received mixed responses composed of (38.9%) agreed (32.8%) neutral, and (28.2%) disagreed. This disparity indicated a greater diversity of job scope among sonographers in Malaysia at different scanning centres or health facilities.

Table 4: Scope of practices of sonographers in Malaysia

Item No.	Agreement, n (%)	Neutral n (%)	Disagreement n (%)	Mean (SD)
1.	130 (99.2%)	1 (0.8%)	0 (0%)	4.8 (0.4)
2.	127 (96.9%)	4 (3.1%)	0 (0%)	4.8 (0.5)
3.	122 (93.1%)	6 (4.6%)	3 (2.3%)	4.6 (0.7)
4.	123 (93.9%)	8 (6.1%)	0 (0%)	4.6 (0.6)
5.	109 (83.2%)	16 (12.2%)	6 (4.6%)	4.3 (0.9)
6.	102 (77.9%)	20 (15.3%)	9 (6.9%)	4.2 (1.0)
7.	129 (98.5%)	2 (1.5%)	0 (0%)	4.8 (0.4)
8.	126 (96.2%)	4 (3.1%)	1 (0.8%)	4.7 (0.6)
9.	125 (95.4%)	6 (4.6%)	0 (0%)	4.7 (0.5)
10.	51 (38.9%)	43 (32.8%)	37 (28.2%)	3.2 (1.1)
11.	94 (71.8%)	26 (19.8%)	11 (8.4%)	3.9 (1.0)
12.	126 (96.2%)	5 (3.8%)	0 (0%)	4.6 (0.6)
13.	118 (90.1%)	13 (9.9%)	0 (0%)	4.5 (0.7)
14.	104 (79.4%)	23 (17.6%)	4 (3.1%)	4.2 (0.9)
15.	122 (93.1%)	6 (4.6%)	3 (2.3%)	4.6 (0.7)

This finding supported by the existing study in the United States (US) and United Arab Emirates (UAE), highlighting variety of roles performed by sonographers involving teamwork with physicians and radiologists to conduct scans, capture images, and report findings must follow the professional standards and ethical guidelines (Abuzaid and Elshami, 2024). By following SOP, sonographers comply with the expectations set by professional bodies and ensure that examinations performed meet the professional benchmarks for competence and performance. According to Bierig

(2022), the influencing factors are due to the rapid advancements in diagnostic technology and growing demands for imaging services of ultrasound. Hence, sonographers should posses a thorough understanding and adhere to their workplace's SOP, thereby fostering high-quality practice and maintaining professional integrity within the scope of sonographers' practices.

This current study suggested a variation in the trend where sonographers are expected to be proficient across all types of ultrasound imaging specialties, such as abdominal, echocardiography, vascular, musculoskeletal, small parts, obstetrics & gynaecology sonography, are probably due to the different demands of scanning centres or health facilities, portraying variety of cases being referred to the scanning centres or health facilities in Malaysia. This finding supported by the existing study where most sonographers are actively working in the fields of abdominal, obstetric, gynaecological, vascular, and small parts sonography (Pessin, 2023). This specialization suggests a focus on expertise within areas of sonography practice rather than a broad spectrum of skills across all specialties throughout the country.

Challenges of Sonographers in Malaysia

Table 5 illustrates the challenges encountered by sonographers in their professional practice. Most respondents approximately 93.1% agreed to the statement of the item number 6, that obtaining a graduate certificate, graduate diploma, master's degree, or doctoral degree in sonography is necessary for employment in Malaysia are the ultimate challenges being a sonographer as a recognized allied health profession in Malaysia. Furthermore, majority of sonographers about 89.3% agreed that they are prone to have WRMSD. Contrary to only around 17.6% respondents agreed that they worked extended hours beyond office hours due to research activities, sonographers are more often working extended hours due to the increased number of patients (74.8%).

Table 5: Challenges of Sonographers in Malaysia

Item No.	Agreement n (%)	Neutral N (%)	Disagreement n (%)	Mean (SD)
1.	77 (58.8%)	32 (24.4%)	22 (16.8%)	3.6 (1.2)
2.	80 (61.1%)	42 (32.1%)	9 (6.9%)	3.9 (1.0)
3.	98 (74.8%)	26 (19.8%)	7 (5.3%)	4.0 (0.9)
4.	117 (89.3%)	11 (8.4%)	3 (2.3%)	4.5 (0.8)
5.	101 (77.1%)	18 (13.7%)	12 (9.2%)	4.1 (1.0)
6.	122 (93.1%)	7 (5.3%)	2 (1.5%)	4.6 (0.7)
7.	71 (54.2%)	35 (26.7%)	25 (19.1%)	4.0 (1.2)

i)	38 (29.0%)	43 (32.8%)	50 (38.2%)	2.9 (1.3)
ii)	98 (74.8%)	24 (18.3%)	9 (6.9%)	4.1 (1.0)
iii)	78 (59.5%)	37 (28.2%)	16 (12.2%)	3.7 (1.1)
iv)	23 (17.6%)	46 (35.1%)	62 (47.3%)	2.6 (1.1)
v)	36 (27.5%)	52 (39.7%)	43 (32.8%)	2.9 (1.2)
vi)	34 (26.0%)	49 (37.4%)	48 (36.6%)	2.7 (1.3)

Association between the scope of practices and challenges encountered by sonographers in Malaysia

Table 6 shows the association between the scope of practices and challenges encountered by sonographers in Malaysia. The p-value was set at <0.05, indicated there was association between variables. Correlation coefficient, r value was set at 0.00-0.25 (weak), 0.25-0.50 (moderate), 0.50-0.75 (strong) and 0.75-1.00 (very strong). The obtained p-value was less than 0.01, and correlation coefficient, r value was 0.37 hence, there was statistically significant moderate positive correlation between the scope of practices and challenges encountered by sonographers in Malaysia. This result suggested as the scope of practices increase, the challenges of sonographers encountered also tend to increase.

Table 6: Association between the scope of practices and challenges encountered by sonographers in Malaysia

	Scope of Practices of Sonographers	
Challenges of Sonographers	Correlation coefficient (r)	0.37
	p-value	<0.01

Throughout this study, the findings show that sonographers in Malaysia encountered several challenges in their professional practices. The most challenging part of being a sonographer in Malaysia is due to the requirement to have a graduate certificate, graduate diploma, masters in sonography or doctoral degree in sonography to be employed in Malaysia. This finding supported the study by Abuzaid and Elshami (2024), where only certified sonographers are permitted to practise sonography. Furthermore, continuous professional development is essential for keeping up to date with the latest advancements in the field (Abuzaid, 2024). Without certifications, it may potentially impact the quality of care to the patient.

This stringent educational requirement is likely influenced by the country's emphasis on academic qualifications and skills for employment. This statement is supported by a previous study, highlighting that sonographer education ranges from strict formal qualifications in some countries to informal on-the-job training and short courses in many others (Miles et al., 2022). This requirement presents several obstacles including lack of educational and training accessibility, financial constraint and significant time needed for focused training (McCormick et al., 2023). As a result, the scarcity of sonographers worsens, leading to less professional recognition and encouragement to pursue career (Elshami et al., 2022).

Furthermore, the finding revealed that having WRMSD is challenging among sonographers in Malaysia, aligned with the study in the UK by Bolton and Cox (2015). Zhang & Huang (2017) stated that sonographers who scan for longer hours per day and attend to more patients tend to report higher levels of musculoskeletal pain and discomfort in specific body areas. A study by Pallotta and Roberts (2016) emphasized that one out of every five sonographers globally WRMSD for over half of their careers eventually terminates their career. Similar to Harrison and Harris (2015) reported that WRMSD can result in long-term disability or career-ending injuries among sonographers. Compounding to this issue is probably due to the inadequacy of ergonomic equipment tailored for sonographers in many Malaysian healthcare facilities. Lack of adjustable tables and poor-quality chairs can force sonographers into uncomfortable positions, increasing their risk of musculoskeletal injuries.

Moreover, findings highlighted that sonographers often work extended hours beyond regular office hours which is partly due to the nature of their clinical responsibilities as such increased number of patients rather than engaging in research activities. Unlike professions that might have defined office hours, the schedule for sonographers can vary widely depending on patient demand, hospital or clinic operating hours, and emergency cases requiring immediate attention. This variability often leads to extended shifts to ensure continuous patient care.

It aligns with studies conducted in the US, UK, and UAE, which indicate that the extended work hours are predominantly driven by clinical obligations rather than research engagement. For instance, Elliott et al. (2009) found fewer sonographers actively participating in research activities, highlighting that their workload is primarily focused on clinical duties. Therefore, the extended work hours for sonographers in Malaysia is challenging primarily due to the clinical obligations to meet patient needs rather than engaging in research activities.

CONCLUSION

As conclusion, the scope of practices of sonographers in Malaysia have expanded, strengthening the need for enhanced recognition and support for their profession. Notably, a significant correlation was found between the

scope of practice and the challenges faced by sonographers, suggesting that increasing the scope of practices of sonographers is associated with increased professional challenges and difficulties. Hence, addressing these challenges could possibly elevates sonographers towards continued delivery of high-quality service. This study highlights the need for enhanced training and regulatory support to ensure sonographers can effectively fulfil their roles. The study limitation is the possibility of influence by several external factors such as changes in healthcare policies and technological advancements might evolve the scope of practices of sonographers over time. Therefore longitudinal studies are suggested to provide a more comprehensive and nuanced understanding of the factors influencing their work environment. Future recommendations include establishing comprehensive training programs, improving workplace ergonomics, and conducting further research to develop strategies that can alleviate the challenges faced by sonographers in Malaysia in the era of expending their scope of practices as the technology advances.

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ORIGINAL ARTICLE

Covid-19 Aftermath: Spirometric and Ultrasonographic Insights into Pulmonary Health of IIUM Kuantan Female Undergraduate Students

Ain Nur Bathrisya Che Rosli[1], Ummi Farhana Hashim[1,*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

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post-covid pulmonary; diaphragm mobility; covid-19 respiratory; pulmonary function

ABSTRACT

Background: COVID-19 has significantly impacted the public, leading to decreased pulmonary function, reduced quality of life, and increased mortality rates and healthcare burdens. The outbreak of COVID-19 has triggered a profound sense of fear and uncertainty regarding health status among individuals, communities, and nations. A specific public health concern related to COVID-19 is the potential for long-term respiratory complications that can affect pulmonary function. **Methods:** A cross-sectional study was conducted with 61 student volunteers from IIUM Kuantan, divided into COVID-19-virgin (n=32) and Post-COVID-19 (n=29) groups. Spirometry and ultrasound examinations were performed to evaluate pulmonary function and diaphragmatic mobility. Participants first underwent a spirometry test, followed by a diaphragmatic mobility assessment using ultrasound, with measurements taken on the right diaphragm during three respiratory actions;: quiet breathing, deep breathing, and voluntary sniffing. The data were analyzed using SPSS version 29.0 with Descriptive Analysis, Mann-Whitney U, and Spearman Correlation tests. **Result:** Among the participants, 51.6% were COVID-19-virgin (n=32), and 46.8% were Post-COVID-19 (n=29). All Post-COVID-19 participants were in Stage-2 of the disease. The Mann-Whitney U test revealed no statistically significant differences in FVC, FEV1, and FEV1/FVC between COVID-19-virgin and Post-COVID-19 participants. However, a statistically significant correlation in diaphragmatic mobility was found during deep breathing, with a moderate negative linear relationship ($p = 0.006$, $r = -0.351$). No statistically significant differences were found in diaphragmatic mobility during quiet breathing and voluntary sniffing. **Conclusion:** The findings suggest that Post-COVID-19 individuals may experience reduced diaphragmatic mobility during deep breathing despite normal spirometric parameters, indicating potential differences in pulmonary health between the groups. The decreased diaphragmatic mobility observed in Post-COVID-19 individuals warrants further investigation to understand the underlying mechanisms and long-term implications.

INTRODUCTION

A key concern regarding COVID-19 is the long-term respiratory sequelae that can impact public health and pulmonary function. Some individuals will experience long-term respiratory complications right after recovering from the acute phase of the disease. This syndrome is frequently referred to as "post-acute sequelae of SARS-CoV-2 infection" or "long COVID." While the majority of individuals who contract COVID-19 fully recover, approximately 10-20% of patients experience a range of medium- and long-term sequelae following their initial illness (Ahmad et al. 2021).

The long-term impact of COVID-19 is characterized by persistent symptoms beyond three months post-infection. The impact on lung function is substantial and has a wide range of effects, affecting many survivors. Studies have shown that even patients with non-severe COVID-19 experience long-term reductions in pulmonary function, functional capacities, and physical activities, necessitating extended healthcare and rehabilitative programs (Alshammari, Shanb, Alsubaiei & Youssef, 2024). Persistent symptoms such as fatigue, dyspnoea, and chest pain are common in prevalence of long-term COVID-19 even months after recovery from the initial infection regardless of the severity of the acute phase of COVID-19 (Tunçer et al, 2023; Patil et al., 2023).

The lungs are the most organ affected by COVID-19 (Mo et al. 2020), so there is no doubt it can affect the respiratory system in a person. Since the long-term consequences of COVID-19 infection on pulmonary function in young adults remain unclear, further studies are necessary to investigate the potential impact of the virus on lung capacity, respiratory efficiency, and overall pulmonary health in this population. While some patients show normal results on pulmonary function tests and echocardiography, they may still experience impaired volitional diaphragm function and control, which

* *Corresponding author.*
E-mail address: ummifarahanahashim@iium.edu.my

correlates with exertional dyspnea (Hadda et al., 2022). Despite the exponential increase in scientific publications and global collaboration on managing acute COVID-19 infection over the last two years, the long-term health effects on COVID-19 survivors remain unresolved. Thus, the present study aimed to investigate the impact of COVID-19 on pulmonary health among undergraduate students at the International Islamic University Malaysia (IIUM) Kuantan, Pahang.

MATERIALS AND METHODS

Ethical Approval

After obtaining ethical approval from the Kulliyyah Postgraduate and Research Committee (Reference no.: IIUM/310/14/11/2 ID No. KAHS 8/24) and IIUM Research Ethics Committee (IIUM/504/14/11/2/ IREC 2024-KAHS/DDIR), a cross-sectional study was conducted among the COVID-19-virgin and Post-COVID-19 who met the inclusion criteria from March 2024 until July 2024.

Participants Recruitment

A total of 32 participants were classified as COVID-19-virgin as they had not been infected with COVID-19. In contrast, 29 participants were classified as Post-COVID-19 being in Stage-2 of COVID-19 based on the COVID-19 Management Guidelines in Malaysia. Ministry of Health (MoH) stated that this group of people with Stage-2 were all symptomatic with no pneumonia detected. Most of them experienced the same common symptoms which are fever, cough, sore throat, fatigue, and headache. None of them were hospitalised during the infection, thus enough for them to fall under the mild level of the National Institute Health (NIH) classification. All 61 participants, including both the COVID-19-virgin (n=32) and Post-COVID-19 (n=29) groups, underwent spirometry and diaphragmatic mobility assessments.

Spirometry Assessment

The main outcome measurements for this assessment are forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), and their ratio, FEV1/FVC. According to the American Thoracic Society, as mentioned and suggested by Jenkins et al. (2014), the highest values of FVC and FEV1 were selected as the most suitable values for analysing and representing pulmonary function. In addition, the FEV1/FVC ratio is also indicative of the volume of air that is expelled from the lungs within the initial second of a forced expiration (Lutfi, 2017). Prior to the assessment, participants were advised to wear comfortable, loose-fitting clothing and to loosen their belts if necessary, to facilitate optimal inhalation and exhalation during the procedure (Güçsav et al., 2023).

The participant was positioned in a sitting while a mouthpiece and a nose clip were given to ensure no air escaped through the nasal passages. The mouthpiece was put inside the designated hole or turbine and gently placed in the participant's mouth. Subsequently, the participant was instructed to perform a deep inhalation through the oral cavity to the fullest extent feasible, followed by forcibly exhaling the air into the designated tube. Following the spirometry assessment, the key parameters of FVC, FEV1, and FEV1/FVC were recorded for each participant. The test was performed a minimum of three times, and the average values were documented.

Diaphragmatic Mobility Assessment

Based on Sierra et al (2023), Diaphragmatic ultrasonography is a valuable, non-invasive, and readily available method for assessing the diaphragmatic mobility (DM). The scanning was conducted using 2 different modes; B-mode and M-mode with a 3.5 MHz curvilinear transducer to locate the position of the DM. A curvilinear transducer was used and placed on the area on anterior subcostal area, between the midclavicular and anterior axillary lines. Ideally, the liver can be utilized as the acoustic window to evaluate the right hemidiaphragm meanwhile the left hemidiaphragm can be evaluated using the spleen window.

The mode of scanning was in B mode and transverse scanning was carried out by looking across the liver for the gallbladder in the centre and the inferior vena cava on the right side of the monitor screen. The right hemidiaphragm was visually represented as a thick, curving, and hyperechoic line as shown in Figure 1. Once the right hemidiaphragm was located, the participant was instructed to take quiet breathing, deep breathing, and voluntary sniffing which were marked by the cursor (Boussuges et al, 2009). The mode of the scan was changed to M mode to identify the highest excursion of the hemidiaphragm. The callipers were placed at the bottom and top of the diaphragm's inspiratory slope to determine the excursion's amplitude. The scan was repeated at least 3 times, and the average measurement was taken. The mean of all the data for each group of variables (DM and spirometry assessment) was calculated. The Mann-Whitney U test was chosen to compare the means of DM of the COVID-19-virgin and Post-COVID-19, and the comparison of the means of spirometry assessment between the COVID-19-virgin and Post-COVID-19. Spearman Correlation was done to describe the relationship between COVID-19 status and DM

assessment.

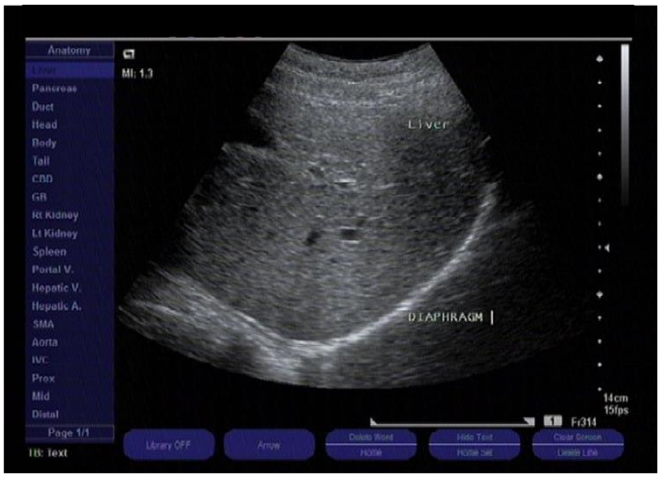

Figure 1: A thick, curved, and hyperechoic line represents the right hemidiaphragm

RESULTS

Descriptive Analysis

A total of 61 female participants from IIUM Kuantan undergraduate students participated in this study and all these participants were assigned to COVID-19-virgin and Post-COVID-19. A frequency analysis test was done to look for the demographic data for this study. Based on Table 1, the COVID-19-virgin (n=32) had the highest percentage of 51.6% meanwhile 46.8% of them were Post-COVID-19 (n=29).

Table 1: Demographic Data of Participants

Category	Frequency (n=61)	Percentage (%)
COVID-19 virgin	32	51.6
Post-COVID-19	29	46.6

Based on Table 2, the mean result from DM assessment using ultrasonography was divided into 3 different readings: Average Quiet Breathing Difference (AQBD), Average Deep Breathing Difference (ADBD), and Average Voluntary Sniffing Difference (AVSD). ADBD in COVID-19-virgin group recorded a higher mean of DM which was 4.88 ± 0.83 cm than the Post-COVID-19 group (4.21 ± 0.77 cm). Besides, the mean of AQBD in the COVID-19-virgin group is 1.19 ± 0.47 cm, and for the Post-COVID-19 group is 1.34 ± 0.48 cm. The mean of AVSD in the COVID-19-virgin group is 1.28 ± 0.46 cm while for the Post-COVID-19 group is 1.38 ± 0.49 cm.

Table 2: Mean of DM in COVID-19-virgin and Post-COVID-19

Assessment	COVID-19-virgin (n = 32)	Post-COVID-19 (n =29)
AQBD (cm)	1.19 ± 0.47	1.34 ± 0.48
ADBD (cm)	4.88 ± 0.83	4.21 ± 0.77
AVSD (cm)	1.28 ± 0.46	1.38 ± 0.49

On the other hand, the spirometry assessment in Table 3 showed the result of the mean FVC and FEV in the Post-COVID-19 group was 2.05 ± 0.47 L and 1.94 ± 0.45 L respectively were higher than the COVID-19-virgin group. The COVID-19-virgin group depicted a value of 2.03 ± 0.40 L and 1.94 ± 0.38 in the mean of FVC and FEV1. Meanwhile, the mean of FEV1/FVC in the COVID-19-virgin group was higher than the Post-COVID-19 group which was 95.30 ± 4.39 % and 94.41 ± 5.12 % respectively.

Table 3: Mean of Spirometry Tests in COVID-19-virgin and Post-COVID- 19

Assessment	COVID-19-virgin (n = 32)	Post-COVID-19 (n = 29)
FVC (L)	2.03 ± 0.40	2.05 ± 0.47
FEV1 (L)	1.94 ± 0.38	1.94 ± 0.45
FEV1/FVC (%)	95.30 ± 4.39	94.41 ± 5.12

Mann-Whitney U test: Spirometry Test

The statistical analysis using the Mann-Whitney U test in Table 4 showed no significant difference in the mean FVC between the COVID-19-virgin and Post-COVID-19 groups. The mean of FVC in the Post-COVID-19 group is higher than the COVID-19-virgin which is 2.05 ± 0.47 L and 2.03 ± 0.40 L respectively. Other than that, the mean of FEV1 between COVID-19-virgin and Post-COVID-19 groups also showed no significant difference. The mean of FEV1 in the Post-COVID-19 group is slightly higher than the COVID-19-virgin which is 1.94 ± 0.45 L and 1.94 ± 0.38 L respectively. There is no reduction in FVC and FEV1 measurements was noted in Post-COVID-19, suggesting that mild-to-moderate cases did not have a long-term negative impact on lung function in young adults (Mogansen et al, 2022)

Table 4: Mean of Spirometry Tests and DM in COVID-19-virgin and Post-COVID- 19

	Status	Mean rank	Mann- Whitney U	Z	p-value
FVC	COVID-19-virgin	29.20	406.50	-0.83	0.41
	Post-COVID-19	32.98			
FEV1	COVID-19-virgin	29.58	418.50	-0.65	0.51
	Post-COVID-19	32.57			
FEV1/FVC	COVID-19-virgin	32.59	413.00	-0.74	0.46
	Post-COVID-19	29.24			
AQBD	COVID-19-virgin	28.42	381.50	-1.59	0.11
	Post-COVID-19	33.84			
ADBD	COVID-19-virgin	36.50	288.00	-2.71	0.01
	Post-COVID-19	24.93			
AVSD	COVID-19-virgin	29.58	418.50	-0.81	0.42
	Post-COVID-19	32.57			

Mann-Whitney U Test: DM Assessment

A Mann-Whitney U test in Table 4 showed that there was no statistically significant difference in the distribution of AQBD and AVSD between COVID-19-virgin and Post-COVID-19, as assessed by DM assessment. Similarly, a study from Vetrugno et al, (2022) revealed that the is no significant difference in DM assessment between AQBD and AVSD. In contrast there is a significant difference in the mean for ADBD in the COVID-19-virgin and the Post-COVID-19 group which is 4.88 ± 0.83 cm and 4.21 ± 0.77 cm respectively. Deep breathing is the most significant for DM assessment in COVID-19 as it aids in allowing better visualization and evaluation of the diaphragm movement (Vetrugno et al, 2022). In addition, ADBD reading is very essential for the evaluation of diaphragmatic mobility and strength compared to the AQBD and AVSD (Boussuges et al, 2022).

Correlation between Covid-19 Status and Diaphragmatic Mobility

There was no significant correlation between COVID-19 status and AQBD and AVSD using Spearman's rank-order correlation with r = 0.206, p=0.112 and r = 0.104, p=0.424 respectively. Similar findings are found in the non-intubated COVID-19 patients, where they experienced a temporary decrease in diaphragm thickness but maintained normal diaphragm movement during quiet breathing, indicating that structural changes did not significantly impact functional capacity (Hadda et al., 2023). There was a moderate negative significant linear corelation r = -0.351, p=0.006 a between COVID-19 status and ADBD using Spearman's rank-order correlation. This is due to deep breathing puts a higher demand on the diaphragm forcing it to contract more forcefully, highlighting possible weakness or dysfunction present (Chandrakumar et al., 2023). In contrast, quiet breathing and voluntary sniffing may not stress the diaphragm as much, resulting in less pronounced differences between post covid-19 and covid-19 virgin.

CONCLUSION

In summary, this study concludes that Stage-2 of COVID-19 does not significantly affect quiet breathing diaphragm measurements (AQBD, AVSD) or lung function parameters (FVC, FEV1 and FEV1/FVC) in young adults. However, a significant reduction in ADBD was observed in the Post-COVID-19 group compared to COVID-19 virgin, indicating potential diaphragm weakness after infection. Additionally, a moderate negative correlation between COVID-19 status and ADBD highlights that deep breathing, which demands greater diaphragm strength, may expose subtle weaknesses in diaphragm function among Post-COVID-19 individuals. While overall lung function appears unaffected, these results suggest that COVID-19 may lead to minor but significant reductions in diaphragm strength and mobility under exertion.

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ORIGINAL ARTICLE

Radionuclides Activity Concentration in Soil Samples from Residential Areas Nearby Gebeng, Kuantan

Nor Mardhiyyah Ahmad Ruzman [1], Fatihah Syafinaz Binti Kamarul Zaman[1*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
radioactivity in soil; soil contamination; radionuclide level

ABSTRACT

Background: The environment today has increased the intake of harmful substance which may cause the health issue among living things. For example, the present of Rare Earth Elements (REE) in most of electronic devices and its present within industrial environment. The usage of REE might cause the production of the radioactive by-products where it may present the radiological risk to the surrounding area nearby to the source of the radioactive material. Neighbourhood and residential areas located within the short radius with industrial zone such as Gebeng, Kuantan are crucial to be concerned as they are exposed to the soil contamination form the radionuclides released during the manufacturing activity at the industrial zone. Therefore, this article aims to determine the radionuclides activity concentration in soil samples from residential areas nearby Gebeng which are Taman Sungai Ular Jaya, Taman Balok Perdana, Taman Baluk Permai and Taman Batu Hitam. **Methods:** The soil samples from four residential areas nearby the Gebeng Industrial Park were collected at the playground area of each residential areas. The rocks, pebbles, dried leaves, roots, and other foreign objects were removed prior to weighing and the sample were dried for 24 hours with 60°C to eliminate the moisture. The sample were stored in a storage room for a month under room temperature for it to reach equilibrium state. To identify the radionuclide activity, the High Sensitivity Gamma Spectrometer (GDM10) was used measure to the concentration. **Results:** The average radionuclide activity concentration for four of residential areas includes ^{40}K, ^{232}Th and ^{226}Ra were 0.584 x 10^{-6} Bq.kg^{-1}, 1.246 x 10^{-6} Bq.kg^{-1} and 2.862 x $^{10-6}$ Bq.kg^{-1} respectively. The ^{40}K was not detected in Taman Balok Perdana. ^{226}Ra was not detected in Taman Batu Hitam. **Conclusion:** The finding revealed that all soil samples contained different levels of radionuclide activity concentration. All the concentration of all radionuclides were found to be within the specific limits recommended by UNSCEAR. Taman Batu Hitam and Taman Balok Perdana recorded undetected ^{226}Ra and ^{40}K respectively while both of Taman Sungai Ular Jaya and Taman Baluk Permai demonstrated similar trend of reading with ^{40}K as the lowest average radionuclide activity concentration and ^{226}Ra as the highest.

INTRODUCTION

Radionuclides are naturally occurring radioactive elements present in the environment, including soil, water, and air. The study of radionuclides in soil is critical because their activity concentrations can directly impact human health and the environment, particularly in residential areas. Gebeng, Kuantan, known for its industrial and residential zones, has drawn attention due to its proximity to industries that may contribute to environmental radiation levels since understanding radionuclide activity concentrations in this area is vital to assess potential health risks. Limited research has been conducted to specifically evaluate residential areas near industrial hubs, such as Gebeng.

The lack of localized data on radionuclides in soil samples from these residential zones highlights a need for focused studies to address potential environmental and health implications. This study aims to measure radionuclide activity concentrations in soil from residential areas near Gebeng and compare the findings with international safety standards specifically UNSCEAR (2000). The results will provide valuable data to guide regulations, assess environmental safety, and raise public awareness about potential radiation exposure. All residential areas are located nearby one of the biggest industrial processing facilities for Rare Earth Elements (REEs) in the world, located in Gebeng, Pahang. The main component is the lanthanide concentrate (LC), which is imported to Malaysia from Australia's Mount Weld mine (Al-Areqi, Majid & Sarmani,2014).

As stated by Missimer et al. (2019) the main cause of naturally occurring radioactivity in rock and soil is from the radionuclides such as mainly the decay chains of Uranium-

* *Corresponding author.*
E-mail address: syafinaz@iium.edu.my

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238 (^{238}U), Thorium-232(^{232}Th), and Potassium-40 (^{40}K). The parent and their daughter's radionuclides' decays are responsible for the release of radiation. The mineralogical composition of soil and rock determines their natural radiation content. Natural radioactivity is relatively high in rock made of minerals containing relatively high amounts of uranium, thorium, and potassium. The radionuclide concentrations of the parent rock are usually reflected in the soils. These were also agreed by Ahmad et al. (2015), where they mentioned that the primary sources of natural radioactivity in soil are of ^{238}U, ^{232}Th, ^{40}K, and ^{226}Ra.

MATERIALS AND METHODS

Sample Preparation

This is an experimental study on radionuclide activity concentration in soil from four selected residential areas which are Taman Sungai Ular Jaya, Taman Balok Perdana, Taman Baluk Permai, and Taman Batu Hitam. The residential areas included in this study were specifically selected based on their close proximity to the Gebeng Industrial Park, which is a significant industrial zone. The distances of these residential areas from the Gebeng Industrial Park as shown in Table 1. The collection of soil samples was carried out for one day at 4 different locations with three different times:11.00 a.m., 11.40 a.m., 12.20 p.m. and 1.00 p.m. (40 minutes interval time between each place). These times were chosen to ensure consistency in environmental conditions, such as temperature and sunlight, which can affect the moisture content and surface characteristics of the soil.

Table 1: The specifications and coordinates of the processing facilities (REE) and the four residential areas.

Point label	Description	Coordinates
Main Point (MP)	Processing facilities for rare earth elements (REE)	4.0028°N, 103.3718°E
Sample 1 (S1)	Distance from main point: 3.99km	4.0158°N, 103.4052°E
Sample 2 (S2)	Distance from main point: 5.09km	3.9570°N, 103.3693°E
Sample 3 (S3)	Distance from main point: 7.54km	3.9355°N, 103.3630°E
Sample 4 (S4)	Distance from main point: 13.3km	3.8834°N, 103.3629°E

200g of soil samples were originally collected from the four selected residential areas with similar size of area which was 30 cm x 30 cm square and a depth of 10 cm. Then, the collected sample were placed into a High-Density Polyethylene (HDPE) plastic bag, each with its label and seal. All the rocks, pebbles, plants, dried leaves, roots, and other objects were removed from all four samples using soil strainer. All samples were dried 24 hours under 60 °C using the dehydrator to eliminate any moisture. The dried samples were then crushed by using mortar and pestle until it became powder. The digital weighing scale was used to measure 30g of the soil samples from each of the residential areas and they were placed into three different containers according to the respective residential areas. In total there were 12 containers which, 3 containers for each residential area. Each container was labelled accordingly and were stored in a storage room for a month under room temperature for it to reach equilibrium state. The radionuclide activity concentration of the samples then were identified and compared with the standard value given by UNSCEAR (2000).

Radioactivity Count

The collected samples from the four residential areas radionuclide activity were counted by using High Sensitivity Gamma Spectrometer Model GDM 10-C which then followed by the analysis using the WinDas Software version 3.4.20. The detector or also known as a scintillation detector, consists of a cylindrical NaI crystal. The measurements of height and the diameter of the crystal is 5cm. The energy resolution is less than 7.0 % Full Width Half Maximum (FWHM) at 661 keV. Meanwhile the high-voltage supply is 10-1500 V which can be adjustable continuously by a 10-turn potentiometer. The Cobalt (Co-60) at 1173.2 keV and 1332.5 keV was used for the calibration purpose to ensure an accurate functioning of the detectors.

The radioactivity concentration was quantified after each sample was run for 43,200 (12 hours) seconds using the GDM 10-C in order to minimize statistical uncertainty. Meanwhile, the background radiation was quantified by the absence of the 12 samples. The net counts for each sample were calculated by subtracting each sample count with the background counts. The mean value for the four residential area soil sample count, were calculated by taking the counts for three sample in each of the area.

Data Analysis

The radioactivity concentration in Bq.kg^{-1} for each sample were calculated using the Equation 1 as given by Sedeeq et al. (2019):

$$\text{Activity concentration (Bq.kg}^{-1}) = \frac{(Net\ count)}{\varepsilon \times I_{\gamma} \times t \times m} \quad (1)$$

Where, I_{γ} = emission probability per decay of the specific peak
ε = absolute gamma peak efficiency for the detector at a particular photopeak
t = is the counting time in seconds
m = mass of the sample in kilogram.

The specific activity of the sample that have different amount of ^{40}K, ^{232}Th and ^{226}Ra was compared by using one value which is the radium equivalent Ra_{eq} by using the Equation 2 given by Sedeeq et al. (2019):

$$Ra_{eq} = A_{Ra} + 1.43A_{Th} + 0.077A_{K} \quad (2)$$

where, A_{Ra} = activity concentration of ^{226}Ra
A_{Th} = activity concentration of ^{232}Th
A_{K} = activity concentration of ^{40}K

The external hazard index (H_{ext}) is used to regulate radiation exposure for the annual effective dose to be limited to below 1 mSv per year. The external hazard index (H_{ext}) can be calculated by using the Equation 3 from Missimer et al. (2019):

$$H_{ext} = \frac{A_{Ra}}{370Bq.kg^{-1}} + \frac{A_{Th}}{259Bq.kg^{-1}} + \frac{A_{K}}{4810Bq.kg^{-1}} \quad (3)$$

RESULT

The activity concentration for ^{40}K was found in three of the areas except Taman Balok Perdana. The range of ^{40}K is from 0.839×10^{-6} Bq.kg^{-1} to 3.061 ×10^{-6} Bq.kg^{-1}. As for the activity concentration for ^{232}Th, it can be found in all samples and the highest average activity concentration value was at Taman Baluk Permai. Meanwhile the lowest activity concentration of ^{232}Th was at Taman Batu Hitam. The result also indicated that ^{226}Ra activity concentration was not detected in the soil samples from Taman Batu Hitam while Taman Balok Perdana recorded the highest ^{226}Raactivity concentraton among the sampled locations. The activity concentrations of all involved radionuclides in soil samples are shown in Table 2.

Table 2: The activity concentrations of radionuclides ^{40}K, ^{232}Th and ^{226}Ra in soil samples

Location	Activity Concentration × 10^{-6} (Bq.kg^{-1})		
	^{40}K	^{232}Th	^{226}Ra
Taman Sungai Ular Jaya	3.061	3.663	ND
	ND	ND	3.929
	ND	0.169	ND
Average	1.020	1.277	1.310
Taman Balok Perdana	ND	0.117	2.170
	ND	2.514	ND
	ND	0.482	17.194
Average	-	1.038	6.455
Taman Baluk Permai	1.037	3.123	ND
	ND	ND	11.046
	0.839	3.104	ND
Average	0.625	2.076	3.682
Taman Batu Hitam	ND	0.467	ND
	2.073	0.560	ND
	ND	0.755	ND
Average	0.691	0.594	-
Minimum	0.625	0.594	1.310
Maximum	1.020	2.076	6.455
Mean	0.584	1.246	2.862

*ND: Not Detectable

The activity concentrations of radionuclides ^{40}K, ^{232}Th and ^{226}Ra in all soil samples are compared to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 2000). All of the samples showed that the values obtained for ^{40}K, ^{232}Th and ^{226}Ra were lower than the UNSCEAR specified values of 400 Bq.kg^{-1}, 30 Bq.kg^{-1} and 35 Bq.kg^{-1} respectively.

All activity concentration of ^{40}K, ^{232}Th and ^{226}Ra from each residential area shows values that are very close to zero, hence the percentage deviation is large or is considered as 100% percentage deviation from the specified values by UNSCEAR. The percentage deviation with the UNSCEAR specified limit is shown in Table 3.

Table 3: The percentage deviation with UNSCEAR specified limit.

Location	Percentage Deviation with UNSCEAR Specified Limit (%)		
	^{40}K	^{232}Th	^{226}Ra
Taman Sungai Ular Jaya	100	100	100
Taman Balok Perdana	-	100	100
Taman Baluk Permai	100	100	100
Taman Batu Hitam	100	100	-

The Radium equivalent (Ra_{eq}) value at Taman Balok Perdana was found to be the highest among all the residential areas investigated, although it remains well below the maximum recommended safety limit of 370 $Bq.kg^{-1,}$ as stated by UNSCEAR.

This suggests that while the Ra_{eq} at Taman Balok Perdana is elevated compared to other locations, it still falls within the safe range for human exposure. On the other hand, Taman Batu Hitam exhibit the lowest Ra_{eq} indicating a comparatively lower presence of radium in the soil in this residential area.

When examining the External Hazard Index (H_{ext}), Taman Balok Perdana again recorded the highest value, reflecting a slightly higher potential for external radiation exposure. Taman Batu Hitam had the lowest H_{ext} indicating a minimal external radiation hazard. Despite these variations, all residential areas studied had a H_{ext} value of less than 1, which signifies that the annual radiation dose received by individuals in these areas is below 1 mSv that is the threshold for additional risk of adverse health effects. The detailed Ra_{eq} and H_{ext} values for the soil samples from the different residential areas are provided in Table 4.

Table 4: The Radium equivalent (Ra_{eq}) and External hazard index (H_{ext})

Location	Activity Concentration × 10^{-6} ($Bq.kg^{-1}$)			Ra_{eq} × 10^{-6} (Bq/kg)	H_{ex} × 10^{-9}
	^{40}K	^{232}Th	^{226}Ra		
Taman Sungai Ular Jaya	1.020	1.277	1.310	3.144	8.990
Taman Balok Perdana	ND	1.038	6.455	7.940	11.454
Taman Balok Permai	0.625	2.076	3.682	6.701	18.778
Taman Batu Hitam	0.691	0.594	ND	0.901	2.437
Minimum	0.625	0.594	1.310	0.901	2.437
Maximum	1.020	2.076	6.455	7.940	18.778
Mean	0.584	1.246	2.862	4.672	10.415

*ND: Not Detectable

CONCLUSION

This experiment aims to measure the radionuclides activity concentrations in soil samples collected from four selected residential areas in Gebeng, Kuantan by using GDM-10C and doing a comparison with the UNSCEAR (2000) recommendation limit. The findings reveal that all the soil samples have various levels of radionuclide activity concentrations with some samples showing concentrations that are below the detection limit for ^{40}K, ^{232}Th and ^{226}Ra. This study's findings might be different from other previous studies, which potentially might be influenced by sample size and detector sensitivity. However, the radionuclide activity concentrations of ^{40}K, ^{232}Th and ^{226}Ra are within the UNSCEAR acceptable threshold.

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ORIGINAL ARTICLE

Evaluation of Ovarian Radiation Dose from Internally Scattered X-rays in Posteroanterior (PA) Chest Radiography With and Without Contact Gonad Shielding: Phantom Study

Siti Nur Atiqah Mat lazin[1], Inayatullah Shah Sayed[1,*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, 25200 Kuantan, Pahang, Malaysia

Keywords:
internally scattered radiation; ovarian dose; ESD; contact shielding; radaition protection

ABSTRACT

Background: Scattered radiation originating from the patient's body disperses unevenly in multiple directions, posing a risk of incidental exposure to radiosensitive organs, such as the ovaries, which may absorb radiation from internally scattered X-rays. Although external radiation shielding is a common practice, internal scatter from within the patient presents additional complexities. This study aimed to quantify the radiation dose received by the ovaries using optically stimulated luminescence dosimeters (OSLDs) in posteroanterior (PA) chest X-ray examinations, both with and without the application of a contact gonad shield. **Methods:** A Siemens Multix Top X-ray imaging system was utilized for this study, operating with tube voltages between 70 kVp and 100 kVp and employing Automatic Exposure Control (AEC). The source-to-image distance (SID) was consistently maintained at 180 cm. The entrance skin dose (ESD) measurements corresponding to the ovaries were conducted using nanoDot OSLDs. These were positioned within the RANDO phantom at slice 29 to align with the anatomical location of the ovaries. Measurements taken with and without the use of a contact gonad shield. **Results:** The recorded ovarian ESD with contact gonad shielding averaged 2.2, 2.4, 3.7, and 3.0 mGy at 70, 80, 90, and 100 kVp, respectively. In contrast, without contact gonad shielding, the average ovarian ESD observed at 1.0, 1.8, 2.6, and 3.1 mGy at the respective tube voltages. Radiation dose (ESD) by each ovary varied based on the kVp and the use of contact gonad shielding. Results indicated an unexpected increase in ovarian dose with the use of a contact gonad shield, and a consistent rise in ESD noted with increasing kVp, irrespective of shielding. **Conclusion:** Scatter radiation in radiography presents a risk to organs beyond the primary imaging area, particularly the ovaries in posteroanterior (PA) chest radiography. Research indicates that higher tube potentials result in increased ESD to the ovaries. Interestingly, contact gonad shielding, a conventional method to reduce exposure, may not significantly lower radiation exposures and could potentially increase dose to ovaries. Therefore, discontinuing contact gonad shields seems justifiable for radiation safety. Optimization of tube voltage and tight collimation are crucial for minimizing ovarian radiation exposure.

INTRODUCTION

The chest X-ray is among the most commonly performed radiological examinations, serving as a primary diagnostic tool to guide further diagnosis, treatment, and follow-up (Sun et al., 2012). Although the radiation dose for each examination is relatively low, the widespread use of chest X-rays contributes to a significant collective dose. Skinner (2015) emphasized that chest radiography is an essential starting point in imaging, offering comprehensive views of the lungs and cardiovascular system through standard posteroanterior (PA) and lateral projections, enhancing patient management and quality of life. However, careful attention to radiation dose is essential. Although the lifetime cancer risk from chest radiography is low, implementing dose-reduction strategies remains critical. Bontrager et al., (2024) highlighted the importance of tailoring projections (PA, AP, or lateral) to fit the patient's anatomy, clinical indications, and safety requirements. Radiation safety in diagnostic radiography includes minimizing patient exposure through collimation, lead shielding, and optimized technical settings to maintain image quality without increasing the dose. Shielding against backscatter radiation is equally important, ensuring that the benefits of radiography outweigh the risks.

The scatter radiation, also known as secondary radiation, disperses in all directions after interacting with body tissues, posing an unnecessary exposure risk to both patients and healthcare staff (Insight Medical Imaging, 2019). Ahmed & Shaddad (2002) reported that scatter

* *Corresponding author.*
E-mail address: inayatullah@iium.edu.my

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radiation occurs when the primary beam interacts with collimators, beam stops, or shielding. An enlarged field size also increases scatter radiation, potentially elevating the patient's radiation dose and diminishing image quality.

The amount of scatter radiation produced is influenced by the object imaged and the exposure settings. High-kVp techniques, frequently used in chest radiography, achieve uniform radiographic density and clearer visualization of lung markings. However, increased kVp also raises scatter radiation, which reduces image contrast. Using a grid suited to the selected tube potential can help minimize scatter radiation. Naji et al., (2017) observed that as kVp exceeds 70, photon penetration increases, but image contrast diminishes. Higher kVp also elevates Compton scattering probability, increasing the scatter-to-primary ratio up to 120 kVp, after which it stabilizes (Ghafarian et al., 2007).

The "As Low as Reasonably Achievable" (ALARA) principle is foundational in radiography, guiding practitioners to minimize radiation doses without compromising diagnostic quality (ICRP, 2007). This principle emphasizes weighing the benefits and risks of radiation exposure and ensuring each exposure is justified by evaluating factors such as body part, examination type, radiation dose, and technical settings (IAEA, 2002). Chest radiography, though involving a relatively low dose, is the most frequent radiological procedure, accounting for 43% of plain radiography cases (Ministry of Health Malaysia, 2009). Its routine use across large patient numbers necessitates that technologists adhere to the ALARA principle, ensuring high-quality imaging with minimal radiation exposure.

Protecting patients of childbearing age from radiation is especially important, as ionizing radiation can have severe biological impacts on radiosensitive tissues like the ovaries (Goodman & Amurao, 2012). Prior research has underscored the need to estimate ovarian doses during PA chest radiography. Ionizing radiation in routine exams like chest radiography is a significant concern, given its daily clinical use and cumulative contribution to the collective effective dose (Matyagin & Collins, 2016). Scatter radiation impacts both radiation safety and image quality. Jaenisch et al., (2010) explained that scatter radiation from X-ray photon interactions affects image clarity and contributes to patient and clinician dose (Abrantes et al., 2017; Lima, 2009). Maddox (2019) noted that scattering results in deflected radiation that travels in various directions, leading to exposure of organs outside the primary imaging area, such as the ovaries. Gonad shielding has traditionally been used to reduce radiation exposure to the ovaries, yet recent studies suggest internal scattered radiation may still reach them.

The absorbed dose quantifies the energy absorbed per unit mass of tissue, assessing potential organ damage from radiation (Andisco, et al., 2014). Goodman & Amurao (2012) explained that ionizing radiation affects biological tissues by displacing electrons from atoms, which can damage cells, produce free radicals, and alter tissue structure. These effects are particularly severe in radiosensitive cells, such as those in ovarian or breast tissue.

This study investigates the etrance skin dose (ESD) to the ovaries during PA chest radiography at different tube potentails. Additionally, it assesses the effectiveness of contact gonad shielding in reducing ovarian exposure. The findings aim to offer valuable insights for future practices, especially implementing effective radiation protection measures.

MATERIALS AND METHODS

In this study, the RANDO phantom, illustrated in Figure 1, was used to simulate a patient for estimating the ESD to the ovaries in PA chest radiography. The phantom is horizontally sectioned into 2.5 cm thick slices, each numbered sequentially for easy identification. It contains holes that can be filled with bone-equivalent, soft-tissue-equivalent, and lung-tissue-equivalent inserts, as described by Tazehmahalleh et al., (2008).

Figure 1: RANDO Phantom used in this study

Fung & Gilboy (2001) identified that the ovarian site corresponds to slice 29 of the RANDO phantom. They further indicated that this location aligns with the iliac spine level, medially positioned relative to the vertical plane, within the true pelvis against the lateral wall.

For this study, a nanoDot OSL dosimeter from Nagase Landauer, Japan, was used (Figure 2). This dosimeter has a minimum detection threshold of approximately 0.1 mGy. It is designed for multiple uses post-exposure to X-rays,

with only a minor sensitivity loss of 0.04% over repeated readouts (Graeper, 2015). Al-Senan & Hatab (2011) reported that OSLDs exhibit excellent homogeneity (<5%) and reproducibility (3.3%), with a linear response.

Figure 2: nanoDot OSLD

The Landauer Microstar Reader (Figure 3) was employed for reading the nanoDot OSL dosimeter. This device operates with inLight Microstar Reader Software (version 5.0) and measures radiation doses by exciting the dosimeter with laser light. Once read, the data is extracted, analyzed, and stored. The reader allows for various calibration and configuration settings; however, it is limited to processing one dosimeter at a time. Pre-irradiation readings of nanoDot OSLDs were recorded to subtract from post-irradiation readings, ensuring accurate dose measurements.

Figure 3: The Landaeur MicroStar OSLD Reader

The data were collected by positioning the RANDO phantom in the posterior-anterior (PA) position. The phantom was placed upright on the table, facing the erect bucky, to simulate standard positioning for a chest X-ray examination. A 35 x 43 cm image receptor was inserted lengthwise inside the erect bucky. The source-to-image distance (SID) was fixed at 180 cm. The imaging parameters used in this study are shown in Table 1. A nanoDot OSLD was placed at the 29th slice of the phantom, identified as the location of the ovaries on both the right and left sides as shown in Figure 4. This placement is based on previous studies and research cited in Bardo et al., 2009.

The x-ray beam was tightly collimated to cover the entire lung region. The experiment then proceeded with the application of contact gonad shield to the phantom during the PA chest radiography. The setup of the RANDO phantom is shown in Figure 5.

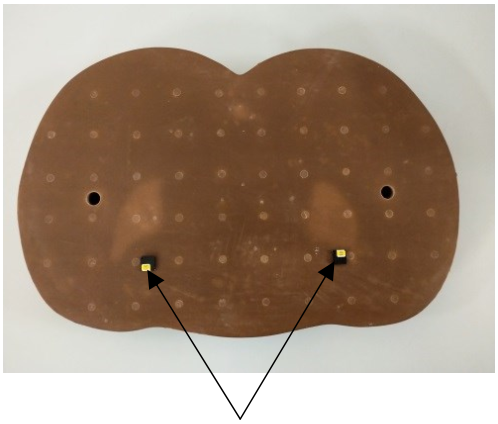

Figure 4: Placement of the nanoDot OSLDs at the 29th slice of the phantom

Table 1: The imaging parameters used in this study

PARAMETERS	DETAILS
Kilovoltage (kVp)	70, 80, 90, 100
Automatic Exposure Control (AEC)	On
Imaging plate size (cm), orientation	35 x 43, lengthwise
Central ray	Perpendicular to the center of IR, midsagittal plane at the level of T7
Source-to-image distance (cm)	180
Focal spot	Broad focal spot (1.0 mm)
Grid (grid ratio)	Moving grid (12:1)
Location of gonad shield	Inferior to iliac crest, 1 inch below the lower costal margin

Figure 5: RANDO phantom positioned PA erect against the erect bucky

The tube potential range for a PA chest x-ray projection varies from 55 to 125 kVp, with an exposure range of 2 to 30 mAs (Ng et al., 1998). Another study by Kim et al., (2007) reported a tube potential range of 54-150 kVp and an exposure range of 18-60 mAs. However, variations in exposure selection are often necessary to account for differences in patient body habitus, weight, and imaging requirements, with the goal of producing high-quality images while minimizing dose.

Statistical Analysis

The data for this study analyzed using IBM's Statistical Package for Social Sciences (SPSS), version 25. The Spearman's correlation test was employed to examine the relationship between the differences in ESD to the ovary during chest X-ray radiography, both with and without contact gonad shielding. The significance was performed at $p < 0.05$.

RESULT

Measured ESD to the Ovaries

ESD measurements corresponding to the ovaries were conducted using a RANDO phantom and nanoDot OSLD with and without contact gonad shielding to determine the effectiveness of gonadal shielding in PA chest radiography. Different tube potentials (with AEC on) were selected.

When using the gonad shield, the ESD to the ovaries showed inconsistencies between the right and left ovary. The ESD was slightly different for the right and left ovaries depending on the tube potential. With 80 kVp, 90 kVp, and 100 kVp, the right ovary received a higher dose than the left; however, at 70 kVp, the left ovary received a higher dose (0.0016 mGy) than the right ovary (0.0006 mGy). On average, the ESD for the right ovary increased at 70 kVp and 90 kVp, then decreased slightly at 100 kVp. The left ovary's ESD showed a fluctuating pattern, as illustrated in Figure 6. The highest ESD for the right ovary was 0.0022 mGy at 90 kVp, while the lowest for the left ovary was 0.0004 mGy at 80 kVp.

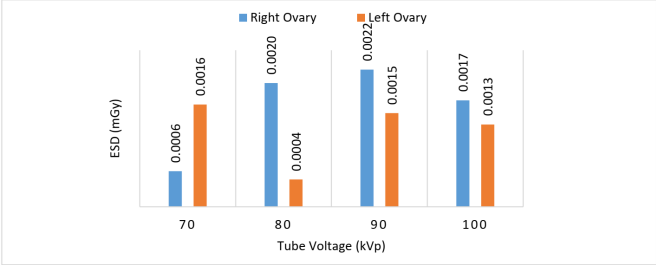

Figure 6: Measured ESD of right and left ovary with different tube potentials (with contact gonad shield)

In contrast, without gonad shielding, the ESD at 70 kVp was undetectable for the right ovary, while the left ovary absorbed a small dose of 0.0010 mGy. As the tube potential increased, the ESD to the right ovary also increased. The left ovary's dose increased up to 90 kVp and then sharply decreased to 0.0001 mGy at 100 kVp. The ESD trends for the right and left ovaries are shown in Figure 7.

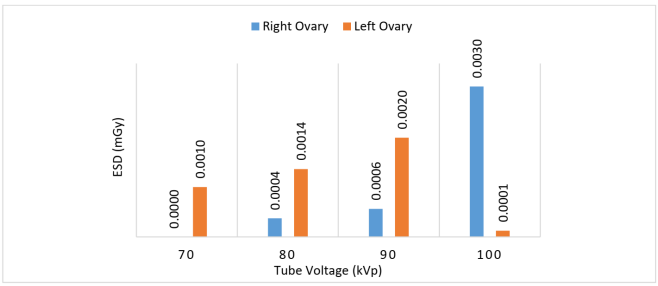

Figure 7: Measured ESD the right and left ovary at different tube potentials (without contact gonad shield)

The left ovary generally received a higher dose than the right, except at 100 kVp, where the highest dose of 0.0030 mGy was recorded. The lowest reading (no ESD) measured at 70 kVp.

The average ovarian ESDs with and without contact gonad shielding is shown in Figure 8. Overall, the total ESD to the ovaries with contact gonad shielding was higher than without it.

Correlation of ESD to the Ovaries and Tube Potential With and Without Contact Gonad Shield

In clinical practice, using contact gonad shielding during PA chest radiography is not a routine. This study primarily ovaries and varying tube potentials, with and without contact gonad shielding.

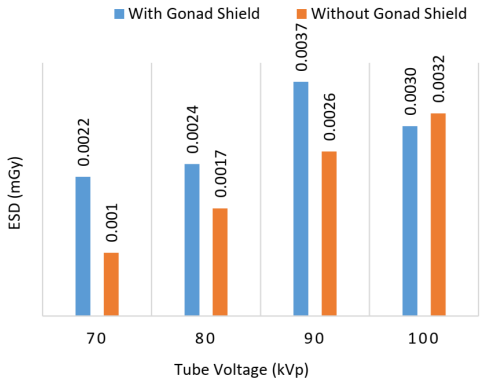

Figure 8: Average ESD to ovaries at different tube potentials with and without contact gonad shield

A bivariate Spearman's correlation test in SPSS was performed, revealing no significant difference between the absorbed dose to the ovaries and tube voltage with or without contact gonad shielding. The p-values were 0.247 (with shield) and 0.299 (without shield), both exceeding the significance level ($p > 0.05$) at a 95% confidence interval. Thus, using contact gonad shielding did not significantly affect the ESD to the ovaries or the tube exposure setting in PA chest radiography.

DISCUSSION

The study investigated the effects of ESD on the ovaries at different tube potentials during PA chest radiography, comparing results with and without the use of contact gonad shielding. No significant differences were observed in the ESD at different tube potentials, with and without the contact gonad shield.

During radiography, X-rays interact with the patient's body, resulting in internal scattering of radiation. This scattered radiation can be absorbed by tissues or organs beyond the targeted projection area, potentially increasing the risk of cancer due to unnecessary radiation exposure. Furthermore, the energy of scattered photons is unevenly distributed and radiates in all directions (Rehn, 2015). An illustration of internally scattered radiation within the phantom is shown in Figure 9.

Even though the ovaries lie outside the collimation area in PA chest radiography, however, still receive a dose from internal scatter. The results show that both the right and left ovaries are exposed to radiation, with variations in the ESD depending on tube potential and ovarian side. This aligns with the observation that scattered radiation disperses in all directions and is unevenly distributed.

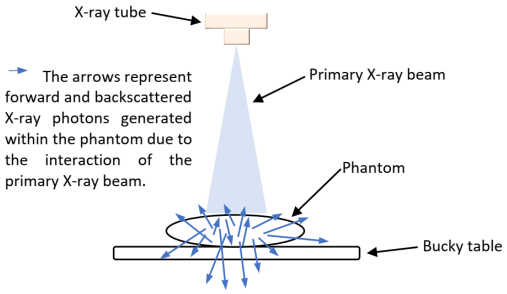

Figure 9: Illustration of internally scattered X-rays within the phantom

Effect of Different Tube Potentials on ESD to Ovaries With and Without Contact Gonad Shield

The highest recorded total ESD to both ovaries was 0.0037 mGy with contact gonad shield, which is still below 0.01 mGy as indicated in previous studies (Ogundare et al., 2009; Njeh et al., 1997). Figures 6 and 7 show that the ESD to the ovaries increases with higher tube potentials (kVp), as greater kVp enhances the X-ray beam's penetrating power and increases scatter radiation (Naji et al., 2017; Ghafarian et al., 2007). Notably, scatter radiation appears to increase with tube potentials up to 120 kVp and then slightly decrease at higher potentials. Thus, a high kVp technique in PA chest radiography may reduce the absorbed dose to the ovaries.

This study used tube potentials between 70 kVp and 100 kVp, selected based on prior research (Ng et al., 1998; Kim et al., 2006). Statistical analysis indicated no significant difference in ESDs to the ovaries across these tube potentials, our findings are consistent with previous research by Rosenstein (1988), which showed that increased kVp results in a higher dose to the ovaries.

Interestingly, the study found that ESD to the ovaries was higher with contact gonad shielding than without, as illustrated in Figures 6, 7 and 8. This contradicts the traditional practice of using contact gonad shields to reduce radiation dose. It suggests that internal scatter radiation generated within the phantom's body during exposure reached to the ovaries, regardless of contact gonad shielding. As Hiles et al., (2020) noted that internal scatter radiation within the patient is challenging to quantify but represents a significant source of secondary radiation exposure to organs outside the primary beam. Shielding one part of the body from another part internally is difficult, as shielding does not effectively reduce radiation dose at greater depths from the primary beam (<17 cm) (Hiles et al., 2020).

Ovaries Dose Differences With and Without Cotact Gonad Shielding

Statistical analysis revealed no significant difference in the ESD to the ovaries across various tube potentials with and without contact gonad shielding. This indicates that gonad shielding minimally affects ESD to the ovaries. Matyagin & Collins (2016) found that gonad shields in PA chest radiography provide only a small reduction in dose to deep-seated organs while slightly increasing skin dose due to scatter from the shield's internal surface. This means that scatter radiation from shielding may reflect back towards the patient. Hiles et al. (2020) also reported that gonad shielding does not significantly reduce dose outside the collimated area, further supporting this study's findings.

According to the American Association of Physicists in Medicine (AAPM, 2019), shielding does little to reduce patient exposure since any potential dose reduction is negligible compared to internal scatter radiation within the patient. Based on current evidence, the use of patient contact shielding is generally unnecessary and not recommended in diagnostic and interventional radiology. This study shows that contact gonad shielding can inadvertently increase patient dose by interfering with automatic dose control or necessitating repeat imaging if image quality is compromised. Effective positioning and optimized protocol parameters are more impactful for dose reduction than using gonad shields (Hiles et al., 2020).

Limitations of the Study

This study has several limitations. Using a RANDO phantom instead of real patients may not fully represent clinical conditions due to body habitus variations. Additionally, minimal ovarian dose from scatter radiation introduced variability in measurements, necessitating multiple measurements for accuracy. Sensitivity and proper application of nanoDot detectors also posed challenges in the experimental setup.

CONCLUSION

This study concludes that increasing tube potential correlates with higher ovarian doses, though contact gonad shielding does not significantly reduce this exposure. In fact, at 90 kVp, ovarian dose was highest with shielding, suggesting shielding may not enhance radiation safety. Therefore, optimizing tube potential and collimation is essential to uphold the ALARA (As Low As Reasonably Achievable) principle for radiation safety. In summary, internal scatter radiation poses a risk to organs outside the primary imaging area, particularly the ovaries in PA chest radiography. Since contact gonad shielding does not consistently reduce ESDs — and may even increase ovarian dose — its routine use appears unnecessary. Focusing on tube voltage optimization and precise collimation offers a more effective approach to minimizing ovarian radiation exposure.

Future Recommendations

For future research, it is recommended to explore a broader range of exposure settings with more than five tube potentials, repeated at least three times for greater accuracy. Additional sensitive organs, such as the thyroid and eyes, could be included in further studies. Additionally, using thermoluminescent dosimeters (TLDs) may offer improved sensitivity for measuring absorbed dose.

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ORIGINAL ARTICLE

Knowledge, Attitude and Practice of Breakfast Consumption among Health Sciences and Non-Health Sciences Students of International Islamic University Malaysia (IIUM)

Siti Zalifah Zahri [1], Nuraniza Azahari, [1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
breakfast consumption; knowledge; attitude; practice; health sciences

ABSTRACT

Background: Regular breakfast consumption is recommended as part of a healthy lifestyle, as it helps individuals meet their nutritional needs and benefits their mental health, emotional well-being, and positive social interactions. However, the prevalence of breakfast consumption remains low among university students. Therefore, this study aims to assess knowledge, attitude, and practice (KAP) levels regarding breakfast consumption among health sciences and non-health sciences students at the International Islamic University Malaysia (IIUM). **Methods:** A convenience sampling method was used to recruit 382 on-campus undergraduate participants, with 191 health sciences students from the Kuantan campus and 191 non-health sciences students from the Kuantan, Gombak, and Pagoh campuses. An online questionnaire was distributed, comprising four sections: sociodemographic information, knowledge, attitude, and practice related to breakfast consumption. **Results:** The results showed that while 66% of IIUM students had a high level of knowledge about breakfast consumption, 92% had only moderate attitudes toward it, and 84% displayed moderate breakfast practice. Health sciences students exhibited significantly higher knowledge levels compared to non-health sciences students. No significant differences were found between knowledge and practice. Notably, significant associations were identified between knowledge and attitude, and between attitude and practice concerning breakfast consumption. **Conclusion:** These findings indicate a need for universities to implement educational programs and interventions to promote regular breakfast consumption and healthier eating patterns among students.

INTRODUCTION

Breakfast is the first meal consumed upon waking from an overnight fast and it is widely recognised as a basis of daily nutrition. This mealtime pattern is closely related to maintaining good and healthy eating habits, improving nutritional value, and supporting cognitive growth (Christensen et al., 2019; Ishida et al., 2020; Yao et al., 2019). In the broader context of establishing a healthy lifestyle, regular breakfast consumption is not merely a dietary suggestion but a strategic response to the rising worldwide challenge of obesity. This widespread health problem which affects not only Malaysia but the entire world, needs thoughtful and educated dietary choices. Many studies have highlighted the importance of breakfast concerning cognitive function and academic performance among students. For instance, Hoyland et al. (2009) reported that students who skipped breakfast faced difficulties in memory tests and demonstrated poorer performance in attention tasks in the morning.

Despite its importance, the number of university students with poor nutritional quality of breakfast is concerning due to poor eating habits. A recent study revealed that approximately 31.8% of Malaysian university students skip breakfast regularly (Jayaveloo et al., 2021). Factors such as time constraints, lack of nutritional knowledge, socioeconomic conditions, and academic pressures have been identified as major contributors to this trend (Lazzeri et al., 2016; Okada et al., 2019; Badrasawi et al., 2021). The growing concern over unhealthy breakfast habits underscores the need for a greater understanding of knowledge, attitude, and practice (KAP) towards breakfast consumption among university students.

Numerous studies have examined the impact of breakfast consumption on academic performance, the factors leading to breakfast skipping, and the relationship between breakfast consumption, snacking behaviour, and BMI. However, limited studies have examined the KAP of breakfast consumption across different academic backgrounds. Assessing these parameters is needed as it would help to identify whether health sciences students, who are generally more exposed to nutrition education, may demonstrate different breakfast habits compared to non-health sciences students.

* *Corresponding author.*
E-mail address: nuraniza@iium.edu.my

This study aims to fill this gap by assesing the KAP of breakfast consumption among health sciences and non-health sciences students at IIUM. By exploring the potential differences between these two groups, the results will deepen our knowledge of how various academic backgrounds influence breakfast consumption. It can also provide university authorities with insightful information about how to provide nutritional education to promote healthier breakfast consumption patterns to meet the student's individual needs. Therefore, this study was conducted to assess the KAP of breakfast consumption among health sciences and non-health sciences students of IIUM that could positively impact not only the students' academic performance but also their overall health.

MATERIALS AND METHODS

Study Population

This study focused on undergraduate students from both health sciences and non-health sciences courses from Kuantan, Gombak and Pagoh campuses. The Kuantan campus had the most health sciences students, majoring in allied health sciences, dentistry, medicine, nursing, and pharmacy, while a smaller group of non-health sciences students at the Kuantan campus majored in science. In contrast, the Gombak and Pagoh campuses had the most non-health sciences students. Students from the Gombak campus study non-health sciences courses such as architecture, economics, education, engineering, information and communication technology, and human science. Meanwhile, the Pagoh campus students only study language management courses.

Sampling Method

This study employed a convenience sampling method for its practicality across three campuses, allowing access to willing participants and accommodating the diversity of students. The inclusion criteria focused on on-campus undergraduate students who were healthy.

Sample Size Calculation

The sample size was determined based on Krenjcie & Morgan's table (1970). The total student population across the three campuses of IIUM was 24,582, with 19,382 students in Gombak, 3,566 students in Kuantan, and 1,634 students in Pagoh. For the calculation, the population size was rounded up to 30,000. The sample size recommended was 379 participants. However, data collection yielded a final sample size of 382 participants.

Questionnaires and Data Collection

A validated KAP survey by Jayaveloo et al. (2021) was used to conduct this study. This questionnaire consisted of four sections, including sociodemographic information, breakfast consumption patterns, KAP, and barriers related to breakfast consumption. However, to fit the objectives of this study, only two sections of this questionnaire were utilized: the sociodemographic part and the KAP part. For the KAP part, there were thirteen knowledge questions, ten attitude questions, and eleven practice questions in this questionnaire. The researchers had already validated the KAP sections in this questionnaire, with the values for the Cronbach alphas for the KAP being 0.722, 0.705, and 0.784, respectively. These alpha values were considered acceptable, indicating the reliability of the questionnaires.

Sociodemographic Questionnaire

The first part of this section comprises questions asking about personal details. It includes gender (female or male), age, Kulliyyah, year of study (1, 2, 3, 4 and 5), marital status (single or married), daily budgets on food (in RM), monthly allowance (in RM), and scholarship (self-sponsored, JPA, MARA, PTPTN, and others).

KAP of Breakfast Consumption

The KAP part comprised three sections. The knowledge section contains thirteen questions using multiple-choice (True, Not Sure and False). The scoring for this question was assigned with zero for incorrect, one for uncertain and two for correct answers. The attitude section consists of ten questions rated on a five-point Likert scale (Strongly Disagree, Disagree, Neutral, Agree and Strongly Agree). Scoring assigned four marks for the most ideal attitude, three for ideal attitude, two marks for the uncertain attitude, one for less ideal attitudes and zero for the least ideal attitudes. Lastly, the practice section included eleven questions also rated on a five-point Likert scale with scoring mirroring the attitude section. The total scores for each category in this questionnaire were computed and classified according to Perumal et al. (2013), where scores less than 40% are considered low, 40% to 80% are moderate, and more than 80% are high.

Data Analysis

The data collected were analyzed using the Statistical Packages for Social Sciences (SPSS) version 29.0 computer program (IBM Corporation, New York, USA). Descriptive analysis was conducted to measure the KAP scores of breakfast consumption among IIUM students. To compare the KAP scores of breakfast consumption between health

sciences and non-health sciences students, the Mann-Whitney U test was employed, as the data were not normally distributed. Additionally, Spearman's correlation was utilized to assess the relationships between the KAP domains of breakfast consumption, providing insights into how these domains interact with one another.

RESULTS

Sociodemographic Characteristics

Table 1 outlines the sociodemographic characteristics of the respondents, comprising 108 (28.3%) males and 274 (71.7%) females. Among them, 252 (65.9%) were from the Kuantan campus, with the largest group being 129 (33.8%) from the Kulliyyah of Allied Health Sciences, followed by smaller numbers from other Kulliyyah: Nursing (13, 3.4%), Pharmacy (14, 3.7%), Medicine (26, 6.8%), Dentistry (11, 2.9%), and Science (59, 15.4%). Additionally, 32 (8.4%) respondents were from the Kulliyyah of Sustainable Tourism and Contemporary Languages at the Pagoh campus. From the Gombak campus, 10 (2.6%) were from the Ahmad Ibrahim Kulliyyah of Law, while others came from various Kulliyyah, including Architecture and Environmental Design (15, 3.9%), Information and Communication Technology (15, 3.9%), Islamic Revealed Knowledge (27, 7.1%), Engineering (13, 3.4%), Economics and Management Sciences (14, 3.7%), and Education (4, 1.0%).

In terms of academic year, the majority were in Year 3, accounting for 132 (34.6%) respondents, while Year 5 had the fewest, with only 4 (1.0%). Regarding funding, most participants were self-funded (34.8%), followed by Majlis Amanah Rakyat (MARA) (23.6%), the National Higher Education Fund Corporation (PTPTN) (22.3%), and the Public Service Department Malaysia (JPA) (11%). Additionally, the largest group of respondents (51.8%) reported daily food expenditures between RM 10 and RM 15, followed by those spending over RM 15 (31.4%) and those spending RM 5 to RM 10 (16.8%).

Table 1: Sociodemographic charateristics of the subjects

Variables	Frequency (n)	Percentage (%)
Gender		
Male	108	28.3
Female	274	71.7
Campus		
Kuantan	252	65.9
Gombak	32	8.4
Pagoh	98	25.7
Kulliyyah		
Kulliyyah of Allied Health Sciences	129	33.8
Kulliyyah of Nursing	13	3.4
Kulliyyah of Pharmacy	14	3.7
Kulliyyah of Medicine	26	6.8
Kulliyyah of Denstistry	11	2.9
Kulliyyah of Science	59	15.4
Kulliyyah of Sustainable Tourism and Contemporary Languages	32	8.4
Ahmad Ibrahim Kulliyyah of Law	10	2.6
Kulliyyah of Architecture and Environmental Design	15	3.9
Kulliyyah of Information and Communication Technology	15	3.9
Abdul Hamid Abu Sulayman Kulliyyah of Islamic Revealed Knowledge and Human Sciences	27	7.1
Kulliyyah of Engineering	13	3.4
Kulliyyah of Economics and Management Sciences	14	3.7
Kulliyyah of Education	4	1.0
Year of study		
Year 1	128	33.5
Year 2	72	18.8
Year 3	132	34.6
Year 4	46	12.0
Year 5	4	1.0
Funding for study		
PTPTN	85	22.3
JPA	42	11.0
Self-funding	133	34.8
MARA	90	23.6
Others	32	8.4
Daily Budget on food (RM)		
RM 5 – RM 10	64	16.8
RM 10 – RM 15	198	51.8
More than RM 15	120	31.4

Knowledge of Breakfast Consumption

Knowledge among IIUM students

Table 2 reveals that only a small proportion of IIUM students (0.5%) demonstrated low knowledge score

regarding breakfast consumption, followed by 128 (33.5%) respondents scoring at a moderate level, while the majority of IIUM students (66%) scored at a high level. The mean knowledge score regarding breakfast consumption is 82.11 ± 12.49.

Table 2: Knowledge level of breakfast consumption among IIUM students.

Knowledge	Frequency	Percentage (%)	Mean ± SD
Low	2	0.5	
Moderate	128	33.5	82.11 ±
High	252	66	12.49

Knowledge among health sciences and non-health sciences students

Table 3 shows that the mean knowledge score for health sciences respondents is 85.46 (SD = 11.39) and for non-health sciences respondents is 78.76 (SD = 12.67). The mean difference of 6.70 has a 95% CI ranging from 4.28 to 9.13, which excludes zero, indicating a significant difference ($p < 0.001$). Thus, the study rejects the null hypothesis, confirming a significant difference in knowledge levels between health sciences and non-health sciences students at IIUM.

Attitude of Breakfast Consumption

Attitude among IIUM students

Table 4 reveals that most respondents, 352 (92.1%), exhibited a moderate attitude toward breakfast consumption. Meanwhile, 15 respondents (3.9%) displayed either a low or high attitude level. The average attitude score was 58.51 ± 11.47, placing it within the moderate range. Thus, IIUM students generally hold a moderate attitude toward breakfast consumption.

Table 3: Knowledge level of breakfast consumption among health sciences and non-health sciences students

Variable	Health Sciences (n = 191)		Non-Health Sciences (n = 191)		Mean Difference (95% CI)	*p*-value
	Mean	SD	Mean	SD		
Knowledge	85.46	11.39	78.76	12.67	6.71 (4.28, 9.13)	< 0.001

Table 4: Attitude level of breakfast consumption among IIUM students.

Attitude	Frequency	Percentage (%)	Mean ± SD
Low	15	3.9	
Moderate	352	92.1	58.11 ±
High	15	3.9	11.47

Attitude among health sciences and non-health sciences students

Table 5 shows that the mean attitude score for health sciences respondents is 59.4 (SD = 11.31) and for non-health sciences respondents is 57.62 (SD = 11.60). The mean difference of 1.80 has a 95% CI ranging from –0.56 to 4.10, which includes zero, indicating no significant difference ($p = 0.066$). Thus, there is no significant difference in attitude between health sciences and non-health sciences students at IIUM.

Practice of Breakfast Consumption

Practice among IIUM students

Table 6 presents those 352 (92.1%) respondents shows a moderate level of practice regarding breakfast consumption, scoring between 40% and 80%. Notably, 55 respondents (14.4%) had a low level of practice, which exceeded the number with a high level (6, 1.6%). The mean practice score was 50.94 ± 11.51, indicating a moderate level overall. Thus, IIUM students generally exhibit moderate breakfast consumption practices.

Practice among health sciences and non-health sciences students

Table 7 shows that the mean of practice level for health sciences respondents is 50.48 (SD = 10.56) and for the non-health sciences respondents is 51.39 (SD = 12.41). The mean difference between these two groups is -0.90 and the 95% CI is from – 3.33 until 1.41, which includes zero, indicating no significant difference ($p = 0.707$). Therefore, there is no significant difference in practice level between health sciences and non-health sciences students at IIUM.

The Relationship Between Knowledge, Attitude, and Practice regarding Breakfast Consumption

Table 8 demonstrates the relationship between knowledge, attitude, and practice regarding breakfast consumption among health sciences and non-health sciences students of IIUM by using Spearman's correlation test. The results show two significant positive correlation between knowledge and attitude ($r = 0.348$, $p < 0.001$) and between attitude and practice ($r = 0.358$, $p < 0.001$). However, no significant correlation was observed between

knowledge and practice (r = 0.067, p = 0.195), as the p-value exceeded 0.05 and the correlation coefficient, r, was close to zero.

Table 5: Attitude level of breakfast consumption among health sciences and non-health sciences students

Variable	Health Sciences (n = 191)		Non-Health Sciences (n = 191)		Mean Difference (95% CI)	*p*-value
	Mean	SD	Mean	SD		
Attitude	59.40	11.31	57.62	11.60	1.80 (-0.56, 4.10)	0.066

Table 6: Practice level of breakfast consumption among IIUM students.

Attitude	Frequency	Percentage (%)	Mean ± SD
Low	55	14.4	
Moderate	321	84.0	50.94 ± 11.51
High	6	1.6	

Table 7: Practice level of breakfast consumption among health sciences and non-health sciences students

Variable	Health Sciences (n = 191)		Non-Health Sciences (n = 191)		Mean Difference (95% CI)	*p*-value
	Mean	SD	Mean	SD		
Practice	50.48	10.56	51.9	12.41	-0.90 (-3.22, 1.41)	0.707

Table 8: Correlation of KAP domain regarding the breakfast consumption.

Item	Correlation, r	*p*-value
Knowledge – Attitude	0.348	< 0.001
Knowledge – Practice	0.067	0.195
Attitude - Practice	0.358	< 0.001

DISCUSSION

Knowledge of Breakfast Consumption

The findings of this study are aligned with recent research by Jayaveloo et al. (2021) in Malaysia and Gupta et al. (2022) in India, which found that most university students have high levels of knowledge regarding breakfast consumption. The study found health sciences students are more likely to possess a greater understanding of healthy lifestyle habits compared to non-health sciences students, likely due to their academic backgrounds. Health sciences students receive more education on these topics and have greater access to information and resources for developing such knowledge.

For example, Stage et al. (2021) reported that teachers with professional training in healthy eating had significantly higher knowledge for promoting health behaviors. Similarly, Matsumoto et al. (2019) found that Japanese adults with higher nutrition knowledge consumed breakfast more frequently.

Attitude of Breakfast Consumption

The study's results are consistent with previous research by Jayaveloo et al. (2021), which found a similar pattern of moderate attitude level towards breakfast consumption among Malaysian students. This suggests that factors such as culture, time constraints, lifestyle, and economic challenges (Abu Bakar et al., 2019 & Okada et al., 2019) may hinder students from adopting a more positive attitude toward breakfast. The lack of disparity between student groups might reflect a common belief among students that breakfast is not significantly related to overall well-being. This finding proposes that even with better knowledge, students may not see the practical importance of breakfast, potentially due to personal habits and established behaviours of skipping breakfast from an early age.

Practice of Breakfast Consumption

The findings indicate that university students generally have moderate level of breakfast habits, suggesting that academic knowledge may not impact these habits. In contrast, Xiao (2023) found that the dietetics students had better breakfast habits than the non-dietetics students. However, that study only focused on dietetics students, while our study also included a wider range of students in health sciences courses such as medical, nursing, pharmacy, and dentistry.

Health sciences students frequently struggle to have breakfast due to busy schedules and early hospital duties, which limit their time. Limited cafeteria hours, as noted by Ackuaku-Dogbe and Abaidoo (2014), further hinder access to breakfast. To improve this situation, cafeterias could consider opening earlier and providing quick breakfast options. Additionally, educating students on the importance of breakfast and offering time management tips could help them incorporate it into their daily routines.

Relationship between Knowledge, Attitude and Practice Regarding Breakfast Consumption

The results of this study were comparable to the recent study by Jayaveloo et al. (2021) and a thesis by Xiao (2023). Both studies reported significant association between knowledge and attitude, as well as attitude and practice. These consistent results across different studies indicate that students' knowledge and attitude influence their breakfast consumption. A student with a high level of knowledge is likely to have a positive attitude towards breakfast. The correlations found in this study suggests that students may be influenced by several factors such as time constraints faced among students with early morning classes. Besides, the availability of healthy breakfast choices on campus is crucial as limited options can discourage students from eating their regular breakfast, even though they recognize its benefits.

To bridge the gap between attitude and practice of breakfast consumption, universities can educate students by organizing educational campaigns about the benefits of breakfast, providing affordable and healthy breakfast choices on campus, and encouraging morning routines that incorporate breakfast. These initiatives would encourage students to promote healthy eating habits and enhance their overall health.

CONCLUSION

In summary, IIUM students exhibit a high level of understanding but moderate level of attitude and practice of breakfast consumption. This highlights that they still struggle to adopt a positive attitude and good practice of breakfast consumption. The study found a significant difference in knowledge levels between health sciences and non-health sciences students, with health sciences students showing greater knowledge, but no significant differences in attitudes or practices. Additionally, significant associations were observed between knowledge and attitude, as well as between attitude and practice, though no correlation was found between knowledge and practice.

This study has several limitations including the absence of analysis on breakfast patterns and barriers to consumption. Future research should focus on these areas as well as the quantity and quality of dietary intake, BMI and CGPA. This will provide a more thorough understanding of breakfast habits and their effects on student health and academic performance.

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ETHICAL APPROVAL

Ethical approval was obtained from the International Islamic University Malaysia Research Ethical Committee (IREC). Participants were provided with digital consent before completing the questionnaire and could withdraw from the survey at any time after signing the agreement if they chose not to participate.

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ORIGINAL ARTICLE

Knowledge, Attitude, and Practice of Dietary Fibre Consumption Among International Islamic University Malaysia (IIUM) Students

Fatima Zahrah Kamarul Azman[1], Nuraniza Azahari[1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

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knowledge; attitude; practice; dietary fibre

ABSTRACT

Background: Dietary fibre provides many advantages to human health and can be found in fruits, vegetables, grains, and other plant-based foods. It has been proven that intake of dietary fibre is low globally and while interventions should focus on all age groups, those targeting young adults should be given priority. Therefore, this study intends to assess the knowledge, attitude, and practice (KAP) of dietary fibre consumption among International Islamic University Malaysia (IIUM) undergraduate students. **Methods:** A cross-sectional study was employed, and the sample population consisted of students of IIUM Kuantan, Gombak, and Pagoh. A validated KAP survey adopted from a previous study was used. The survey was created using Google Forms and disseminated through online platforms. A total of 381 students (190 health science and 191 non-health science) participated in this study. **Results:** The results found that the students had moderate levels of knowledge (69.7 ± 10.3%) and practice (57.3 ± 18.3%), as well as high positive attitude (86.5 ± 10.1%) towards dietary fibre consumption. There were no significant differences in KAP scores between health science and non-health science students. Nonetheless, there was a significant relationship between knowledge and practice (p = 0.022), and between attitude and practice (p < 0.001). On the other hand, no significant relationship was found between knowledge and attitude (p = 0.587). **Conclusion:** Nutritional interventions that incorporate aspects of knowledge and attitudes should be developed to promote better practices and habits of dietary fibre consumption among university students.

INTRODUCTION

According to the Codex Alimentarius 2009, “dietary fibre means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans” (de Menezes et al., 2013, p.1). Dietary fibres have a variety of structures and properties, however they are primarily divided into soluble and insoluble fibres.

Consuming adequate dietary fibre is crucial as it is good for the gut and general health. Its role may be indirect and not immediate, but it plays a significant function in the health maintenance of the body's systems such as the digestive and immune systems. Its contribution to the evacuation of bowels is the most widely recognised and accepted fact worldwide (Barber et al., 2020). Dietary fibre also serves as a prebiotic in the intestine. It is through nutrient enrichment and modification of gut microbiota and the immune system that prebiotics are able to strengthen human health (Yadav et al., 2022).

Despite the well-established health benefits of dietary fibre, it is one of the food components that many people of all ages around the globe, including Malaysia, have yet to reach its recommended daily intake amount. For example, students at International Islamic University Malaysia (IIUM) Kuantan campus consumed around 5 g of dietary fibre per day as compared to the Malaysian national guideline of 20 g to 30 g per day (Abdul Rahim & Mat Jusoh, 2023; Ministry of Health Malaysia [MOH], 2017). This problem may stem from the apparent disconnect between the prevalence of NCDs and the potential role of dietary fibre in lessening their risks among this population.

There exists a need in understanding the knowledge, attitude, and practice (KAP) regarding dietary fibre consumption among university students. To date, studies on KAP of dietary fibre consumption particularly among Malaysian university students have yet to be conducted or published. Lack of data in this area could possibly hinder the policymakers and healthcare professionals from planning and implementing suitable dietary interventions for this population. Therefore, this study aims to determine the KAP of dietary fibre among students of IIUM. The scores were then compared between health

* *Corresponding author.*
E-mail address: nuraniza@iium.edu.my

science and non-health science students. Furthermore, the correlation between the KAP domains was investigated.

MATERIALS AND METHODS

Study Participants

This cross-sectional study was conducted online on IIUM undergraduate students who were studying in Kuantan, Gombak, and Pagoh campuses. There is a total of 14 kulliyyahs or faculties in the mentioned campuses. Six faculties are in Kuantan, namely Kulliyyah of Allied Health Sciences (KAHS), Kulliyyah of Dentistry (KOD), Kulliyyah of Medicine (KOM), Kulliyyah of Nursing (KON), Kulliyyah of Pharmacy (KOP), and Kulliyyah of Science (KOS). Meanwhile, there are seven faculties in Gombak, including Kulliyyah of Islamic Revealed Knowledge and Human Sciences (KIRKHS), Kulliyyah of Law (KOL), Kulliyyah of Architecture and Environmental Design (KAED), Kulliyyah of Economics and Management Sciences (KENMS), Kulliyyah of Education (KOED), Kulliyyah of Engineering (KOE), and Kulliyyah of Information and Communication Technology (KICT). Lastly, only one faculty is located at Pagoh, which is Kulliyyah of Sustainable Tourism and Contemporary Languages (KSTCL). Those taking health science courses were those in KAHS, KOD, KOP, KOM, and KON.

The sample size was determined using the Krejcie and Morgan table. Hence, a minimum of 379 participants was needed. The students were eligible to participate in the study if they were healthy, aged from 19 to 25 years old, and living on campus. International students, pregnant and lactating students, and students who were undergoing low-fibre diet due to medical reasons were excluded from this study. A total of 381 students were recruited using convenience sampling.

Questionnaire

A set of questionnaires was created through adopt and adapt method from a previous study by Mat Daud et al. (2018) with some modifications. The online survey was created by using Google Forms and distributed to students via social media. There were four sections in the questionnaire: sociodemographic information, knowledge of dietary fibre, attitude towards dietary fibre, and practice of dietary fibre consumption. The KAP scoring method and categorisation of the KAP scores were based on the original study.

The first section contained questions about respondents' gender, age, year of study, kulliyyah, marital status, and monthly allowance. The second section comprised 24 factual items with "yes" and "no" answer options. A correct answer was given one mark while a wrong answer was given zero mark. Therefore, the total score for this section was 24 marks. The third section contained 12 items that aim to assess the students' opinions regarding the health effects and importance of dietary fibre. The five-point Likert scale was used as the answer options (strongly disagree, disagree, neutral, agree, and strongly agree). Two marks were given to the positive scale, one mark for the neutral scale, and zero mark for the negative scale. The total score for this section was 24 marks. The final section consisted of 12 items with "yes" and "no" answer options. This section evaluated the students' daily dietary behaviour relating to dietary fibre, including food preferences and frequency of dietary fibre intake. As for the scoring, a favourable practice received one mark, while any unfavourable practice received zero mark (Mat Daud et al., 2018). In total, the maximum score for this section was 12 marks. For each KAP section, the mean score percentage was categorised into either low (< 40%), medium (40% – 80%), or high (> 80%) category (Mat Daud et al., 2018).

Statistical Analysis

The data in this study was analysed using the Statistical Package for the Social Sciences (SPSS) Version 20. For all tests, the significance level was set to 0.05, with 95% confidence level. Descriptive analysis was used to determine the KAP scores of the students. Meanwhile, independent samples *t*-test and Mann-Whitney U test were used to compare the KAP scores between health science and non-health science students. Lastly, to examine the correlation between the KAP domains, Spearman's correlation test was utilised.

RESULTS

General Characteristics of the Participants

According to Table 1, a total of 190 health science (50 males, 140 females) and 191 non-health science (46 males, 145 females) students participated in this study. The average age of the respondents was 21.7 ± 1.4 years old. Most of the respondents were third year students (31.2%) and the least participated category of students was from fifth year students (1.6%). Most respondents were from KAHS (51.5%) for the health science group and KOS (38.2%) for the non-health science group.

Table 1: Sociodemographic information distribution of IIUM students (*n* = 381)

Characteristic	Total (N = 381)		Health Science (N = 190)		Non-health Science (N = 191)	
	n	**%**	***n***	**%**	***n***	**%**
Gender						
Male	96	25.2	50	26.3	46	24.1
Female	285	74.8	140	73.7	145	75.9
Age[a] (years)	21.7	1.4	21.6	1.2	21.9	1.6
Year of Study						
Year 1	87	22.8	43	22.6	44	23.0
Year 2	103	27.0	57	30.0	46	24.1
Year 3	119	31.2	56	29.5	63	33.0
Year 4	66	17.3	30	15.8	36	18.8
Year 5	6	1.6	4	2.1	2	1.0
Kulliyyah						
KAHS	97	25.5	97	51.5		
KAED	8	2.1			8	4.2
KOD	5	1.3	5	2.6		
KENMS	12	3.1			12	6.3
KOED	12	3.1			12	6.3
KOE	12	3.1			12	6.3
KICT	20	5.2			20	10.5
KIRKHS	31	8.1			31	16.2
KOL	5	1.3			5	2.6
KOM	25	6.6	25	13.2		
KON	34	8.9	34	17.9		
KOP	29	7.6	29	15.3		
KOS	73	19.2			73	38.2
KSTCL	18	4.7			18	9.4
Marital status						
Single	376	98.7	189	99.5	187	97.9
Married	5	1.3	1	0.5	4	2.1
Monthly allowance (RM)						
< 300	113	29.7	51	26.8	62	32.5
300 – 500	124	32.5	65	34.2	59	30.9
501 – 1000	125	32.8	65	34.2	60	31.4
> 1000	19	5.0	9	4.7	10	5.2

[a]Mean (*SD*)

KAP Scores of Dietary Fibre

Table 2 shows the KAP scores of IIUM students. The knowledge of IIUM students on dietary fibre was at the medium level (69.7 ± 10.3%). The health science students (70.0 ± 10.2%) have a comparable knowledge score with the non-health science students (69.4 ± 10.5%).

Remarkably, the students have a positive attitude towards the importance of dietary fibre since their mean score fell into the high category (86.5 ± 10.1%). Furthermore, the mean attitude score of health science students (86.6 ± 9.8%) was similar to that of non-health science students (86.1 ± 10.5%).

Lastly, the health science students (58.1 ± 17.3%) have a comparable practice score to non-health science students (56.5 ± 19.4%). The mean practice score of the overall students fell into the medium category (57.3 ± 18.3%).

Table 2: KAP score percentage of health science, non-health science, and overall students

Domain	Percentage Score (Mean ± *SD*)		
	Health Science (N = 190)	Non-health Science (N = 191)	Total (N = 381)
Knowledge	70.0 ± 10.2	69.4 ± 10.5	69.7 ± 10.3
Attitude	86.8 ± 9.8	86.1 ± 10.5	86.5 ± 10.1
Practice	58.1 ± 17.3	56.5 ± 19.4	57.3 ± 18.3

Comparison of KAP Scores Between Health Science and Non-health Science Students

Knowledge and attitude scores

Based on Table 3, Mann-Whitney U test was used to analyse the difference in knowledge and attitude scores between the health science and non-health science students. For the knowledge domain, it was discovered that there was no significant difference between the two groups (U = 17588, n_1 = 190, n_2 = 191, p = 0.601), with a small effect size (0.027). On the other hand, there was no significant difference in the attitude scores between the two groups (U = 17537, n_1 = 190, n_2 = 191, p = 0.568), with a small effect size (0.029).

Table 3: Comparison of knowledge and attitude scores between health science and non-health science students (Mann-Whitney U test)

Domain	Mean rank		Mann-Whitney *U*	*Z*-value	*p*-value	Effect size
	Health science (*n* = 190)	Non-health science (*n* = 191)				
Knowledge	193.93	188.08	17588.00	-0.523	0.601	0.027
Attitude	194.20	187.82	17537.00	-0.571	0.568	0.029

Practice scores

The difference in practice scores between the health sciences and non-health sciences students was explored using independent samples *t*-test. From the analysis, as seen in Table 4, there was no significant difference between the two groups (p = 0.404).

Table 4: Comparison of practice scores between health science and non-health science students (Independent samples *t*-test)

Variable	Health science (n = 190)		Non-health science (n = 191)		Mean differences (95% CI)	*t*-statistics (df)	*p*-value
	Mean	*SD*	Mean	*SD*			
Practice (%)	58.1	17.3	56.5	19.4	1.60 (-2.13, 5.27)	0.853 (379)	0.404

Association Between KAP Domains

Spearman's rank order correlation was used to determine the associations between knowledge and attitude, knowledge and practice, as well as attitude and practice. The results are presented in Table 5. Among the three associations analysed, only two of them produced significant results, which were knowledge and practice (r = 0.117, n = 381, p = 0.022) and attitude and practice (r = 0.206, n = 381, p < 0.001). Even though significant, the associations showed weak positive relationships. On the other hand, the knowledge and attitude association had the weakest positive relationship and was the only one without a significant outcome (r = 0.028, n = 381, p = 0.587).

Table 5: Spearman's correlation analysis between the KAP domains

Association	Spearman's Correlation Test (n = 381)	
	r-value	*p*-value
Knowledge and attitude	0.028	0.587
Knowledge and practice	0.117	0.022
Attitude and practice	0.206	< 0.001

DISCUSSION

Based on the results, the general knowledge level of the students was at the moderate level. The finding on knowledge classification was consistent with a previous study done on Malaysian adolescents, although its mean was a little lower compared to the current study (54.4 ± 11.3%) (Mat Daud et al., 2018). The slight difference in the scores may be attributed to the increased health information-seeking behaviour among young adults. That is, apart from themselves, they also tend to search health information for their families and peers to show support for them (Thorsteinsdottir & Kane, 2018). This behaviour allows them to obtain more knowledge regarding healthy living, including proper nutrition and diet. The knowledge scores of health science and non-health science students can be considered comparable to each other. Health science students are generally taught about the importance of healthy eating towards human health in greater details and have more nutrition-related learning materials, which may include emphasis on eating plenty of dietary fibre, especially fruits and vegetables. Despite that, people nowadays can retrieve any information quickly using the internet, including those pertaining to dietary fibre (Mat Daud et al., 2018; Georgiou & Moshogianni, 2023; Rohin et al., 2021).

Next, the students have a high level of positive attitude and good perception towards the importance of dietary fibre. It can be concluded that the students were aware of the benefits of dietary fibre, regardless of their academic background.. This outcome matters because, through regular practice of this mindset, it can help people of all ages gradually eat more dietary fibre. A previous study by Yen and Lim (2019) on university staff recorded the same score classification as the present study, although its mean attitude score (88.57 ± 8.44%) was a little higher. The similarity in both studies can be attributed to the participants' educational level, in which study participants in both studies have received and were receiving tertiary education at higher institutions. People with higher education levels, regardless of their field of study, tend to have better nutrition awareness and habits (Azizi Fard et al., 2021; Hearty et al., 2007). According to Hearty et al. (2007), age also contributes to the positive attitude among adults towards healthy eating. This may be due to their roles in family and disease prevention.

Similar to knowledge score, the mean practice score of the total student was at moderate level. Majority of the students did not eat vegetables in each meal (n = 203) and did not consume fruits daily (n = 283). The moderate practice level may serve as evidence that there are still many Malaysian young adults who have yet to achieve the desirable behaviour to achieve the recommended dietary fibre intake. University students' dietary choices are multifactorial. Findings in previous studies by Wan Zakaria

et al. (2021) and Yun et al. (2018) revealed that many university students consumed inadequate dietary fibre, mainly fruits and vegetables, because they favoured cheap and accessible foods rather than healthy ones. Another study in Norway found that young adults who lived far from their parental home had declining intakes of vegetables and fruits (Winpenny et al., 2018). Moreover, it was observed that participants in the present study had the lowest practice score when compared to two similar KAP studies (Mat Daud et al., 2018; Yen & Lim, 2019). These disparities may be due to environmental factors. For instance, many university students face financial constraints and packed academic schedule that could disrupt the amount and quality of their overall food intake (Gamba et al., 2021).

Even though the knowledge level was concluded to be on the moderate level, the correlation test proved that it did not have any significant link to the attitude level. Based on the results, it is possible that the students' knowledge of dietary fibre was just superficial, and hence insufficient to have a major impact on their attitudes. Aside from that, attitude towards food among university students can be influenced by many factors, and knowledge may contribute only a small percentage to it. Common factors like food preference and aversion play a huge part in forming attitude revolving dietary fibre. For example, cravings and preference for healthy foods such as salads were not common among adults even though they know that the foods are good for them (Van Dyke et al., 2024).
In contrary, the students' practice level regarding dietary fibre consumption was significantly associated to their knowledge and attitude levels. An individual who lacks knowledge or have a negative perception of dietary fibre are less likely to prioritise its consumption. In fact, positive attitude was one of the major factors that can influence the intentions to consume at least three servings of vegetables among university students (Nguyen et al., 2020). Furthermore, a study conducted among Italian university students revealed that knowing nutritional characteristics of food was one of the key variables influencing their daily diet choices (Savelli et al., 2019). Therefore, improving students' knowledge and attitudes regarding dietary fibre is critical for fostering improved eating practice and habits.

CONCLUSION

In summary, this study assessed the KAP levels of dietary fibre consumption among undergraduate students of IIUM. The results demonstrated that the students have moderate levels of knowledge and practice, and a high level of positive attitude. However, no significant differences in the scores were found between health science and non-health science students, indicating that these two student groups have similar KAP levels. Besides that, it was discovered that the practice level was highly influenced by knowledge and attitude. Thus, interventions incorporating these two factors should be conducted to gradually improve dietary fibre intake in this population. .

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ORIGINAL ARTICLE

Knowledge and Dietary Adherence of Caregivers on Malaysian Dietary Guidelines and Their Relationship to The Nutritional Status of Young Children in Kelantan

Nor Anis Tasnim Ab Shukor[1], Nurul Hazirah Jaafar [1,2,*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Background: Malaysia is facing dual challenges of stunting and obesity among young children. To address these issues, the Malaysian Dietary Guideline (MDG) was introduced. This study evaluates the knowledge and dietary adherence of caregivers to the MDG and its impact on the nutritional status of young children. **Methods:** A cross-sectional study was conducted among selected kindergartens in Kelantan, whereby children's height and weight were measured, and caregivers were interviewed on knowledge of MDG. The correlation between caregivers' knowledge, adherence to MDG, and their children's nutritional status was evaluated using the Spearman correlation and Chi-square test. **Results:** A total of 60 pairs of caregivers and their children participated in the study. The prevalence of underweight, stunting, obesity, and wasting was 17%, 23%, 10%, and 7%, respectively. Caregivers demonstrated a moderate level of knowledge regarding the MDG. Adherence to the MDG for vegetables and fruit was poor and none adhered to the fat recommendation. Nevertheless, most of them (83%) followed sugar recommendations. No significant correlation was observed between caregivers' knowledge of MDG and the children's status of underweight ($p=0.693$), stunting ($p=0.652$), or wasting ($p=0.240$). However, a significant correlation was identified between caregiver sugar consumption and their children's stunting status ($p<0.05$). **Conclusion:** Stunting remains the most common nutritional problem among young children. Caregivers exhibit a moderate knowledge level and poor adherence towards MDG. Hence, further exploration is required to facilitate practical strategies for improving diet quality among young children.

Keywords:
MDG; nutritional status; knowledge; dietary adherence; young children

INTRODUCTION

Malnutrition in all its forms raises the dangers of morbidity and mortality throughout life. Children typically suffer from this because they do not consume or do not take enough proper foods. Children who are overweight may not obtain adequate micronutrients while stunted children more likely to become obese.

The issue of malnutrition is a growing concern, especially in low- and middle-income countries. According to a survey conducted in NHMS 2015, the prevalence of underweight was 12.4%, stunting was 17.7%, and wasting was 8.1% among children under 5 years old. However, in 2019, these numbers increased to 14.1% for underweight, 21.8% for stunting, and 9.1% for wasting (IPH, 2019). The prevalence of overweight and obesity among children below 5 years old is 5.6%. According to the WHO (2021), undernutrition is a contributing factor in about 45% of fatalities in children under the age of five. The number of cases of malnutrition has been increasing over the years up until now.

In Malaysia, the National Plan of Action for Nutrition includes the development of the Malaysian Dietary Guidelines (MDG) as part of its efforts to prevent nutrition-related disorders. The original MDG was published in 1999 and consisted of eight key messages. Subsequently, the

* *Corresponding author.*
E-mail address: hazirahjaafar@iium.edu.my

MDG underwent several revisions, resulting in MDG 2010, and the latest version, MDG 2020, which includes 14 key messages and 52 key recommendations. These revisions were made to address the challenges of both undernutrition and overnutrition.

All of the aforementioned MDGs are aimed at individuals aged 18 to 59 years old. Meanwhile, in 2013, the Ministry of Health published the Malaysian Dietary Guidelines for Children and Adolescents (MDGCA). MDGCA is appropriate for healthy children and adolescents from birth to the age of 18. It is made up of 15 key messages to serve as a complete resource for Malaysian children and adolescents in ensuring optimal growth.

Nonetheless, although the MDG has been in place since 1999, Malaysians are still unaware of them (Norimah et.al., 2010). There are various limitations faced by Malaysians to understand and practise MDG in their daily life. Hence, this study aims to evaluate the knowledge and dietary adherence to Malaysian Dietary Guidelines (MDG) and its associated factors among caregivers of young children in Kelantan.

MATERIALS AND METHODS

Participants

A cross-sectional study was conducted among caregivers with children aged below 5 years old, whereby stratified random sampling was used to recruit the participants. In particular, 9 kindergartens were randomly selected from 5 districts in Kelantan, Malaysia. Data were collected between February 2023 and April 2023 in 5 districts of Kelantan, Malaysia. A total of 90 caregivers who registered their children at 9 kindergartens were selected from the list using simple random sampling, whereby their numbers in the list were randomly picked using a number generator application. They were recruited if their children were 5 years old and below. Caregivers of children with chronic illnesses that can affect their eating habits were excluded from the study.

Anthropometric measurements

Anthropometric measurements include the height and weight of the children. The height was measured in centimetres (cm) using SECA roll-up measuring tape with wall attachment (SECA 206), while the weight was measured in kilograms (kg) using SECA weighing scale. For children who cannot stand independently, knee height was measured, and their height was estimated using the Stevenson equation (Haapala et. Al., 2015). Meanwhile, for children who could not stand independently, the weight was taken along with the caregiver, then subtracted by the caregiver weight to get the children's weight. The nutritional status of the children was categorised using the WHO classification (WHO, 2008).

Knowledge on the Malaysian Dietary Guideline (MDG) Questionnaire

The knowledge on MDG was assessed using a validated questionnaire by Norimah et al., (2021) which contains 20 questions that assessed the knowledge of MDG 2020 and the Malaysian Food Pyramid 2020. Caregivers were required to choose one answer and be given one point for a correct answer. The total score of this questionnaire is 100 with the following categories: <50% indicate poor MDG knowledge, 51% to 74% moderate MDG knowledge, and > 75% good MDG knowledge.

Dietary Adherence towards MDG Questionnaire

Dietary adherence towards MDG was assessed using a validated questionnaire by Mohd Shukri & Karami, (2023) which consists of 9 questions on respondents' intake of 9 food groups according to the requirements guided by the MDG 2020 and Malaysian Food Pyramid 2020. The respondents are required to report the number of servings they consumed daily for the nine food groups. Respondents who followed the suggested serving sizes were marked as adhering whereas those who did not follow the recommendations were marked as non-adherence.

Statistical Analysis

A descriptive analysis was conducted to describe the participant's characteristics and the nutritional status of young children. Spearman correlation test was used to evaluate the correlation between caregivers' knowledge of MDG and their children's nutritional status. Meanwhile, the Chi-square test was used to investigate the association between caregivers' dietary adherence to MDG and the children's nutritional status. The chi-square test was also used to evaluate the association between household income and children's nutritional status and caregiver's adherence to MDG. Significant values were determined using a p-value <0.05. All analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 26.0.

Ethical Approval

This study has been granted ethical approval by the International Islamic University Malaysia Research Ethical Committee (IREC) (KAHS 3/23).

RESULTS

Characteristics of participants

In Table 1, 60 caregivers and their children participated in this study. There was a moderate response rate (63.2%) as only 60 out of 90 distributed questionnaires were returned. Most participating caregivers were female (73.3%), those aged between 30 to 39 years old (68.3%), having the highest level of education (38.3%), and were employed (80%). On average, the monthly household income is RM 4935.35 (SD±3447.78). Nonetheless, most caregivers (33.3%, n = 20) have an income between RM 1000 and RM 2500 monthly.

Sixty participating children aged one to five years old, of which 56.7% were males and 43.3% were females. The mean age of the children was 3.48 years (SD±1.36), with the majority aged 4 years old (21.7%).

Table 1: Sociodemographic characteristics and anthropometric measurement of children (N=60)

Characteristics	n (%)	Mean ±SD
Caregivers		
Age		
21-29 years	5 (8.4)	36 ±6.65
30-39 years	41(68.3)	
40-49 years	14(23.3)	
Gender		
Male	16(26.7)	
Female	44(73.3)	
Educational level		
Degree/Master/PhD	23 (38.3)	
Diploma	21 (35.0)	
SPM	16 (26.7)	
Occupation status		
Employed	48 (80.0)	
Self-employed	10 (16.7)	
Not working	2 (3.3)	
Household income		
≤ RM 1000	2 (3.3)	4935.35
RM 1001- RM 2500	20(33.3)	±3447.78
RM 2501 - RM 5000	18 (30.0)	
RM 5001 - RM 7500	6 (10.0)	
RM7501 - RM 10000	10(16.7)	
≥ RM 10000	4 (6.7)	
Children		
Age of child		
1 year	6 (10.0)	3.48±1.36
2 years	10(16.7)	
3 years	12(20.0)	
4 years	13(21.7)	
5 years	19(31.7)	
Gender		
Male	34(56.7)	
Female	26(43.3)	
Child's weight (kg)		13.05±3.30
Child's height (cm)		93.49±12.04
BMI (kg/m^2)		13.39±3.01
Nutritional status		
Weight-for-age (WAZ-score)		-0.91±1.19
Normal	50 (83.3)	
Underweight	10 (16.7)	
Height-for-age (HAZ-score)		-1.19±1.20
Normal	46 (76.7)	
Stunting	14 (23.3)	
Weight-for-height (WHZ-score)		-0.38±1.31
Normal	50 (83.3)	
Overweight	6 (10.0)	
Wasting	4 (6.7)	

Nutritional status of young children

On average, children weighed 13.05kg (SD±3.30), with 93.4cm height (SD±12.04), and had a BMI of 13.39kg/m2 (SD±3.01). Regarding their mean z-scores for weight-age, height-age, and weight-height-age, the children's scores were -0.91 (SD±1.19), -1.19 (SD±1.20), and -0.38 (SD±1.31) respectively. In terms of their nutritional status, 16.7% were underweight, 23.3% were stunted, 6.7% were wasted and 10% were overweight (Table 1).

Caregiver knowledge and dietary adherence to the Malaysian Dietary Guideline (MDG)

Most caregivers (53.3%) have moderate knowledge of MDG, while 6.7% of caregivers have poor knowledge.

In Table 2, the majority did not adhere to the recommendation for fat (100%), vegetables (95%), fruits (81.7%), milk (73.7%) and cereals intake (68.3%). Caregiver

dietary adherence was shown in sugar (83.3%) and protein-based food intake i.e., poultry (78.3%), fish (70%), and legumes (71.7%).

Table 2: Dietary adherence to MDG (N=60)

Food groups	Adhere		Not adhere		Mean ±SD
	n	(%)	n	(%)	
Vegetable	3	(5.0)	57	(95.0)	1.43±0.60
Fruit	11	(18.3)	49	(81.7)	1.52±1.05
Cereals	19	(31.7)	41	(68.3)	2.05±1.02
Poultry	47	(78.3)	13	(21.7)	1.88±0.78
Fish	42	(70.0)	18	(30.0)	1.28±0.72
Legumes	43	(71.7)	17	(28.3)	1.13±0.75
Milk	16	(26.7)	44	(73.7)	1.42±0.81
Fats	0	(0.0)	100	(100.0)	1.60±0.92
Sugar	50	(83.3)	10	(16.7)	1.57±1.03

Correlation between caregivers' knowledge of MDG and their children's nutritional status

The children's status for underweight [r (10) = -0.052, p=0.693], stunting [r (14) = 0.059, p=0.652], and wasting [r (4) = -0.154, p =0.240] did not significantly correlate with the caregiver's knowledge of the MDG.

Association between caregivers' dietary adherence to MDG and nutritional status of their children

In this study, no association was found between caregivers' dietary adherence and children's underweight status. However, a higher prevalence of non-adherence in vegetables, fruits, rice/cereal and milk/milk products intakes was observed among caregivers with underweight children.

Similarly, no significant association was found between caregivers' dietary adherence and the children's overweight and wasting status. However, a higher prevalence of non-adherence in vegetables and rice/cereal intakes was observed among caregivers with overweight children.

Nonetheless, there is a significant association found between caregivers' adherence to sugar intake and the stunting status of their children, (X^2 (1) = 3.149, p<0.05). Higher prevalences of non-adherence in vegetables, fruits, and milk/milk products intakes were observed among caregivers with stunting children.

Association between household income and children's nutritional status and caregivers' dietary adherence

There is a significant association found between house income and stunting status (X^2 (1) = 6.051, p<0.05) (Table 3), whereby a higher prevalence of stunting was observed in those with incomes <RM5000.

Nonetheless, no significant association was found between household income and caregivers' dietary adherence (Table 3). However, higher prevalences of non-adherence in all food groups were found in those with incomes <RM5000.

DISCUSSION

The study found that stunting was the prevalent nutritional issue among young children in Kelantan. This aligns with previous research, indicating a higher prevalence of stunting among children under 5 years old in Malaysia which may be attributed to early feeding difficulties and poor dietary quality (Lee et.al., 2022). In this study, caregivers showed poor adherence to fats/oils, vegetables, fruits, rice/other cereals/wholegrain products/tuber, and milk/milk products intake. Studies have linked high stunting to poor diet quality, emphasizing the importance of consuming diverse animal-sourced foods for better growth (Krasevec et.al., 2017). Poor diet quality was also associated with an increased risk of childhood obesity (Kranz et.al., 2008).

In this study, most caregivers in Kelantan have moderate MDG awareness. This finding is comparable to Norimah et al. (2010), who found that the majority of Malaysian adults have a moderate understanding of the MDG and asserted that education is strongly correlated with knowledge. This situation can be elucidated by a study conducted in Canada, where the study found a persistently low level of knowledge and understanding of the official dietary guidelines among adults, despite their awareness of the

guidelines (Vanderlee et.al., 2015). This discrepancy can be attributed to the unequal opportunity in accessing and comprehending the guidelines. These findings align with a study, whereby a lack of familiarity with the guidelines hindered participants from fully understanding them (Brown et.al., 2011). Furthermore, Norimah et al. (2010) reported moderate knowledge of dietary guidelines due to a low comprehension of the terms used in the guidelines.

Table 3: Association between household income and children's nutritional status and caregiver's dietary adherence (N=60)

Variables	Household Income			n	X^2-statistic (df)	*p*-value
	< RM5000 n (%)	RM5000 – RM9999 n (%)	>RM10000 n (%)			
Children's nutritional status						
Wasting status						
Normal	29 (48.3)	11 (18.3)	9 (15)	49	3.677 (4)	0.452
Overweight	4 (6.7)	3 (5)	0 (0)	7		
Wasting	3 (5)	0 (0)	1 (1.7)	3		
Underweight status						
Normal	28 (46.7)	12 (20)	10 (16.7)	50	2.857 (2)	0.240
Underweight	8 (13.3)	2 (3.3)	0 (0)	10		
Stunting status						
Normal	28 (46.7)	8 (13.3)	10 (16.7)	46	6.051 (2)	0.049
Stunting	8 (13.3)	6 (10)	0 (0)	14		
Caregiver's dietary adherence						
Vegetable						
Adhere	2 (3.3)	0 (0)	1 (1.7)	3	1.287 (2)	0.526
Not adhere	34 (56.7)	14 (23.3)	9 (15.0)	57		
Fruit						
Adhere	7 (11.7)	2 (3.3)	2 (3.3)	11	0.201 (2)	0.904
Not adhere	29 (48.3)	12 (20.0)	8 (13.3)	49		
Rice, other cereals, wholegrain products and tubers						
Adhere	9 (15.0)	5 (8.3)	5 (8.3)	19	2.399 (2)	0.301
Not adhere	27 (45.0)	9 (15.0)	5 (8.3)	41		
Poultry / Meat / Egg						
Adhere	27 (45.0)	13 (21.7)	7 (11.7)	47	2.385 (2)	0.303
Not adhere	9 (15.0)	1 (1.7)	3 (5.0)	13		
Fish						
Adhere	22 (36.7)	13 (21.7)	7 (11.7)	42	4.837 (2)	0.089
Not adhere	14 (23.3)	1 (1.7)	3 (5.0)	18		
Legumes						
Adhere	23 (38.3)	11 (18.3)	9 (15.0)	43	3.056 (2)	0.217
Not adhere	13 (21.7)	3 (5.0)	1 (1.7)	17		
Milk and milk products						
Adhere	9 (15.0)	2 (3.3)	5 (8.3)	16	3.933 (2)	0.140
Not adhere	27 (45.0)	12 (20.0)	5 (8.3)	44		
Sugar						
Adhere	29 (48.3)	11 (18.3)	10 (16.7)	50	2.429 (2)	0.297
Not adhere	7 (11.7)	3 (5.0)	0 (0)	10		

**Notes: The chi-square test was used to evaluate the association between household income and children's nutritional status and caregiver adherence to MDG.*

In this study, most caregivers did not follow recommendations for vegetable (1.43 servings per day) and fruit (1.52 servings per day) intake. Our findings were similar to the prior study that factors such as habit, attitude, societal influence, and limited availability of fruits and vegetables at home may contribute to this inadequacy (Koo et.al., 2016). According to McIvar et al. (2021), caregivers' consumption of fruits and vegetables was found to significantly predict their children's intake.

All caregivers did not adhere to fat intake recommendations, reporting an average intake of only 1.6 servings, below the recommendation. However, it is uncertain whether this reflects an accurate estimation or if caregivers underestimated their fat intake. Similar findings have been reported in other studies, showing either insufficient or excessive fat consumption depending

on the age range of the children (Monnard & Fleith, 2021). Since caregivers are in charge of cooking and purchasing food at home, their adherence to recommended fat intake will potentially influence the children's consumption.

The study found no correlation between the knowledge of MDG among caregivers and the nutritional status of their children. This is consistent with another study that reported that the possession of nutrition knowledge by caregivers does not seem to have an impact on the nutritional status of children in Ghana. (Forh et.al., 2022). The main factor preventing caregivers from applying nutrition knowledge is financial difficulties caused by unemployment. These difficulties increase malnutrition by reducing the quality of food consumed and leading to "hidden hunger". (Siddiqui et.al., 2020).

This study highlights a significant link between household income and stunting cases among young children. It reports that the prevalence of stunting is higher in the B40 category, which refers to households with an income of less than RM 5000 (Department of Statistics, 2022). A review by Rahma & Mutalazimah (2022) supports this finding, as majority of reviewed articles showed a significant relationship between family income and the incidence of stunting in children under five. An in-depth analysis by Boomers and colleagues (2019) further explains that higher stunting rates were observed in the poorest quartile compared to the richest quartile. Low household income can predispose children to stunting because families may not be able to afford nutritious and diverse foods (Nuraeni & Suharno, 2020). This pattern can be observed from our data even though no statistical significance was found. A large proportion of non-adherence to all food groups was reported from those households with income <RM5000.

The strength of this study lies in its investigation of the nutritional condition of young children in Kelantan and the correlation between caregiver knowledge and dietary adherence to the Malaysian Dietary Guidelines (MDG). While previous research has primarily focused on the impact of the MDG on the lifestyles of adolescents and adults, this study aims to determine whether knowledge of and adherence to the MDG can influence the nutritional status of young children. However, the interpretation of the findings should be with caution due to the small sample size, which may not adequately represent the diverse communities in Kelantan.

CONCLUSION

The findings reveal a concerning prevalence of stunting and most caregivers possess moderate knowledge of the MDG while not adhering to the recommended vegetable and fruit intakes. Children from lower-income families exhibit lower nutritional status and a higher prevalence of non-adherence to most food groups. Nutritionists and dietitians should prioritize the MDG and raise public awareness about its significance. In order to tackle the issue of moderate knowledge regarding the MDG, the Nutrition Department of the Ministry of Health should consider using simple terms and key messages in the guidelines.

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ORIGINAL ARTICLE

Association Between Diabetes-Related Knowledge, Perceived Adherence to Lifestyle Changes and Physical Activity Level Among Type 2 Diabetes Mellitus Patients at SASMEC@IIUM

Nurul Hanis Zafira Ahmad Bajuri[1], Noraishah Mohamed Nor[1, 2], Wan Ahmad Syahril Rozli Wan Ali[3]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3] Department of Internal Medicine, Sultan Ahmad Shah Medical Center, International Islamic University Malaysia, Pahang, Malaysia

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type 2 diabetes mellitus; diabetes knowledge; physical activity level; perceived adherence

ABSTRACT

Background: Diabetes-related knowledge is fundamental to effective diabetes management, influencing self-management and health outcomes. Changes in lifestyle, including diet modification and physical activity, are all necessary for effective nutrition treatment. Therefore, this study aims to identify the relationship between diabetes-related knowledge and physical activity levels with perceived adherence to lifestyle changes among type 2 diabetes mellitus (T2DM) patients. **Methods:** Questionnaires consisting of Diabetes Knowledge Test (DKT), Perceived Adherence Lifestyle Modification (PALM-Q), and International Physical Activity Questionnaire (IPAQ) were used through self-administers. The data were analysed using Statistical Package for the Social Sciences (SPSS). A total of 33 respondents, T2DM patients aged 18 and above in SASMEC@IIUM, were involved in this study. **Results:** The Spearman Correlation test found no association between diabetes-related knowledge and perceived adherence to lifestyle changes and physical activity level ($p>0.05$). Additionally, the Chi-Square Independence test shows a significant association between perceived adherence to lifestyle changes and physical activity level ($p>0.05$). **Conclusion:** It can be concluded that there is no association between diabetes-related knowledge and perceived adherence to lifestyle changes and physical activity level, yet there is a significant association between perceived adherence to lifestyle changes and physical activity level among T2DM patients in SASMEC@IIUM.

INTRODUCTION

Research Background

Type 2 Diabetes Mellitus (T2DM) is a significant health concern, with increased prevalence among individuals over 30 years old in the past decade (Hussein et al., 2015). Usually, once the individual is diagnosed with diabetes for the first time, they will be referred to a dietitian to proceed with lifestyle change recommendations. However, not all patients are able to comply and maintain the recommended advice. A high prevalence of noncompliance with lifestyle advice was seen among T2DM patients in Malaysia, where just 16.4% of people with diabetes follow the dietary plans recommended by dietitians (Chew et al., 2013). A study conducted at the University of Malaya Medical Centre found that Malaysian diabetes patients are prone to consuming a high carbohydrate and fat diet (Hussein et al., 2015). This also indicates that they still have an unhealthy lifestyle, even after being diagnosed with diabetes.

* *Corresponding author E-mail address: ishah@iium.edu.my*

Practising healthy eating and increasing physical activity are necessary for improving health. Klinovszky et al. (2019) found that following physical exercise recommendations improves blood glucose levels and provides benefits. Noncompliance, on the other hand, has more severe implications for patients. T2DM patients frequently have poor diet adherence due to a failure to understand, perform, and sustain the necessary previous experiences (Al-Salmi et al., 2022).

Poor adherence to lifestyle interventions remains a persistent barrier to optimal diabetes management, leading to uncontrolled blood sugar levels and increased risk of complications. This underscores the need to investigate how patients' diabetes-related knowledge influences their perceived adherence to lifestyle changes and physical activity levels. Adequate knowledge about diabetes plays a critical role in empowering patients to take charge of their health, adopt healthier behaviours, and manage their condition more effectively. Yet, gaps in patient education continue to exist, contributing to suboptimal lifestyle changes. Thus, the current study aims to understand the association between diabetes-related knowledge, adherence to lifestyle changes, and physical

activity among patients at SASMEC@IIUM.

MATERIALS AND METHODS

Study Area

This study was conducted at Sultan Ahmad Shah Medical Centre at International Islamic University Malaysia (SASMEC@IIUM) Kuantan, Pahang. The data were collected at Medical Clinic 1 and Medical Clinic 2.

Study Design

A cross-sectional study was conducted to collect study samples.

Study Population

The study population involves patients diagnosed with T2DM at the Medical Clinics 1 and 2 in SASMEC. All T2DM patients who are above 18 years old and able to understand Malay were included in the study. Whereas T1DM, GDM, patients, and patients below 18 years old were excluded.

Sampling Method

Convenience sampling was used as it is the most practical sampling method for this research. It was conducted by approaching any participants based on the inclusion and exclusion criteria in SASMEC. Only patients who provided consent were invited to join the study.

Data Collection

The questionnaire consists of a few sections, which are socio-demographic, the Diabetes Knowledge Test (DKT) (Md Aris et al.,2018), the Perceived Adherence Modification Questionnaire (PALM-Q) (Nor et al., 2022), and the International Physical Activity Questionnaire (IPAQ) (Shamsuddin et al., 2015). All the questionnaires have been validated in Malay.

Socio-demographic questionnaire

Data like age, gender and ethnicity were collected in the first section of the questionnaire.

Diabetes Knowledge Test (DKT)

A validated Malay version of the simplified diabetes knowledge test (DKT) was used for this section. Questions regarding diabetes-related knowledge consisting of correct, incorrect, and don't know answer options were included in the second section. It has 20 questions, consisting of 18 questions focusing on general diabetes knowledge and two questions specifically for diabetes patients who take insulin. A correct answer was given one mark, while an incorrect answer received no mark. This questionnaire aims to identify the knowledge levels regarding diabetes among T2DM patients. There is no specific cut-off point, and the highest mark is 20. However, a higher score reflects a better understanding of diabetes management, which can be used to infer the respondent's level of knowledge about their condition (Md Aris et al.,2018).

Perceived adherence modification questionnaire (PALM-Q)

PALM-Q was a questionnaire that determined the perceived adherence levels among T2DM patients, including knowledge, beliefs, and barriers. The questionnaire consists of 18 questions. The response option is in Likert-scale format with four choices: Strongly Disagree, Disagree, Agree, and Strongly Agree, with points of 4, 3, 2, and 1, respectively. The scoring was used to categorize respondents into three groups: the presumed perceived adherence with 54 points and above, unpredictable perceived adherence with a score of 32-53; and perceived non-adherence, which scores less than or equal to 31 (Nor et al., 2022).

International Physical Activity Questionnaire (IPAQ)

The IPAQ questionnaire, which uses a shortened version of 7 questions, required respondents to self-report their daily physical activity. The IPAQ-M monitors the frequency and duration of time spent in vigorous-intensity, moderate-intensity, and sedentary activities such as sitting and sleeping. Participants were instructed to report on their activities during the previous seven days, including only activities that lasted 10 minutes or more per session. The total amount of time was then used to categorize the participants as either sufficiently active or insufficiently active based on their ability to meet the physical activity guidelines by the NHMS 2019, at least 150 minutes of moderate-intensity per week.

RESULTS

Demographic Data

A total of 33 Malay with T2DM patients participated in this study. The majority of respondents were from the age group of 40 – 59 years old, which includes 18 (54.5%), followed by 60 and above and 22 – 39 years old, with 11 (33.3%) and 3 (9.1%), respectively. In contrast, the least respondents came from the age group of 18 – 21 years old

with 1 (3%). Out of the 33 respondents, 17 (51.5%) were female and 16 (48.5%) were male. Table 1 shows the demographic data of the participants.

Table 1: Demographic data of the respondents (n=33)

Demographics	Subjects (n=33)	
	n	%
Age		
18 – 21 years old	1	3
22 – 39 years old		
40 – 59 years old	3	9.1
60 years above	18	54.5
	11	33.3
Gender		
Male	16	48.5
Female	17	51.5

Diabetes-related Knowledge

The respondents were asked regarding diabetes-related knowledge. Table 2 displays the lowest score as 7, while the highest is 17, with a mean score of 11.15.

Table 2: Diabetes-related knowledge among T2DM patients in SASMEC (n=33)

Variable	Minimum	Maximum	Mean± SD
Diabetes-related knowledge	7	17	11.15 ± 2.539

Association of Diabetes-related Knowledge and Perceived Adherence to Lifestyle Changes

Table 3 indicates the correlation between diabetes-related knowledge and perceived adherence to lifestyle changes. There is no significant correlation, and a weak positive correlation was found with a p-value of 0.732 (r = 0.062). Similarly, the correlation between diabetes-related knowledge and physical activity levels was not significant with p-value > 0.05. However, the variables showed a weak negative correlation (Table 4), indicating that participants with good diabetes-related knowledge participate less in physical activities.

Association of Perceived Adherence to Lifestyle Changes and Physical Activity Levels

The result from the Chi-Square Test shows the association between perceived adherence to lifestyle changes and physical activity levels among T2DM patients.

Table 3: Correlation between diabetes-related knowledge and perceived adherence to lifestyle changes and physical activity level (n=33)

Variable	*r*-value	*p*-value
Diabetes-related knowledge and perceived adherence to lifestyle changes	0.062	0.732
Diabetes-related knowledge and physical activity level	-0.242	0.175

Participants were categorized into three physical activity levels: low (11 participants, 33.3%), moderate (15 participants, 45.5%), and high (7 participants, 21.2%). A significant association was found between physical activity level and perceived adherence to lifestyle changes, X^2 (2, n=33) = 7.457, p = 0.017, Cramers V = 0.480.

DISCUSSION

Diabetes-related Knowledge

This study revealed that the mean scores of diabetes-related knowledge among T2DM patients were in a good category. Since all participants answered more than half of the questions correctly, they had moderate and acceptable levels of knowledge. Other studies by Al-Qazaz et al. (2010) and Fitzgerald et al. (2016), showed similar results, with more than half of the participants having good knowledge regarding diabetes. Additionally, T2DM patients in Kuala Muda District, Kedah, have good diabetes-related knowledge and demonstrate good attitudes and practices in diabetes management (Abbasi et al., 2018). However, compared to a study conducted by Lee et al. (2019), in a primary care clinic in Seremban reported lower diabetes knowledge scores, with only 3.6 % of the respondents well-versed regarding diabetes. The low diabetes knowledge scores recorded in the survey could be attributed to Negeri Sembilan having the highest diabetes prevalence among Malaysian states, according to NHMS 2019.

The differences in diabetes knowledge might be due to numerous factors such as demographic profiles like age and ethnicity, the duration for which patients had T2DM, and the tools used to assess knowledge (Hamuleh et al., 2010). Furthermore, variations in the availability and

quality of diabetes education programs in certain areas may impact participants' knowledge. This highlights the need for standardized educational programs to improve the overall understanding of diabetes and improve health outcomes.

Association between Diabetes-related Knowledge with Perceived Adherence to Lifestyle Changes and Physical Activity Level.

Higher diabetes knowledge is associated with better adherence among T2DM patients (Yeh et al., 2018), and higher levels of physical activity (Klupa et al., 2016; Sodeno et al., 2022).However, this study found no association between diabetes-related knowledge and perceived adherence to lifestyle changes or physical activity levels. An improved knowledge may not ensure sustained commitment to food and lifestyle changes. A study by Ahola & Groop (2013 emphasized that there is no association between knowledge and adherence due to social support, denial of current disease, and depressive symptoms negatively impact adherence. Adherence to dietary and physical activities involves many interrelated factors beyond individual knowledge.

Financial constraints and access to healthy foods significantly determined adherence (Peter et al., 2022). The high costs of healthy food items with time constraints restrict food choices, as people usually opt for something quick and easy. Beyond knowledge, addressing behavioral, psychological, and environmental barriers to adherence is essential (Yeh et al., 2018). Healthcare providers should incorporate strategies to enhance adherence to lifestyle changes.

Patients with poor knowledge lack of basic understanding needed for effective self-management. They are likely more vulnerable to the same psychological, social, and environmental barriers that affect those with higher knowledge (Marciano et al., 2019). This aligns with the general understanding that knowledge is fundamental for effective diabetes self-management.

A study by Martin et al. (2021) and Pelluri et al. (2022) found no significant relationship between physical activity and diabetes knowledge, suggesting that motivation is essential in determining the level of physical activity among T2DM patients. Research by Sazlina et al. (2013) on interventions to promote regular physical activity among older adults found that peer support groups, goal setting, and individualized coaching are essential for engagement. Knowledge of diabetes alone does not seem significant in promoting physical activity.

Many studies emphasize that factors such as individual current disease status; BMI, especially obesity and overweight individuals, age, lifestyle behavior, and mental health significantly influence physical activity (Colberg et al., 2010; Daryabor et al., 2020; Tyson et al., 2010). Individuals with higher BMI, particularly those who are obese or overweight, are often associated with decreased engagement in physical activity and are uninterested in managing their weight and improving their overall health (Duta et al., 2023).

According to a few studies, people will not exercise even if they have substantial knowledge about diabetes because of psychological barriers or a lack of motivation (Al-Salmi et al., 2022; Harrington & Henson, 2021; Klinovszky et al., 2019). These studies highlight the difficulty in changing behavior and the need for comprehensive interventions targeting behavioral, psychological, and informational components.

Association Between Perceived Adherence to Lifestyle Changes and Physical Activity Level

This study found an association between perceived adherence to lifestyle changes and physical activity level. When individuals have high perceived adherence to lifestyle changes, their physical activity levels are expected to increase. High perceived adherence indicates that patients feel they are successfully following their prescribed lifestyle modifications, which may include diet, medication adherence, and mental health practices (Klinovszky et al., 2019). This sense of success can enhance motivation and self-efficacy, leading patients to engage more actively in physical exercise as part of their overall commitment to improve health (Shabirah et al., 2022). When patients perceive themselves as adherent, they may also be more likely to adopt additional positive behaviors, including increased physical activity, because they recognize the benefits and feel capable of integrating these behaviors into their daily routines.

Furthermore, perceived adherence may foster positive feedback where the successful adoption of one healthy behavior reinforces the adoption of others. For instance, patients who feel confident in their dietary changes and medication adherence might be more willing to incorporate regular physical activity, perceiving it as another manageable and beneficial component of their lifestyle. This holistic approach to adherence can lead to comprehensive improvements in health and well-being.

CONCLUSION

In conclusion, increased knowledge alone did not lead to higher perceived adherence to lifestyle changes, including physical activity. On the other hand, physical activity levels are influenced by patients' perceived adherence to lifestyle changes. While knowledge is essential, motivation plays a more significant role in prompting behavioral changes among T2DM patients. Therefore, healthcare providers should prioritize fostering behavioral change rather than focusing solely on imparting knowledge.

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ORIGINAL ARTICLE

Formulation and Sensory Evaluation of Ginger-Permeated Biscuits: A Study on Flavour, Texture, and Consumer Acceptability

Uswah Mansurah Zainudin[1] and Muhammad Muzaffar Ali Khan Khattak[1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Ginger-Permeated, Biscuits, Spices, Sensory, Evaluation,

ABSTRACT

Introduction: The production of biscuits fortified with spices that offer health benefits is currently limited in variations. This study aims to formulate ginger biscuit recipes that achieve high acceptability. **Methods:** Three formulations of ginger-flavoured biscuits were created by incorporating additional ingredients such as chocolate chips and raisins, using buckwheat flour as the base. The sensory attributes and overall acceptability of the three formulations. Formulation 1 was based on only sugar, formulation 2 was enhanced with chocolate chips, and formulation 3 was enriched with raisins. A panel of thirty volunteers was randomly selected to evaluate the acceptability of the biscuits. The data were statistically analysed using One-way Analysis of variance (ANOVA). **Results:** The sensory characteristics revealed no significant differences among the formulations for their appearance, aroma, taste, crunchiness and overall acceptance. Overall, the data indicates that all biscuit formulations were acceptable to the panellists. **Conclusions:** All ginger-permeated biscuit formulations were equally acceptable to the panellists in quantity and other ingredients like sugar, chocolate chips or raisins.

*Corresponding author.
E-mail address: muzaffar@iium.edu.my

INTRODUCTION

Muffins, biscuits, cakes, and cookies are baked confectionery products consumed worldwide for sensory appeal. In both industrialised nations and emerging economies, these products contribute to obesity and type II diabetes due to their high sugar and fat content. Sugar and fat play multiple roles in baked confectionery products, influencing their structure, texture, shelf life, flavour, and aroma. Significant efforts have been made to modify product formulations to reduce sugar and fat content without compromising quality. Ginger, scientifically known as Zingiber officinale, is a dietary component widely used in food and beverages to enhance flavour. Beyond its culinary uses, ginger is well-known for its health benefits, aiding in the management of diabetes and hyperlipidaemia. In addition to its anti-diabetic, antioxidant, anti-obesity, and hypolipidemic properties, ginger possesses anti-inflammatory, neuroprotective, anti-glycating, and androgenic effects. Furthermore, ginger has been shown to influence carbohydrate metabolism, organ morphology, and metabolic profiles (Siregar et al., 2022). In Malaysia, the value of cookies and biscuits sold in 2022 was nearly 3.29 billion Malaysian ringgit. Compared to the previous year, the manufacturing sales value of cookies and biscuits has grown (Statista, 2023). This trend indicates a rising demand for confectionery products, with consumers increasingly seeking out these types of food. Spices such as ginger in confectionery products like biscuits can enhance the functional food market while providing health benefits to consumers.

Therefore, this project aims to create a ginger-flavoured biscuit formulation that is acceptable and offers health benefits. It would provide a choice of confectionery product, specifically biscuits, that is highly acceptable across various sensory attributes.

MATERIALS AND METHODS

Development of Ginger Biscuits

The composition of the biscuits is presented in Table 1, with three different formulations produced. The ginger biscuit formulations consist of various ingredients. For each batch, the core ingredients include buckwheat flour, whole wheat flour, sugar, baking soda, ginger powder, vegetable oil, egg, and water. The first formulation contained no additional ingredients. In the second formulation, chocolate chips were added, while the third included raisins. All ingredients were thoroughly mixed to form a uniform dough, which was then shaped into circular portions. Each portion of dough was placed on baking

paper lined on a tray and baked for about fifteen minutes in a preheated oven at 180°C. Once baked, the biscuits were cooled to room temperature and stored in an airtight container.

Table 1: The composition of ginger biscuits of three formulations.

	Formulation		
	F1	F2	F3
Buckwheat Flour (g)	70	70	70
Whole Wheat flour (g)	30	30	30
Sugar (g)	50	50	50
Baking Soda (g)	1.25	1.25	1.25
Ginger Powder (g)	7.5	7.5	7.5
Vegetable oil (g)	25	25	25
Egg (g)	20	20	20
Water (g)	7	7	7
Chocolate Chip (g)	-	20	-
Raisins (g)	-	-	20

Panellists

Thirty panellists consisting of students from the International Islamic University Malaysia, were recruited for this study. Students with health issues or who had lost the ability to sense smell or taste were excluded from participating in this study.

Sensory Evaluation

The sensory evaluation was carried out in the sensory evaluation laboratory, Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences. The intended sensory parameters, score options, and numerical rankings were listed on the evaluation forms of the panellists. The biscuits were rated using a 9-point hedonic scale and tested on several acceptability parameters, including appearance, aroma, taste, and texture. The appearance of the ginger biscuits was evaluated for their colour and shape, while their aroma was assessed for its fragrance. For the taste, the ginger biscuits were judged on sweetness, and the texture was evaluated in terms of crunchiness and chewiness. The hedonic scale ranged from 'extremely like' to 'extremely dislike,' with scores ranging from 1-9. To measure the level of liking and overall pleasantness or unpleasantness of the consumption experience of the biscuits. The evaluation was conducted over five sessions, each consisting of six panellists. Each panellist was served three biscuit samples from different formulations, with an evaluation form, each corresponding to one biscuit sample. Panellists were provided with a glass of plain water to cleanse their palate between tastings. All panellists were instructed to refrain from discussing or communicating with each other during the session. Each session lasted approximately 10 - 15 minutes, with a 5-minute gap between sessions for room evacuation and preparation for the next group.

STATISTICAL ANALYSIS

The collected data were entered into the Statistical Package for the Social Sciences (SPSS Version 12.01) and sorted for analysis. The mean scores for each sensory attribute i.e. appearance (colour and shape), aroma, taste (sweetness), texture (crunchiness and chewiness), and overall acceptance were compared among the three different formulations using One-way analysis Variance (ANOVA). The significance level was set at $p< 0.05$ at 95% CI. A post hoc test was conducted using the Tukey HSD test to determine the significant differences between the three formulations' sensory characteristics.

RESULTS

The results of this study are presented in Table 2. The sensory attributes evaluated included appearance (colour and shape), aroma, taste (sweetness), texture (chewiness and crunchiness), and overall acceptability. The statistical analysis revealed no significant differences across the three ginger biscuit formulations in these sensory parameters. This indicates that the panellists found all formulations equally acceptable, regardless of the differences in ingredients between the samples. Formulation 1 was a basic ginger biscuit, formulation 2 contained chocolate chips, and formulation 3 included raisins. Despite these ingredient variations, the overall sensory experience for the panellists remained consistent. Although formulation 2, which contained chocolate chips, tended to score slightly higher in some areas, such as appearance, aroma, sweetness, and crunchiness, these differences were not statistically significant. This suggests that chocolate chips may have offered a slight edge in preference for some attributes, but not enough to distinguish it markedly from the other formulations regarding overall acceptability. The lack of significant differences in sensory attributes indicates that the variations in ingredients did not lead to strong preferences among the panellists, and all formulations were similarly well-received. The consistent level of acceptance across the different formulations highlights the versatility of the base recipe, which performed well regardless of the additional ingredients. Overall, the results suggest that each ginger biscuit formulation was equally appealing to the panellists, making any of them a viable option for further development.

Table 2 The Mean score of the Sensory Characteristics between Formulations

Sensory Characteristics	N	F1	F2	F3	Significance Level
		Mean ± SD	Mean ± SD	Mean ± SD	
Colour	30	7.47 ± 1.33	7.60 ± 1.19	7.40 ± 1.45	p= 0.839 NS
Shape	30	7.83 ± 1.26	7.93 ± 1.02	7.57 ± 1.48	p= 0.513
Aroma	30	6.97 ± 1.27	7.40 ± 1.35	6.80 ± 1.27	p= 0.188
Sweetness	30	6.73 ± 1.31	7.27 ± 1.20	6.87 ± 1.46	p= 0.274
Crunchiness	30	5.10 ± 1.40	5.90 ± 1.32	5.83 ± 1.29	p= 0.041
Chewiness	30	6.23 ± 1.50	6.53 ± 1.55	6.30 ± 1.64	p= 0.739
Overall Acceptance	30	6.63 ± 1.22	7.17 ± 1.32	6.67 ± 1.37	p= 0.213

DISCUSSION

Sensory evaluation in foods is defined as a tool or a technique used to measure human responses to food, ultimately influencing consumer perceptions (Golden et al. (2010). Sensory characteristics such as appearance, aroma, colour, texture, and taste are key factors affecting food quality and consumer preferences. The sensory evaluation was conducted in a controlled laboratory environment, ensuring factors like lighting, ventilation, noise, and extraneous odours did not interfere with the results. Panellists were instructed to avoid discussing or communicating with one another to decrease distractions and bias. Additionally, they were required to cleanse their palates between samples to enhance the accuracy of the evaluation and maintain responsiveness to new stimuli (Kemp, 2008).

The colour of ginger biscuits is a critical quality factor in consumer acceptance (Sharif et al., 2017). Yang et al. (2019) found that while ginger-free biscuits appeared plain, those with 1% ground ginger had a more golden yellow shade. In this study, the final ginger biscuits had a golden-brown colour, likely due to the higher proportion of buckwheat flour, which is more fibrous and darker than wheat flour. Baking at 180°C also contributed to this golden-brown colour through the Maillard reaction, which occurs at temperatures above 160°C (Mesías et al., 2016). The panellists found the appearance of all biscuit formulations to be acceptable. Similarly, aroma plays an important role in the perceived quality of ginger biscuits, often influencing whether a product is accepted or rejected before tasting. Sharif et al. (2017) noted that a pleasant aroma enhances taste. Filipčev et al., (2012) found that the ginger aroma masked the buckwheat scent in composite biscuits, without significantly altering taste. We recorded, no differences in the aroma acceptability between the three formulations. However, Formulation 2, which contained chocolate chips, scored the highest for aroma on the hedonic scale.

Furthermore, the taste acceptability also increased with adding ginger and chocolate chips. The slight bitterness of the chocolate is probably balanced by the sweetness of the biscuits, contributing to higher acceptability. While all three formulations were generally accepted, Formulation 2 had the highest overall preference since statistically no differences were recorded for the taste in the formulations under investigation (Hayek, & Ibrahim, 2013)..

Texture is another critical factor in biscuit acceptability and consumers generally prefer a balance between crunchiness and chewiness. Buckwheat flour contributes to the hardness and tractability of biscuits, increasing flour added (Filipčev et al., 2012). However, the addition of fat, such as oil, acts as a lubricant and improving dough malleability and moulding properties (O'Sullivan, 2017). The ginger biscuits in this study were chewier than crunchy, with chewiness scoring an average of 6.35, compared to 5.61 for crunchiness. Both textures were deemed acceptable, with scores indicating "slight liking" and "neutral" responses, respectively.

For any confectionary product, overall acceptability is a critical measure of consumer perceptions, encompassing all sensory attributes. There were no statistical differences, however, formulation 2 was preferred across all sensory parameters, with an overall acceptance score of 7.17. This suggests that adding chocolate chips or raisins enhances consumer acceptance, as formulations without these ingredients received lower scores, possibly due to the stronger buckwheat flavour overpowering the ginger.

CONCLUSIONS

This study aimed to propose a new variation of confectionary products such as biscuits with some health benefits and to compare the acceptability of the three formulations. Thus, it can be concluded that this study can produce good ginger biscuit recipes that have good appearance (colour and shape) aroma, taste (sweetness), texture (crunchiness and chewiness), and overall acceptance. These findings showed that ginger biscuits were generally well-received, demonstrating that this product may be regarded as being well-received by panellists. As a result, the findings of this study can be used to produce different confectionery goods with certain health advantages.

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ORIGINAL ARTICLE

Effect of Perceived Adherence to Lifestyle Changes On Quality of Life, Body Mass Index, And Blood Glucose Status For T2DM Patients @SASMEC

Elzehra Balqis Binti Azmi[1], Noraishah Binti Mohamed Nor[1, 2*], Wan Ahmad Syahril Rozli Wan Ali[3]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2] Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Department of Internal Medicine, Sultan Ahmad Shah Medical Center, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Type 2 Diabetes Mellitus (T2DM); lifestyle modification; perceived adherence; Quality of Life (QoL); blood glucose level

ABSTRACT

Background: Adopting a healthier lifestyle with effective self-management can improve diabetes outcomes. For diabetic patients, perceived adherence is crucial in helping them sustain the recommended lifestyle changes. Thus, the current study was conducted to determine the association of perceived adherence level to lifestyle changes with the Quality of Life (QoL), body mass index (BMI), and blood glucose level of T2DM patients. **Methods:** Thirty-seven T2DM patients were recruited from the Medical Clinic at SASMEC@IIUM. All participants were interviewed and completed survey questions regarding the perceived adherence to lifestyle changes and quality of life. **Results:** Results found that most of the participants were obese 20 (54.1%), few were underweight 2 (5.4%), normal weight 8 (21.6%) and overweight 7 (18.9%). Most participants, 23 (62.2%) had presumed perceived adherence, and 14 (37.8%) had unpredictable perceived adherence, with no participants categorised as perceived non-adherence. There is no significant difference between perceived lifestyle changes and body mass index. The average total quality of life score was 40.4, indicating a good quality of life. There was a significant difference between perceived adherence to lifestyle change and quality of life. For most participants, 21 (60%) fasting blood glucose levels were equal to or more than 7.0 mmol/L, while 14 (40%) participants had normal fasting blood glucose values (<7.0mmol/L). The result found no significant difference between perceived adherence to lifestyle change and blood glucose status. **Conclusion:** This study highlights the substantial impact of perceived adherence to lifestyle changes on the quality of life (QoL) among diabetes patients, emphasising the importance of promoting adherence to improve overall well-being. However, no association was found between perceived adherence, BMI, or blood glucose levels. These findings indicate that the influence on metabolic outcomes such as BMI and blood glucose is more complex and likely influenced by other factors.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a non-communicable disease that is concerning in Malaysia as it involves almost 1 in 5 adults in Malaysia (National Health Morbidity Survey, 2019). According to Ismail et al. (2023), T2DM is a condition where the level of blood glucose increases. It may lead to several organ dysfunctions, such as heart disease, blood vessels, eyes, kidneys, and nerves. According to Abdulaziz Alrashed et al. (2023), a few factors influence the development of T2DM, such as lifestyle habits, physical attributes, and family history.

A study concluded that, as the complication related to T2DM is prolonged and arises, the Quality of Life (QoL) may be reduced because the complication may influence the blood glucose level and insulin resistance, increasing the other risk factors (Zan et al., 2024). Therefore, T2DM can influence the QoL level in many ways, depending on the disease management. According to Bujang et al. (2018), three main domains in QoL that have been used over a decade in assessing the quality of life level in Diabetes patients are"satisfaction," "impact," and "worry."

The body mass index (BMI) classification of underweight, overweight, and obese can affect a person's health and increase the risk of various health problems (WHO, 2010). In a study by Chaib et al. (2023), they reported that half and one-third of the T2DM patients were overweight and obese, respectively. T2DM patients can generally manage and control their blood glucose, adhering to lifestyle

* *Corresponding author.*
E-mail address: ishah@iium.edu.my

modifications such as eating low carbohydrates, reducing sugar intake, and doing regular physical activities (Price, 2016). Ghosh et al. (2023) suggested that it is necessary to investigate individual issues regarding adherence to lifestyle changes to achieve effective and efficient treatment goals. Hence, this study aims to determine the effect of perceived adherence to lifestyle changes on QoL, BMI, and blood glucose status.

MATERIALS AND METHODS

Study Design

This study was conducted in the Medical Clinic at Sultan Ahmad Shah Medical Centre (SASMEC@IIUM), Kuantan Pahang. A cross-sectional design was used for this research. Cross-sectional study may provide high efficiency of data collection and lower and control study costs. The convenience sampling method was used as the data collection method.

Study Population

The study population involves patients diagnosed with T2DM who attend the Medical Clinic in SASMEC. The inclusion and exclusion criteria of participants are presented in Table 1.

Table 1: Inclusion and exclusion criteria of the participants.

Inclusion	Exclusion
•T2DM Patients •18 years old and above •Understand the Malay language	•T1DM Patients •Gestational Diabetes Patients •Paediatric Patients

Data Collection

A validated questionnaire was used during the data collection. The questionnaire consists of three sections: Section 1 contains the sociodemographic information, including gender, age, race, BMI, weight, height, and biochemical data. Moreover, the fasting blood glucose (FBG)(mmol/L) and HbA1c (%) levels were collected through i-Pesakit. The researcher also used the weight scale to measure weight and a stadiometer to measure height. The data were collected by interviewing the participants to avoid misunderstanding the questionnaire.

Section 2 contains the Perceived Adherence Level Modification Questionnaire (PALM-Q) to assess perceived adherence levels among T2DM patients (Nor et al., 2022). This questionnaire consists of a total of 18 questions that have four answer options for each question (Strongly Agree, Agree, Disagree, and Strongly Disagree). This questionnaire was developed to determine the factors influencing adherence levels among T2DM to lifestyle modifications. The scoring for this questionnaire is divided into three levels: 1) Perceived non-adherence if the score is 31 and below, 2) Unpredictable perceived adherence if the score recorded is from 32 to 53, and 3) Presumed perceived adherence if the score is 54 and above.

Section 3 of the questionnaire covers the revised version of the Diabetes Quality of Life Questionnaire (DqoL), which has 13 items, which is convenient for patients to answer all questions. Based on the Likert scale, this questionnaire provides five answer options (1: Very satisfied, 2: Moderately satisfied, 3: Neither satisfied nor dissatisfied, 4: Moderately dissatisfied, 5: Very dissatisfied). The higher the score, the poorer will be the QoL.

Statistical Analysis

The sociodemographic data collected were analysed using descriptive statistics by measuring the percentage, mean, and standard deviation (SD) of the sociodemographic results, biochemical results, anthropometry measurements, and level of adherence to lifestyle change. The Independent t-test was used to identify the association between perceived adherence with QoL and body mass index (BMI). The Mann-Whitney U test was used to determine the association of perceived adherence to lifestyle change with blood glucose status. The data obtained were assessed using Statistical Package for the Social Sciences version 20.0 (SPSS 20.0).

RESULTS

Sociodemographic Data

A total of 37 T2DM patients participated in this study. Table 2 shows the sociodemographic data of the selected patients. The researcher interviewed 18 male patients and 19 female patients. The overall age range of the patients is between 40 and 59 years old (48.6%). The majority were Malay patients, with 97% (36) and one Indian (2.7%) patient. The data show that out of 37 patients, only 5.4% (2) fall into the underweight category, normal BMI was 21.6% (8), overweight was 18.9% (7), obese class one was 29.7% (11), obese class two was 10.8% (4), obese class three was 13.5% (5), and the mean BMI among the T2DM patients was 28.2 kg/m^2.

Out of 37 patients, only 35 were assessed regarding adherence to lifestyle changes and blood glucose status because the remaining participants did not have complete blood glucose data in the system. Therefore, among 35

patients, there are 40% (14) among all patients had normal fasting blood glucose readings (<7.0mmol/L), while the other 60% (21) of patients had elevated levels of fasting blood glucose readings (>7.0mmol/L). The mean perceived adherence to lifestyle modification mean score is 56.9±10.72, the overall diabetes QoL mean score is 40.4±12.91, and the mean FBG levels are 8.9mmol/L±3.99, indicating that the average FBG among patients reading is high (>7.0 mmol/L). Looking at each domain under Diabetes Quality of Life (DqoL), the mean scores for satisfaction, worry, and impact domains were 41.5±13.85, 38.8±17.09, and 40.2±20.46, respectively. The descriptive analysis of the PALM-Q shows no patient was categorised as perceived non-adherence. There are 14 totals (37.8%) in unpredictable perceived adherence and 23 (62.2%) in presumed perceived adherence.

Table 2: Sociodemographic data of selected participants

Variables	**Frequency (%)**	**Mean (±SD)**
Gender		
Male	18 (48.6)	
Female	19 (51.4)	
Age (year)		
Young adult (18-21)	1 (2.7)	
Adult (22-39)	3 (8.1)	
Middle Age (40 – 59)	18 (48.6)	
Older adults (≥60)	15 (40.5)	
Weight		73.4 (19.12)
Height		1.6 (1.62)
BMI (kg/m^2)		28.2 (6.51)
Underweight	2 (5.4)	
Normal	8 (21.6)	
Overweight	7 (18.9)	
Obese	20 (54.1)	
Race		
Malay	36 (97.3)	
Indian	1 (2.7)	
FBG		8.9 (3.99)
< 7.0 mmol/L	14 (40)	
≥ 7.0 mmol/L	21 (60)	
PALM-Q (Overall Score)		56.9 (10.72)
Perceived non-adherence	0 (0)	
Unpredictable Perceived Adherence	14 (37.8)	
Presumed perceived adherence	23 (62.2)	
QoL (Overall Score)		40.4 (12.91)
Satisfaction Domain		41.5 (13.85)
Impact Domain		38.8 (17.09)
Worry Domain		40.2 (20.46)

Perceived Adherence To Lifestyle Modification And Quality Of Life

Table 3 indicates that there is a significant difference in the unpredictable perceived adherence (46.9±12.69) and presumed perceived adherence (36.4±11.57) conditions; t (35) = 2.592, p = 0.014. Hence, the QoL scores of patients who scored presumed perceived adherence are lower than those who scored unpredictable perceived adherence.

Perceived Adherence To Lifestyle Modification And Body Mass Index

Table 4 compares perceived adherence levels and participants' body mass index (BMI). From the independent sample t-test, there is no significant difference between the unpredictable perceived adherence (M=27.6, SD=6.70) and presumed perceived adherence (M=28.6, SD=6.51) conditions; t (35) = -1.0375, p = 0.645. Hence, the BMI of patients who scored

Table 3: Comparison of Perceived Adherence to Lifestyle Modification Score and DQoL Score

Variable	Unpredictable Perceived Adherence (n =14)		Presumed Perceived Adherence (n=23)		Mean difference (95% CI)	t-statistics (df)	p-value
	Mean	SD	Mean	SD			
Overall DQoL Score	46.9	12.69	36.4	11.57	10.54 (2.28, 18.79)	2.592 (35)	0.014

presumed perceived adherence was slightly lower than those who scored unpredictable perceived adherence.

Table 4: Comparison of Perceived Adherence to Lifestyle Modification Score and Body Mass Index

Variable	Unpredictable Perceived Adherence (n =14)		Presumed Perceived Adherence (n=23)		Mean difference (95% CI)	t-statistics (df)	p-value
	Mean	SD	Mean	SD			
BMI (kg/m^2)	27.6	6.70	28.6	6.51	-1.0375 (-5.56, 3.49)	-0.465 (35)	0.645

Perceived Adherence To Lifestyle Modification And Fasting Blood Glucose Levels

The mean fasting blood glucose levels among participants who scored unpredictable perceived adherence (mean rank = 21.17, n = 12) were significantly higher than participants who scored presumed perceived adherence (mean rank = 16.35, n = 23) U = 100, z = -1.322 (corrected for ties), p = 0.186, two-tailed. This effect can be described as "small" (r = 0.223), and is illustrated in Figure 2. There is no significant difference between the groups.

DISCUSSIONS

Perceived Adherence to Lifestyle Changes and Quality of Life

Results found a significant difference in diabetes patients' QoL with unpredictable perceived adherence and presumed perceived adherence among T2DM patients. Patients with high perceived adherence scores have lower DQoL scores. Bujang et al. (2018) described that the lower the score of the DQoL, the better adherence to lifestyle modifications.

This result aligned with another related study by Karki et al. (2023), which found that patients with T2DM may improve their overall QoL when complying with lifestyle interventions. A study by Jing et al. (2018) concluded a few factors that could influence the QoL in T2DM patients: physical activity level, frequency of blood glucose check, complications, hypertension, diabetes duration, high red meat diet, and depression.

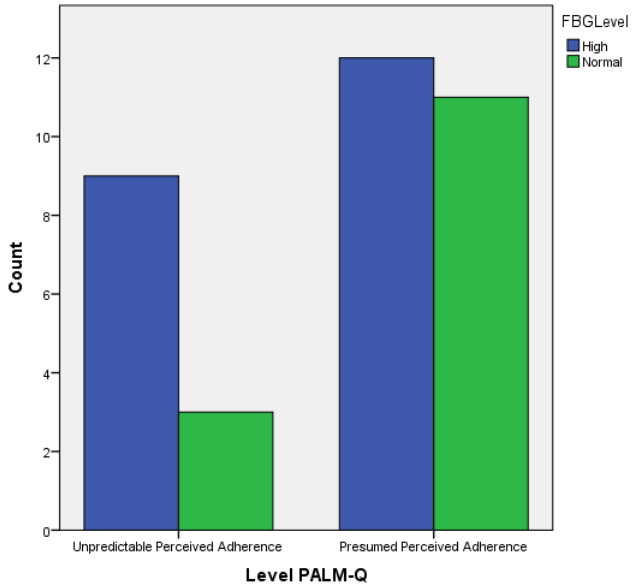

Figure 2: Graph bar for perceived adherence to lifestyle modification score and fasting blood glucose level

The study also found that complications of T2DM, such as physical discomfort and decreased physical activity, also influence QoL in T2DM patients.

According to Nor et al. (2022), the PALM-Q used in this study emphasised the important and exclusive domains of T2DM patients' adherence to lifestyle modifications, such as knowledge, support, practice, motivation and barriers. The revised version of the Diabetes Quality of Life (DQOL) questionnaire has also been improved regarding the influence of other health conditions. A study by (MacDonald et al., 2021) also supports that adherence to lifestyle modification improves overall QoL. Therefore,

adhering to lifestyle modifications recommended by the health care provider is crucial in enhancing the overall QoL of T2DM patients.

Perceived Adherence to Lifestyle Changes with Body Mass Index and Blood Glucose Levels.

The result indicated no significant difference between unpredictable perceived and presumed perceived adherence with BMI among T2DM patients. The study found no association between patients with higher perceived adherence and lower BMI classification. The result contradicts from the research conducted by Burgess et al. (2017) and Düz et al. (2020), who suggested that BMI decreases when the perceived adherence to lifestyle change level increases. Another similar study by Baillot et al. (2015) found that lifestyle modification can improve weight in obese patients.

Patients with higher BMI can have high perceived adherence to lifestyle modification compared to the patients with lower perceived adherence to lifestyle modification because of extrinsic factors such as motivation, awareness and social supports. Therefore, it can be concluded that BMI did not affect perceived adherence to lifestyle modification, and BMI is not an accurate measure of adherence to lifestyle modification among T2DM patients. The factors determining an individual's BMI do not solely depend on adherence to a healthy lifestyle, such as exercising regularly and practising healthy eating habits. Besides, other factors that affect the BMI of patients should be considered; for example, the BMI may be influenced by genetics (Silventoinen & Konttinen, 2020), psychological stress (Delnevo et al., 2021), and metabolic rates (Astrup et al., 1999).

Moreover, no significant difference was found in the current study between perceived adherence to lifestyle changes and blood glucose levels. However, a study by Yang et al. (2016) found the opposite result: high adherence to lifestyle modification has a better-fasting blood glucose status. Similar to pharmaceutical therapy, lifestyle modification has been demonstrated to delay the progression of complications and significantly lower the chance of developing chronic diseases Al-salami et al., 2022). The difference in results may be explained by the reliance on self-reported adherence measures in this study, which are affected by social desirability bias and may not accurately reflect actual behaviour.

CONCLUSIONS

This study highlights the significant impact of perceived adherence to lifestyle changes on the quality of life (QoL) among diabetes patients, underscoring the importance of promoting adherence to improve overall well-being. However, no association was found between perceived adherence, BMI, or blood glucose levels. These outcomes indicate that while lifestyle change adherence may improve the quality of life (QoL), the influence on metabolic outcomes such as BMI and blood glucose is more complex and more likely influenced by other physiological, psychological, medical conditions and environmental factors. Future interventions should aim to address these factors to optimise patient outcomes comprehensively.

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ORIGINAL ARTICLE

Association Between Diabetes-Related Knowledge, Perceived Adherence to Lifestyle Changes and Physical Activity Level Among Type 2 Diabetes Mellitus Patients at SASMEC@IIUM

Nurul Hanis Zafira Ahmad Bajuri[1], Noraishah Mohamed Nor[1, 2], Wan Ahmad Syahril Rozli Wan Ali[3]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3] Department of Internal Medicine, Sultan Ahmad Shah Medical Center, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
type 2 diabetes mellitus; diabetes knowledge; physical activity level; perceived adherence

ABSTRACT

Background: Diabetes-related knowledge is fundamental to effective diabetes management, influencing self-management and health outcomes. Changes in lifestyle, including diet modification and physical activity, are all necessary for effective nutrition treatment. Therefore, this study aims to identify the relationship between diabetes-related knowledge and physical activity levels with perceived adherence to lifestyle changes among type 2 diabetes mellitus (T2DM) patients. **Methods:** Questionnaires consisting of Diabetes Knowledge Test (DKT), Perceived Adherence Lifestyle Modification (PALM-Q), and International Physical Activity Questionnaire (IPAQ) were used through self-administers. The data were analysed using Statistical Package for the Social Sciences (SPSS). A total of 33 respondents, T2DM patients aged 18 and above in SASMEC@IIUM, were involved in this study. **Results:** The Spearman Correlation test found no association between diabetes-related knowledge and perceived adherence to lifestyle changes and physical activity level ($p>0.05$). Additionally, the Chi-Square Independence test shows a significant association between perceived adherence to lifestyle changes and physical activity level ($p>0.05$). **Conclusion:** It can be concluded that there is no association between diabetes-related knowledge and perceived adherence to lifestyle changes and physical activity level, yet there is a significant association between perceived adherence to lifestyle changes and physical activity level among T2DM patients in SASMEC@IIUM.

INTRODUCTION

Research Background

Type 2 Diabetes Mellitus (T2DM) is a significant health concern, with increased prevalence among individuals over 30 years old in the past decade (Hussein et al., 2015). Usually, once the individual is diagnosed with diabetes for the first time, they will be referred to a dietitian to proceed with lifestyle change recommendations. However, not all patients are able to comply and maintain the recommended advice. A high prevalence of noncompliance with lifestyle advice was seen among T2DM patients in Malaysia, where just 16.4% of people with diabetes follow the dietary plans recommended by dietitians (Chew et al., 2013). A study conducted at the University of Malaya Medical Centre found that Malaysian diabetes patients are prone to consuming a high carbohydrate and fat diet (Hussein et al., 2015). This also indicates that they still have an unhealthy lifestyle, even after being diagnosed with diabetes.

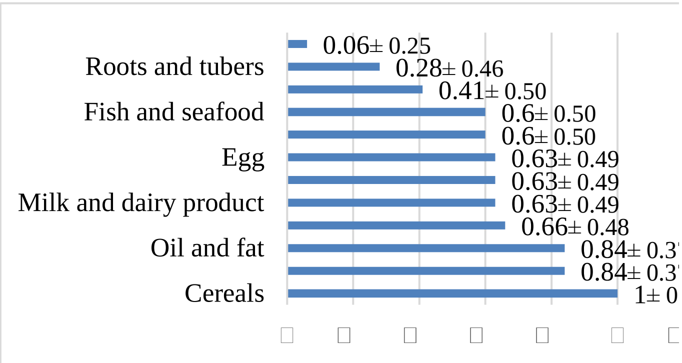
** Corresponding author E-mail address: ishah@iium.edu.my*

Practising healthy eating and increasing physical activity are necessary for improving health. Klinovszky et al. (2019) found that following physical exercise recommendations improves blood glucose levels and provides benefits. Noncompliance, on the other hand, has more severe implications for patients. T2DM patients frequently have poor diet adherence due to a failure to understand, perform, and sustain the necessary previous experiences (Al-Salmi et al., 2022).

Poor adherence to lifestyle interventions remains a persistent barrier to optimal diabetes management, leading to uncontrolled blood sugar levels and increased risk of complications. This underscores the need to investigate how patients' diabetes-related knowledge influences their perceived adherence to lifestyle changes and physical activity levels. Adequate knowledge about diabetes plays a critical role in empowering patients to take charge of their health, adopt healthier behaviours, and manage their condition more effectively. Yet, gaps in patient education continue to exist, contributing to suboptimal lifestyle changes. Thus, the current study aims to understand the association between diabetes-related knowledge, adherence to lifestyle changes, and physical

Diet Diversity Scores

Figure 1: Mean dietary diversity of the different food groups



Feeding Behaviour of Children with Disabilities

Association between nutritional status and diet diversity among children with disabilities

DISCUSSION

Nutritional Status

Feeding Behaviour

Association between nutritional status and diet diversity

Diet Diversity Scores

CONCLUSION

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ORIGINAL ARTICLE

A Study of Students' Satisfaction with Mahallah Cafeterias at The International Islamic University Malaysia (IIUM), Kuantan, Pahang

Nur Falihah Mohd Fauzi[1], Roszanadia Rusali[1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
food service; cafeteria; satisfaction.

ABSTRACT

Background: As the primary customers of the campus cafeterias, students largely depend on the food service provided to meet their dining needs without seeking off-campus alternatives. These services significantly impact students' overall quality of life, varying satisfaction across campus facilities, accommodations, and food choices. This study aims to evaluate students' satisfaction with campus cafeteria food services. **Methods:** A cross-sectional study was conducted in three student residential cafeterias at a university campus in Kuantan, Pahang. A total of 113 students participated in the study. A self-administered online questionnaire was distributed via messaging platforms using Google Forms. The questionnaire consisted of three sections: (1) sociodemographics, (2) visiting characteristics, (3) food service satisfaction questionnaire. **Results:** The majority of the students were satisfied with the cafeteria services. The total mean scores of all domains indicated that the respondents were satisfied with all food service attributes. Price and value fairness recorded the highest mean score, followed by ambience, service quality, food quality, and food variety. The correlation analysis revealed significant relationships between all food service attributes and overall satisfaction ($p < 0.01$). Service quality has the strongest positive correlation with the overall satisfaction score ($r = 0.582$, $p < 0.01$), and price and value fairness ($r = 0.426$, $p < 0.01$) has the weakest correlation with overall satisfaction. **Conclusion:** : The results revealed that all domains, namely food quality, ambience, service quality, price and value fairness, and food variety have a significant relationship with students' satisfaction levels, providing insights and practical recommendations to the food service providers on how to improve their service and increase students' satisfaction levels..

INTRODUCTION

Food service is an important sector that involves the process of preparation, distribution, and provision of food and beverages to consumers outside the home. In higher education institutions, campus food service is one of the key sectors influencing students' quality of life (El-Said & Fathy, 2015). Given that students make up most of the food service customers at the universities, it is crucial to comprehend students' satisfaction thoroughly. The diversity of student populations in higher education institutions, driven by increasing enrollment from different states and nations and generational transitions results in distinct dietary and cultural preferences that influence individuals' satisfaction with the food service (Smith et al., 2020). Therefore, ensuring that campus food service meets the expectations of these diverse groups is essential in creating a positive environment and fostering a sense of home, especially for students living away from home.

Assessing students' satisfaction with cafeteria food service is important to identify their needs and enhance their overall food service experience. Students' experience with campus cafeterias will directly influence their overall campus experience and well-being. A positive dining experience is thought to lead to a positive campus experience, which includes a conducive and supportive environment favorable for academic and personal development. Therefore, it is important to monitor all aspects of the food service to ensure the well-being and satisfactory experience of the students during study.

Despite the significance of campus food services, studies worldwide revealed higher levels of dissatisfaction. In a study conducted in Karachi, Pakistan, 63.6% of medical students expressed dissatisfaction with the food services in their school cafeterias, likely due to unmet expectations regarding the quality and delivery of the services. (Ahmed et al., 2019). Meanwhile, at Jiangsu University, China, 57.7% of students conveyed dissatisfaction with the university canteen (Wenjing, 2019). In Malaysia, 24.4% expressed either dissatisfaction or very dissatisfaction with the cafeteria service at their university (Nadzirah et al., 2013). Other than that, according to Smith et al. (2020), only 34% of United States students were satisfied with on-campus dining facilities. Overall, these numbers represent

* *Corresponding author.*
E-mail address: roszanadia@iium.edu.my

that most students are unsatisfied with university food service worldwide.

Although numerous studies have explored students' satisfaction with university food service, there may be a limited focus in research specifically addressing campuses where most students are from health science faculties. The students are particularly aware of the importance of balanced and nutritious meals due to the nature of their studies, making the quality of food services especially crucial for their well-being. Thus, this study aims to assess student satisfaction and investigate its relationship with food service attributes..

MATERIALS AND METHODS

Study Design

This research used a cross-sectional study design based on a close-ended online questionnaire to assess the satisfaction level of IIUM Kuantan students with the Mahallah cafeteria food service. **Sampling Method**

This study involved students of IIUM Kuantan from six faculties: one medical faculty, four health sciences faculties, and one science-based faculty. Based on the total number of students, the sample size of this study was 346, according to Krejcie and Morgan's (1970) table for a given population.

A convenience sampling method was used to obtain the subjects. Students who met the inclusion criteria included (1) campus students, (2) local and international students, and (3) students who have visited all three on-campus cafeterias at least once. Before answering any questions, a consent form was provided to each respondent to ensure they understood the privacy and confidentiality of the information gathered from the survey.

Ethical Consideration

Ethical approval was obtained from the Kulliyyah Postgraduate and Research Committee (KPGRC) and the International Islamic University Malaysia Research Ethical Committee (IREC) (IREC 2024-KAHS/DNS5).

Data Collection

This study was conducted using a self-administered online questionnaire using Google Forms. The questionnaire was disseminated to student residents' WhatsApp groups and campus Telegram, which consisted of male and female students.

The questionnaire consists of three sections: (1) sociodemographics, (2) visiting characteristics, and (3) food service satisfaction questionnaire. All the respondents were asked to rate their satisfaction with all hostel cafeterias: Cafeteria A, Cafeteria B, and Cafeteria C.

For the sociodemographic data, the questions include age, gender, faculty, study level, academic year, and family household income. For the visiting characteristics, the questions include which cafeteria the respondents mostly visit, the number of visits per day, and the average spending at the cafeteria.

The food service satisfaction questionnaire was adapted from several researchers, including Hall (2013) and Smith et al. (2020). The questionnaire comprised five domains related to food service satisfaction: food quality, food variety, service quality, price and value, and ambience, with 19 items. Several modifications were made to the instrument to improve its validity and better fit the research population. The respondents rated their satisfaction level by selecting any one of the 5-point Likert scale, ranging from 1 (very dissatisfied), 2 (dissatisfied), 3 (neutral), 4 (satisfied) and 5 (very satisfied). The cut-off point will be the midpoint 3. A mean score of 3 and above is considered satisfying, whereas below 3 three will be considered regarded as dissatisfying (Smith et al., 2020).

Statistical Analysis

The statistical data analysis was performed using Statistical Package for the Social Sciences (SPSS) statistical software, Windows Version 20.0. Descriptive statistics were performed to identify the frequency and percentage of categorical data for the sociodemographic data of respondents, while the mean and standard deviation were calculated for continuous data. Descriptive analysis was also used to assess satisfaction levels. Additionally, Pearson correlation analysis was performed to determine the relationship between each independent variable and student satisfaction.

RESULTS AND DISCUSSION

Descriptive Analysis

A total of 113 campus students were involved in this study. The sociodemographic data of the respondents is shown in Table 1. The age range of the respondents is between 19 and 34, including undergraduate and postgraduate students, with an average age of 22 years (SD=1.85). Of the 113 respondents, 110 were undergraduate students, and only 3 were postgraduate students. Most of the students who filled out the survey were female (84.1%) and male

15.9%. For the family household income, 40.7% were categorized as B40, with a family household income of less than RM 4,850. About 36.3% were in the M40 category, with family income ranging from RM 4,851 to RM 10,970. The remaining 23% were in the T20 category, with a family income of more than RM 10,971. Besides, nearly half (43.4%) of the respondents were third-year students, followed by second-year (23.9%), first-year (21.2%), fourth-year (10.6%), and fifth-year students (0.9%). Approximately half (54.9%) of the students were from the Faculty of Allied Health Sciences, followed by the Faculty of Science (16.8%), Faculty of Nursing (10.6%), Faculty of Medicine (8.8%), and Faculty of Pharmacy (8.0%). The minority of respondents were from the Faculty of Dentistry (0.9%).

Table 1: Sociodemographic data of respondents (n=113)

	Frequency (n)	Percentage (%)
Age (Mean ± SD)	21.93 ± 1.85	
Gender		
Female	95	84.1
Male	18	15.9
Study level		
Undergraduate	110	97.3
Postgraduate	3	2.7
Year of study		
Year 1	24	21.2
Year 2	27	23.9
Year 3	49	43.4
Year 4	12	10.6
Year 5	1	0.9
Faculty		
Allied Health Sciences	62	54.9
Dentistry	1	0.9
Medicine	10	8.8
Nursing	12	10.6
Pharmacy	9	8.0
Science	19	16.8
Household income		
< RM 4,850	46	40.7
RM 4,851 – RM 10,970	41	36.3
>RM 10,971	26	23.0

Table 2 presents the visiting characteristics of the respondents. More than half (72.6%) of the respondents visit Cafeteria A daily, followed by Cafeteria B (15.9%) and Cafeteria C (11.5%). Regarding duration, most respondents, accounting for 43.4%, have visited the cafeteria for three years throughout their study. Following this, 27.4% of the respondents have used the cafeteria for 2 years, while 17.7% have dined there for less than a year. Besides, 7.1% have been cafeteria customers for a year, 3.5% for four years, and 0.9% for over four years. For the frequency of dining at the cafeteria, approximately half (49.6%) of the students visit the cafeteria twice per day, followed by once per day (39.8%), and thrice per day (9.7%). Only a minority visit the cafeteria more than three times daily (0.9%). As for the daily expenses at the cafeteria, more than half of the students (65.6%) were reported to spend between RM 5 and RM 10. Following this, 26.6% spent RM 11 to RM 15, and 6.3% spent between RM 16 to RM 20 daily. Only 0.9% of the students reported spending less than RM 5, and 0.9% spent more than RM 20 at the cafeterias daily.

Table 2: Behavioral characteristics of the respondents (n = 113)

	Frequency (n)	Percentage (%)
Mostly visited cafeterias		
Cafeteria A	82	72.6
Cafeteria B	18	15.9
Cafeteria C	13	11.5
Duration of dining at the cafeteria		
Less than 1 year	20	17.7
1 year	8	7.1
2 years	31	27.4
3 years	49	43.4
4 years	4	3.5
More than 4 years	1	0.9
Frequency of visits to the cafeteria per day		
1 time	45	39.8
2 times	56	49.6
3 times	11	9.7
More than 3 times	1	0.9
Average daily expenditure at the cafeteria		
< RM 5	1	0.9
RM 5 – RM 10	74	65.5
RM 11 – RM 15	30	26.6
RM 16 – RM 20	7	6.2
> RM 20	1	0.9

The respondents' overall satisfaction with each hostel cafeteria was summarized in Figure 1. Cafeteria B received a total of 69% for satisfaction, indicating that the cafeteria excels and fulfils most of the students' expectations regarding the food service provided. One of the contributing factors is the lower price and reasonably good portion size of the meals. According to the researcher's observation, there is an approximate difference of RM 1 to RM 2 for similar meals and dishes compared to the other two cafeterias. Additionally, the higher satisfaction level

with Cafeteria B may have resulted from the hygienic environment. As for Cafeteria B, it was graded with "A" for its premise. According to the Food Hygiene Regulations (2009), the A grade means that the premises got 80% to 100%, which indicates a good level of cleanliness. Factors influencing food premises grades include location, water supply, pest control, ventilation, food storage, toilet facilities, food handlers' attire and health, food preparation practices, and temperature (Badrul et al., 2024; Kaur et al., 2021). Food premises grading provides individuals with an overview of cleanliness and sanitation standards within the premises. This proves that maintaining a hygienic environment may enhance students' satisfaction. Cafeteria A was placed second for overall satisfaction with 53.1%, followed by Cafeteria C (45.2%). Cafeteria A is the most spacious and has the most customers. However, a lower satisfaction level may be due to the lower level of cleanliness of the dining due to grading and cooking areas. Cafeteria C is reported as having the lowest satisfaction score, which might result from the limited menu, as it was observed to have limited options for breakfast and lunch menus. Thus, students have to travel to other cafeterias to buy food. Overall, the majority of the respondents rated Cafeteria A and B as satisfied, while the majority rated Cafeteria C as neutral.

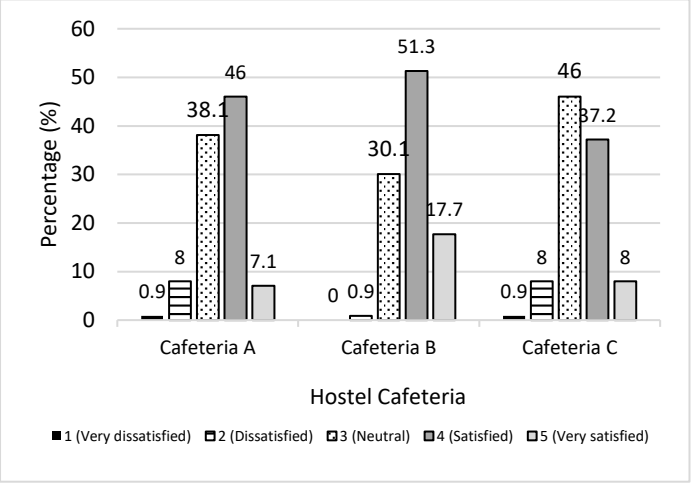

Figure 1: Percentage of total students' satisfaction level with hostel cafeterias

As presented in Table 3, overall, the total mean scores of all domains were above 3, indicating that the respondents were satisfied with all the food service attributes. The high score for price and value fairness indicates that students were most satisfied with the prices offered at the cafeterias. This was supported by previous studies by Mahmood (2023) that found almost half of the students were satisfied with the pricing of the food. This indicates that the food prices were perceived as reasonable and affordable for university students with limited budgets, given the portion size received. Following price and value fairness, the domain ambience also received a high score, reflecting the cafeteria environment's comfortability and cleanliness. The result was consistent with the findings of Rajpoot and Gahfoor (2020) and Asghar (2023). These results show the importance of maintaining a good physical environment with a pleasant view, hygiene, and comfortable seating to leave a positive dining experience.

On the other hand, food quality and variety recorded the lowest satisfaction scores by the students. The lowest score, indicating the most dissatisfaction in the food quality domain, was the freshness of food, which may be related to the ingredients used, such as chicken, fish, and vegetables.

The descriptive analysis of the food quality domain revealed that the taste of the food has the highest mean value (M = 3.63, SD = 0.746) while the freshness of the food has the lowest mean value (M = 3.21, SD = 0.871) (Table 3). The lowest score, indicating the most dissatisfaction in the food quality domain, was the freshness of food, which may be related to the ingredients used, such as chicken, fish, and vegetables, which might affect the taste and texture of the food. According to the World Health Organization (WHO) (2022), the freshness of food correlates with the safety of the food, meaning that non-fresh food, especially raw food, potentially poses a harmful effect, such as foodborne illness, to consumers. To ensure food safety, it is essential to serve dishes at proper temperatures, which both Cafeteria A and B manage using a bain-marie to keep food warm and quality. However, most food items at the three cafeterias are not adequately covered, leaving them vulnerable to contamination from flies and other pests. This poor practice poses a high risk of foodborne illnesses, which could deter students from returning to the cafeteria.

Regarding food variety, the variety of fruits and vegetable options has the lowest means (M = 3.04, SD = 1.093). It was observed that all three cafeterias provided many types of vegetable dishes, but they were similar every day. Moreover, the only cafeteria that offers cut fruits is Cafeteria A, but the variety is very limited, which raises students' dissatisfaction with the availability of fruits and vegetables. Moreover, the absence of a chiller or freezer in hostel buildings limits the types and number of fruits the students can buy off-campus and store. Thus, the limited availability and variety of fruits at the cafeterias pose a barrier for the students to consume adequate fiber in their daily meals (Borrelli, 2016).

Table 3: Descriptive analysis of items in each domain

Items	Mean	Std. Deviation
Food Quality	3.45	0.690
Taste of food	3.63	0.746
Appearance of food	3.50	0.836
Freshness of food	3.21	0.871
Nutritional content of food	3.44	0.801
Ambience	3.67	0.74
Cleanliness of facilities	3.54	0.887
Cleanliness of cutlery and crockery	3.50	0.937
Seating comfortability	3.73	0.858
Appropriate lighting	3.92	0.908
Service Quality	3.62	0.714
Courteous staff	3.66	0.902
Staff respond to request	3.67	0.871
Staff apply hygiene procedures while serving food	3.55	0.845
Staff work quickly	3.65	0.924
Length of operating hours	3.56	1.141
Price and Value Fairness	3.68	0.861
Reasonable price	3.65	0.935
Appropriate portion size	3.71	0.893
Food Variety	3.41	0.701
Variety of fruits and vegetables options	3.04	1.093
Variety of breakfast menu	3.26	0.989
Variety of lunch menu	3.85	0.899
Variety of dinner menu	3.50	0.888

Pearson Correlation Analysis

Table 4 summarizes the result of the Pearson Correlation analysis used to identify which attributes strongly influence overall satisfaction. The correlation analysis showed a significant relationship as the p-value was less than 0.05 ($p < 0.01$) for all domains. Service quality strongly correlates with the overall satisfaction score ($r = 0.582$, $p < 0.01$). It is followed by ambience ($r = 0.529$, $p < 0.01$), food quality ($r = 0.520$, $p < 0.01$), and food variety ($r = 0.469$, $p < 0.01$). The domain price and value fairness have the weakest positive correlation with overall satisfaction ($r = 0.426$, $p < 0.01$).

Table 4: Result of correlation analysis

	Variables	1	2	3	4	5	6
1	Food Quality	1					
2	Ambience	.568*	1				
3	Service Quality	.598*	.671*	1			
4	Price and Value Fairness	.347*	.392*	.500*	1		
5	Food Variety	.427*	.451*	.564*	.382*	1	
6	Overall satisfaction	.520*	.529*	.582*	.426*	.469*	1

*All the correlations are significant at the p-value <0.05.

Among the five domains, the correlation analysis showed that service quality has the strongest positive correlation with overall satisfaction. This result corresponds with the previous studies (Serhan & Serhan, 2019; Asghar, 2023). This positive relationship between service quality and satisfaction indicates the importance of excellent service in predicting the students' perception of the cafeteria's food service. If students feel their needs are fulfilled, their satisfaction with the service increases as they receive a pleasant experience. Therefore, cafeteria employees should receive continuous training in handling and greeting customers politely and attentively to maintain a friendly and pleasing atmosphere in the dining area.

Following service quality, ambience, food quality, and food variety also exhibit significant positive relationships with overall satisfaction. Interestingly, although the domain price and value fairness also positively influence satisfaction level, it has the weakest correlation, indicating that the students put less priority on price than other attributes such as service quality, ambience, food quality, and food variety. This aligns with the findings by Abdullah et al. (2019) and Mahmood (2023) that the students might perceive reasonable and affordable prices for the food and beverages offered. This shows that multiple factors influence students' satisfaction.

While this study provides valuable insights, certain limitations should be acknowledged. First, the sample size is much lower than required due to a limited number of eligible respondents and time constraints. Thus, the generalizability of the result could not represent the whole university population in Kuantan, Pahang. Also, the comparison between groups, such as gender, could not be made due to an unproportioned number of respondents. Therefore, future research could consider comparing demographic factors such as gender and year of study, and this could be done by ensuring sufficient sample sizes were collected, with a proportional number of each group. Second, the study area only includes three residential cafeterias on campus, while there are many more cafeterias in each faculty building. Expanding the scope to include all the cafeterias on campus, such as the ones at faculty buildings, in future studies would provide more insights into the satisfaction levels with cafeterias' food service within the campus.

CONCLUSION

This study explored students' satisfaction levels with the food service attributes of on-campus cafeterias in Kuantan. The results revealed that all five domains, namely food quality, ambience, service quality, price and value fairness, and food variety, significantly correlate with

students' satisfaction levels. The service quality domain has the strongest positive correlation with overall satisfaction, followed by the ambience, food quality, food variety, and price and value fairness. These findings contribute to understanding several food service areas that may need improvement to enhance the students' satisfaction levels with their dining experience on campus.

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ORIGINAL ARTICLE

Hospital Food Service Satisfaction Level and Associated Factors among Inpatients in a Teaching Hospital

Mimi Nur Syuhada Ahmad Nasirin[1], Roszanadia Rusali[1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Hospital food service; satisfaction level; inpatients

ABSTRACT

Background: Hospital food services play a significant role in aiding with the process of recovery and the well-being of the patients apart from the treatment received and the medication as such. Monitoring and assessing the level of satisfaction with hospital food services among patients is important to provide them with first-rate service that can meet their dietary requirements and needs. Thus, the objective of this study was to assess the level of satisfaction with hospital food service and associated factors among inpatients in a teaching hospital. **Methods:** This survey was conducted among 34 patients aged 18 – 65 years old who admitted at a teaching hospital in Kuantan, Pahang. Those who consumed at least three hospital main meals including breakfast, lunch, and dinner were asked to complete a questionnaire which had 3 sections: a) socio-demographic background, b) general characteristics, and c) food service satisfaction questionnaire (Patients' Satisfaction toward Hospital Food Service Questionnaire. **Results:** Majority of the patients were satisfied with the food service provided(n = 9, 26.5%), followed by highly satisfied (n = 8, 23.5%), moderate (n = 8, 23.5%), dissatisfied (n = 6, 17.6%), and highly dissatisfied (n = 3, 8.8%). In addition, the results identified a significant correlation between food attributes, staff issues, meal distribution time, physical and social factors and overall satisfaction ($p < 0.01$). **Conclusion:** This study provides valuable insight into patient satisfaction with hospital food services and the factors associated with it. These findings underscore the need for continuous monitoring and improvement in hospital food services to better meet patient expectations and enhance their overall hospital experience.

INTRODUCTION

Background

Hospital food services play a significant role in aiding with the process of recovery and the well-being of the patients apart from the treatment received and the medication as such. It is because, in the process of getting better, patients need a healthy and well-balanced diet that suits their needs in addition to the medical treatment. Monitoring and assessing the level of satisfaction with food services among patients is important to provide them with first-rate service that can meet their dietary requirements and needs (Azeman et al., 2018). However, many people have a negative perception of hospital food, believing that it is bland, unappetizing, flavourless, cold, improperly displayed, and poorly served. Also, malnutrition may occur among hospitalised patients due to inadequate consumption of food among them (Ibrahim et al., 2017; Mangunsong & Junadi, 2018). Undernutrition is a common malnutrition issue in hospital settings and can arise among patients due to dissatisfaction with food service. This is because, according to Theron & O'Halloran (2022), majority of hospitalised patients had low dietary intake and poor absorption. Other than that, patients also fail to reach their energy needs for various reasons including loss of appetite, prescribed fasting, and nausea (Rinninella et al., 2023).

It also found that the level of satisfaction with hospital food services is distinct in every country that has been studied. In Saudi Arabia and Pakistan, the overall satisfaction with the quality of food services was 78.8% and 91% respectively (Abdelhafez et al., 2012; Sadaf et al., 2018). In contrast, research conducted in Malaysia revealed that only 53.3% of patients evaluate hospital food services as 'okay', and 32% of them rated hospital food services as either 'very good' or 'good' (Aminuddin et al., 2018). Identifying the factors that contribute to the dissatisfaction is important to make a better strategy to improve food services. When the root of the problem has been identified, then the healthcare organization can improve the quality of care that meets the patient's expectations and generate the presence of a patient-centered approach. Vijayakumaran et al. (2016) found that patients admitted to hospitals that use an in-house food service system had a better overall experience than hospitals using outsourced food service. The existing literature reviews lack of study that investigate the satisfaction of patients at a teaching hospital that used an outsourced centralized food service system. The study outcome will be useful in gaining insight into other similar

* *Corresponding author.*
E-mail address: roszanadia@iium.edu.my

healthcare settings that practice an outsourced food service model. This study is aimed to assess the hospital food service satisfaction level and associated factors among inpatients in a teaching hospital in Kuantan, Pahang.

MATERIALS AND METHODS

Study design and setting

A cross-sectional study design was used in this study. The study was conducted in a teaching hospital in Kuantan, Pahang.

Study population

The subjects were selected among inpatients in all wards excluding ICU and paediatrics wards in a teaching hospital located in Kuantan, Pahang. Eligible to participate in this study were adult patients aged 18 – 65 years old, who consumed at least a breakfast, lunch, and dinner from the hospital meals regardless of the length of stay in the hospital, received a normal and/or therapeutic diet, and were able to communicate.

Sampling method and sample size

Stratified sampling was used in this study. The patients were grouped based on designated wards; medical, surgery, orthopaedics, obstetrics and gynaecology (O&G) wards.. Within each ward, patients were randomly selected for inclusion based on predefined inclusion and exclusion criteria. This approach ensured that the sample included patients from all designated wards, providing a comprehensive representation of the patient population across the hospital. The sample size for this study was 34 subjects .

Ethical Consideration

Ethical approval was obtained from the Kulliyyah Postgraduate and Research Committee (KPGRC) (KAHS30/24) and from the International Islamic University Malaysia Research Ethical Committee (IREC) and Sultan Ahmad Shah Medical Centre (SASMEC) (IIR24-43).

Research Instruments

The satisfaction of patients toward hospital food service and associated factors was measured using the Patients' Satisfaction Towards Hospital Food Services Questionnaire adapted from Boughoula et al. (2020). The questionnaire was primarily self-administered by the patients. However, the researcher assisted when needed to ensure clarity and completeness. Before distribution, the researcher explained the study's objectives and provided detailed instuctions on how to complete the questionnaire. The questionnaires were distributed during mealtimes for convenience, and the completed forms were collected by the researcher once the patients had finished. The questionnaire comprised three different sections: A) socio-demographic, B) general characteristics, and C) food service satisfaction questionnaire.

Section A: Socio-demographic

This part included questions such as age, gender, education level, occupational sector, household income, marital status, and races.

Section B: General characteristics

This section included questions about types of wards, medical condition, length of hospital stay, type of diet, intake of food during hospital stay , and dependency on hospital food.

Section C: Food service satisfaction

Patients Satisfaction with Hospital Food Service questionnaire was used (Boughoula et al. 2020). It was translated back-to-back from English to Malay. The questionnaire was reviewed by to experts specializing in Teaching English as a Second Language (TESL) and four lecturers who have backgrounds in food service and dietetics to provide feedback on the content and clarification of terms before the actual data collection commenced. The questionaire comprised four underlying dimensions of patients' satisfaction with hospital food service including dimension food attributes, staff issues, meal distribution time and physical and social dimensions. There were 12 questions on food quality attributes in the dimension of food attributes; 4 questions dealt with staff issues; 5 questions in the dimension of mealtimes, and 3 questions related to environment in the physical and social dimension sector. Patients were asked to show their level of satisfaction by selecting a response on a 5-point Likert scale with the maximum point was 5, and the minimum point was 1. The highest scale was 5 for highly satisfied, 4 for satisfied, 3 for moderate, 2 for dissatisfied, and the lowest scale was 1 for highly dissatisfied. A mean score of $\leq$2.50 was considered as dissatisfied, with a score of $\geq$2.50 but $<$3.50 was moderate, and a score of 3.50 was satisfactory.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 17.0. Descriptive statistics were used to summarize the subjects' socio-demographic, general characteristics data and satisfaction levels. The association between overall satisfaction and associated factors influencing patients' satisfaction with

hospital food service was examined using Spearman's rank correlation analysis with a significant value p, 0.05.

RESULTS

Socio-demographic background

A total of 34 inpatients from a teaching hospital aged between 20 to 65 years old were recruited in this study with the majority of the subjects aged between 51 and 65 years old (n = 22, 64.7%). Overall, more females (n = 18, 52.9%) than males (n = 16, 47.1%) participated in this study. In addition, it was found that most subjects had completed secondary education (n = 11, 32.4%). Besides, the highest number of subjects were either retired or not working (n = 13, 38.2%). The majority of the patients had a household income range of less than RM 5250 (n = 28, 82.4%). In terms of marital status, most of the patients were married (n = 30, 88.2%). Last but not least, the majority of subjects recruited were Malay (n = 33, 97.1%). (Table 1).

Table 1: Socio-demographic characteristics of inpatients in teaching hospital (n=34)

Characteristics	Variables	Frequency (n)	Percentage (%)
Age	1	0	0
	≤20	3	8.8
	21 – 30	5	14.7
	31 – 40	4	11.8
	41 – 50	22	64.7
Gender	Male	16	47.1
	Female	18	52.9
Educational Level	No education/ primary	9	26.5
	Secondary	11	32.4
	Diploma	5	14.7
	Bachelor/ Master/PhD	9	26.5
Occupational Sector	Private	7	20.6
	Government	10	29.4
	Self	4	11.8
	Not working/ retired	13	38.2
Household Income (RM)	≤RM 5250	28	82.4
	RM 5250 – RM 11819	6	17.6
	≥RM 11 819	0	0
Marital Status	Single	3	8.8
	Married	30	88.2
	Widow	1	2.9
Race	Malay	33	97.1
	Chinese	0	0
	Indian	1	2.9
	Others	0	0

General characteristics of inpatients in a teaching hospital

About 18 patients (52.9%) came from internal medicine wards. Next, the most common medical problems among participants were diabetes (n = 7, 20.6%) and hypertension (n = 7, 20.6%). The majority of participants stayed less than a week in the hospital (n = 25, 73.5%). Aside from that, the highest number of participants in this study received the therapeutic diet (n = 20, 58.8%). Besides, the majority of the participants responded that their intake did not change during their hospital stay (n = 18, 52.9%). Lastly, most of the participants did not depend solely on the hospital food (n = 22, 64.7%). (Table 2)

Table 2: General characteristics of inpatients in a teaching hospital (n=34)

Characteristics	Variables	Frequency (n)	Percentage (%)
Type of wards	Internal Medicine	18	52.9
	Surgery	9	26.5
	Orthopaedics	4	11.8
	O&G	3	8.8
Medical status	None	5	14.7
	Diabetes	7	20.6
	Kidney disease	2	5.9
	Stroke	6	17.6
	Hypertension	7	20.6
	Others	7	20.6
Length of hospital stay	≤1 week	25	73.5
	1 – 2 weeks	8	23.5
	2 – 4 weeks	1	2.9
Type of diet	Normal	11	32.4
	Therapeutic	20	58.8
	Not sure	3	8.8
Intake of food during hospitalisation	Decreased	16	47.1
	Not changed	18	52.9
	Increased	0	0
Dependence on hospital food	Yes	12	35.3
	No	22	64.7

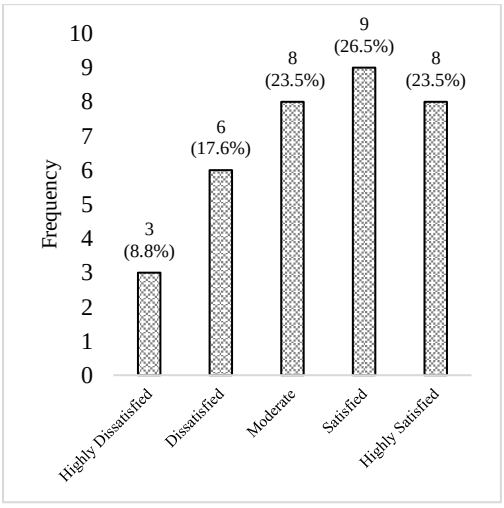

Figure 1: Overall food service satisfaction levels among teaching hospital patients (n=34)

Table 3: The mean satisfaction score according to the food service dimensions (n=34)

Food service dimension	**Mean score ± SD**
Food attributes	
The meal tastes nice	3.38±1.28
I like the way vegetables are cooked	3.41±1.23
The meat quality (chicken and fish) served to me is the best	3.74±1.05
The texture of meals is good and suitable for my condition	3.91±1.24
Portion size of my meals are suitable and enough for me	4.35±0.95

The drinks served are just at the right temperature	4.09±1.00
The hot foods are just at the right temperature	4.00±1.16
The cold foods are just at the right temperature	4.00±1.23
I can choose healthy food in the hospital	3.91±1.06
The colour of my meals is attractive	3.65±1.13
The smell of my meals is nice and good	3.59±1.19
The fruit served is fresh	4.53±0.71
Staff issues	
The staffs who deliver and collect my meals are neat and cleans	4.74±0.62
The staffs (nurse or foodservice personnel) are willing to help patient with eating difficulties	4.12±0.91
The staffs have explained to me about my diet	3.18±1.11
The staffs who deliver and collect my meal are friendly and polite	4.35±0.77
Meal distribution time	
The mealtime for breakfast is suitable	4.65±0.65
The mealtime for lunch is suitable	4.65±0.65
The mealtime for tea is suitable	4.65±0.65
The mealtime for dinner is suitable	4.65±0.65
The meal served punctually according to schedule	4.68±0.59
Physical and social	
The hospital or ward scent stops me from enjoying my meals	4.53±0.75
The noise at hospital or ward disturbs me from enjoying my meals	4.50±0.75
The duration given to finish the meal is enough	4.62±0.60
Overall satisfaction	
Overall, I am satisfied with the food service in this hospital	3.82±1.26

Patients' satisfaction towards hospital food service

Overall satisfaction of hospital food service

The mean score for overall satisfaction with the food service in the present study reported a satisfactory level among patients. The frequency and percentage of overall satisfaction with hospital food services are presented in Figure 1. Majority of the patients were satisfied with the food service provided in the teaching hospital (n = 9, 26.5%), followed by highly satisfied (n = 8, 23.5%), moderate (n = 8, 23.5%), dissatisfied (n = 6, 17.6%), and highly dissatisfied (n = 3, 8.8%).

In Table 3, statements from patients' satisfaction with the hospital food service questionnaire and the mean score of each statement were presented. Among the four dimensions studied, participants were most satisfied with the dimension of meal distribution time (4.65±0.63), followed by physical and social (4.55±0.60), staff issues (4.10±0.58), and food attributes (3.88±0.87). The most positively rated statement was "The staff who deliver and collect my meals are neat and clean" (4.74±0.62). Meanwhile, the statements "The staff has explained to me about my diet," "The meal tastes nice," and "I like the way vegetables are cooked" were the lowest on the list with the scores of 3.18±1.11, 3.38±1.28, and 3.41±1.23, respectively. Thus, it can be concluded that the participants were satisfied with the food service provided by this hospital.*Relationship between the associated factors and overall satisfaction*

Table 2 presents the relationship between the associated factors and overall satisfaction level. The correlations between overall patient satisfaction and various factors influencing hospital food services, "food attributes," "staff issues," "meal distribution time," and "physical and social" were evaluated. The results showed a significant correlation between all the factors and overall satisfaction.

Table 2: Relationship between associated factors and overall satisfaction

Variables	1	2	3	4	5
1 Food Attributes	1				
2 Staff Issues	0.335*	1			
3 Meal Distribution Time	0.569*	0.625*	1		
4 Physical and Social	0.385*	0.491*	0.772*	1	
5 Overall Satisfaction	0.827*	0.590*	0.563*	0.371*	1

*All the correlations are significant at the 0.01 level (2-tailed)

DISCUSSION

The most important findings were that, overall, patients were satisfied with the food service provided in this hospital and each of the food service dimensions. Other than that, the highest satisfaction was with meal distribution time, and the lowest was with food attributes. Firstly, the result indicated the patients were satisfied with overall food services in the teaching hospital. This level of satisfaction was higher compared to the other studies in countries like Iran (Safarian et al., 2018) and Egypt (Al-Torky et al., 2016). A possible justification for the variation in satisfaction includes the distinct menus provided by each hospital, differences in the target populations, the influence of various methodologies, and the diverse individual values of patients (Abdelhafez et al., 2012).

In addition, mealtime distribution received the highest score of all the factors. This finding is consistent with the study by Saus & Sucheran (2021) and Safarian et al., 2018), which found high satisfaction with meal distribution time. Patients were most likely satisfied with all mealtimes: breakfast, lunch, evening tea, and dinner, agreeing that the meal was distributed on time. When meals are served

on time, patients are less likely to be overly hungry or have reduced appetite, which can negatively impact their food intake. A study by Teka et al. (2022) discovered that delays in meal service had a negative impact on patients' perception of meal taste and temperature, resulting in lower satisfaction levels.

Another interesting finding is that physical and social aspects received the second-highest score. The majority of the patients were satisfied with the hospital's environment, including the smell and noise, stating that it did not disturb them from enjoying their meals. From the researcher's perspective, the physical and social aspects received a high score in this study because of several factors. First, there were no unpleasant smells in the wards, such as medication smells or bodily fluids, which could reduce patients' appetite. In addition, the patients stated that there was no loud noise, such as sound from medical equipment or staff conversation, that could disrupt mealtimes.

Besides, it is observed in this study that patients were satisfied with the staff issues. The findings revealed that the majority of patients were pleased with the neatness and cleanliness of the food delivery staff. This implies that the staff likely maintained high standards of hygiene and appearance, which is vital in a healthcare setting. Regardless, it should also be noted that one of the statements in the staff issue dimension, which is "The staff have explained to me about my diet", had the lowest score among individual statements. Patients claimed that the staff just put the food on the table and did not explain whether it was a normal or therapeutic diet. As the teaching hospital was an outsourced food service system, the staff distributing the meal may lack necessary nutritional skills or not received adequate training on dietary requirements to explain the meal to the patients. Patients might be confused about why certain foods are included or excluded from their meals without proper explanation. As a result, staff should take the time to explain each meal, making patients feel informed and valued. Healthcare food service personnel play a crucial role as they are responsible for preparing and serving a substantial number of meals daily. In addition, their work is vital not only for maintaining patient health through proper nutrition but also for enhancing the overall patient experience during their stay in healthcare facilities (Osman et al., 2022).

Another finding is that dimension food attributes had the lowest score of the four dimensions studied. This study is consistent with the findings of Mangunsong & Junadi (2018), Miyoba & Ogada (2019), and Rapo et al. (2021). Some subjects expressed concern about food characteristics such as taste, smell, color, and texture of the food. In this context, they complained that the food was sometimes unappetizing and bland and that fish dishes often had a fishy smell, causing patients' appetites to decrease. They also claimed that the color of their meals was unappealing and the texture of their meal was not suitable for their health condition. However, this output may be less relevant for patients on therapeutic diets, where dietary restrictions frequently limit the use of salt, sugar, and any other flavour enhancers in order to meet specific dietary requirements. According to Safarian et al. (2018), patient dissatisfaction with the taste and appearance of hospital foods could be due to the unfamiliarity of the food, changes in the daily diet, medical conditions, or the effects of medication.

While this study provides valuable insights into patient satisfaction with hospital food services, several limitations should be acknowledged. First, the study was conducted in a single teaching hospital. In addition, this study focuses on a single point in time to assess patient satisfaction. Patient satisfaction with hospital food services may fluctuate throughout the course of hospitalization due to various factors, such as changes in health status, meal delivery experiences, or alterations in the hospital environment. To capture these variations, future studies should collect satisfaction data at multiple time points, such as admission, mid-stay, and discharge, for a better understanding of how satisfaction evolves and is influenced by recovery or changes in the hospital environment.

CONCLUSION

This study provides valuable insight into patient satisfaction with hospital food services and the factors associated with it. Overall, the patients express satisfaction with the food service provided at the teaching hospital, highlighting the importance of timely meal distribution and the physical and social aspects of the hospital environment. However, it is important to take note of additional factors, such as food attributes and staff issues, which received lower satisfaction scores need to be noted as well. These findings underscore the need for continuous monitoring and improvement in hospital food services to better meet patient expectations and enhance their overall hospital experience.

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ORIGINAL ARTICLE

The Development of an Educational Video on Sports Nutrition for Silat Athletes in Malaysia

Nur Athirah Mohd Zin[1], Muhamad Ashraf Rostam[1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords: sports nutrition; silat athletes; educational video

ABSTRACT

Background: Possessing sound knowledge of sports nutrition will influence optimal daily nutritional intake thus producing ideal athletic performance, especially during competitions. Educational videos are effective tools to increase knowledge about sports nutrition. However, limited resources are available that fit exclusively to our Malaysian athletes, particularly in Silat. **Methods:** A sports educational video was developed which focused on the required dietary intake for competition day, emphasizing the importance of practicing nutrient timing at every game window. The first draft of the video was evaluated in terms of suitability, understandability, and actionability. The Suitability Assessment of Materials (SAM) was completed by experts to identify the suitability of the video contents for Silat athletes as the target population. Meanwhile, Silat athletes were recruited to evaluate the understandability and actionability of the video. They were required to determine if they could understand and act on the information from the video. **Results:** The video with a duration of 6 minutes and 56 seconds was produced to match the unique demands of Silat Olahraga competitions, offering dietary recommendations specifically for Silat athletes. The final total score for suitability evaluation was 86 percent which indicates that the educational video is considered superior material for the suitability assessment of educational content. Meanwhile, the understandability evaluation yielded a score of 367 points out of a possible 372 points, resulting in a percentage of 99 percent. For actionability, the score was 92 out of 93 points, yielding a percentage of 99 percent. **Conclusion:** The evaluation findings from experts and targeted respondents among Silat athletes concluded that the newly developed nutritional education video is suitable for use and has an acceptable level of understandability and actionability.

INTRODUCTION

Silat, or traditional martial arts, is well known in Southeast Asia, including Indonesia, Brunei, Philippines, Singapore, and Malaysia. It is one of the most significant cultural heritages in Malaysia as well as Nusantara Indonesia. In 2019, it gained acknowledgment from the United Nations Educational, Scientific, and Cultural Organization (UNESCO) and was enlisted as an intangible cultural heritage of our country, Malaysia (Yulisman, 2019). As Silat is a form of combative sport used to have intermittent or high-intensity training, greater carbohydrate consumption among athletes is always relevant to provide extra strength and increase muscle glycogen production.

Throughout prolonged and intense training activities, higher carbohydrate intake is a must according to the specific recommended intake for athletes to overcome the reduction of glycogen storage. In the context of Seni Silat Gayung Fatani Club, coaches will plan multiple training activities for their athletes as preparation before competing tournaments (H. Mohd Ariff, personal communication, December 5, 2023). Various types of comprehensive training must be completed with a duration of at least six months before the date of the competition. The effectiveness of prolonged training was proven in a study to make Silat exponents able to develop the highest strength during performance (Shapie et al., 2022). Therefore, proper dietary intake is essential to support this type of lifestyle.

*Corresponding author.
E-mail address: ashrafrostam@iium.edu.my

Sports Nutrition Knowledge

Nutrition knowledge helps athletes make optimal choices for their diet. Sports nutrition knowledge covers many aspects including food portion for athletes, meal timing and refueling, food for injuries and recovery, hydration, and fluid balance. Each of the these different aspect has significant impact on athletes not only in achieving peak sports performance but also in the process of recovering muscle and body, lowering potential injuries and exhaustion (Thomas et al., 2016). Limited knowledge on nutrition may affect unhealthy eating behaviour and increase the risk of injury (Close et al., 2019; Klein et al., 2021).

Video as an Intervention

Educational videos related to sports nutrition is an effective platform to instill proper dietary practices among athletes (Brame, 2016). Videos have become a preferable platform for providing information and knowledge as they have a considerable potential to capture a broader audience (Tuong et al., 2014). It can easily be accessed by the audience, whether on any social media platform or online application like YouTube. Online video is fitting for educational intervention methods as one research study by Juhong et al., (2023). Nevertheless, there are limited numbers of reliable and factually correct educational videos found on the YouTube platform. According to a study that examined the reliability and quality of sports nutritional videos on YouTube, among 114 videos, only 22.8 percent of them had evidence-based knowledge of nutrition information, while the remaining videos were associated with misbelief, anecdotal, personal experience, and not supported by evidence. The majority of videos were presented by non-professional persons while the videos that contained the correct and reliable nutrition information regarding sports were delivered by dietitians, athletes and trainers, and other sports nutrition professionals (Kiss et al., 2023). Furthermore, there is a limited number of sports nutrition videos that fits exclusively for Malaysian athletes, particularly in the area of Silat. Therefore, this research is conducted to develop a suitable, understandable, and actionable educational video for the use of Malaysian Silat atheletes.

MATERIALS AND METHODS

Research Design

This study was designed to develop an educational video and validate its contents. The sports educational video was developed using CapCut and Canva. The contents of the video were based on credible and reliable sources such as journals and research articles. The topic of the video was the dietary intake for competition day emphasising the importance of practicing nutrient timing at every game window. The video draft was then evaluated in terms of suitability, understandability, and actionability.

Participants

There were two different groups of population involved in this study. The first group was among a panel of six experts in nutrition and dietetics who were selected based on their academic backgrounds and working experiences. The second group was the main target viewers of this video, particularly Silat athletes of *Silat Seni Gayung Fatani* Club in Melaka. The inclusion and exclusion criteria for the field experts and targeted viewers are shown in Table 1 and Table 2, respectively.

Table 1: The inclusion and exclusion criteria for the evaluation of suitability among experts.

Category	Inclusion	Exclusion
Participants	1. Experts in nutrition and dietetics 2. Have at least two years of working experience	Not an expert in nutrition and dietetics

Table 2: The inclusion and exclusion criteria for the evaluation of understandability and actionability among target viewers.

Category	Inclusion	Exclusion
Participants	1. Athletes aged 13-21 2. Silat athletes of Seni Gayung Fatani club 3. Athletes who have experience in joining at least one silat competition	Athletes aged below 13 years old

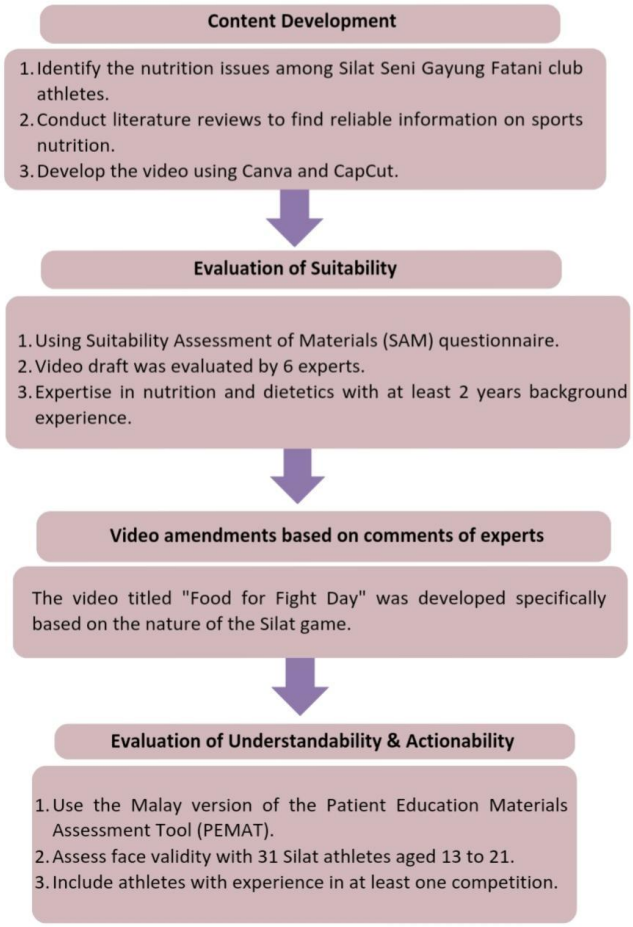

Figure 1: Methodology flow chart

Figure 1 shows the flow chart of the research methodology.

Phase 1: Development of an educational video on sport nutrition

The educational video on sports nutrition was designed to empower Silat athletes with crucial knowledge about nutrient timing and hydration strategies tailored specifically for their sport's competitive demands. The video's content focused on key topics, including the role of macronutrients as energy sources, pre-event meals, during-event snacks, post-event recovery meals, and effective hydration strategies.

The content was meticulously developed based on a comprehensive literature review, with selected scientific articles forming the backbone of the educational material (refer to Table 5). The video embraced an engaging format, seamlessly combining voiceover explanations with visually captivating graphics created using Canva®. Final edits, such as sound adjustments and the addition of subtitles, were handled using CapCut®, ensuring the video was both professional and accessible to diverse audiences.

Recognizing the audience's linguistic preferences, the video was created in Malay, the native language of most viewers, and English subtitles were added to accommodate non-Malay speakers. English information from the literature review were translated into Malay by the researcher, who is a native speaker, ensuring accuracy, cultural relevance, and ease of understanding.

Before reaching the target audience, the video underwent a rigorous evaluation process by six experts specializing in sports nutrition and education. These experts assessed the footage on multiple dimensions: content quality, literacy demand, graphics, and cultural appropriateness**.** Only after their validation did the video proceed to the next stage, where respondents evaluated its understandability and actionability. By prioritizing cultural sensitivity, scientific accuracy, and viewer engagement, this educational video is a valuable tool to guide Silat athletes toward peak performance and informed nutrition practices on competition day.

Phase 2 (a): Evaluation of suitability

The Suitability Assessment of Materials (SAM) tool was utilised in this study to measure the suitability of the video in terms of video content, literacy demand, graphics, layout, learning stimulation or motivation, and the culture of the intended viewers (Doek et al., 1996). And the total number of items that would be assessed for this study is only 10 items. A panel of six evaluators consisting of two sports dietitians, one combat sports officer, and three lecturers with expertise in nutrition and dietetics reviewed the content of the educational video and evaluated it according to the online survey of SAM that had been disseminated through their email. This evaluation was carried out after they watched the educational video provided via a YouTube link, which had been shared together with the Google form link for evaluation in their email.

Phase 2 (b): Evaluation of understandability and actionability

The Patient Education Materials Assessment Tool for Audio-visual Materials (PEMAT-A/V) questionnaire was used in this study to assess the understandability and actionability of the video (Wong et al., 2019). The Patient Education Materials Assessment Tool (PEMAT) questionnaire was chosen as an assessment tool in this

study. It functioned to determine whether target respondents would be able to understand and act on information from the video. It is a systematic method for the evaluation of education material to test the understandability and actionability of user education materials (Shoemaker et al., 2014). They are Content, Word choice and style, Organization, Layout and design, and Use of visuals with total of 12 items. For actionability, there are 3 items assessed. To streamline the evaluation process, a WhatsApp® group named "Respondents for Educational Video" was established to gather all the respondents who volunteered to participate in this study. Then, they were provided links to watch the educational video and access the online PEMAT questionnaire to complete the evaluation process. Similarly, in Phase 2 (b), they were instructed to watch the educational video before attempting to answer the questionnaire.

RESULTS & DISCUSSION

Development of the video

The educational video entitled "*Pemakanan di Hari Pertandingan*" which in english means "Food for Fight Day" is aimed to provide Silat athletes with precise and reliable information on sports nutrition, emphasising the crucial role of nutrient timing on tournament day. The video with a duration of 6 minutes and 56 seconds, was meticulously designed to match the unique demands and timing of Silat Olahraga competitions, offering dietary recommendations specifically for Silat athletes. The video was structured into seven areas which are 1) introduction, 2) types of macronutrients, 3) food for before the tournament, 4) food for during the tournament, 5) food for after the tournament, 6) strategies for staying hydrated, and 7) summary. The final editing, including sound adjustments and the addition of subtitles, was completed using a video editing software, CapCut. The structure and content of the video based on each focus area is summarised in Table 5.

Evaluation of suitability assessment

The educational video received a total suitability score of 83 out of 96 points, translating to an impressive 86 percent. To calculate this, the total score was divided by the maximum possible score and then multiplied by 100 to convert it into a percentage.

According to Doak et al. (1996), materials with a percentage rating between 70 and 100 percent are classified as superior for educational suitability. This indicates that the video not only meets but exceeds the criteria for high-quality, engaging, and effective educational content. These results underscore the video's strength in delivering clear, actionable, and culturally relevant information tailored to the target audience.

Table 3: Score for the suitability of educational video on content (n=6)

Question	Score	Frequency (%)
Purpose of the video		
- The purpose is explicitly stated in title, or cover illustration, or introduction	2	5 (83.3%)
- The purpose is not explicit. It is implied, or multiple purposes are stated	1	1 (16.67%)
- No purpose is stated in the title, or cover illustration or introduction	0	0 (0%)
Content about behaviours		
- The essence of the material is application of knowledge/ skills aimed at desirable reader behaviours rather than non behaviour facts	2	4 (66.7%)
- At least 40 percent of content topics focus on desirable behaviour or actions	1	2 (33.3%)
- Nearly all topics are focused on non behaviour facts	0	0 (0%)
Scope of the video		
- The scope is limited to and focused on essential information directly related to the purpose. Experience shows it can be learned in the time allowed.	2	4 (66.7%)
- The scope is expanded beyond the purpose, no more than 40 percent is nonessential information. Key points can be learned in the time allowed.	1	2 (33.33%)
- The scope is far out of proportion to the purpose and time allowed.	0	0 (0%)
Vocabulary used		
- All three factors: i) Common words are used nearly all the time, ii) Technical concept, category, and value judgment (CCVJ) words are explained by examples, iii) Imagery words are used as appropriate for content.	2	3 (50%)
- i) Common words are frequently used, ii) Technical and CCVJ words are sometimes explained by examples, iii) Some jargon or math symbols are included.	1	3 (50%)
- Two or more factors: i) Uncommon words are used, ii) No examples are given for technical and CCVJ words, iii) Extensive jargon	0	0 (0%)

Type of graphics		
- Both factors: (i) Simple, adult-appropriate, line drawings/sketches are used. (ii) Illustrations are likely to be familiar to the viewers.	2	4 (66.7%)
- One of the superior factors is missing.	1	2 (33.3%)
- None of the superior factors are present.	0	0 (0%)
Relevance of illustrations		
- Illustrations present key messages visually so the reader/viewer can grasp the key ideas from the illustrations alone. No distractions.	2	5 (83.3%)
- Illustrations include some distractions.	1	1 (16.7%)
- Insufficient use of illustrations. Factors : (i) Confusing or technical illustrations (non-behaviour related), (ii) No illustrations	0	0 (0%)
Captions used for graphics		
- Explanatory captions with all or nearly all illustrations and graphics.	2	5 (83.35)
- Brief captions used for some illustrations and graphics.	1	1 (16.7%)
- Captions are not used	0	0 (0%)
Match in logic, language, and experience (LLE)		
- Central concepts/ideas of the material appear to be culturally similar to the LLE of the target culture.	2	5 (83.3%)
- Significant match in LLE for 50 percent of the central concepts.	1	1 (16.7%)
- Clearly a cultural mismatch in LLE.	0	0 (0%)

Evaluation of Understandability and Actionability

The understandability evaluation of the educational video scored an impressive 367 out of 372 points, equating to 99 percent. According to Shoemaker et al. (2014), such a high percentage reflects exceptional clarity, ensuring that the material is easy for the target audience to comprehend. Similarly, the actionability evaluation achieved 92 out of 93 points, also resulting in 99 percent. As per Shoemaker et al. (2014), this high score highlights the material's effectiveness in empowering the audience to take informed actions based on the information presented. These outstanding scores underscore the video's success in delivering both accessible and actionable content, making it a powerful tool for educating Silat athletes on sports nutrition.

Table 4: Frequency and percentage of the understandability assessment for the educational video (n=31)

Item	Score	Responses	Frequency (%)
Understandability			
Content			
The material makes its purpose completely evident.	1 0	Agree Disagree	31 (100%) 0 (0%)
Word Choice & Style			
-The material uses common, everyday language.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
-Medical terms are used only to familiarize the audience with the terms. When used, medical terms are defined.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
-The material uses the active voice.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
Organization			
- The material breaks or "chunks" information into short sections.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
- The material's sections have informative headers.	1 0	Agree Disagree	31 (100%) 0 (0%)
- The material presents information in a logical sequence.	1 0	Agree Disagree	31 (100%) 0 (0%)
-The material provides a summary.	1 0	Agree Disagree	31 (100%) 0 (0%)
Layout & Design			
- The material uses visual cues to draw attention to key points.	1 0	Agree Disagree	31 (100%) 0 (0%)
- Text on the screen is easy to read.	1 0	Agree Disagree	31 (100%) 0 (0%)
- The material allows the user to hear the words clearly.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
Use of Visual Aids			
The material uses illustrations and photographs that are clear and uncluttered.	1 0	Agree Disagree	31 (100%) 0 (0%)
Actionability			
- The material clearly identifies at least one action the user can take.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
- The material addresses the user directly when describing actions.	1 0	Agree Disagree	30 (96.8%) 1 (3.2%)
- The material breaks down any action into manageable, explicit steps	1 0	Agree Disagree	31 (100%) 0 (0%)

Structure and Content

Table 5: Content structure and references of educational videos

Focus Area	Content	Sources/References
1. Introduction	Overview of the history and background game of *Silat* sport in Malaysia such as types of training in *Silat Olahraga*.	Personal communication, H. Ariff, 29 December 2023
2. Type of macronutrients	Explanation of the role of carbohydrates, protein, and fat in the body. • Function of carbohydrates as the main source of energy. • Function of protein is to build muscles in the body. • Function of fat as a fuel source**.**	Thomas, D. T., Erdman, K. A., & Burke, L. M. (2016). Position of the Academy of Nutrition and Dietetics, Dietitians of Canada, and the American College of Sports Medicine: Nutrition and Athletic Performance. *Journal of the Academy of Nutrition and Dietetics*, *116*(3), 501–528. https://doi.org/10.1016/j.jand.2015.12.006
3. Pre-meal for competition	Explanation of nutrient timing for food intake before the competition. **3 to 4 hours before the competition.** • Choose a complete and balanced meal that high in carbohydrates, moderate in protein, and low in fat. • Carbohydrate feedings before exercise can help to restore glycogen stores. • Examples of food such as white rice with side dishes, cereals. **1 to 2 hours before the competition.** • Avoid food high in fat/ protein/fiber and low glycemic index food. • This food is prolonged in digestion and can disturb athletes' focus during their game. • Examples of food such as carbohydrate snacks; biscuits, a slice of white bread with jam, two medium-sized bananas.	
4. Meal during competition	Explanation of nutrient timing during the competition. • Choose simple carbohydrates that can easily be digested • Each game round includes a 1-minute break, with three rounds totalling 2 minutes of play • Food that suits the game timing during the break such as mineral water, sports drinks, and fruit juice.	Moore, D. R. (2021). Protein Requirements for Master Athletes: Do They Need More Than Their Younger Contemporaries? *Sports Medicine*, *34*(S1), 1-5. https://doi.org/10.1007/s40279-021-01510-0
5. Post meal for competition	Explanation of the importance of post-event meal. • Application of 3R practice after game; Rehydrate, Rebuild & Refuel. • Within 30 minutes after the event	

	• Rehydrate: Consume water and electrolyte drinks • Rebuild: Consume carbohydrates and protein. Food examples such as egg sandwiches, milk • Refuel: Consume complete meals within 2 hours after the game is important. To accelerate glycogen resynthesis and hasten the recovery process.	
6. Hydration strategy for training and competition	Essential guidelines and strategies to keep hydrated for performance and recovery during tournaments and training sessions. • Strategy to keep hydrated • 500 ml water, 2 hours before training • 250 ml water, 15 minutes before training • 250 ml water, during training or competition • Four cups of water after the match which equals 800 ml	Thomas, D. T., Erdman, K. A., & Burke, L. M. (2016). Position of the Academy of Nutrition and Dietetics, Dietitians of Canada, and the American College of Sports Medicine: Nutrition and Athletic Performance. *Journal of the Academy of Nutrition and Dietetics*, *116*(3), 501–528. https://doi.org/10.1016/j.jand.2015.12.006
7. Summary	Recap of key points covered in the video, reinforcing the importance of nutrient timing and hydration in optimizing athletic performance for *Silat* athletes. • Importance of nutrient timing to ensure sufficient energy levels during competition. • Provide negative impacts of dehydration that lead to deficient performance in training or sports performance.	Kerksick, C. M., Arent, S., Stout, J. R., Campbell, B., Wilborn, C. D., Taylor, L., Kalman, D., Smith-Ryan, A. E., Kreider, R. B., Willoughby, D., Arciero, P. J., VanDusseldorp, T. A., Ormsbee, M. J., Wildman, R., Greenwood, M., Ziegenfuss, T. N., Aragon, A. A., & Antonio, J. (2017). International Society of Sports Nutrition position stand nutrient timing. *Journal of the International Society of Sports Nutrition*, *14*,33. https://doi.org/10.1186/s12970-017-0189-4

CONCLUSION

It can be concluded that the newly developed nutritional education video is suitable for use and has an acceptable level of understandability and actionability.

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ORIGINAL ARTICLE

Unveiling Knowledge, Attitude and Practice on Carbonated Drinks Intake Among Male and Female Young Adults in Pekan, Pahang

Nurfarzana Mohamad Zailani[1], Aliza Haslinda Hamirudin[1,2*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords: carbonated drinks; knowledge; attitude; practice; young adults

ABSTRACT

Background: Consumption of carbonated soft drinks has increased over the years, contributing to health issues such as obesity and non-communicable diseases (NCDs) particularly diabetes. Various factors influencing young adults to consume carbonated drinks, but research remains limited. This study aimed at assessing knowledge, attitude and practice (KAP) on carbonated drinks consumption among young adults in Pekan, Pahang specifically comparison between males and females. **Methods:** A cross-sectional study was conducted among a total of 94 respondents (n=47 males, n=47 females) aged 18 to 35 years old. The KAP questionnaires were distributed across residential areas in Pekan, Pahang. Statistically significance was set at $p<0.05$. **Results:** No significant difference was detected in knowledge score between males and females ($p=0.831$) indicating there was no difference among males and females related to knowledge and understanding level on carbonated drinks. Meanwhile, significant differences were identified for both attitude ($p=0.049$) and practice ($p=0.032$) scores in percentage between males and females. Males exhibited greater attitude on consumption and higher practice on carbonated drinks intake compared to females. **Conclusion:** Findings indicate similar level of knowledge between genders. Males had negative attitude and greater practice on carbonated drinks intake than females. Thus, it is imperative for targeted strategies according to genders in nutrition education and health promotion strategies. Enhancing awareness on adverse health effects related to carbonated drinks intake could improve knowledge and further prevent rising rate of NCDs.

INTRODUCTION

Findings from the Malaysian Adult Nutrition Survey (MANS) conducted in October 2002 and December 2003 on dietary consumption patterns showed that the majority of the population drank plain water at least six times daily; with plain water identified as the most frequently consumed beverage (Norimah et al., 2008). Similarly, the National Health and Morbidity Survey (NHMS) in 2012 also stated that most of the estimated population (59.2%) consumes five or more times plain water daily. Although soft drinks were not reported as the most frequent beverage daily, this does not imply that the population limits their consumption. Over the years, the beverage intake patterns have changed drastically compared to those reported more than a decade ago. The recently conducted NHMS 2023 revealed that 1 in 5 adults did not drink adequate plain water daily (Institute for Public Health, 2024).

* *Corresponding author.*
E-mail address: aliza@iium.edu.my

Globally, there is a shift from the consumption of water to sugar-containing beverages such as soft drinks and fruit juices (Muckelbauer et al., 2013, Popkin, 2011). This clearly demonstrates that carbonated drink is one of the preferred choices of drink. There are many types of sugar sweetened beverages such as carbonated drinks available in the market. In particular, young adults' population have the tendency to consume this type of beverages. This phenomenon is a concern that needs to be addressed accordingly to prevent non-communicable disease occurrence. Lack of nutritional knowledge on beverages intake also encourages people to drink more carbonated drinks (Miller et al., 2020). High sugar content and calories in carbonated drinks contribute to high energy intake which could lead to weight gain (Vartanian et al., 2007). High carbonated drinks intake is mostly driven by the sweet taste, with influence from family and friends also contributing to this problem (Dinkhoff, 2009). Young adults commonly observe the type of beverages their family and friends usually drink, and they will also mirror the intake to be socially accepted. The affordability of these beverages is also another factor contributing to high intake of carbonated drinks among young adults. This trend can lead to increased risk of non-communicable disease such as diabetes. Ministry of Health (2020) reported that Pahang has the third-highest diabetes prevalence in Malaysia, at 25.7%. Given the limited

research on consumption of carbonated drinks in Pekan, Pahang, this study is therefore warranted in this region. To raise awareness in the community, it is important to identify on what people know about certain things, how they feel and how they behave. Based on Ajzen's Theory of Planned Behaviour, it stated that an individual will expect to conduct a behaviour when they see it positively, believe what other people want them to do and perceive it to be under their own control (Ajzen, 1989). Thus, this study aimed to assess knowledge, attitude and practice on carbonated drinks intake among young adults, both males and females in Pekan, Pahang.

MATERIALS AND METHODS

Study Design and Sampling Strategy

A cross-sectional study was conducted whereby the relationship between outcome and other variables of interest was examined. Convenience sampling was applied in this study and the respondents were recruited from various residential areas in Pekan, Pahang.

Source of Population

Samples consist of young adults aged 18 to 35 years old in line with the age range of young adults in a Malaysian study by Zulfakar et al., (2023), both males and females. Inclusion criteria for the population was young adults and residents of Pekan, Pahang. Exclusion criteria were children, adults aged ≥36 years old, people who lived in other regions, people who had been diagnosed with diabetes and diseases which require fluid restriction.

Sample Size Calculation

Two means formula was used for sample size calculation:

$$n = \frac{2\,\sigma^2}{\Delta^2}\,(Z_{\alpha/2} + Z_{\beta})^2$$

Where, $Z_{\alpha/2}$ = 1.96 (for 95 % confidence interval)

Z_{β} = 0.84 (for 80 % power)

Δ = detectable difference

σ = standard deviation in population (based on literature)

σ = ¼ (max score - min score)

= ¼ [(12.7 + 3.3) – (12.7 – 3.3)] (Pacific & Hoefkins, 2014)

= ¼ (16 – 9.4)

= 1.65

$$n = \frac{2\,(1.65)^2}{1^2}\,(1.96 + 0.84)^2$$

$$= \frac{5.445}{1}\,(7.84)$$

= 5.445 (7.84)

= 42.69

≈ 43 samples for one group

10% attrition rate for dropout and refusal to participate were included.

= 43 + 10%

= 43 + 4.3

= 47.3

≈ 47 samples for one group

In this study, two groups were needed to compare between males and females. Total samples needed were 94 subjects (n=47 males, n=47 females).

Data Collection

A structured questionnaire was used to collect data which was adopted from a previous study (Kharde et al., 2013). Before implementing the research, a pilot study was performed among 10% of required sample size to test the face validity of questions in the questionnaires. A total of 10 respondents consists of 5 males and 5 females answered the questionnaires for the pilot study. Most of them responded that they understand all questions.

For data collection, potential respondents were approached and explanations about the study were provided. An informed consent was completed by each respondent prior to their participation. The respondents filled in the questionnaires under the supervision of the researcher to ensure all the respondents responded to the study questions. Ethics approval obtained from IIUM Research Ethical Committee (IREC) (ID No: IREC 2019-070). The details in the questionnaires were divided into 4 parts consist of sociodemographic data, knowledge on carbonated drinks intake, attitude on carbonated drinks intake and practice on carbonated drinks intake.

Questions on knowledge regarding carbonated drinks

The questions were in objective format where the subjects needed to select the answer according to their level of understanding. Knowledge was measured with 10 statements focusing on caloric value of carbonated drinks, sugar contents in carbonated drinks, components of carbonated drinks (sweetener, flavouring, colouring, preservatives and additives) and health effects of carbonated drinks (obesity, tooth erosion and bone fractures). The subjects need to choose answers based on the questions either true or false which gave them 10 score points as total score. One mark was given for the correct answer and 0 for wrong answer. The score point was then converted into percentage.

Questions on attitude regarding carbonated drinks

The questions consist of 5 questions in which the respondents need to tick one of the answers given which is either 'Yes' or 'No'. A numerical score was assigned to each choice. One score was given if the respondents choose 'Yes' which indicated that they had negative attitude toward consumption of carbonated drinks. For question 3, one score was given if the respondents choose 'No' indicating a negative attitude in consumption of carbonated drinks. Then, total score point was calculated and converted into percentage (%). The highest score obtained showed that respondents had negative or higher attitude toward consumption of carbonated drinks. Meanwhile, lowest score point showed that they had positive attitude which means that they were not enjoying and not addicted to consume carbonated drinks.

Questions on practice regarding carbonated drinks

The questions consist of 4 questions. "A 4-point scale was used to assess the frequency of carbonated drink consumption and the average quantity (in glasses) consumed at a time. Meanwhile, one mark was given when the respondents choose 'No' regarding practice on reading the ingredients list of carbonated drinks. Similarly, one score point was given for each response regarding factors influencing to consume carbonated drinks. Then, total score point was calculated and converted into percentage (%). The highest score obtained showed that respondents had higher practice toward consumption of carbonated drinks meanwhile lowest score point showed that they had lower practice which means that they were not consuming carbonated drinks frequently.

Statistical Analysis

Data was analysed using SPSS version 12.0.1. Descriptive statistics was used to analyse sociodemographic data. To compare knowledge, attitude and practice between males and females of young adults regarding carbonated drinks , independent-t test was used for normally distributed data. Meanwhile, Mann-Whitney U test was used for non-parametric test. *P-value* was set at $p < 0.05$ as statistically significant.

RESULTS

Sociodemographic Characteristics

A total of 94 respondents of young adults both males and females in Pekan, Pahang had participated in this study. The distribution of respondents based on sociodemographic characteristics is presented in Table 1.

There were 47 male respondents (50%) and 47 female respondents (50%). Most of the respondents were unmarried (74.5%) compared to respondents that already married (25.5%). For the educational level, 31 respondents (33%) only studied until PMR or SPM level, 56 respondents (59.6%) were Diploma or Degree holders and 7 respondents (7.4%) stated other education level. Among 94 respondents, there were 28 (29.8%) full-time employees, 5 (5.3%) part-time employees, 9 (9.6%) self-employed, 13 (13.8%) unemployed and 39 (41.5%) students. Next, 40 respondents (42.6%) have no income per month. The number of respondents with income less than RM 1000 per month and range between RM 1000 to RM 3000 were same which is 24 respondents (25.5%). The number of respondents for income per month from RM 3001 to RM 5000 and more than RM 5000 were 4 (4.3%) and 2 (2.1%), respectively. Lastly, most of the respondents (95.7%) stated that they are free from disease and did not have any problems with their health status. There were only 4 respondents (4.3%) stated that they had other diseases such as cholesterol problem, sinusitis, vertigo and G6PD.

Table 1: Sociodemographic characteristics of young adults (n = 94)

Variables	Number of respondents (N)	Percentage (%)
GENDER		
Male	47	50
Female	47	50
MARITAL STATUS		
Single	70	74.5
Married	24	25.5
EDUCATION LEVEL		
PMR/SPM	31	33
Diploma/Degree	56	59.6
Others	7	7.4
EMPLOYMENT STATUS		
Full Time	28	29.8
Part Time	5	5.3
Self-employment	9	9.6
Unemployment	13	13.8
Student	39	41.5
INCOME PER MONTH		
<RM1000	24	25.5
RM 1000-3000	24	25.5

RM 3001 – 5000	4	4.3
>RM5000	2	2.1
None	39	42.6
HEALTH PROBLEM		
No	90	95.7
Others	4	4.3

Knowledge on Carbonated Drinks Intake between Males and Females

Table 2 presents the knowledge of respondents on carbonated drinks. The lowest score obtained among 94 respondents was 30% meanwhile the highest score was 100%. There were 5 males and 6 females score 100% which showed that they got all correct answers and indicated that they know and aware about calorie content, sugar content, ingredients and long term health effects regarding carbonated drinks. Most of the respondents had an average knowledge as the majority of them score from 60% and above.

The mean percentage scores for males and females were 67.87±20.21 and 68.72±18.37, respectively. There was no significant difference in knowledge scores between males and females (p=0.831), indicating similar level of knowledge between genders.

Attitude on Carbonated Drinks Intake between Males and Females

Table 3 shows results related to attitude on carbonated drinks intake. Sixty percent was the highest score and 0 percent was the lowest score obtained among 94 respondents for attitude on carbonated drinks intake. Zero percent indicated that the respondents had low or positive attitude toward consumption of carbonated drinks which means that they are not really enjoying or dislike to consume carbonated drinks. Meanwhile, 60% showed that the respondents had high and negative attitude toward carbonated drinks intake which means that they enjoyed and preferred to consume carbonated beverages. The highest number of respondents that got the highest mark was males with 5 respondents compared to females with 1 respondent. Thus, the higher the score obtained by respondents, the more negative the attitude is.

Mann-Whitney U test was conducted due to data was not normally distributed. *p-value* obtained from the test was 0.049. There was a significant difference in attitude score in percentage between males and females. The mean of attitude score among males (52.59±20.41) was higher compared to females (42.41±15.5). The results demonstrated that males had higher or negative attitude toward consumption of carbonated drinks which indicated that they enjoyed and preferred to consume carbonated beverages compared to their female counterparts.

Practice on Carbonated Drinks Intake between Males and Females

Table 4 demonstrates practice on carbonated drinks among young adults. 30 percent was the highest score point and 0 percent was the lowest score point obtained among 94 respondents. 0 percent indicated that the respondents had low practice toward consumption of carbonated drinks which means that they do not consume carbonated drinks more often, meanwhile, 30 percent showed that the respondents had higher practice toward carbonated drinks intake which means that they consume carbonated beverages more often. The highest number of respondents that got the highest mark was males with 3 respondents compared to none among females. Independent sample T-test was conducted and *p-value* obtained from the test was 0.032 which is less than 0.05, so, there was a significant difference in practice score in percentage between males and females. The mean practice score among males (13.54±6.56) was higher compared to females (10.864±5.31). In short, males had higher practice toward consumption of carbonated drinks which indicated that they consume carbonated beverages more often.

Table 2: Number of respondents (%) for each score on knowledge

Gender	Score Point (%)								Mean (SD)
	30	40	50	60	70	80	90	100	
Male	4 (8.5%)	5 (10.6%)	1 (2.1%)	9 (19.2%)	9 (19.2%)	11 (23.4%)	3 (6.4%)	5 (10.6%)	67.87 (20.21)
Female	1 (2.1%)	4 (8.5%	5 (10.6%	12 (25.5%)	7 (14.9%)	10 (21.3%)	2 (4.3%)	6 (12.8%)	68.72 (18.37)

Table 3: Number of respondents (%) for each score on attitude

Gender	Score point (%)						Mean (SD)
	0	20	40	60	80	100	
Males	20 (42.6%)	14 (29.8%)	8 (17.0%)	5 (10.6%)	0	0	52.59 (20.41)
Females	28 (59.6%)	13 (27.7%)	5 (10.6%)	1 (2.1%)	0	0	42.41 (15.5)

Table 4: Number of respondents (%) for each score on practice

Gender	Score point (%)						Mean (SD)
	0-5	6-10	11-15	16-20	21-25	26-30	
Males	3 (6.4%)	12(25.5%)	17(36.1%)	6(12.8%)	6(12.8%)	3(6.4%)	13.54 (6.56)
Females	8 (17.0%)	12(25.5%)	18(38.3%)	7(14.9%)	2(4.3%)	0	10.864 (5.31)

DISCUSSION

Knowledge on Carbonated Drinks Intake among Young Adults

No significant difference in knowledge score between males and females was identified in this study. Both genders are considered to have similar level of knowledge. This finding was coherent with result of previous study by Pacific and Hoefkins (2014). Nevertheless, other studies showed contradictory findings with greater knowledge among females (O'Leary et al., 2012; Azzeh & Hamouh, 2022); due to males often underestimate the sugar and calorie content. Females have tendency to recognize healthier options to carbonated drinks in comparison to males, due to males' preference towards satisfaction and taste which dominate over their healthier options understanding (Nergiz-Unal et al., 2016; Azzeh & Hamouh, 2022).

Even though women tended to have higher levels of knowledge compared to men, the technology has changed the method on how information can be accessed (Corby, 2007). Regardless of males or females, equal access to information via internet and other sources of information may influence their knowledge. It is important for young adults to acquire a credible and reliable information about the carbonated drink due to massive amount of online information nowadays, which can lead to misinformation and misinterpretation.

Attitude on Carbonated Drinks Intake among Young Adults

There was a significant difference in attitude score between males and females, with higher score among males compared to females. This indicates males had negative attitude toward carbonated drinks intake; with consistent findings showed by Pacific and Hoefkins (2014). Redondo et al. (2014) highlighted that beverages specific attributes also influence consumers' preferences of certain type of drinks.

Young adults can become addicted to carbonated drinks if the taste of carbonated drink meets their preference. Social acceptance plays a pivotal role of carbonated drinks intake among males than females who are more incline by healthy eating and trends with their peers (Pollard et al., 2016; Duncan et al., 2022).

Weight management and body image are of concerns among females which reflects their attitudes in sugar sweetened beverages (SSBs). Consequently, they become cautious in the intake compared to males who favour enjoyment and taste over adverse effects to health (O'Leary et al., 2012; Azzeh & Hamouh, 2022). It is worth to note that cultural attitudes between gender have a significant role in beverages intake. Some culture encourages more intake of sugary drinks among makes as it relates with masculinity, but females are expected to adopt healthier lifestyle in the society (Nergiz-Unal et al., 2016; Khan et al., 2021).

Practice on Carbonated Drinks Intake among Young Adults

Our study found a significant difference in practice score between males and females, with higher score in males compared to females which demonstrates that males had higher practice in carbonated drinks consumption than female. The finding was parallel with result reported by Dinkhoff (2009), which further showed that the percentage of males consumed soft drinks was twice compared to females.

Moreover, Zoellner et al. (2012) reported that men and younger people drink more regular soft drinks compared to females. Other studies also indicate that males are more likely to consume SSBs daily than female who are more prone to health concerns (O'Leary et al., 2012; Pollard et al., 2016). Moreover, females commonly opt for carbonated drinks intake occasionally rather than as part of their regular dietary intake (Pollard et al., 2016; Duncan et al., 2022). They are also more receptive to health campaigns aims at lowering sugary drink and promoting healthier beverages options intake than their males counterpart (Azzeh & Hamouh, 2022).

Limitation and Strength

Due to the answers provided by the respondents regarding knowledge of carbonated drinks were specific and need to choose only one answer, there were possibilities of respondents to answer the questionnaires by assumption. Meanwhile, when asking to answer the questionnaires, some of female respondents mentioned that they had not taken any carbonated drinks for a while potentially opting for a perceived favourable response. Despite that, the use of questionnaire facilitated study completion with the presence of researcher at the time of data collection is a notable strength of this study. Data collection is cost effective as only papers and pen were needed.

CONCLUSION

This study indicated that both males and females of young adults showed no significance difference in knowledge regarding carbonated drinks. Notable gender differences were identified for attitudes, and practices regarding carbonated drink intake among young adults. Males demonstrated negative attitude toward consumption of carbonated drinks compared to females; in which males prioritize taste of carbonated drinks leading to higher consumption than females. Nutrition education strategies to address the differences are warranted to promote healthier choices in young adults according to gender. Additionally, further strategies to raise awareness on effects of consuming carbonated drinks can be developed which can help reduce the incidence of non-communicable disease especially diabetes.

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ORIGINAL ARTICLE

Relationship Between Body Image Perception and Stress Towards Eating Behaviour Among IIUM Students

Ain Salsabila Selamat[1], Muhamad Ariff Ibrahim[1,*], Mohd Nazir Mohd Nazori[2], Nurulwahida Saad[3] & Siti Adibah Waisulqrnai[3]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Department of Biomedical Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

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body image perception, stress; eating behaviour, university students

ABSTRACT

Background: University students, facing academic and personal challenges, often experience stress that can worsen body image concerns, leading to unhealthy eating patterns like overeating, restrictive eating, or disordered eating. Therefore, the main objective of this research is to assess the relationship between body image perception and stress towards eating behaviour among students at the International Islamic University Malaysia (IIUM). **Methods:** The study used a cross-sectional design, in which samples were obtained using a convenient sampling, with a total of 384 students. Data was collected using the Perceived Stress Scale (PSS), the Body Image Scale for Youth (BISY), and the Dutch Eating Behaviour Questionnaire (DEBQ). **Results:** Stress is significantly associated with emotional eating ($r = 0.142$, $p < 0.01$). Body image perception also showed a significant relationship with restraint ($r = 0.301$, $p < 0.01$), emotional ($r = 0.197$, $p < 0.01$), and external eating behaviours ($r = 0.155$, $p < 0.01$). Cultural values ($r = 0.167$, $p < 0.01$) and social support ($r = 0.122$, $p < 0.01$) weakly correlate with external eating. Negative associations exist between body evaluation and both restraint ($r = -0.129$, $p < 0.05$) and emotional eating ($r = -0.122$, $p < 0.05$). Health and spirituality priorities negatively related to restraint ($r = -0.186$, $p < 0.01$) and emotional eating ($r = -0.144$, $p < 0.01$). Multiple regression analysis showed dimension body image perception (emotion and behaviour) predicts restraint and emotional eating behaviour. Results also showed that dimension emotion and behaviour, perceived social support and perceived cultural values are significant predictors of external eating behaviour. **Conclusion:** These findings underscore the complex interplay between stress, body image perception, and eating behaviours among IIUM students, highlighting the need for comprehensive support systems to address these interrelated issues.

INTRODUCTION

As people age, their eating behaviours change, influenced by physiological, psychological, social, and genetic factors (Osorio et al., 2002; Grimm & Steinle, 2011). Life transitions can significantly disrupt eating patterns, often leading to weight gain and an increased risk of obesity later in life (El Ansari et al., 2012; Gordon-Larsen et al., 2004). University students frequently rely on fast food and simple meals due to time restrictions and a lack of cooking facilities, thus endangering the healthy diet that is necessary to sustain their health and intellectual achievement (Morse & Driskell, 2009; Florence et al., 2008).

Body image perception and stress also play a crucial role in shaping eating behaviours. Body image is defined as how individuals view their appearance based on societal standards that can negatively impact their self-esteem and lead to disordered eating (Cash & Pruzinsky, 1990; Glashouwer et al., 2019). When students struggle with body dissatisfaction, they become more susceptible to mental health issues, including anxiety and eating disorders, which can persist into adulthood (Perkins & Brausch, 2019). Stress is another critical factor, often triggered by academic pressures, personal challenges, and social expectations. Studies have shown that stress influences eating behaviours, with students engaging in emotional eating or unhealthy eating patterns as a coping mechanism (Torres & Nowson, 2007; Papier et al., 2015).

This study aims to explore the relationship between stress, body image perception, and eating behaviours among IIUM students. University students are particularly vulnerable to stress, which, combined with a negative body image, can lead to poor eating habits, affecting both their physical and mental well-being. Understanding these

* *Corresponding author.*
E-mail address: ariffib@iium.edu.my

interconnected factors is essential for developing effective strategies to promote healthy eating behaviours, enhance mental health, and support students' overall well-being. This research offers insights that can inform the development of focused treatments to promote better eating habits and enhance students' academic and personal outcomes.

MATERIALS AND METHODS

Study Participants

This study adopted a quantitative, cross-sectional study to investigate the relationships between stress, body image perception, and eating behaviour among International Islamic University Malaysia (IIUM) students. The quantitative approach allowed for the collection of measurable data that could be statistically analysed, providing focused insights into these issues. The research was conducted online and included students from IIUM's four main campuses: Gombak (19,382 students), Kuantan (3,566 students), Pagoh (1,634 students), and the Centre for Foundation Studies in Gambang (3,600 students). In total, 28,182 students were enrolled across these campuses at the time of the study.

The Kuantan Campus has six faculties: the Kulliyyah of Allied Health Sciences, Dentistry, Medicine, Nursing, Pharmacy, and Science. At the Gombak campus, seven faculties are established, including the Kulliyyah of Islamic Revealed Knowledge and Human Sciences, Law, Architecture and Environmental Design, Economics and Management Sciences, Education, Engineering, and Information and Communication Technology. The Pagoh campus hosts a single faculty, the Kulliyyah of Sustainable Tourism and Contemporary Languages, and includes from Gambang Campus which consists of foundation students. A sample size of 379 students was determined using Krejcie and Morgan's (1970) method, which ensures a representative sample for a population of this size. A total of 384 students from all campuses were recruited in two weeks using convenience sampling.

Questionnaire

A set of questionnaires was developed using the adopt-and-adapt method based on prior studies by Jalali-Farahani et al. (2022), Cohen et al. (1983), and Van Strien et al. (1986). The survey, created via Google Forms, was distributed through email, WhatsApp, Telegram, and Instagram. It consisted of four sections: sociodemographic data, stress, body image perception, and eating behaviour. Body image was assessed using the Body Image Scale for Youth (BISY), which measured ten themes, including personal characteristics, health priorities, cultural values, and body evaluation. Most items used a five-point Likert scale, with scores transformed to a 0–100 range, with higher scores indicating more negative body perception.

The Perceived Stress Scale (PSS) (Cohen et al., 1983) measured stress levels, with total scores ranging from 0 to 40 and categorized as low, moderate, or high. Eating behaviours were evaluated using the Dutch Eating Behaviour Questionnaire (DEBQ) (Van Strien et al., 1986), which focuses on restrained, emotional, and external eating, with higher scores indicating stronger eating tendencies.

Statistical Analysis

The Statistical Package for the Social Sciences version 29 was used to analyse the data. The sociodemographic data's percentage, mean, and standard deviation (SD), stress level score by PSS, body image scale score, and eating behaviour score from the DEBQ questionnaire were all analysed using descriptive analysis. Additionally, the association between eating behaviours, body image perception, and stress was examined using Pearson Correlation and multiple regression.

RESULTS

General Characteristics of the Participants

According to Table 1, a total of 384 students comprised 77.9% (n=299) female students and 22.1% (n=85) male students. The majority were aged 22 to 23 (40.6%), followed by 20 to 21 (31.8%). All participants identified as Malay, with undergraduates accounting for 69.0%, foundation students 19.3%, and postgraduates 11.7%. The Kuantan Campus had the highest response rate at 52.6%, followed by the Centre for Foundation Studies (19.3%) and the Gombak campus (16.9%). Most respondents were from the Kulliyyah of Allied Health Sciences (37.5%), and most participants lived on campus. Regarding body mass index (BMI), 61.2% had normal BMIs, while 17.7% were underweight, 15.9% overweight, and 5.2% obese.

Table 1: Sociodemographic Factors of Respondents (N=384)

Characteristic	Categories	Frequency	Percentage (%)
Gender	Male	85	22.1
	Female	299	77.9
Age	18-19	95	24.7
	20-21	122	31.8
	22-23	156	40.6
	24 & above	11	2.9
Campus	CFS	74	19.3
	Kuantan	202	52.6
	Gombak	65	16.9
	Pagoh	43	11.2
Kulliyyah	AHASKIRKHS	44	11.5
	AIKOL	12	3.1
	KAED	12	3.1
	KAHS	144	37.5
	KENMS	17	4.4
	KICT	8	2.1
	KOD	2	0.5
	KOE	20	5.2
	KOED	7	1.8
	KOM	8	2.1
	KON	18	4.7
	KOP	11	2.9
	KOS	35	9.1
	KSTCL	46	12.0
Body Mass Index (BMI)	Underweight	68	17.7
	Normal	235	61.2
	Overweight	61	15.9
	Obese	20	5.2

Level of Stress, Body Image Perception, and Eating Behaviour

According to Table 2, 70.6% (n=271) of the students experienced moderate stress. There was a slight variation in prevalence between the high and low-stress categories, with 14.6% (n=56) and 14.8% (n=57), respectively. It was reported that 21.4% (n=82) students have high levels of body image perception under the dimension of emotion and behaviour while 78.6% (n=302) students have low levels of body image perception. Table 2 shows that only 0.3% (n=1) of IIUM students have a high body image perception level under the body evaluation level. In comparison, most of the students have a low level of body evaluation, which was 99.7% (n=383).

Furthermore, more than half of the students had high personal characteristics and strategies scores under the body image perception level of 64.8% (n=249) while 35.3% (n=135) had low levels of personal characteristics and strategy. It also revealed that more than half of the students, precisely 57.3% (n=220), scored high in personal characteristics and strategy within the context of body image perception. In contrast, 42.7% (n=164) of the students had low levels in these areas. Moreover, a significant majority of the students, accounting for 55.5% (n=213), exhibited high scores in perceived social support within the context of body image perception. A smaller proportion, 44.5%, demonstrated low levels in these aspects. 6.5% (n=23) of students have low priority of health and spirituality and 94.0% (n=361) have high levels of body image perception in this dimension. According to the data in the Table 1, 13.5% of the students, corresponding to 52 individuals, reported having low perceived cultural values. In contrast, a substantial majority, 86.5%, equating to 332 students, exhibited high levels of body image perception within this dimension.

For the eating behaviour level, 64.3% (n=247) of IIUM students have a higher level of restrained eating behaviour while 35.7% (n=137) students have a low level. The study results show that 249 (64.8%) students have higher levels of eating behaviour under the context of emotions. Meanwhile, 135 (35.2%) IIUM students have low levels of emotional eating behaviour. Table 2 shows results from the study that the majority of the IIUM students 98.2% (n=377) have higher levels of external eating behaviour while only 1.8% (n=7) reported having a low level of eating behaviour under the context of external.

Table 2: Level of stress, Body Image Perception and Eating Behaviour

Variables	Level	n	%
Stress	High	56	14.6
	Moderate	271	70.6
	Low	57	14.8
Body image perception			
Emotion & behaviour	High	82	21.4
	Low	302	78.6
Body evaluation	High	1	0.3
	Low	383	99.7
Personal characteristics & strategies	High	249	64.8
	Low	135	35.2
Social models	High	220	57.3
	Low	164	42.7
Perceived social support	High	213	55.5
	Low	171	44.5
Priority of health and spirituality	High	361	94.0
	Low	23	6.0
Perceived cultural values	High	332	86.5
	Low	52	13.5
Emotional eating behaviour	High	249	64.8
	Low	135	35.2
External eating behaviour	High	377	98.2
	Low	7	1.8
Restrained eating behaviour	High	247	64.3
	Low	137	35.7

Correlation Among Variables

Table 3 shows the findings of the Pearson Correlation analysis among IIUM students associated with stress, seven dimensions of body image perception, and three types of eating behaviour (restrained, emotional, and external). The study found a strong correlation between stress and emotional eating ($r = 0.142$, $p < 0.01$), yet no relationship with restrained or external eating behaviour. Body image perception has a significant association with restricted, emotional, and external eating behaviours ($r = 0.301$, $p < 0.01$, $r = 0.197$, $p > 0.01$, and $r = 0.155$, $p < 0.01$). On the other hand, a correlational analysis found a significant association between perceived cultural values and external eating ($r = 0.167$, $p < 0.01$), as well as the perceived social support dimension of body image perception ($r = 0.122$, $p < 0.01$).

Table 3: Correlation between stress, body image perception and eating behaviour

Variables	1	2a	2b	2c	2d	2e	2f	2g	3	4
1. Stress	-									
2. Body image perception										
a. Emotion & Behaviour	.437**	-								
b. Body evaluation	-.396**	-.560**	-							
c. Personal characteristics & strategies	-.295**	-.460**	.605**	-						
d. Social model	-.216**	-.272**	.469**	.366**	-					
e. Perceived social support	-.160**	-.208**	.356**	.291**	.293**	-				
f. Priority of health & spirituality	-.206**	-.296**	.323**	.280**	.145**	.238**	-			
g. Perceived cultural values	.149**	.182**	-.045	.021	-.081	.036	.127*	-		
3. Restrained eating behaviour	.086	.301**	-.129*	-.048	-.001	-.008	-.186**	.024	-	
4. Emotional eating behaviour	.142**	.197**	-.122*	.010	-.013	-.043	-.144**	.059	.191**	-
5. External eating behaviour	.042	.153**	-.034	-.036	.050	.122*	.092	.167**	-.111*	.353**

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Multiple Regression Among Variables

Table 4 indicates that the variables significantly predicted restrained eating behaviour, with an R-value of 0.325 and an R^2 value of 0.106, explaining 10.6% of the variance. The F-value demonstrated a significant relationship among the variables ($F (2, 384) = 14.981$, $p < 0.05$), suggesting they contribute to restrained eating behaviour among IIUM students.

Additionally, the emotional and behavioural dimensions significantly predicted restrained eating behaviour ($b = 0.314$, $p < 0.05$), as did the priority of health and spirituality ($b = -0.120$, $p < 0.05$). No significant differences were found between body evaluation dimensions and restrained eating behaviour.

Table 4: Regression analysis between body image perception (emotion and behaviours, body evaluation, and priority of health and spirituality) and restrained eating behaviour

Model	*B*	*SE*	*Std B*	*t*	*Sig.*
1. Emotion and behaviour	.009	.002	.314	5.30	.000
2. Body Evaluation	.007	.005	.086	1.44	.152
3. Priority of Health and Spirituality	-.024	.010	-.120	-2.33	.021
Model summary	R = .325 R^2 = .106 *Adj.* R^2 = .099 *SE* = 8.70 $F(2, 384) = 14.981$, $p < .001$				

Table 5 shows an R-value of 0.224 and an R^2 value of 0.050, indicating a 5% variance among the variables. The results were statistically significant (F (2, 384) = 5.013, p < 0.05), confirming that these variables collectively predicted emotional eating behaviour.

Moreover, as per Table 5, the emotion and behaviour dimension of body image perception significantly predicted emotional eating behaviour (b = 0.153, p < 0.05). No significant predictive differences were found for stress, body evaluation, or the priority of health and spirituality regarding restrained eating behaviour.

Table 5: Regression analysis between stress, body image perception (emotion and behaviour, body evaluation, priority of health and spirituality), and emotional eating behaviour

Model	*B*	*SE*	*Std B*	*t*	*Sig.*
1. Stress	.123	.109	.064	1.130	.261
2. Emotion and Behaviour	.006	.002	.153	2.400	.017
3. Body Evaluation	.002	.006	.019	.299	.765
4. Priority of Health and Spirituality	-.024	.014	-.092	-1.720	.087
Model summary	*R* = .224 R^2 = .050 *Adj.* R^2 = .040 *SE* = 11.60 *F*(2, 384) = 5.013, *p* < .001				

Table 6 indicates an R-value of 0.255 and an R^2 value of 0.065, reflecting a 6.5% variance among the variables. The analysis demonstrated that these variables significantly predicted external eating behaviour (F (2, 384) = 8.835, p < 0.05). According to Table 6, emotion and behaviour (b = 0.161, p < 0.05), perceived social support (b = 0.151, p < 0.05), and perceived cultural values (b = 0.132, p < 0.05) significantly predicted external eating behaviour among IIUM students.

Table 6: Regression analysis between body image perception (emotion and behaviour, perceived social support, and perceived cultural values) and external eating behaviour

Model	*B*	*SE*	*Std B*	*t*	*Sig.*
1. Emotion and Behaviour	.003	.001	.161	3.11	.002
2. Perceived Social Support	.013	.005	.151	2.97	.003
3. Perceived Cultural Values	.014	.005	.132	2.61	.009
Model summary	*R* = .255 R^2 = .065 *Adj.* R^2 = .058 *SE* = 5.96 *F*(2, 384) = 8.835, *p* < .001				

DISCUSSION

Stress is prevalent among university students, often described as feeling overwhelmed, anxious, or exhausted. This study conducted at IIUM found that 70.6% of students experience moderate stress levels, which aligns with similar findings from Yikealo et al. (2018), who reported that 71% of students in Eritrea also experienced moderate stress. In contrast, a study in Selangor found that 44.6% of university students reported moderate to high stress levels (Wong et al., 2023). Additionally, research from Sultan Qaboos University in Oman showed that 75.1% of students reported moderate stress, reinforcing that stress is common across various academic settings. These findings highlight the significant emotional burden university students face, particularly as they navigate the challenges of higher education.

Numerous factors contribute to stress among university students, with academic performance being a primary concern. According to AlJaber et al. (2019), first-year students in Riyadh experience more stress than their senior counterparts. The heightened demands placed on students often increase stress levels, especially during examinations, with preclinical students reporting more extreme stress than their peers (AlJaber et al., 2019). Similar findings from Sultan Qaboos University suggested that impending exams may have influenced reported stress levels, with many students expressing heightened anxiety in preparation for assessments (Alkhawaldeh et al., 2023). Cumulatively findings suggest that academic pressures, alongside personal circumstances and social expectations, play a critical role in elevating stress levels among students, leading to a detrimental impact on their overall well-being.

Concerns about body image perception have also emerged, particularly regarding the influence of social media on emotional well-being. The results from the IIUM study indicated that many students reported dissatisfaction with their body image, with five out of seven dimensions reflecting high levels of concern. This mirrors findings from Divecha et al. (2022), which indicated that only 66% of medical students in Oman had an accurate body image perception. Similarly, a study conducted by Manar et al. (2019) found that only 30.75% of students were satisfied with their body image, emphasizing that societal pressures and media portrayals significantly impact students' perceptions of themselves. The desire to conform to certain body ideals often leads to feelings of inadequacy and dissatisfaction, contributing to an unhealthy body image among university students, regardless of gender.

The relationship between stress and eating behaviour is significant, with many IIUM students exhibiting high levels of restrained, emotional, and external eating behaviours. Research indicates that stress often leads to unhealthy eating patterns, including overeating and skipping meals (Choi, 2020). Kowalkowska & Poínhos (2021) found that women displayed higher levels of emotional eating, while men tended to exhibit uncontrolled eating behaviours. This suggests that gender may influence how students cope with stress concerning their eating habits. Overall, this study concludes that stress has a significant correlation with emotional eating behaviours, indicating that increased stress levels can exacerbate unhealthy eating patterns among university students. However, it is essential to note that this research has limitations, including a narrow focus on a single university, which may not represent broader student experiences. Additionally, the existing literature on body image perceptions influencing eating behaviour is limited, suggesting a need for further exploration in this area to understand better the complexities of stress, body image, and eating behaviours among university populations.

CONCLUSION

This study revealed that most students experienced moderate stress levels. There are significant relationships between body image perception and eating behaviours, with regression analysis identifying body evaluation and the prioritization of health and spirituality as predictors of restrained eating, and stress and body image perception influencing emotional eating. These findings underscore the intricate relationship between stress, body image, and eating behaviours among university students. Stress was found to play a crucial role in driving emotional eating, while body evaluation and personal health priorities were closely linked to restrained eating behaviours. Addressing the interrelated challenges of stress, body image, and eating behaviours demands a holistic approach. By promoting mental well-being, positive self-perception, and healthy behaviours, universities can foster an environment that supports students personal and academic success.

RECOMMENDATIONS

To improve the current study, future research could refine methodologies and explore additional factors affecting stress and eating behaviours in students. Future research should consider mix method design to provide detailed explanation on how the variables are correlated to each other. This approach can also provide clues to the thought process that linked the variables. Additional factors such as coping mechanism, mood, and mental illnesses should be explored its effect towards stress and eating behaviours. Awareness campaigns and educational programs are also recommended to teach students effective stress management strategies and foster positive body image perceptions.. Additionally, future studies could broaden the scope to investigate other variables such as sleep quality, social media usage, and academic performance that may impact students' eating behaviours.

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ORIGINAL ARTICLE

Relationship Between Nutrition Literacy and Stress Towards Eating Behaviour Among IIUM Students

Nurul Najah Azzahra Mohd Zafrullah[1], Muhamad Ariff Ibrahim[1,2,*], Nurulwahida Saad[3], Siti Adibah Waisulqrnai[3] & Mohd Nazir Mohd Nazori[4]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Department of Biomedical Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[4]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

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Eating behaviour; nutrition literacy; stress; students

ABSTRACT

Background: The rising prevalence of stress and its influence on eating behaviours among university students is becoming a significant concern, especially in regard to nutrition literacy. This study examined the relationship between nutrition literacy, stress, and eating behaviour among students enrolled at the International Islamic University Malaysia (IIUM). **Methods:** This study used a cross sectional design and a convenience random sampling, to obtain a total sample of 384 students. A combination of questionnaires including socio-demographic questions, the Short Nutrition Literacy (S-NutLit), the Perceived Stress Scale (PSS), and the Dutch Eating Behavior Questionnaire (DEBQ), was given to respondents. **Results:** The study revealed a majority of students scoring a high nutrition literacy level for functional and critical, 86.7% and 79.4% respectively. There was a significant association between critical nutrition literacy and restrained eating behaviour ($r=0.123$, $p<0.01$). The stress level reported also was in moderate level which was only 70.6%. In addition, there was a significant association between stress and emotional eating behavior ($r=0.142$, $p<0.01$). The result from regression analysis showed that stress and critical nutrition literacy were significant predictors of restrained and emotional eating behaviour. **Conclusion:** Hence, these findings highlight the potential for enhancing students' awareness of a healthy lifestyle by addressing the relationship between nutrition literacy and stress. Thus, it can serve as a guide to provide a good intervention in managing stress and increasing nutrition literacy level among university students.

INTRODUCTION

A healthy diet is essential for optimal body function, providing necessary nutrients and energy. The World Health Organization (2020), emphasizes key aspects of a healthy diet, including balanced energy intake, reduced saturated and trans fats, increased fruit and vegetable consumption, and limited sugar and salt. Nutrition and academic demands can lead to poor food choices, such as a higher intake of snacks and fast food (Barrington et al., 2014).

* *Corresponding author.*
E-mail address: ariffib@iium.edu.my

literacy, knowledge and skills related to healthy eating helps individuals make informed dietary choices, which is crucial for university students as it affects their physical and mental health and overall academic performance.

However, university students often struggle to maintain healthy eating habits due to academic and social pressures. Increased stress levels from independent living

Eating behaviours are influenced by environmental, social, and biological factors, including personal preferences and nutrition knowledge (Kabir et al., 2018).

Given the health risks associated with poor eating behaviour, like obesity and non-communicable diseases,

this study investigates the relationship between nutrition literacy, stress, and eating behaviors among university students (Davison et al., 2019). According to the National Health Morbidity Survey (2023), the prevalence of overweight or obesity was 54.4% in Malaysia, which kept increasing from 2011 to 2023 by approximately 10%. The epidemic of obesity in Malaysia is an issue of significant concern due to its possible implications for other metabolic syndromes, such as hypertension, dyslipidemia, and impaired glucose or insulin metabolism, which contribute to a significant amount of the worldwide disease burden (Alberti et al., 2005). One of the main factors contributing to the growth of those metabolic syndromes is poor eating behaviour, which is characterized by unhealthy dietary choices and lifestyle behaviours (Peters et al., 2020). Additionally, insufficient understanding of nutrition (Zeng et al., 2022) and psychological factors (Hill et al., 2022) such as perceived stress, depression, boredom, and anxiety, have been linked to poor eating behaviour.

The relationship between nutrition literacy and stress is complex. While nutrition literacy aids in making healthier choices, stress can disrupt decision-making, hindering individuals' ability to choose healthy options (Moehlecke et al., 2020). Stress is linked to various eating behaviours, including emotional eating, which often results in the consumption of high-calorie foods during stressful times (Černelič-Bizjak & Guiné, 2022). Stress can also lead to restrained eating, where individuals try to control their intake but may end up binge eating when restrictions are unsustainable (Poínhos et al., 2015).

Stress heightens sensitivity to external food cues, such as impulsive eating due to food appearances even when not hungry (Oliver et al., 2000). Therefore, the interaction between stress and nutrition literacy on eating behaviours requires further exploration. In addition, the research on eating behaviour often overlooks university students in comparison to children and adults (Nuur Fazliza Wan Zakaria et al., 2021). Young adults are the most vulnerable group to engaging in unhealthy eating behaviour due to the combination of rapid changes in physical growth and psychosocial development they encounter (Ganasegeran et al., 2012). Nevertheless, there exists a lack of empirical research investigating the correlation between nutrition literacy, stress, and eating behavior, particularly within the context of university students. Understanding how stress influences dietary choices among those with high nutrition literacy is crucial for creating targeted interventions to promote healthier eating in university students.

This study specifically examines how stress affects emotional, restrained, and external eating behaviours among IIUM students. Insights gained from this research can inform future health promotion strategies focused on stress management and improving nutrition literacy to encourage healthier eating habits.

MATERIALS AND METHODS

Subjects

All IIUM students aged 18 years old and above were recruited to participate. Ethical approval was sought from the Kulliyyah Postgraduate and Research Committee (KPGRC) and International Islamic University Malaysia Research Ethical Committee (IREC) under the identification number IREC 2024-(KAHS/NS9) before conducting data collection.

Socio-Demographic Factors

This part consisted of the questionnaire on the participants' socio-demographic factors such as gender, age, race, campus, academic level, kulliyyah, year of study, current living (on campus, off campus, living with family), and self-reported anthropometry measurements.

Short Nutrition Literacy Scale (S-NutLit)

This section consisted of 11 questions. The first five questions focused on functional nutrition literacy, while the remaining six address critical nutrition literacy both used a 5-point Likert scale.

Perceived Stress Scale (PSS)

This part of the questionnaire consisted of 10 questions to measure the level of stress among IIUM students. The score was calculated by reversing responses to the four positively stated items (items 4, 5, 7, and 8) and then totaling across all scale items (e.g., 0 = 4, 1 = 3, 2 = 2, 3 =1 & 4 = 0). Meanwhile, questions 2, 4, 5, and 10 were combined to form a short 4-item scale. It showed that a high level of stress of the participants obtained a maximum 27 score which is more than 27, 14-26 was considered a moderate level of stress while the minimum score is less than 13.

Dutch Eating Behavior Questionnaire (DEBQ)

The part of the questionnaire contained 33 questions that assessed three dimensions of eating behaviour: restrained, emotional, and external eating. Responses

were measured on a 5-point Likert scale from 1 (never) to 5 (very often). The first 10 questions focused on restrained eating, questions 11 to 23 addressed emotional eating, and questions 24 to 33 covered external eating.

Statistical Analysis

The data was analysed with the Statistical Package for the Social Sciences Version 29 (SPSS version 29.0). Descriptive analysis was performed to calculate the percentage, of socio-demographic data, nutrition literacy level, stress scale and eating behaviour score. Pearson Product-Moment Correlation and multiple regression were utilised to investigate the connection between nutrition literacy, stress and eating behaviour.

RESULTS

Socio-Demographic Factors

A total of 384 students were recruited, including 77.9% (n =299) female and 22.1% (n=85) male. Most of the respondents were at the age of 22-23 years old (40.6%, n =156), followed by 20-21 years old (31.8%, n = 122), 18-19 years old (24.7%, n = 95), 24 and above (2.9%, n = 11). All respondents were Malay race. Undergraduate students 69.0% (n=265) were the majority while there were 19.2% (n=74) foundation students, and the remaining 11.7% (n=45) were postgraduate students. The majority of the respondents were from IIUM Kuantan campus respondents (52.6%, n=202), while the least number of respondents were from Pagoh campus at (11.2%, n=43). Only one respondent reported living of campus with their family.

Table 1: Sociodemographic results

Variables	Categories	*n*	*%*
Gender	Male	85	22.1
	Female	299	77.9
Age	18-19	95	24.7
	20-21	122	31.8
	22-23	156	40.6
	24 & above	11	2.9
Race	Malay	384	100
Campus	CFS Gambang	74	19.2
	Kuantan	202	52.6
	Gombak	65	16.9
	Pagoh	43	11.2
	Year 1	95	24.7
	Year 2	67	17.5
	Year 3	90	23.4
	Year 4	58	15.1
Academic level	Foundation	74	19.2
	Undergraduate	265	69.0
	Postgraduate	45	11.7
Living Campus	On Campus	383	99.7
	Stay with Family	1	0.3
Kulliyyah	AIKOL	12	3.1
	KAED	12	3.1
	KAHS	144	37.5
	KENMS	17	4.4
	KICT	8	2.1
	KIRKHS	44	11.5
	KLM	46	12.0
	KOD	2	0.5
	KOE	20	5.2
	KOED	7	1.8
	KOM	8	2.1
	KON	18	4.7
	KOP	11	2.9
	KOS	35	9.1

Nutrition Literacy Level

Functional Nutrition Literacy

It was reported that most of the students were on the high functional nutrition literacy level, shown by 333 students with a prevalence of 86.7%. As for the low functional nutrition literacy categories, there was a slight prevalence difference, showing that 13.3% of the students with 51 respondents were in the low functional nutrition literacy category.

Critical Nutrition Literacy

The analysis showed that most of the students showed a high critical nutrition literacy level, with a prevalence of 79.4 % among 305 students. 20.6% (n=79) revealed low levels of critical nutrition literacy.

Stress Level

A total of 56 students with a prevalence of 14.6% have a high stress level. Most of the respondents have a moderate stress level which was 70.6%, as shown by 271 respondents. 14.8% of the students, or 57 respondents, were found to have low-stress levels.

Eating Behaviour Level

A descriptive analysis reported that most of the students were on a highly restrained eating behaviour level, a high emotional eating level, and a high external eating level.

Table 2: Level of Nutrition Literacy, Stress & Eating Behaviour

Variables	Level	n	%
Functional nutrition literacy	High	333	86.7
	Low	51	13.3
Critical nutrition literacy	High	305	79.4
	Low	79	20.6
Stress	High	56	14.6
	Moderate	271	70.6
	Low	57	14.8
Restrained eating	High	247	64.3
	Low	137	35.7
Emotional eating	High	249	64.8
	Low	135	35.2
External eating	High	377	98.2
	Low	7	1.8

Correlation Between Nutrition Literacy, Stress, and Eating Behaviours

Pearson correlation test was done to investigate the relationship between nutrition literacy and stress towards eating behaviour. Table 3 indicates the results of the correlation analysis between functional nutrition literacy, critical nutrition literacy, stress, and three dimensions of eating behaviour that consist of restrained, emotional, and external eating behaviour among IIUM students.

The results of correlation analysis revealed a significant relationships between stress and emotional eating (r=.142, p<0.05), critical nutrition literacy and restrained eating (r=.123, p<0.05). Finally, there was a positive relationship between functional nutrition literacy and critical nutrition literacy (r=.670, p<0.05). Based on correlation analysis all sub dimension that measure eating behaviour showed significant relationship to each onther.

Table 3: Correlation Test for Nutrition Literacy, Stress and Eating Behaviour

	Variables	1	2	3	4	5
1	Stress	1				
2	Functional nutrition literacy	-.64	1			
3	Critical nutrition literacy	-.50	.670**	1		
4	Restrained eating	.086	.093	.123*	1	
5	Emotional eating	.142**	-.052	-0.48	.191**	1
6	External eating	0.42	-.099	-.081	-.111*	.353**

*Correlation is significant at the 0.05level (2-tailed)

** Correlation is significant at the 0.001 level (2-tailed)

Regression Between Critical Nutrition Literacy, Stress, and Restrained Eating Behaviour

Regression analysis was conducted to analyse the significance of the predictor which is critical nutrition literacy and stress toward restrained eating behaviour. According to Table 4 above, R^2 value = 0.024 showed only a 2.4 % variance between the variables. *F* value showed that there is a significant relationship between the variables that prove that critical nutrition literacy can lead to restrained eating behaviour among IIUM students F (2, 381) = 4.615, p < 0.001.

It is found that critical nutrition literacy (b = 0.09, p < 0.001) is significantly predictive of restrained eating behaviour among IIUM students. The result showed that the restrained eating behaviour increased by 0.283 for every one-unit increase in critical nutrition literacy. However, it is only 2.4%, which is very low for critical nutrition literacy to be a predictor of restrained eating behaviour.

Table 4: Predictors to Restrained Eating Behaviour

Predictor	*B*	*SE*	*Beta*	*t*	*Sig.*
(Constant)	20.89	2.51			
Stress	0.137	0.075	0.092	1.82	0.070
Critical nutrition literacy	0.283	0.112	0.128	2.52	0.012
Model summary	R = .154 R^2 = .024 *Adj.* R^2 = .019 *SE* = 9.070 $F(2, 381) = 4.615$, $p < .001$				

Regression Between Critical Nutrition Literacy, Stress, and Emotional Eating Behaviour

Regression analysis was conducted to identify the significance of the predictor which is critical nutrition literacy and stress towards emotional eating behavior among IIUM students. According to Table 5, R^2 value = 0.022 showed only a 2.2% variance between the three variables. F value demonstrated a significant relationship that proved critical nutrition literacy, and stress can lead to emotional eating behaviour among IIUM students F (2, 381) = 4.28, p < 0.001. It is found that stress (b = 0.269, p < 0.001) is significantly predictive of emotional eating behaviour among IIUM students.

Table 5: Predictors to Emotional Eating Behaviour

Predictor	***B***	***SE***	***Std B***	***t***	***Sig.***
(Constant)	34.850	3.254			
Stress	0.269	0.097	0.140	2.766	0.000
Critical nutrition literacy	-0.118	0.145	-0.041	-0.816	0.415
Model summary	R = .148				
	R^2 = .022				
	Adj. R^2 = .017				
	SE = 11.741				
	$F(2, 381) = 4.280$, $p < .001$				

DISCUSSION

Nutrition Literacy Level

The primary objective of this study was to assess the nutrition literacy level among IIUM students. Findings show that the majority of IIUM students have a high level of nutrition literacy, contrasting with a study by Liao et al., (2019) which reported that college students in Taiwan had suboptimal nutrition literacy. According to Liao et al. (2019), Taiwanese college students were confident in obtaining information due to their Internet skills but struggled to assess the credibility of online health resources. The difference in findings may be due to the educational background of the IIUM respondents, many of whom are in healthcare-related programs with greater exposure to nutrition information.

Additionally, this study found that students' functional nutrition literacy scores were slightly higher than their critical nutrition literacy. Functional nutrition literacy involves basic skills in understanding nutritional information, while critical nutrition literacy requires advanced skills to evaluate, identify misinformation, and reflect on nutrition based on personal needs. Zhang et al. (2022), suggest that individuals with strong functional nutrition knowledge may retain it even without critically engaging with it. Silva (2023) emphasizes the importance of practical skills for applying nutritional information to achieve a balanced diet. These results suggest that although IIUM students can meet their immediate dietary needs, there is potential for improvement in their capacity to critically evaluate more intricate nutrition issues.

Stress Level

This study revealed that most IIUM students have a moderate stress level, which is consistent with the findings from Wong et al. (2023). In a study by Wong et al. (2023), several characteristics were identified as contributors to stress in university students, including sleeping patterns, gender, socioeconomic status, and ethnicity. Research indicates that college students exhibit a greater susceptibility to mental health conditions, such as stress, anxiety, and depression, as compared to the general population.

Nutrition Literacy and Eating Behaviour

This study examines the relationship between two dimensions of nutrition literacy which are critical and functional, and three types of eating behaviours (restrained, emotional, and external) among IIUM students. The findings revealed a significant association between critical nutrition literacy and restrained eating behaviour. Students with higher critical nutrition literacy are more conscious of their dietary intake and more likely to control food consumption to achieve or maintain their desired weight or health status. This controlled eating behaviour reflects a form of dietary restraint, where individuals intentionally limit food intake to manage body weight. Consistent with Poínhos et al. (2015), who found Portuguese nutrition students with higher critical literacy, especially females, were more inclined toward restrained eating, these behaviours can be beneficial if students practice flexible restraint by balancing their diet without strict limitations (Nagrath et al., n.d.).

In contrast, no significant association was found between functional nutrition literacy and any of the three eating behaviours. Functional nutrition literacy involves basic skills like reading food labels and understanding dietary information, which is important for informed eating choices but may not directly impact restrained, emotional, or external eating behaviours. The ability to

acquire and comprehend nutrition information alone does not necessarily impact how students manage their eating habits, especially in response to emotions or external cues. As Alzaben et al. (2021) noted, while nutrition education increases knowledge, it doesn't always lead to behaviour changes, pointing to a gap between knowledge and its practical application. Additionally, functional literacy alone may not sufficiently predict eating behaviours, as factors such as stress and emotions often play a more significant role, especially in emotional eating (Macht, 2008). Higher-level literacy skills, combined with a supportive environment, may, therefore, be necessary to impact eating behaviours effectively (Gibbs & Chapman-Novakofski, 2012).

Stress and Eating Behaviour

This study revealed a significant association between stress and emotional eating, indicating that students under high stress are more likely to eat in response to sadness, frustration, or anxiety rather than hunger. Shah et al. (2023) found a positive correlation between perceived stress and emotional overeating among Malaysian adolescents, suggesting that students turn to palatable foods for immediate comfort. However, this behaviour often fails to improve mood in the long term and may lead to consuming nutrient-poor foods, potentially resulting in feelings of shame (Carpio-Arias et al., 2022). Additionally, no significant association was found between stress and restrained eating, suggesting that stress does not necessarily drive students to limit their food intake, as restrained eating tends to relate more to cognitive control and dietary goals than emotional states. However, Herhaus & Petrowski (2021) reported conflicting results, finding that stress could lead to restrained eating, potentially causing overeating once the restraint phase ends.

CONCLUSION

In conclusion, the study found a significant link between stress and emotional eating behaviour, indicating that higher stress levels lead students to use food as a coping mechanism, which can result in unhealthy eating habits. Additionally, there was a strong correlation between critical nutrition knowledge and controlled eating behaviour; students with higher critical nutrition literacy tended to practice more restrained eating, suggesting a more mindful approach to their food choices.

Future research should investigate additional factors that influence eating behaviour among students, such as physical activity, sleep patterns, mental health, and socioeconomic status. These factors may play significant roles in shaping eating habits, as nutrition literacy and stress are just a small part of the picture. Exploring these factors with stress and nutrition literacy could offer a more holistic well being, deeper understanding of the determinants of eating behaviour in the student population.

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ORIGINAL ARTICLE

Optimization of High Antioxidant Smoothie from A Mixture of Milk, Fruits and Vegetables by Response Surface Methodology (RSM)

***Badr Eddin Kharsa[1], Muhammad Bin Ibrahim[1,2,3,*], Abd Almonem Doolaanea[4], Mohd Nur Nasyriq Bin Anuar[5],* Azizah Othman[6]**

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Institute of Planetary Survival for Sustainable Well-being (PLANETIIUM), Level 2, International Islamic University Malaysia, Jalan Hospital, 25100 Kuantan, Pahang, Malaysia
[4]Research and Development Sabrena Experience, 500 Dragon Street Suite 160, Dallas, Texas, USA
[5]Discipline of Basic Health Sciences, Pharmacology and Toxicology, Faculty of Pharmacy, Universiti Sultan Zainal Abidin, Besut Campus, 22200, Besut, Terengganu, Malaysia
[6]School of Industrial Technology, Faculty of Applied Sciences, Universiti Teknologi MARA, 40450 Shah Alam, Selangor Malaysia

ABSTRACT

Introduction: Smoothie which is mainly prepared from fruits and vegetables is a good source of health-promoting bioactive compounds, primarily antioxidants, which actively modulate disease development by inhibiting ROS-mediated reactions in the body. Smoothies represent an excellent and convenient alternative to promote the daily consumption of fruits and vegetables. **Methods:** The optimum combination of the five factors (carrot, beet, lettuce, pineapple, and banana) used to obtain the highest yield of total phenolic content (TPC), DPPH, and FRAP was analyzed using the central composite design by response surface methodology. These frutirs and vegetables used due to their availability and well-known health benefits. The effects of carrot (X1: 25-60g), beet (X2: 25-60g), lettuce (X3: 25-60g), pineapple (X4: 30-70g), and banana (X5: 25-60g), on the three variables (Y1, Y2, and Y3) were tested. **Results:** RSM generated 50 formulations**.** The experimental outcomes were adequately fitted into a second-order polynomial model regarding TPC (R^2 = 0.9436, p = 0.0001), DPPH (R^2 = 0.9292, p = 0.001), and FRAP (R^2 = 0.0.9176, p = 0.001). The optimum combination was 25 g of carrot,25 g of beet, 25.55 g of lettuce, 70 g of pineapple, and 30.05 g of banana. The predicted results for TPC, DPPH, and FRAP were 21.87 mg GAE/100 g, 37.17 mmol TE /100g, and 54.12 mmol TE /100g, respectively. The experimental outcomes were close to the predicted results: 21.97±0.99 mg GAE/100 g, 36.86±0.76 mmol TE /100g, and 52.26±1.52 mmol TE /100g, respectively. **Conclusion:** As a result, RSM successfully optimized the range of variables. Consequently, the optimal combination of fruits and vegetables provided the highest antioxidant content and activities, which can be used as a functional smoothie.

Keywords:
Smoothie; RSM; antioxidant; phenolic content

INTRODUCTION

Due to the increased prevalence of lifestyle diseases and awareness of the significance of a healthy lifestyle by the public, the market for functional foods and beverages has been growing and developing very quickly (Gayathry & John, 2021).

Milk contains several essential nutrients and is applied in beverage preparation to optimize nutritional content, texture, and overall consumer acceptability (Panda et al., 2023). Bananas, pineapple, carrot, beet, and lettuce are known to have several health benefits due to their bioactice compounds (Abd Halim et al., 2023; Netshiheni et al., 2019).

Despite the well-known health benefits of consuming fruits and vegetables, Malaysians are not consuming enough (Rodríguez-Verástegui et al., 2016). Thus, consuming fruits and vegetables should be promoted

* *Corresponding authors*

*E-mail address: **badr.kh19@gmail.com** **and** abumaisarah@iium.edu.my*

through the development of ready-to-eat with minimal and nonaggressive treatments. Accordingly, smoothies represent an excellent and convenient alternative to promote the daily consumption of fruits and vegetables. Therefore, high-antioxidant smoothies could be supplementary products for managing and preventing diseases and an alternative natural product of artificial fake functional food in the market (Tkacz et al., 2021).

Response Surface Methodology (RSM) is a combination of statistical and mathematical methodologies to improve processes, design, and formulate a product (Pinheiro et al., 2020). As such, this research aimed to develop and formulate a high-antioxidant smoothie from a mixture of milk, carrot, beet, lettuce, pineapple, and banana using response surface methodology.

MATERIALS AND METHODS

Chemicals and Reagents

All chemicals were from analytical grades obtained from Sigma, Merck, and Fisher Scientific.

Smoothie Preparation and Antioxidant Extraction

Figure 1 shows the ingredients used in smoothie preparation. The smoothie mixture consisted of two parts. The first is milk, which represents 35% of the whole mixture. The second part of the mixture contains a combination of fruits and vegetables, making up 65% of the whole mixture. Smoothie preparation was conducted at the Food Analysis Laboratory in Kulliyyah of Allied Health Sciences, International Islamic University Malaysia. The mixture was blended until the mixture was homogeneous. After that, the smoothie mixture was kept in the freezer for further analysis. However, antioxidant extraction was according to the method described by Rodríguez-Verástegui et al. (2016).

Figure 1: The ingredients used in smoothie preparation

Experimental Design

Response surface methodology was used to determine the optimum levels of carrot, beet, lettuce, pineapple, and banana for maximizing the antioxidant content and activities of the smoothie mixture on three dependent variables (responses), namely, total phenolic content (TPC), DPPH, and FRAP. The relationship between the process variables and the optimized formulation of the smoothie, in terms of its TPC, DPPH, and FRAP, was identified by adopting two factors inscribed central composite design (CCD). The independent variables investigated were carrot (X_1:25-60 g), beet (X_2: 25-60 g), lettuce (X_3: 25-60 g), pineapple (X_4:30-70 g), and banana (X_5: 30-70 g). The optimized independent variables were coded at 3 levels -1, 0, +1 (Table 1). Fifty randomized experiments were constructed.

Total Phenolic Content and antioxidant activities

The TPC was determined based on the method described by Rodríguez-Verástegui et al. (2016). DPPH and FRAP assays was conducted according to Abdullah et al. (2021).

Table 1: Coded and actual value levels of independent variables used for the optimization of high antioxidant smoothie by RSM

Independent variables	Unit	Factor	Coded level				
			-1	0	1	Axial (-α)	Axial (+α)
Carrot (X_1)	Gram	X1	25	42.5	60	0.88	84.12
Beet (X_2)	Gram	X2	25	42.5	60	0.88	84.12
Lettuce (X_3)	Gram	X3	25	42.5	60	0.88	84.12
Pineapple (X_4)	Gram	X4	30	50	70	2.43	97.57
Banana (X_5)	Gram	X5	30	50	70	2.43	97.57

Statistical Analysis

The statistical analysis used the Design-Expert Version 6.0.10 (Minneapolis, MN) software. The results were expressed as mean values. The response surface analysis was utilized to verify the regression coefficient and statistical significance of the experimental data models intended to optimize the response variables. The adequacy of the model was predicted through the regression analysis (r^2) and the ANOVA analysis ($p<0.05$). The desired aim was set in numerical optimization to generate the optimal conditions and point prediction outcomes of the model.

Model verification

The experimental data for TPC, DPPH, and FRAP were calculated based on the optimum conditions suggested by RSM software. The response surface model was verified by comparing the independent factors' experimental value with the optimized model's predicted value.

RESULTS AND DISCUSSION

Fitting the Model

The experimental values of TPC (Y1), DPPH (Y2), and FRAP (Y_3) were employed in multiple linear regression analysis performed using response surface analysis to fit the polynomial equation. The minute difference between the experimentally obtained response values and the predicted values indicates that an adequate model was obtained. The coefficient of the determination (R^2), adjusted (R^2), predicted (R^2), probability values (p), coefficient of variation (CV), and lack-of-fit values for response variables are tabulated in Table 2**.** The coefficients of determination (R^2) obtained were 0.94, 0.93, and 0.92 for TPC, DPPH, and FRAP, respectively, therefore indicating that approximately (91-94%) of the variations described by the model (Fan et al., 2008). In this study, the probability (p values) were less than < 0.01 for all of the response models suggesting that the models for the responses are statistically significant. None of the models displayed a significant lack of fit, suggesting that all the second-order polynomial models correlated well with the obtained results . The coefficient of variation (CV) is a measure of deviation from the mean values, which shows the reliability of the experiment. In general, CV<10% indicates better reliability. From the present findings, the TPC, DPPH, and FRAP showed low CV values (<5). Moreover, it is desirable to have sufficient precision (signal-to-noise ratio) greater than 4 (Nissar et al., 2017). In the current study, all parameters displayed a high degree of adequate precision.

Table 2 : Statistical parameters obtained after the implementation of a two-factor central composite experimental design

Coefficient	TPC	DPPH	FRAP
R^2	0.94	0.93	0.92
Adj R^2	0.90	0.88	0.86
Pred R^2	0.81	0.75	0.75
(p value)	< 0.01	< 0.01	< 0.01
Lack of fit	0.13	0.56	0.63
C.V	4.82	4.53	3.77
Adequate precision	19.64	16.15	18

Effect of The Independent Variables on TPC, DPPH, and FRAP

The second-order polynomial regression equation explained the effect of five independent variables on TPC, DPPH, and FRAP through the significant (p<0.05) coefficient. For TPC (Y1), the combination of fruits and vegetables showed a significant (p<0.05) effect regarding the first-order linear effect (X_1, X_2, X_3, X_4, and X_5), second-order quadratic effect (p<0.05) (X_1^2, X_2^2, X_4^2 *and* X_5^2), and interaction effect (p<0.05) ($X_1.X_4$, $X_2.X_4$, $X_2.X_5$, $X_3.X_5$ and $X_4.X_5$).

The predicted model observed for TPC (Y_1) Eq. (2) was:

TPC = +13.56 - 0.49 (X_1) -0.72 (X_2) - 0.55(X_3) + 1.30 (X_4) - 1.21(X_5) + 0.39 (X^2_1) + 0.61(X^2_2) + 0.65(X^2_4) + 0.55 (X^2_5) - 0.35 ($X_1.X_4$) + 0.39($X_2.X_4$) + 0.54 ($X_2.X_5$) + 0.38($X_3.X_5$) - 0.68($X_4.X$) (2)

Based on Eq. (2), carrot, beet, lettuce, and banana had shown a negative effect on total phenolic content. Meanwhile, pineapple exhibited a positive effect on TPC. The total phenolic content of the formulations decreases as the proportions of carrot, lettuce, beet, and banana increase. On the other hand, the total phenolic content (TPC) increases as the proportion of pineapple increases, which causes the most significant rise in TPC. Eq. (2) showed that TPC positively related to the quadratic effect of independent variables (carrot, lettuce, banana, and pineapple). In terms of interactions between factors, X_4 (pineapple) exhibited a significant negative effect with X_1(carrot) and X_5 (banana), while the interaction effect with X_3 (lettuce) was significantly positive ($p<0.05$). Subsequently, the individual quantity of each component used in smoothie production significantly affected the total phenolic content.

The total phenolic content for the 50 formulations varied from 12.481 mg/100g – 22.065 mg/100g gallic acid. The lowest concentration of TPC was measured when the formulation was set at (X_1= +1, X_2= +1, X_3= +1, X_4= -1 and X_5 = -1). Meanwhile, the highest concentration was measured when the formulation was at (X_1= -1, X_2 = -1, X_3= -1, X_4= +1 and X_5= -1). This indicated that the presence of pineapple in the mixture had a more significant impact than other variables on the increase in the phenolic content of the samples.

3D response surface plots were built to interpret the interactive effects of independent variables based on multiple linear regression equations, which can further assist in process optimization, help decide the optimal process conditions, and explain the cumulative effect of input variables on response values (Yang et al., 2019). Figure 2 reveals a linear and quadratic effects of variables in total phenolic content.

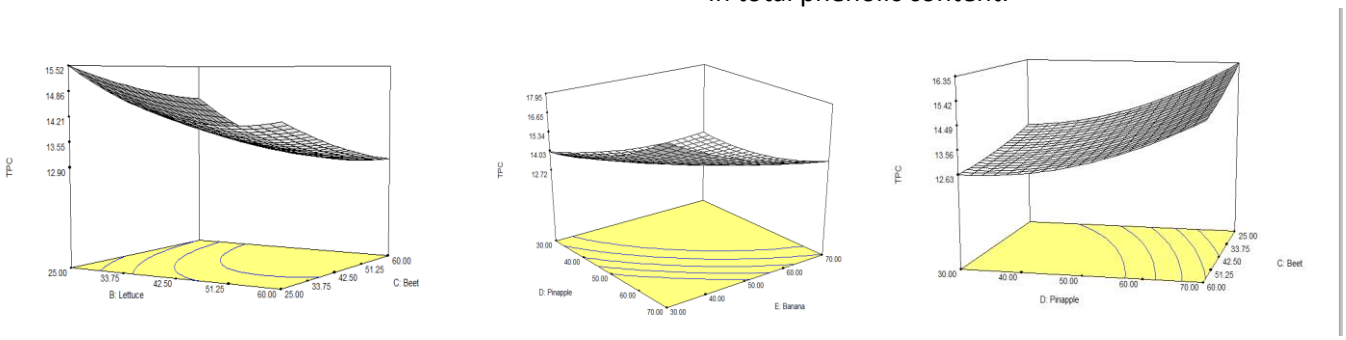

Figure 2 : Three-dimensional effect of variables on TPC

For DPPH, the combination of fruits and vegetables showed significant ($p<0.001$) effect regarding first-order linear effect (X_1, X_2, X_3, X_4 and X_5), second-order quadratic effect ($p<0.05$) (X_1^2, X_2^2,X_3^2 X_4^2, *and* X_5^2) and interaction effect ($p<0.05$) ($X_1.X_4$, $X_2.X_4$ and X_4X_5) towards DPPH (Y_2). The predicted model observed for DPPH (Y_2) was calculated according to Eq. (4)

$$\textbf{DPPH} = +25.59 - 0.87X_1 - 1.75X_2 - 0.94X_3 + 2.04X_4 - 1.33X_5 + 0.80\,(X^2_1) + 0.37\,(X^2_2) + 1.23\,(X^2_3) + 0.78\,(X^2_4) + 0.98\,(X^2 5) - 0.64X_1X_4 + 0.85X_2X_4 - 0.69X_4X_5 \quad (4)$$

Except for pineapple, which had a ($p<0.05$) significant positive correlation with DPPH, other variables had a significant ($p<0.05$) negative correlation with DPPH.
The negative correlation of the four variables (carrot, beet, lettuce, and banana) with DPPH indicates that as the concentration of these variables increases, DPPH decreases. In contrast, pineapple showed a positive correlation with DPPH. Any increase in pineapple causes a rise in DPPH level. It can be seen from Eq. (4) that DPPH is positively related to the quadratic effect of the five independent variables. Interaction terms between factors showed that X4 (pineapple) had a significant ($p<0.05$) negative effect with X1(carrot) and a significant positive effect with X_2 (beet). Subsequently, the individual quantity of each component used in smoothie production had a significant effect on the DPPH.
The DPPH values for the 50 formulations varied from 22.38-37.86 mmol/100g Trolox. The results showed that DPPH exhibited the lowest value (22.38 mmol/100g Trolox) when the formulation was set at (X_1= 0, X_2= 2.378, X_3=0, X_4=0 and X_5 = 0). Meanwhile, the highest level of DPPH value measured when the formulation was at (X_1= -1, X_2 = -1, X_3= -1, X_4= +1 and X_5= -1).
Figure 3 shows a linear and quadratic effects of variables on DPPH values. This might be due to the interactions between phytochemical compounds due to various factors (Educational & Panchor, 2020).

For FRAP, the combination of fruits and vegetables showed significant ($p<0.001$) effect regarding first-order linear effect (X_1, X_2, X_3, X_4, and X_5), second-order quadratic effect ($p<0.05$) (X_1^2, X_2^2, X_4^2 *and* X_5^2) and interaction effect

(p<0.05) ($X_1.X_4$, $X_1.X_5$, X_3X_4, X_3X_5 and X_4X_5). The predicted model observed for FRAP (Y_3) was calculated based on Eq.(5)

FRAP = +45.81 -1.23 (X_1) -2.36 (X_2) +1.02 (X_3) + 2.20 (X_4) - 1.15 (X_5) + 0.77 (X^2_1) - 0.58 (X^2_2) + 1.05(X^2_4) + 0.99 (X^2_5) - 1.11 (X_1X_4) + 1.01 (X_1X_5) - 0.91 (X_3X_4) -1.60 (X_3X_5) +1.21 (X_4X_5) (5)

The significant quadratic showed that three independent variables (carrot, beet, and banana) showed a significant (p<0.05) negative effect on FRAP. On the other hand, lettuce and pineapple showed a significant (p<0.05) positive impact on FRAP. FRAP values decrease with an increase in carrots, beet, and bananas. Meanwhile, FRAP values increase with an increase in pineapple and lettuce. Considering the quadratic effects of variables, Equation 5 showed that carrot, pineapple, and banana showed a significant (p<0.05) positive correlation with FRAP, while lettuce showed a negative quadratic effect (p <0.05). The interaction terms between ($X_1.X_4$), (X3.X4), and (X3.X5) showed a negative significant (p<0.05) effect on FRAP value, while (X1.X5) and (X4.X5) showed a positive significant effect on FRAP (p<0.05).

The FRAP value for the 50 formulations varied from 36.48 – 60.85 mmol/100g Trolox. The lowest level of FRAP value (36.48 mmol/100g Trolox) was measured when the formulation number was (X 1= 0, X2 = 2.37, X3= 0, X4= 0, and X_5= 0). Meanwhile, the highest value of FRAP was measured when the formulation was (X_1= -1, X_2 = -1, X_3= 1, X_4= 1 and X_5= -1). Figure 4 reveals a linear and quadratic effects of variables on FRAP values

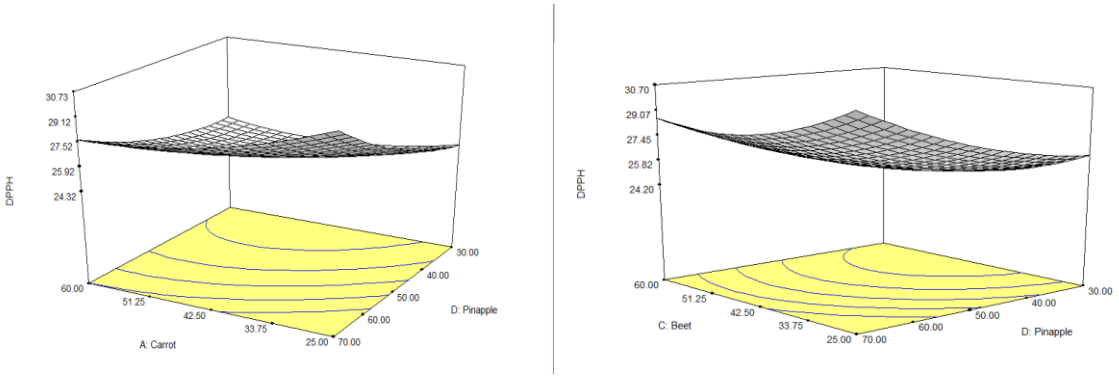

Figure 3 : Three-dimensional effect of variables on DPPH

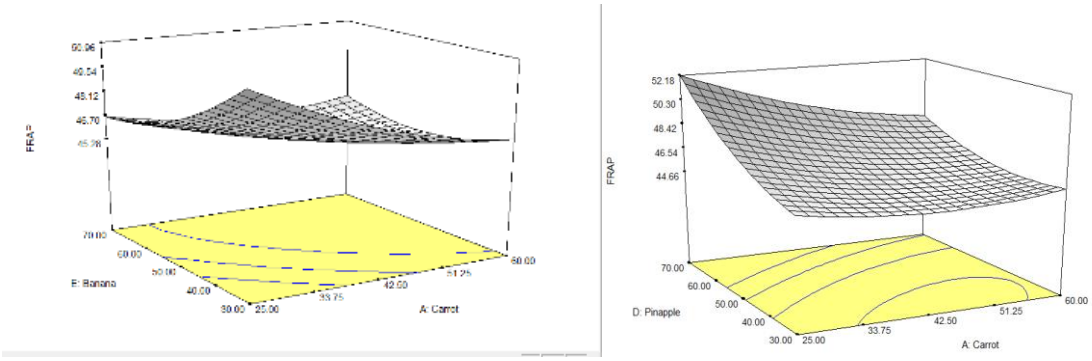

Figure 4 : The three-dimensional effect of variables on FRAP

The present global trend toward a healthy lifestyle has increased demand for convenient fresh meals that are rich in nutritional content. Thus, preparing a mixture of fruit and vegetables rich in antioxidants and having a good taste is the goal of this research. To date, fruits and vegetables such as , carrot, lettuce, beet, pineapple, and banana have been reported to contain a significant amount of phytochemical compounds that can prevent several diseases (Castillejo et al., 2016).

The phenolic content in the abovementioned fruits and vegetables is effective in absorbing and neutralizing free radicals. In this study, the observed positive and negative effects of variables and their interactions on total phenolic content might be due to the interactions between phytochemicals compounds in each factor (Stig et al., 2009). Furthermore, one study conducted by Ibrahim et al. (2022) revealed that a smoothie with a higher ratio of pineapple exhibited a higher value of total phenolic content. Also, the increase in TPC with the reduction of carrot, beet, lettuce, and pineapple might be due to the pro-oxidant activity, which may occur on factors (Michaëlsson et al., 2018). As far as

reviews are concerned, pineapple is reported to be a novel antioxidant fruit that is rich in phenolic and flavonoid content. It also shows a strong antioxidant activity. Thus, higher phenolic content could be attributed to the inherent antioxidant properties of pineapple itself. Also, a consideration of the synergistic effects of different factors in the smoothie mixture and how all factors together contribute to the phenolic content and antioxidant capacity of the smoothie should be taken (Uduwana et al., 2023).

Several methods are used to measure antioxidant activity, with the DPPH assay being the most common. Another assay is FRAP (ferric-reducing/antioxidant power), which measures the conversion of a Fe_{3+}/ferricyanide complex to the ferrous form (Zou et al., 2015). The presence of pineapple in the mixture had a greater impact than other variables on the increase in the antioxidant activities measured by DPPH and FRAP. The antioxidant activity of the 50 formulations increases with total polyphenol contents. Also, geographical and climate conditions may affect the concentration of antioxidants in each factor. Additionally, the synergistic effects of each factor in the smoothie mixture contribute to the antioxidant activities (Uduwana et al., 2023).

Optimization of Responses and Verification of Model

Each industrial process requires optimization as it has a direct influence on product quality and process efficiency. Each of the investigated responses might be optimized independently on a target value; however, each has its optimum parameters, but not all of them are in great correlation, indicating that improving one response could have the opposite effect on another. However, by using RSM approach and desirability function (D), several responses can be optimized simultaneously (Saikia et al., 2020).

In this study, the independent variables were studied in range; meanwhile, the responses were maximized to obtain a mixture with high TPC, DPPH, and FRAP values. Therefore, the TPC, DPPH, and FRAP values of the mixture were simultaneously optimized according to the target presented in Table 3. Numerical optimization has been used to determine the best condition for independent variables from various solutions generated. Considering the degree of desirability (D) (0.905), the optimum combination was determined to be 25 g of carrot,25 g of lettuce, 25.55 g of beet, 70 g of pineapple and 30.05 g of banana with the predicted response values for TPC, DPPH and FRAP 21.87 mg/100g gallic acid, 37.17 mmol/100g Trolox, and 54.12 mmol/100g Trolox, respectively.
The combination that yielded the optimum condition was repeated to test the response surface models' ability to predict the optimal response values. The observed values of the total phenolic content, DPPH, and FRAP were 21.97±0.99 mg/100g gallic acid, 36.86±0.76 mmol/100g Trolox, and 52.26±1.52 mmol/100g Trolox, respectively. The experimental and predicted values were compared to verify the response surface model. The predicted and the experimental values were compared by the degree of difference. The differences for TPC, DPPH, and FRAP were 0.46%, 0.8%, and 3.43%, respectively. Therefore, the experimental values were close to the predicted values, and the model was verified (Table 3).

Table 3 : Simultaneously optimized conditions with target and predicted values of responses.

Response	Target	Predicted value	Experimental value	% Difference
TPC mg GAE/100g	Maximized	21.87	21.97±0.99	0.46%,
DPPH mmol TE /100g	Maximized	37.17	36.86±0.76	0.8%
FRAP mmol TE /100g	Maximized	54.12	52.26±1.52	3.43%

Experimental results were expressed as mean ±standard deviation (n=3)

CONCLUSION

The optimum combination that produced the highest TPC, DPPH, and FRAP from a mixture of fruits and vegetables was determined using a central composite design by response surface methodology. An adequate model equation was generated to predict the influences of the independent variables and their optimum level in the combination. TPC, DPPH, and FRAP successfully verified the high antioxidant combination. The final combination to prepare 100 grams of this smoothie is as follows: Milk: 35 grams, carrot: 9.25-gram, beet: 9.25-gram, lettuce: 9.5-gram, pineapple: 25.9 gram and banana: 11.1 gram. Thus, this combination can be considered optimal for the research's desired objective, which is to obtain a combination with high antioxidant content and activities.

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ORIGINAL ARTICLE

Ocular Surface Integrity, Dry Eye Signs and Symptoms in Wearers of Coloured Soft Contact Lenses from Different Sources

Hilman Muqriez Mohamad[1], Noor Ezailina Badarudin[2], Ilyanon Zahari[1,3], Mohamad Hanif Hajar Maidin[1,4,*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Department of Optometry and Visual Science, Management Science University, Shah Alam, Selangor, Malaysia
[3]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Kuantan, Pahang, Malaysia
[4]Ophthalmic Science Research Group (OSReG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Coloured soft contact lenses; optometry; non-optometry; dry eye; contact lens discomfort

ABSTRACT

Background: This study explored the effects of wearing coloured soft contact lenses (CL), sourced from both optometry and non-optometry providers, on ocular surface integrity and dry eye signs and symptoms. **Methods:** Five participants were randomly assigned to wear a pair of contact lenses from one of the two sources for one month, followed by a one-month washout period, after which they switched to lenses from the other source. Ocular surface integrity was assessed through measurements of tear meniscus height (TMH), non-invasive keratograph tear film breakup time (NIKBUT), and tear breakup time (TBUT) at three intervals: during the initial visit, one week post-wear, and one month post-wear. Additionally, participants completed the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) at the one-week and one-month follow-up visits to evaluate dry eye status. Repeated measures ANOVA was used to analyse changes in ocular surface integrity over the one-month period, while paired sample t-tests were conducted to assess changes in CLDEQ-8 scores between the one-week and one-month follow-ups. **Results:** The repeated measures ANOVA showed no significant differences in TMH, NIKBUT, or TBUT between the two types of contact lenses over the one-month period ($p > 0.05$). Similarly, paired samples t-tests revealed no significant changes in CLDEQ-8 scores between the base line, one-week and one-month follow-up visits ($p > 0.05$). **Conclusion:** The study concluded that there were no significant differences in ocular surface integrity or dry eye symptoms between coloured soft contact lenses obtained from optometry and non-optometry sources after one month of wear.

INTRODUCTION

Contact lenses are vital medical devices used to correct vision, alter appearance, and manage specific ocular conditions. Despite their widespread use and proven benefits, they are not without risks (Wu et al., 2010). While generally considered safe when used properly, many wearers experience discomfort, including dryness, irritation, and fatigue, particularly with prolonged wear (Kojima, 2018). The Tear Film and Ocular Surface Society (TFOS) International Workshop on Contact Lens Discomfort (CLD) identified several factors contributing to this discomfort, especially the mismatch between contact lenses and the natural ocular environment (Nicholas et al., 2013). Research consistently demonstrates a strong correlation between contact lens discomfort and dry eye conditions, highlighting the importance of proper lens fit and care (Chalmers & Begley, 2006; Nichols & Sinnott, 2006; Kojima, 2018).

In the U.S., the Food and Drug Administration (FDA) enforces rigorous pre- and post-approval processes to ensure the safety and efficacy of contact lenses (Saviola, 2003). This regulatory oversight is crucial, particularly due to concerns about infections and complications linked to unregulated decorative lenses. In 2002, responding to growing health concerns, the FDA collaborated with organizations like the American Academy of Ophthalmology and the Contact Lens Association of Ophthalmologists. This partnership resulted in amendments to the Federal Food, Drug, and Cosmetic Act (Public Law 109–96), strengthening public safety by regulating all contact lenses—whether corrective or cosmetic—as medical devices (Rhee et al., 2022).

In Malaysia, the Medical Device Authority (MDA) rigorously regulates contact lenses under the Medical Devices Act 2012 (Act 737) for corrective lenses and the Medical Devices Order (Proclamation 2017) for non-corrective lenses. Section 5(1) of Act 737 mandates that all imported and marketed medical devices, including contact lenses, must meet strict registration and compliance requirements. These regulations ensure that only safe,

* *Corresponding author.*
E-mail address: hanifmaidinl@iium.edu.my

high-quality devices, adhering to the Medical Devices Regulations 2012, are legally sold. Furthermore, the Optical Act 1991 stipulates that only registered optometrists and opticians with the Malaysian Optic Council (MOC) CL certification are authorized to prescribe, dispense, or sell contact lenses to the public, adding an essential layer of consumer protection. This regulatory framework safeguards the health of contact lens users and underscores the importance of purchasing lenses through licensed and compliant channels to minimize the risks associated with unregulated products.

Despite that, public awareness of the importance of purchasing MDA-certified contact lenses from registered optometry practices remains limited. This issue is exacerbated by the increasing trend of globalization, where consumers are turning to online platforms, as well as local flea markets, to purchase contact lenses. A study by Fogel and Zidile (2008) revealed that individuals who bought lenses through these unregulated channels often failed to adhere to regulatory guidelines, raising significant concerns about the quality and safety of these products. The use of unregulated contact lenses poses serious risks to eye health, including complications like those observed with improperly used traditional lenses (Lim et al., 2019).

The effects of using contact lenses from both registered optometry practices and unregulated sources on ocular surface integrity and dry eye symptoms remain insufficiently studied. This research aims to investigate these impacts, highlighting the differences in safety and quality, with the goal of raising consumer awareness and promoting safer, more informed practices.

MATERIALS AND METHODS

This was a double-masked, prospective pilot study designed to identify ocular surface integrity, and the signs and symptoms of dry eye associated with the use of coloured contact lenses. As this study involved human participants, ethical clearance (IREC 2023-KAHS/DOVS11) was obtained from the IIUM Research Ethics Committee (IREC), in compliance with the 2013 World Medical Association Declaration of Helsinki.

Five subjects were enrolled in the study. The inclusion criteria required participants to be neonates, healthy, non-smokers, with no history of allergies, medications, ocular disease, dry eye, or previous refractive surgery (Ward et al., 2010; Urgacz et al., 2015; Sambhi et al., 2020). Subjects had corneal parameters within a base curve range of 8.6 to 9.0 mm, refractive errors between 0.00 DS and -4.00 DS, astigmatism less than -1.25 DC, and were able to tolerate spherical equivalent correction.

All participants provided informed consent before data collection began. Subjects were initially screened using the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire, with a cutoff score of 19 (Ngo et al., 2013). Baseline data were gathered through a preliminary examination, including measurements of tear meniscus height (TMH), non-invasive keratograph tear film breakup time (NIKBUT), and tear breakup time (TBUT). TMH and NIKBUT were measured using the Oculus Keratograph 5M (OK5M), while TBUT was assessed using fluorescein dye instilled on the tarsal conjunctiva and examined with slit-lamp biomicroscope (SLB).

Each subject was then fitted with daily-wear coloured soft contact lenses (CL) with a replacement modality of one month. In this double-masked study, neither the participants nor the researchers knew the source of the CL being provided. It could be non-optometry contact lens (NOCL) or optometry contact lens, (OCL). All participants were supplied with the same lens care regimen, which included a multipurpose solution and a lens case. Subjects were asked to record the date, wearing duration, and any comments regarding their CL wear in a research diary, which was used to monitor their CL wearing behaviour.

After one week and one month, participants returned for aftercare visits. During these visits, they were asked about any symptoms experienced while wearing the CL. They were also required to complete the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8), which assessed symptoms such as dryness, discomfort, blurry vision, as well as coping mechanisms like resting eyes or removing lenses to alleviate discomfort (Chalmers et al., 2012). The primary aim was to evaluate the overall status of symptoms and satisfaction among soft contact lens (SCL) wearers. Following each visit, participants underwent a further assessment of TMH, TBUT, and NIKBUT. After the first month, subjects were given a one-month washout period before commencing wear with the second pair of CLs. The same procedures were then repeated during the subsequent follow-up period.

Data Analysis

The data were analysed using IBM SPSS Statistics (Version 29, SPSS Inc., Armonk, New York, USA). Normality was assessed using the Shapiro-Wilk test, along with evaluations of skewness and the coefficient of variation (Mishra et al., 2019; Demir, 2022). The data were considered normally distributed if skewness values fell within the acceptable range for standard error, and the

coefficient of variation was less than 30%. For normally distributed data, a one-way repeated measures ANOVA and paired t-tests will be used for statistical comparisons. If the data do not meet the normality assumptions, non-parametric alternatives such as the Kruskal-Wallis test and the Wilcoxon signed-rank test will be employed.

RESULTS

The study evaluated the changes in TMH, NIKBUT, TBUT and CLDEQ-8 scores over time for both non-optometry and optometry contact lens users. Given that the data were normally distributed, repeated measures ANOVA was applied to examine the changes in data collected over a one-month period. Additionally, paired sample t-tests were employed to analyse changes in the CLDEQ-8 scores between the one-week and one-month aftercare visits. The results showed no statistically significant differences across all measured parameters over the study period. Detailed statistical results are presented below.

Tear Meniscus Height

For the non-optometry contact lens users, TMH showed a slight decrease over time from a mean of 0.24 at baseline to 0.21 at the second follow-up, but this change was not significant (F (2, 3) = 0.95, p = 0.48). Similarly, for the optometry contact lens users, TMH fluctuated slightly, with a baseline mean of 0.24, an increase to 0.25 at the first follow-up, and a decrease to 0.23 at the second follow-up, which was also not statistically significant (F (2, 3) = 0.41, p = 0.70). Result of TMH is summarised in Table 1.

Non-Invasive Keratograph Break-Up Time

NIKBUT for non-optometry contact lens users decreased from a mean of 14.00 at baseline to 8.20 at the second follow-up (F (2, 3) = 1.28, p = 0.46). Optometry contact lens users also showed a decrease in NIKBUT from 14.00 at baseline to 9.20 at the second follow-up (F (2, 3) = 3.42, p = 0.17), but neither change was statistically significant. Result of NIKBUT is summarised in Table 2.

Tear Break-Up Time

TBUT for non-optometry contact lens users decreased from a mean of 6.40 at baseline to 5.20 at the second follow-up (F (2, 3) = 1.69, p = 0.32). Optometry contact lens users showed slight fluctuations in TBUT, from 6.40 at baseline to 5.60 at the first follow-up and then to 6.20 at the second follow-up (F (2, 3) = 2.25, p = 0.25), but these changes were not statistically significant. Result of TBUT is summarised in Table 3.

CLDEQ-8 Score

The CLDEQ-8 scores for participants NOCL showed a slight increase from a mean of 14.80 at one week to 16.40 at one month, although this change was not statistically significant (t (4) = 0.94, p = 0.38). Conversely, CLDEQ-8 scores for optometry CL remained stable, with a mean score of 10.20 at both time points (t (4) = 0.00, p = 1.00). Result of CLDEQ-8 score are summarised in Table 4.

Table 1: Analysis of TMH Changes Over Time in Non-Optometry and Optometry Contact Lens Users

Parameter	N	Mean (mm)	± SD	F(df)	p
TMH for NOCL				0.95 2(3)	0.48
Baseline	5	0.24	0.02		
1 Week	5	0.23	0.04		
1 Month	5	0.21	0.03		
TMH for OCL				0.41 2(3)	0.70
Baseline	5	0.24	0.02		
1 Week	5	0.25	0.04		
1 Month	5	0.23	0.05		

Table 2: Analysis of NIKBUT Changes Over Time in Non-Optometry and Optometry Contact Lens Users

Parameter	N	Mean (s)	± SD	F(df)	p
NIKBUT for NOCL				1.28 2(3)	0.46
Baseline	5	14.00	7.17		
1 Week	5	10.60	7.19		
1 Month	5	8.20	5.31		
NIKBUT for OCL				3.42 2(3)	0.17
Baseline	5	14.00	7.17		
1 Week	5	10.20	5.26		
1 Month	5	9.20	2.16		

Table 3: Analysis of TBUT Changes Over Time in Non-Optometry and Optometry Contact Lens Users

Parameter	N	Mean (s)	SD	F(df)	p
TBUT for NOCL				1.692(3)	0.32
Baseline	5	6.40	0.54		
1 Week	5	5.80	1.30		
1 Month	5	5.20	1.30		
TBUT for OCL				2.2502(3)	0.25
Baseline	5	6.40	0.54		
1 Week	5	5.60	1.14		
1 Month	5	6.20	0.83		

Table 4: Comparing mean CLDEQ-8 score between 1 week and 1 month for Non-Optometry CL and Optometry CL

Group	Time Point	Mean CLDEQ-8 Score	Standard Deviation (SD)	t value	p
NOCL	1 Week	14.8	3.114	0.94	0.38
	1 Month	16.4	2.191		
OCL	1 Week	10.2	1.643	0	1.00
	1 Month	10.2	2.168		

DISCUSSION

This study aimed to assess whether coloured soft contact lenses from optometry and non-optometry sources impact ocular surface integrity and dry eye symptoms in wearers. Our findings revealed no statistically significant differences in TMH, NIKBUT, TBUT, or CLDEQ-8 scores between the two groups over a one-month period as daily wear. Despite the material for non-optometry contact lenses being unknown, these results suggest that coloured soft contact lenses from both sources did not compromise ocular surface integrity or exacerbate dry eye symptoms. TMH values remained within established normal ranges (Lamberts et al., 1979; Savini et al., 2006), and NIKBUT and TBUT values aligned with expected limits for healthy individuals (Mohidin & Amran, 2004; Koh et al., 2016). Similarly, CLDEQ-8 scores, which reflect subjective experiences of dryness and discomfort, showed no significant differences between the two groups, suggesting comparable comfort for users (Chalmers et al., 2012).

The material composition of contact lenses plays a crucial role in wearer comfort, safety, and overall ocular health. Lenses obtained through optometry practices, such as the SEED Monthly Colour Lens UV used in this study, are made from hydrogel materials, Polymycon with 38% of water content, known for their oxygen permeability and material durability suitable for daily wear. In contrast, uncertified lenses from non-optometry sources pose significant risks due unknown properties to potential inadequacies in these properties, as well as the lack of regulatory oversight (Bhagat, 2022). The absence of proper certification raises concerns about oxygen permeability, moisture retention, and biocompatibility, which can compromise wearer safety. Additionally, expired contact lenses may deteriorate in quality, leading to complications such as irritation, infections, or reduced vision correction, especially when parameters shift after their expiry dates (Kim et al., 2017).

This pilot study emphasizes the crucial role of regulatory bodies in safeguarding public health through strict oversight of contact lenses (Nichols et al., 2013). Ensuring the quality and safety of lens materials is paramount in preventing ocular complications (Moreddu et al., 2019). Eye care professionals play a key role in educating patients about the risks associated with uncertified lenses, including unregulated coloured lenses that are widely available online and in markets. By advocating for certified lenses and proper usage practices, healthcare providers can reduce the incidence of complications such as corneal infections and allergic reactions.

Microbial keratitis, a severe eye infection often linked to contact lens wear, is a growing concern. In Hospital Serdang, 47.2% of microbial keratitis cases were associated with contact lens usage (Omar et al., 2017). Similarly, 45.5% of pseudomonas keratitis cases were connected to contact lenses (Balasegar et al., 2024). These statistics underscore the need for enhanced vigilance and regulatory enforcement in Malaysia to mitigate risks related to contact lens use.

Stronger enforcement is necessary, as our search through online Malaysian legal databases, including the Current Law Journal (CLJ), Lexis, and Westlaw, revealed no judicial cases related to the unauthorized sale of contact lenses under the Optical Act 1991 or Medical Devices Act 2012. Therefore, it is essential for regulatory bodies to enforce these laws rigorously to protect public health and ensure compliance within the optical industry.

Despite the insights provided, this study has limitations. Its short duration (one month) may not capture the long-term effects of contact lens wear from different sources. Future

research with a longer follow-up period is needed to better understand the potential long-term impact of uncertified lenses on ocular health.

CONCLUSION

In conclusion, while this study found no significant differences in ocular surface integrity or dry eye symptoms between coloured contact lenses obtained from optometry and non-optometry practices over a one-month period of use. It would be premature to assume that all non-optometric contact lenses are safe for long-term use. The lack of safety certification and regulatory oversight associated with non-optometry contact lenses still poses potential risks to ocular health. Therefore, caution should be exercised when selecting contact lenses, with a strong preference for those sourced from certified optometry practices to ensure wearer safety and long-term ocular health.

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ORIGINAL ARTICLE

Correlation Between Axial Length Measurements Obtained from Aladdin Optical Biometer and Axial Length Estimator

Adib Fadzly Jefli[1], Muhammad Afzam Shah Abdul Rahim[1,2,*], Firdaus Yusof Alias[1,2]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Background: Myopia is a significant public health concern associated with ocular pathologies like retinal detachment and glaucoma. Accurate measurement of axial length (AL) is crucial in myopia management. The Topcon Aladdin HW3.0 biometer is considered a gold standard, while the Axial Length Estimator (ALE) provides a cost-effective formula-based alternative. The ALE is a newer, more accessible tool for estimating axial length, using readily available clinical data like refractive error and corneal curvature. This study evaluates the correlation between the two methods and examines AL differences between genders. **Methods:** In this cross-sectional study, 99 participants underwent AL measurements using both the Topcon Aladdin HW3.0 and ALE formula. Statistical analysis included Pearson correlation, paired-sample t-tests, and independent-sample t-tests. **Results:** A strong positive correlation between the two methods was found ($r = 0.853$, $p < 0.0005$). However, a statistically significant difference was noted between the mean AL values ($p = 0.032$). Gender comparison yielded no significant difference in AL values using either method. Our findings suggest a strong correlation between the Topcon Aladdin HW3.0 biometer and the ALE. Despite this, the significant difference in mean AL values highlights potential limitations of the ALE, particularly in the precise measurement required for myopia management. The sample size may influence the lack of gender differences in AL. **Conclusion:** The ALE offers a promising alternative for AL measurement but is limited by significant differences from the biometer values, especially in clinical settings requiring precision. Further research is necessary to determine the ALE's clinical applicability.

Keywords:
myopia; axial length; Topcon Aladdin HW3.0 Biometer; Axial Length Estimator; myopia management

INTRODUCTION

Myopia, a significant public health concern, is characterized by a refractive error leading to blurred distance vision. This condition occurs when parallel light rays entering the eye converge to a focal point in front of the retina while the eye is in its relaxed state (Flitcroft, 2012; Dolgin, 2015). Anatomically, myopia can be attributed to several factors, including an elongated axial length of the eyeball, excessive corneal curvature, or a lens with an unusually high refractive power (Vitale, Sperduto, & Ferris, 2004). Elongation of the eyeball is the most common cause and results in increased axial length, which shifts the focal point forward from the retina (Morgan et al., 2018). Additionally, increased corneal curvature or lens power can contribute to the condition by altering the eye's refractive capabilities (Young, 2009; Wildsoet, 2011).

The World Health Organization highlights the significant public health burden posed by myopia (Holden et al., 2016). Research underscores myopia as a major risk factor for various ocular pathologies including cataracts (Pan et., 2013), glaucoma (Chen et al., 2012), retinal detachment (Mattioli et al., 2009), and myopic maculopathy (Ruiz-Medrano., 2019). Remarkably, the heightened risks associated with myopia are comparable to those linked to hypertension for stroke and heart attack (Cooper & Tkachenko, 2018). Measurement of axial length (AL) serves as a critical tool in research aimed at understanding myopia progression and developing control strategies. Axial length denotes the distance from the front surface of the cornea to a specific point within the retina, typically at the retinal pigment epithelium Bruch's membrane (Bhardwaj & Rajeshbhai, 2013).

* *Corresponding author.*
E-mail address: afzamshah@iium.edu.my

The most substantial elongation of the eyeball, reflected in AL, occurs during early life, with the most rapid growth observed within the first 3 to 6 months. This growth gradually decelerates over the next two years, reaching adult size by approximately three years of age (Hou et al., 2018). Among the ocular structures influencing the refractive state of the human eye, significant attention is devoted to the cornea, aqueous humor, lens, vitreous humor, and axial length.

Notably, axial length is a key parameter for measuring both myopia and hyperopia (Young et al., 2007). Research by Tideman et al. (2016) further highlights the significance of axial length (AL) as a predictor for the development of eye problems in adults with myopia. By measuring AL in children, eye care professionals can gain valuable insight for determining the urgency of implementing a myopia management plan. According to existing literature, an AL exceeding 26mm serves as a crucial threshold. Beyond this point, the risk of developing sight-threatening complications associated with myopia significantly increases (Chamberlain et al., 2019). Recent advancements have seen the introduction of sophisticated instruments for measuring axial length. These include devices like the IOLMaster series (Zeiss), Lenstar (Haag-Streit), and Aladdin (Topcon). While traditionally used to determine intraocular lens power for cataract surgery, the application of the instruments above has expanded to include myopia control research (Chamberlain et al., 2019). However, the significant cost barrier may limit their accessibility for optometrists interested in myopia management.

In response to the challenges posed by expensive axial length instrumentation, Morgan et al. (2020) proposed a novel method for estimating ocular axial length in clinical settings. This method utilizes commonly available optometric measurements such as refractive error, corneal curvature, and back vertex distance, integrated into software tools such as the Axial Length Estimator (ALE) from CooperVision that enables estimation of AL.

Studies on the Caucasian populations regarding the accuracy of the ALE had been conducted (Morgan et al., 2020; Breslin et al 2013; Saunders et al.,1920 -1922). However, to our knowledge, there was no prior research investigating the correlation between AL measurements obtained with the Topcon Aladdin HW3.0 Biometer (Tokyo, Japan) and those derived from the ALE. This study aimed to fill this gap by evaluating the relationship between these two methods for assessing axial length.

MATERIALS AND METHODS

Study Design

This cross-sectional study design followed the Declaration of Helsinki and was approved by the IIUM Research Ethics Committee (IREC) (IREC 2023-KAHS/DOVS11). Healthy individuals aged 19 to 25 years were included in this study if their visual acuity (VA), measured using a logMAR chart, was 0.00 or better. Exclusion criteria comprised a history of ocular trauma or surgery, current use of medications that may affect the tear film or corneal thickness, and the wearing of contact lenses. Data was collected at the IIUM Optometry Clinic, Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia. Sample size calculated using G*Power, version 3.1.9.2 (Faul et al., 2007, 2009; Prajapati et al., 2010) revealed that this study requires 84 participants. At the end of the study, we managed to obtain 99 participants, and they were fully informed of the study purpose, and informed consent was obtained prior to data collection.

Data Collection

Data collection commenced with subjective refraction assessments, followed by keratometry using the Oculus Keratograph 5M (OculusOptikgeräte GmbH, Wetzlar, Germany), and AL measurement via the Topcon Aladdin HW 3.0 Biometer. After the procedures, participants were dismissed. The collected data were subsequently input into the ALE formula created by Morgan et al. (2020), available at (https://coopervision.co.uk/practitioner/tools-and-calculators/optiexpert/optiexpert-web#/axial-calculator).

Statistical Analysis

The data was analysed by using Statistical Package for Social Science (SPSS) software (Version 29 for Windows; SPSS Science, Chicago, Illinois, USA). As proposed by Mishra et al, (2019), the normality of data was analyses using the Shapiro-Wilk and the results showed that all the data was normally distributed with $p>0.05$ (Demir, 2022). To assess the association between AL measurements obtained from the Topcon Aladdin HW3.0 biometer and those estimated using the ALE, Pearson correlation analysis was employed. Additionally, independent-samples t-tests were conducted to compare AL values obtained from the Topcon Aladdin and the ALE between genders. In addition, paired-samples t-tests were performed to investigate if there are statistically significant differences in AL values between the two measurement methods.

RESULTS

The mean age of the participants enrolled in this study was 21.4±1.00 years old (range 20–23 years old). Of these participants, 74 were female and 25 were male. Table 1 provides a summary of the descriptive statistics for the investigated parameters, including the degree of myopia and AL measurements obtained using both the Topcon Aladdin HW3.0 and the ALE.

Table 1: The mean and SD of all the investigated parameters.

Parameters	Mean ± SD		
	Total (n=99)	Female (n=74)	Male (n=25)
Degree of Myopia, Spherical Equivalent (D)	-1.94±2.010	-2.04±1.986	-1.64±2.089
Axial Length, Topcon Aladdin HW3.0 (mm)	24.032±1.052	24.080±1.049	23.850±1.072
Axial Length, ALE (mm)	24.151±0.934	24.179±0.943	24.071±0.918

Spherical equivalent for the degree of myopia across all participants was -1.94±2.01D. When broken down by gender, although non-statistically significant, females had slightly higher myopia (-2.04±1.986D) compared to males (-1.64±2.089D).

The AL measurements obtained using the Topcon Aladdin HW3.0 Biometer showed a mean value of 24.032±1.052mm across all participants. Females had a mean axial length of 24.080±1.049mm, while males had a mean of 23.850±1.072mm.

When compared to Topcon Aladdin HW3.0, the ALE showed higher mean AL across the sample (24.151±0.934mm vs. 24.032±1.052mm). The breakdown by gender revealed that females had a mean AL of 24.179±0.943mm, while males had a mean of 24.071±0.918mm.

Axial Length Correlation: Topcon Aladdin HW3.0 and ALE

When combining all the participants, Pearson's correlation demonstrated a strong, positive, and statistically significant correlation between the mean AL values measured by the Topcon Aladdin HW3.0 and those obtained by the ALE, r (98)=0.853, p<0.005, (24.032±1.052mm vs. 24.151±0.934mm) as shown in Table 1 and Figure 1.

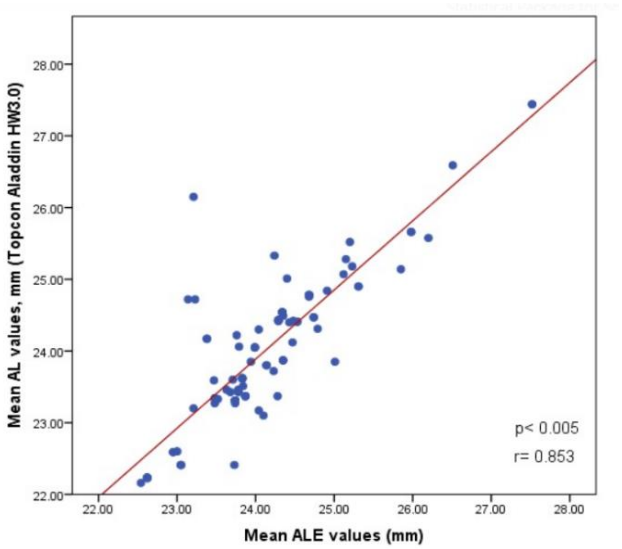

Figure 1: The correlation between mean AL values obtained from Topcon Aladdin HWC3.0 and ALE.

The strong positive correlation suggests that the AL measurements from the Topcon Aladdin HW3.0 biometer and the ALE tend to move together in the same direction. In other words, if the biometer measured a longer AL for an eye, the estimator also predicted a longer AL for that same eye, and vice versa. This reflects the minor differences in AL values obtained between the two methods observed in our study (Table 1).

Comparison of AL Values: Topcon Aladdin HW3.0 vs. ALE

Using the whole population, paired samples t-test revealed a statistically significant difference between the mean AL values obtained using the Topcon Aladdin HW3.0 and the ALE, (24.032±1.052mm vs. 24.151±0.935mm, respectively), t (98)=2.172, p=0.032 (Table 1).

Comparison of AL Values Between Genders Using Topcon Aladdin HW3.0

Levene's test revealed no statistically significant difference in variances between the two genders (p>0.05). This

indicates the existence of homoscedasticity of variances for AL values obtained using Topcon Aladdin HW3.0. Thus, the results of the independent t-test revealed that the difference in mean AL values obtained using the Topcon Aladdin HW3.0 between females and males was not statistically significant (24.080±1.049mm vs. 23.850±1.072mm), t (98)=0.667, p=0.450 (Table 1).

DISCUSSION

The strong correlation observed between the Topcon Aladdin HW3.0 Biometer and the Axial Length Estimator (ALE) carries significant practical implications for clinical practice, particularly in the realm of myopia management. This robust agreement suggests that the ALE, which utilizes readily available optometric measurements such as refractive error and corneal curvature, offers a cost-effective and reliable alternative to more sophisticated biometry devices (Mora et al., 2019). In resource-limited settings, where the acquisition and maintenance of advanced biometry equipment like the Topcon Aladdin HW3.0 Biometer may be financially or logistically challenging, the ALE stands out as an invaluable tool (Gibson et al., 2017). By leveraging common optometric measurements, the ALE enables clinicians to accurately measure axial length without the need for expensive and specialized equipment. This accessibility is crucial in facilitating the early detection and effective management of myopia, thereby potentially mitigating the risk of progression to severe ocular pathologies commonly associated with high myopia (Holden et al., 2016; Cooper & Tkatchenko, 2018).

The strong, statistically significant positive correlation observed in this study could imply a high degree of agreement between the axial length (AL) measurements obtained using both methods (Table 1). This correlation indicates that the ALE measurements are closely related to those of the Topcon Aladdin HW3.0 Biometer. Consistent with our findings, Morgan et al. (2020) reported a strong correlation (r^2 = 0.83) between the ALE and the actual AL values obtained from biometers. However, a more critical evaluation would involve the 95% limits of agreement (LoA). These LoA define the range within which one can be 95% confident that the estimated AL reflects the true value. In Morgan et al. (2020) study, the LoA was +0.73mm, translating to approximately +3.0% of the average AL measurement. This implies that 95% of the ALE estimates will fall within roughly +0.73mm of the actual AL. In myopia management, this range may be considered large, potentially limiting the estimator's usefulness in monitoring myopia progression (Li et al., 2021).

When combining the whole population, this study also noted a small but statistically significant difference between AL values obtained from Topcon Aladdin HW3.0 and ALE (Table 1). We believe that this difference occurs due to the inherent nature of the methods, whereby Topcon Aladdin HW3.0 uses infrared to measure the AL while the ALE uses a mathematical formula to estimate the AL.

Moreover, the physiological differences between males and females might still play a role, even if not evident in our current study. Previous studies have suggested that hormonal variations, anatomical differences, and even environmental factors can influence ocular measurements (Lee & Park, 2017). Therefore, the lack of significant differences in the present study does not conclusively negate the possibility of gender-related variations in AL values. Flitcroft et al. (2012) postulated that growth hormone could contribute to the observed trend of longer AL in males, as opposed to females. Supporting this notion, several studies have identified significant correlations between height and weight with various measurable parameters within the eye (Wu et al., 2007; Eysteinsson et al., 2005). Notably, lens thickness appears to be an exception, showing no significant correlation with body size. Additionally, when researchers controlled for the influence of age and gender, individuals with greater height and weight consistently exhibited eyes with statistically longer AL, deeper anterior chambers, and deeper vitreous chambers (Eysteinsson et al., 2005). In the present study, no statistically significant differences in AL measurements were observed between genders using the Topcon Aladdin HW3.0 Biometer and the ALE. This result is consistent with previous research suggesting that gender-based variation in AL measurements is minimal within similar demographic groups (Smith et al., 2018; Jones et al., 2019). For instance, Smith et al. (2018) reported that gender differences in AL were negligible in a cohort of young adults, and Jones et al. (2019) similarly found no significant gender-related discrepancies in AL among a diverse population

STUDY LIMITATIONS

Interpreting these results requires careful consideration of several methodological factors. One critical issue is the potential gender imbalance in the study sample. The unequal representation of males and females may introduce bias, potentially skewing the observed differences in AL values between genders. As demonstrated by Brown et al. (2020), gender imbalances in study samples can lead to distorted findings, underscoring the importance of a balanced demographic to ensure accurate and generalizable conclusions.

Furthermore, discrepancies in measurement techniques or sample characteristics across studies may contribute to variations in the observed outcomes (Lee et al., 2021; Taylor et al., 2022). This study's limitations must also be acknowledged. The sample was restricted to a specific demographic group comprising young adults, limiting the generalizability of these findings to broader populations. Additionally, the cross-sectional design of the study, while useful for capturing correlations at a single point in time, does not allow for the assessment of longitudinal changes in AL or myopia progression.

RECOMMENDATIONS FOR FUTURE RESEARCH

Future research should focus on several key areas to further validate and expand the utility of the ALE. First, studies should aim to include a more diverse population sample across various geographic and demographic settings to ensure the generalizability of the findings. Investigating the performance of the ALE in different ethnic groups is particularly important, given potential anatomical variations that may affect axial length measurements (Wong et al., 2010).

Additionally, longitudinal studies are recommended to assess the long-term accuracy and reliability of the ALE in tracking myopia progression and in predicting future ocular pathologies (Saw, Gazzard, & Shih-Yen, 2005). Comparing the estimator's performance with emerging biometry technologies will also be crucial to ensure its continued relevance and accuracy (Flitcroft, 2012). As such, a validation study on the reproducibility and repeatability of the ALE should be conducted (Kang et al., 2015).

Furthermore, future research should explore the integration of the ALE into routine clinical practice, examining its impact on clinical outcomes and patient care. Evaluating the cost-effectiveness of the estimator in various healthcare settings could provide valuable insights into its economic benefits (Maule et al., 2016). Finally, it would be beneficial to develop and test educational interventions aimed at training clinicians on the effective use of the ALE, thereby enhancing its adoption and utilization in diverse clinical environments (Zhao et al., 2018). These recommendations will not only reinforce the validity of the ALE but also potentially broaden its application, ultimately contributing to improved management of myopia and associated ocular conditions.

CONCLUSION

In conclusion, the study demonstrates a strong correlation and agreement between AL measurements obtained from the Topcon Aladdin HW3.0 Biometer and those estimated using the ALE. This finding supports the potential use of the estimator as a practical and cost-effective tool in myopia management, particularly in settings where access to advanced biometry devices is limited. However, further research is needed to confirm these results across diverse populations and clinical contexts and to further assess the validity of the ALE.

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ORIGINAL ARTICLE

An Investigation on the Correlation Between Axial Length Values Obtained Via Lenstar LS900 and Axial Length Estimator

Nurfara A'inn Hailamir[1], Muhammad Afzam Shah Abdul Rahim[1,2,*], Firdaus Yusof Alias[1,2]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Background: Myopia, commonly known as nearsightedness, is associated with excessive eye elongation, leading to impaired distance vision. Recognizing axial length (AL) as a crucial parameter in managing myopia has prompted this study. The Axial Length Estimator Software (ALE) by CooperVision offers a cost-effective alternative for measuring AL, particularly for optometry centres that cannot afford biometry instruments. However, there is a lack of studies investigating the correlation between AL values acquired through the Lenstar LS900 (Haag-Streit, Bern, Switzerland) and ALE. This study aimed to determine the correlation of AL values between Lenstar LS900 and ALE, investigate any significant differences between the AL values obtained via both methods and explore any gender-related differences in AL values measured by each method. **Methods:** In this cross-sectional study, the AL of 99 participants (emmetrope and myope) were measured using Lenstar LS900 and compared to AL values obtained from the ALE. Estimating AL using ALE requires obtaining corneal curvature and refractive power values. For this purpose, corneal curvature was measured using the Oculus Keratograph 5M (OK5M, Oculus, Wetzlar, Germany), while refractive power was determined through subjective refraction assessments. **Results:** The AL values obtained via both methods showed a strong positive correlation ($r=0.862$, $p<0.005$). No statistically significant differences in AL between both methods were observed. There were also no statistically significant gender-related differences in the AL values obtained by either method. **Conclusion:** The AL values obtained via both methods exhibited a strong positive correlation with no statistically significant differences. Further validation studies are required to confirm the accuracy of ALE across diverse populations and clinical settings.

Keywords:
myopia, axial length, Lenstar LS900, Axial Length Estimator (ALE)

INTRODUCTION

Myopia has garnered the most extensive research attention among all refractive errors (Young, 2007; Tideman et al., 2018). Approximately one-fifth of the world's population is predicted to become highly myopic by 2050, with myopia affecting half of the world's population (Holden et al., 2016). Due to its widespread occurrence and strong relationship with significant clinical disorders, myopia is a significant public health concern (Cooper & Tkatchenko, 2018; Shinojima et al., 2022; Du et al., 2021), especially when its prevalence is high (Pan et al., 2012).

Myopia is associated with excessive eye elongation, causing images of distant objects to fall in front of the retina, resulting in blurry distance vision (Baird et al., 2020). The degree of myopia can be divided into low myopia consisting of sphere power that is less than -3 diopters (D), medium myopia which falls between -3D to -6D and high myopia which is more than -6D (Goss et al., 2006). Any degree of myopia can elevate the risk of adverse ocular tissue changes. This risk significantly increases in cases of pathologic myopia. Pathologic myopia can result in irreversible visual impairment or blindness and is associated with sight-threatening conditions such as glaucoma, cataracts, retinal detachment, and macular holes (Bullimore & Brennan, 2019; He et al., 2021; Morgan et al., 2020). High myopia causes the globe to enlarge excessively and gradually, leading to the sclera, choroid, Bruch membrane, retinal pigment epithelium (RPE), and neural retina begin to deteriorate (Young, 2007).

* *Corresponding author.*
E-mail address: afzamshah@iium.edu.my

Axial length (AL) is a key parameter for both myopia and hyperopia (Young, 2007). The AL measures the depth of the eye's anterior chamber, the thickness of the lens, and the depth of the vitreous chamber (Meng et al., 2011; Tanaka et al., 2024). Children who have myopic parents are more likely to be affected and have longer AL compared to children who do not have myopic parents (Kurtz et al., 2007). Furthermore, a substantial proportion of the association between AL and myopia can be attributed to hereditary factors, indicating that AL and myopia may share common genetic determinants (Dirani et al., 2008). Thus, this study focuses on the importance of AL as a vital parameter in managing myopia cases. In contemporary optometry practice, optical partial coherence interferometry and ultrasonic velocity measurement equipment are utilized to measure AL and evaluate patients' degrees of myopia (Meng et al., 2011). There are two methods for doing ultrasound biometry: immersion technique and applanation or the probe contacting the cornea (Sen & Tripathy, 2024). The optical low-coherence reflectometry-based Lenstar LS900 (Haag-Streit, Bern, Switzerland) provides an accurate, fast, and easy measurement of ocular variables such as the AL (Jasvinder et al., 2011).

A study by Wang and Chang (2013) investigated the predictability of intraocular lens (IOL) power calculations using the IOLMaster and alternative IOL power calculation formulas in eyes with variable ALs. The study found that both methods were comparable, suggesting the use of alternative formulas in Taiwanese healthcare facilities lacking IOLMaster. However, Wang and Chang (2013) study was conducted on a Chinese population in Taiwan. Thus, the results may not apply to the Malay population in Malaysia due to different eye features.

To date, we were not aware of any study that has attempted to investigate the correlation between AL values acquired via Lenstar LS900 (Haag-Streit, Bern, Switzerland) and Axial Length Estimator (ALE) developed by CooperVision. This is a limitation as it is unclear whether ALE's calculation method can be efficiently and accurately used for the Malaysian population, particularly in monitoring the AL.

Thus, the primary purpose of this study was to investigate the correlation between AL values obtained using an optical biometer (Lenstar LS900) and the calculation method (ALE).

MATERIALS AND METHODS

Study Design

This study adhered to the Declaration of Helsinki's principles on human research. Ethical approval was granted by the IIUM Research Ethics Committee (IREC 2023-KAHS/DOVS3). As proposed by Kang (2021), the G*Power software was used to determine the sample size for this study. This cross-sectional study recruited 99 participants from IIUM Kuantan students (25 males, 74 females) aged 20 to 23, with spherical refractive errors ranging from plano to -8.50D and cylindrical power less than -2.00DC.

The inclusion criteria for this study comprised students from the International Islamic University Malaysia, Kuantan, aged 19 to 25 years, who were generally healthy and free from any diseases. Participants were also not taking any medications or drugs, had never undergone refractive surgery, and had a spherical refractive power ranging from plano to -9.00D with a cylindrical power of less than -2.00DC.

Data Collection

All 99 participants were informed about the study and provided written consent before participation. They were then asked a series of questions to gather background information and ensure they met the inclusion criteria. Objective refraction using dry retinoscopy and subjective refraction was performed on participants to obtain their refractive error and back vertex distance was also measured. The participants' corneal radius of curvature was measured three times using the Oculus Keratograph 5M (OK5M, Oculus, Wetzlar, Germany), and the AL was measured five times using Lenstar LS900. The refractive power, corneal radius of curvature, and back vertex distance were entered into the ALE software to calculate the estimated AL values (ALE). The AL values produced by ALE were then used for statistical analysis.

Statistical Analysis

Data were analysed using the Statistical Package for Social Science Software (SPSS) version 20 for Windows (SPSS, Inc., Chicago, IL, USA). Initial analysis using the Shapiro-Wilk normality test confirmed that all our data was normally distributed and thus, parametric tests were used for subsequent analysis. The Pearson correlation coefficient assessed the correlation between AL values obtained via Lenstar LS900 and ALE. Paired t-tests were used to investigate differences in AL between the methods. Independent t-tests were further employed to

examine gender-related differences in AL obtained via each method.

RESULTS

Table 1 provides the mean and standard deviation (SD) values of key parameters assessed in the study, both for the total sample (n = 99) and separately by gender (female: n = 74; male: n = 25). The mean degree of myopia, represented by the spherical equivalent (D), was found to be -1.94±2.010 D across the total population. Females exhibited slightly higher levels of myopia (-2.04±1.986 D) compared to males (-1.64±2.089 D). However, the differences in the degree of myopia between genders were not subjected to statistical significance testing in this study.

The AL measurements, taken with the Lenstar LS900, indicated a mean of 24.076±1.097 mm for the total group, with a marginally longer mean AL observed in females (24.119±1.054 mm) compared to males (23.949±1.232 mm). Measurements from the ALE yielded a slightly higher mean AL (24.151±0.934 mm) than the Lenstar LS900, with females at 24.179±0.943 mm and males at 24.071±0.918 mm. These results suggest minor variations in myopia severity and AL based on gender, although not confirmed statistically.

Table 1: Mean and standard deviation (SD) of the investigated parameters for the total population and by gender.

Parameters	Mean±SD		
	Total (n = 99)	Female (n = 74)	Male (n = 25)
Degree of Myopia, Spherical Equivalent (D)	-1.94±2.010	-2.04±1.986	-1.64±2.089
Axial Length, Lenstar LS900 (mm)	24.076±1.097	24.119±1.054	23.949±1.232
Axial Length, ALE (mm)	24.151±0.934	24.179±0.943	24.071±0.918

Correlation Between AL Obtained via Lenstar LS900 and ALE

The bivariate Pearson's correlation established a strong, statistically significant positive linear relationship between AL values obtained via Lenstar LS900 and ALE, r(98) = 0.862, p < 0.005 (Figure 1).

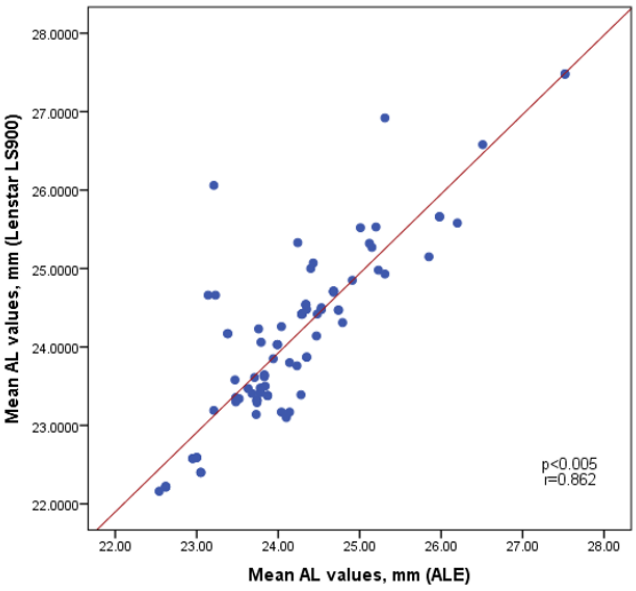

Figure 1: Scatter plot showing the correlation between AL values (mm) obtained via Lenstar LS900 and ALE.

Difference Between AL Obtained via Lenstar LS900 and ALE

The paired samples t-test found no statistically significant difference between AL values obtained via Lenstar LS900 and ALE (24.076±1.097 mm vs. 24.151±0.934 mm), t (98) = 1.339, p = 0.184.

Gender-Related Differences in AL Obtained via Lenstar LS900

There was homogeneity of variances for AL values obtained via Lenstar LS900 for males and females, as assessed by Levene's test for equality of variance. The results from the independent t-test revealed that the mean AL value obtained from Lenstar LS900 between females and males was not statistically significant (24.119±1.054 mm vs. 23.949±1.232 mm), t (98) = 0.667, p = 0.506.

Gender-Related Differences in AL Obtained via ALE

Similarly, there was also a homogeneity of variances for AL values obtained via ALE for males and females, as assessed by Levene's test for equality of variance. Independent t-test results revealed no statistically significant difference in mean AL values obtained from ALE between females and males (24.179±0.943 mm and 24.071±0.918 mm), $t(97) = 0.497$, $p = 0.620$.

DISCUSSION

When it is not feasible to measure the AL of the eye using biometry equipment, optometrists may find it beneficial to estimate the AL of the eye using mathematical formulae to better monitor the progression of myopia. The estimation involves incorporating refractive error, vertex distance, and the corneal radius of curvature, which are all easily obtained during a clinical visit. The ALE formulae proposed by Professor Philip Morgan were used to calculate AL, considering the spherical refractive power and corneal radius of curvature (Morgan et al., 2020). Previous research by Ojaimi et al. (2005) and AlMahmoud et al. (2011) have shown that refractive error, corneal radius of curvature, and AL are highly correlated, validating the parameters used in this current study's estimation method.

A study by Queirós et al. (2022) found a strong ($r > 0.750$) correlation between the estimated and measured AL values, with no statistically significant differences between the two. Kim et al. (2019) also found a statistically significant correlation between the measured and calculated AL in which $r = 0.871$ for the emmetropic group, $r = 0.904$ for the hyperopic group, $r = 0.955$ for the myopic group, and $r = 0.967$ overall. These findings are consistent with our results, which show a strong, statistically significant positive correlation between AL values obtained via Lenstar LS900 and ALE, with no statistically significant differences between the two methods.

Gender-related differences in AL have been previously reported. Roy (2015) found no statistically significant differences in AL between genders in the emmetropic group. However, in the myopic group, a significant difference was observed, with males having longer ALs. Similarly, other studies (Lee, 2009; Tang et al., 2020; Diez et al., 2019; Twelker et al., 2009) reported that males generally have longer ALs, larger corneal radius of curvature, and deeper anterior chamber depths compared to females. However, our study found no statistically significant gender-related differences in AL values obtained via Lenstar LS900 and ALE. This discrepancy might be due to the inclusion of both emmetropic and myopic participants in our study, as well as the imbalance in the male-to-female ratio, with a higher proportion of females.

Queirós et al., (2022) stated that although ALE offers an alternative approach to measuring AL, it should not replace objective measurements obtained via optical biometry. The AL values obtained through biometry are considered 'true' measurements, unlike mathematically derived estimates. Nevertheless, the estimation method provided by ALE can be a valuable tool in clinical decision-making for myopia management when true AL measurements are not available.

STUDY LIMITATIONS

The ALE software allowed only a 0.05 mm step when incorporating the corneal radius of curvature value. Consequently, the corneal curvature was rounded to the nearest available number, which might affect the precision of the estimated AL values. Accurate AL measurement has become a critical component in the management of myopia. It is not only essential for regular follow-up appointments to track the progression of the condition but also plays a significant role in the future classification of the risk of visual impairment (Galvis et al., 2022). Ensuring the precision of these measurements is therefore paramount to providing effective and comprehensive care for myopic patients.

Additionally, the sample size of this study was relatively small and limited to the population of IIUM Kuantan. This restriction might influence the generalizability of the study outcomes (Faber & Fonseca, 2014). In addition, the unequal numbers of males and females could have impacted the results of the current study.

RECOMMENDATIONS FOR FUTURE RESEARCH

Future research should include participants from diverse age groups, ensuring a balanced number of males and females. The calculation method used in this study (ALE) does not account for the age of the population; thus, further investigation is needed to determine whether the relationship formula should be adjusted for different age ranges. Additionally, studies are necessary to examine if the same pattern observed in this study is present in paediatric populations.

In future research, incorporating statistical methods such as Bland-Altman analysis, intraclass correlation coefficient, and coefficient of variation will provide a more comprehensive evaluation of the estimation methods.

Exploring other factors that might influence AL estimation, such as anterior chamber depth, lens thickness, and vitreous chamber depth, could also refine the estimation formulas. Further, longitudinal studies tracking the progression of myopia using both measured and estimated AL would be valuable in assessing the long-term reliability and validity of these methods. By addressing these areas, future research can enhance the accuracy and reliability of AL estimation, ultimately improving myopia management and patient care.

CONCLUSION

This study demonstrates that the ALE Software by CooperVision presents a viable alternative to the Lenstar LS900 for measuring AL. This approach provides a quick and cost-effective means of estimating AL, which is particularly beneficial for optometrists engaged in myopia management when access to commercial biometers is limited. For detailed and continuous AL assessment, a commercial biometer is recommended for the most accurate measurements. Further validation studies are essential to confirm the reliability and validity of ALE as a tool for myopia management.

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ORIGINAL ARTICLE

Evaluating the Tobii Pro Fusion-120Hz Eye Tracker for Clinical Use

Anis Najihah Mohamed Nazim[1], Fatin Amalina Che Arif[1], Ilyanoon Zahari[1,2], Noor Wafirah Shafee[1,2,*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Background: This study aims to evaluate the performance of the Tobii Pro Fusion-120Hz in producing normative data for saccadic peak velocity, with the results compared to the higher sampling rate EyeLink 1000 Plus, which has already been validated for clinical use. **Methods:** Thirty participants (aged 20-23) with normal ocular motility and best-corrected visual acuity of 0.2 log MAR or better were recruited. Exclusion criteria included high myopia, ocular trauma, brain injuries, and the use of rigid gas-permeable contact lenses. Saccadic movements were measured using the Tobii Pro Fusion-120Hz eye tracker. Data were recorded and analysed using Tobii Pro Lab Software and SPSS version 23. Calibration accuracy and precision thresholds were set at 0.5° and 0.2°, respectively. Participants completed 24 saccadic trials tested binocularly, and the recorded peak velocity data was compared with data validated using the higher sampling rate devices (500Hz). **Results:** The one-sample t-test showed no significant difference in saccadic peak velocity (p = 0.40) between the lower sampling rate and the higher sampling rate, indicating that the former can produce saccadic peak velocity measures comparable to those of the latter. **Conclusion:** Normative data for saccadic peak velocity were provided in this study using the Tobii Pro Fusion-120Hz, confirming its accuracy for clinical assessments and its potential for clinical application.

Keywords:
saccadic peak velocity; eye-tracking; EyeLink 1000 Plus; Tobii Pro Fusion-120Hz; ocular motility

INTRODUCTION

Eye movements are integral to the ability of the visual system to produce a single, clear image. Among these movements, saccades are rapid, voluntarily initiated eye movements that bring target objects into the fovea, enabling clear vision of moving objects. Saccadic movements are characterized by latency, peak velocity, and accuracy (Shafee, 2021). These parameters are critical for detecting eye movement anomalies, indicating various visual and neurological conditions (Clark et al., 2019).

Until recently, the magnetic scleral search coil was considered the gold standard for recording eye movements (Collewijn et al., 1988). However, studies have shown that scleral coils, being invasive, can potentially harm the cornea even before any visual tasks (Irving et al., 2003). With technological advances, non-invasive video-based eye-tracking systems using infrared (IR), such as EyeLink (Van Der Geest & Frens, 2002), have become popular in research and have been shown to produce results comparable to the search coil method.

Despite the potential of eye trackers to provide reliable and quantitative evaluations of eye movements, their clinical application remains limited (Clark et al., 2019). Objective eye recording techniques are not widely used in clinical settings to monitor conditions affecting eye movements, such as ocular nerve palsy or brain injuries (Clark et al., 2019; Shafee, 2021). To ensure their utility in clinical diagnosis, the feasibility and accuracy of these instruments must be thoroughly assessed, as any deviation or inaccuracy in data recording could compromise their effectiveness.

This study aims to evaluate the performance of the Tobii Pro Fusion-120Hz in measuring saccadic peak velocity in a healthy population, with the results compared to data from the higher sampling rate EyeLink 1000 Plus, which has been validated for clinical use The normative data obtained can serve as a benchmark for assessing and monitoring patients with eye movements anomalies in clinical settings, despite the lower sampling rate of the Tobii Pro Fusion-120Hz.

* *Corresponding author.*
E-mail address: wafirah@iium.edu.my

As no previous research has examined normative data for saccadic movements using this device, its accuracy for clinical applications has not yet been established.

MATERIALS AND METHODS

The study employed a cross-sectional design with convenience sampling. Participants were selected based on availability and meeting the inclusion criteria. This method was chosen to efficiently gather data from a specific population within a limited timeframe.

This study adhered to the Tenets of the Declaration of Helsinki for research involving human subjects and received ethical approval from the IIUM Research Ethics Committee (IREC 2023-KAHS/DOVS15). The number of participants in this study was determined based on previous eye movement recording (EMR) studies that have assessed eye trackers in healthy populations. These studies, such as those by (Huaman & Sharpe, 1993; Shafee, 2021; Yang & Kapoula, 2006), have shown that a smaller sample size is generally sufficient for evaluating the accuracy and performance of eye trackers in this context. Since the primary aim of this study was to assess the device's capability in measuring saccadic peak velocity rather than generalizing to a broader population, a large sample size was not required. Additionally, EMR studies typically focus on the reliability and performance of the technology within a controlled group, and the results from similar studies have been consistent with smaller sample sizes. Therefore, a formal sample size calculation was not deemed necessary for this study. The sample size chosen aligns with those used in prior research, where the goal was to establish initial performance benchmarks for the device rather than statistical power for hypothesis testing.

Participant

All participants underwent a comprehensive optometric examination before recruitment and fulfilled the following inclusion criteria; age between 18-23 years, normal ocular motility test (OMT) results, best-corrected visual acuity (VA) of 0.2 log MAR or better in both eyes (measured using ETDRS chart), no history of ocular trauma or brain injuries and no significant underlying ocular pathology or systemic disorder. The age group in our study was carefully controlled to match the demographics of the population from which the EyeLink normative values were derived. Specifically, we ensured that the age range of participants in our study aligned with that of the previous population, as saccadic eye movement performance is influenced by aging (Shafee, 2021; Abel et al., 1983). This control was implemented to minimize age-related differences and ensure consistency in saccadic peak velocity measurements, thereby enhancing the validity of our comparisons.

All included participants had myopia less than -6.00, as higher myopic corrections can affect accurate calibration at eccentric points (Shafee, 2021). Participants who were using rigid gas permeable (RGP) contact lenses were excluded from this study as RGP usage could lead to abnormal eye recording results, especially in horizontal eye movements at eccentric positions (Shafee, 2021).

Eye Tracker Setup

Saccadic movements were measured using the Tobii Pro Fusion-120Hz eye tracker. The eye tracker was mounted on a monitor positioned 60 cm from the participant, subtending a visual angle of 0.53 degrees. Data were recorded on an HP Pavilion laptop equipped with Tobii Pro Lab Software.

Procedure

Participants completed the eye tracking using Tobii Pro Fusion-120Hz with their best-corrected visual acuity, ensuring that any refractive errors were properly corrected during the eye tracking assessments. This approach was crucial to maintaining the accuracy of the saccadic measurements and ensuring that the visual acuity of all participants met the inclusion criteria of 0.2 logMAR or better. The remaining inclusion criteria were confirmed through standard clinical tests that do not involve direct eye contact, including OMT, cover test at distance and near, and history taking. The informed consent was obtained after confirming that the participants met the inclusion and exclusion criteria.

Participants were instructed to follow on-screen instructions while resting their head on a head and chin rest to ensure stability throughout the test. Calibration accuracy and precision thresholds were set at 0.5° and 0.2°, respectively. Participants who did not meet these thresholds were instructed to recalibrate.

A black cross target of size 0.25° appeared at the center of the screen for 1-3 seconds, then reappeared at ±10° horizontally from the center for 1-2 seconds. This setup prompted participants to rapidly move their eyes to the new target position and fixate on it, ensuring accurate measurement of visually triggered saccadic eye movements.

Each participant completed 24 saccadic trials binocularly, with an equal number of targets presented on both the left and right sides of the screen center. The entire

measurement, including the calibration process, took approximately 5 minutes per participant. Eye movements can be examined either binocularly or monocularly, depending on the study's objectives (Hooge et al., 2019). This study selected binocular recordings to accurately observe and analyze the interaction between both eyes and assess normative saccadic coordination in subjects with normal ocular motor function. While monocular recordings can minimize irritation, especially in studies involving invasive methods (Irving et al., 2003), binocular recordings were essential for a comprehensive evaluation of eye movement dynamics in this case.

Data Analysis

Data recorded by Tobii Pro Lab Software was transferred to Microsoft Excel 365 for filtering abnormal and extraneous data. After filtering, a pivot table was created to obtain the average mean of each saccadic peak velocity for all participants. The primary variable analysed was saccadic peak velocity. This study provides normative saccadic peak velocity data using video recordings from a lower sampling rate eye tracker. Saccadic peak velocity was chosen as the primary parameter because it has been shown to detect the onset of ocular movement dysfunction and to clearly track improvements over time, as demonstrated in previous research (Metz et al., 1970; Shafee, 2021).

Normality testing was conducted using the Shapiro-Wilk test, skewness, P-P plot, and histograms (Mishra et al., 2019). Based on these results, the data were considered normally distributed. A one-sample t-test was then conducted to compare the average mean peak velocity recorded by the Tobii Pro Fusion-120Hz with the mean data established from previous clinical study (Shafee, 2021).

The methodology employed—using a one-sample t-test to compare current data with established benchmarks—follows established practices in ocular motor research (Mack et al., 2017). This approach is justified given the need to compare new tools against reliable standards. The relevance of high-resolution tracking in clinical settings is further supported (Shafee, 2021), reinforcing the applicability of the Tobii Pro Fusion-120Hz for detailed ocular assessments.

Statistical Analysis

Statistical analysis was performed using SPSS version 23. The data's normality was checked, and a one-sample t-test was performed to compare the accuracy of saccadic peak velocity measurements from the lower sampling rate eye tracker with those obtained from a higher sampling rate eye tracker used in previous study (Shafee, 2021).

RESULTS

Participants in the study were healthy individuals aged 18-23 with normal ocular motility test results. All participants had a best-corrected visual acuity of 0.2 log MAR or better in both eyes and myopia of less than -6.00D. These criteria were set to ensure accurate calibration of the eye tracker, as ocular misalignment or high myopia could interfere with the results (Shafee, 2021).

One-Sample T-Test

A one-sample t-test was conducted to compare the average saccadic peak velocity recorded by the Tobii Pro Fusion-120Hz with the mean peak velocity data from the EyeLink 1000 Plus (Shafee, 2021). The one-sample t-test was used to compare the mean of saccadic peak velocity obtained with the Tobii Pro Fusion-120Hz eye tracker against a known value from the EyeLink 1000 Plus, which is a higher sampling rate device. This test is appropriate for assessing whether the mean saccadic peak velocity measured by the Tobii Pro Fusion-120Hz differs significantly from the established mean obtained from the EyeLink 1000 Plus (Mack et al., 2017).

The comparison was made with a known value (the mean from the EyeLink 1000 Plus) to determine if the observed data from the Tobii Pro Fusion-120Hz are consistent with or deviate from the established benchmark. The average saccadic peak velocity measured using the EyeLink 1000 Plus was 327 m/s, while the Tobii Pro Fusion-120Hz measured 323 m/s. These values reflect the performance of both eye trackers, demonstrating that the measurements from the latter are closely aligned with those of the former eye tracker. Table 1 shows that there was no significant difference in saccadic peak velocity measurements between the Tobii Pro Fusion-120Hz and the EyeLink 1000 Plus eye trackers ($p = 0.31$).

Table 1: One-sample T-test comparing saccadic peak velocity

Parameter	Test Value	Mean ±SD	t-value	df	Mean Difference	p-value
Saccade peak velocity (m/s)	327	323 ± 42.6	1.053	15	15.79	0.31

DISCUSSION

This study aims to evaluate the performance of the Tobii Pro Fusion-120Hz in measuring saccadic peak velocity in a healthy population, with the results compared to data from the higher sampling rate EyeLink 1000 Plus, which has been validated for clinical use. The findings confirm that the Tobii Pro Fusion-120Hz provides valid saccadic peak velocity measurements, comparable to those obtained with the EyeLink 1000 Plus, supporting its potential for clinical assessments. Previous study highlights the value of high-resolution tracking in detecting subtle eye movement abnormalities and monitoring recovery (Shafee, 2021), making the Tobii Pro Fusion-120Hz a valuable tool for similar clinical assessments. The efficacy of eye tracking in differentiating neurological disorders was further supported, emphasizing the role of precise tracking in clinical diagnostics (Marx et al., 2012). Eye trackers have been proven valuable in clinical settings due to their ability to provide precise and detailed measurements of ocular movements.

Additionally, research has shown that eye trackers can effectively identify and differentiate various eye movement disorders, such as nystagmus (Rosengren et al., 2020; Wong et al., 2006) and can be used to evaluate visual attention and cognitive processes (Katz et al., 2019). These applications underscore the potential of eye-tracking technology to enhance diagnostic accuracy and improve patient management in clinical practice.

However, it is acknowledged that the sampling strategy could be improved. Although this study focused on a specific demographic for consistency, limitations in sample size and diversity are recognized. For future research, it is recommended that a larger and more diverse sample be included to enhance the generalizability of the findings. Additionally, exploration of other saccadic parameters, such as saccadic latency and gain, is highly recommended to provide a more comprehensive assessment of the eye tracker's performance. These adjustments will help to strengthen the study's conclusions and offer more robust insights into its clinical applicability.

The Tobii Pro Fusion-120Hz eye tracker shows strong potential for clinical use, offering saccadic peak velocity measurements with accuracy comparable to the EyeLink 1000 Plus. This capability enhances its suitability for diagnosing and managing eye movement anomalies, supporting more precise and effective clinical evaluations.

CONCLUSION

The study demonstrates that the Tobii Pro Fusion eye tracker, operating at 120Hz, reliably measures saccadic peak velocity, with results closely aligning with those obtained from the higher sampling rate EyeLink 1000 Plus. However, the present study has limitations, including a small and specific sample. Future research should use a larger and more diverse sample and explore other saccadic parameters like latency and gain. These improvements will help confirm the Tobii Pro Fusion-120Hz's effectiveness in clinical settings for assessing and monitoring eye movement issues.

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ORIGINAL ARTICLE

Comparison of Optic Disc Morphology Between Glaucomatous and Non-Glaucomatous Myopic Eyes Using Swept-Source Optical Coherence Tomogaphy (SS-OCT)

Wan Nuramalin Wan Abd Manas[1], Mohd Radzi Hilmi[2,*], James Stuart Wolffsohn[3]

[1]Department of Optometry and Visual Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Ophthalmic Research Group, Aston University, Birmingham, UK.

Keywords:
glaucoma; myopia; optic disc;
ganglion cell layer; retinal nerve fiber layer

ABSTRACT

Background: The rising global prevalence of myopia is a growing concern for clinicians, as it predisposes patients to severe ocular pathologies including glaucoma. Myopia can be associated with clinical features that resemble glaucomatous damage, which make an accurate glaucoma diagnosis challenging, particularly among patients with normal intraocular pressures. This study aimed to compare the optic disc morphology, macular retinal ganglion cell layer and retinal nerve fiber layer (RNFL) between non-glaucomatous and glaucomatous myopic eyes using swept-source optical coherence tomography (SS-OCT). **Methods:** 100 participants were recruited which included 50 glaucomatous eyes and 50 non-glaucomatous eyes. All participants underwent standard optometric examination which includes best-corrected visual acuity (BCVA), standard retinoscopy, slit-lamp biomscroscopy, intraocular (IOP) measurement, visual field testing using automated perimetry and fundus examination using SS-OCT. The SS-OCT modalities used for optic nerve head measurements (rim area, disc area, vertical cup-to-disc ratio and cup volume) was 3D Disc 6.0×6.0 mm mode while 3D Macula 7.0×7.0 mm mode was used for macula area measurements. **Results:** The disc area, rim area, vertical cup-to-disc ratio, cup volume, macular ganglion cell layer and total retinal nerve fibre layer thickness were all found comparable between glaucomatous and non-glaucomatous groups (all $P > 0.05$). **Conclusion:** This study found no significant differences in the optic disc parameters and macular ganglion cell layer of glaucomatous and non-glaucomatous myopic eyes.

INTRODUCTION

Myopia is a common visual impairment worldwide, with increased prevalence were noted especially in developing countries including Malaysia. Developing countries and asian countries has been noted as having higher probability of having myopia (Melo et al., 2006; Sung et al., 2016). Changes in behaviours and predominant near work among younger generation has been noted as one of main contributors of myopia (Sun et al., 2023). The association of myopia and primary open angle glaucoma (POAG) is well established (Jonas et al., 2020; Zhang et al., 2022). Many studies had confirmed the association were even more prominent in higher degree of myopia (Xu et al., 2007; Kuzin et al., 2010; Perera et al., 2010; Czudowska et al, 2010).

Glaucoma is a group of disorders with characteristic of progressive degeneration of the optic nerve, with loss of retinal ganglion cells, thinning of the retinal nerve fiber layer (RNFL), and increasing excavation of the optic disc (Schuster et al, 2020). The pathophysiology of glaucoma is complex with increased in intraocular pressure (IOP) and low perfusion pressure leads to increase in gradient across the lamina cribrosa (LC), which cause papillary hypoperfusion. This process leads to changes in structural and remodelling of LC, which cause disruption of axonal transport in the optic nerve fibres. Previous studies had suggested that optic disc (Zhang et al., 2022; Sugihara et al., 2021), macular retinal ganglion cell layer (Nouri-Mahdavi et al., 2013; Seo et al., 2017) and retinal nerve fiber layer (RNFL) (Knight et al., 2012; Yamashita et al., 2013) are important structures in detecting glaucoma.

* *Corresponding author.*
E-mail address: mohdradzihilmi@iium.edu.my

However, there are limited evidence on comparison of optic disc characteristics in non-glaucomatous and glaucomatous myopic patients in Malaysia population. Thus, this study aimed to compare the morphological features of optic disc, macular retinal ganglion cell layer and RNFL in non-glaucomatous and glaucomatous myopic eyes using swept-source optical coherence tomography (SS-OCT).

METHODS

100 participants were recruited in this prospective cross-sectional study, based on their visits in a university-based Optometry clinic. All patients were briefed and informed about all procedures and their consent obtained prior to data acquisition. This study was conducted in accordance with the tenets of the Declaration of Helsinki and approved by the institution ethical board (IREC 2019-KAHS(U)). The inclusion criteria includes aged 20 - 50, spherical equivalent refraction (SER) from -0.50 to -7.00 DS (Jonas et al., 2002) and axial length between 22 to 26 mm. For the control/non-glaucomatous group, additional criteria were set which includes IOP < 20 mmHg, absence of glaucomatous optic neuropathy, nerve fiber layer defects and glaucomatous VF defects (Schuster et al, 2020). While for glaucomatous group, presence of glaucomatous optic neuropathy and VF damage. Patients with significant ocular surface diseases such as recurrent pterygium, corneal opacity or irregularity were excluded (Che Azemin et al., 2016; Hilmi et al., 2019; Hilmi et al., 2020). A condition in which fundus photography could not be measured due to obstruction of the central cornea were also excluded (Hilmi et al., 2019; Noor Syahira et al., 2020).

All participants underwent standard optometric examination which includes best-corrected visual acuity (BCVA) measurement using LogMAR chart, slit-lamp biomicroscopy, Goldmann Applanation Tonometry (GAT) and anterior chamber angle was measured using anterior OCT (CASIA-2; Tomey Corporation, Nagoya, Japan). Visual field (VF) testing were done using automated perimetry Humphrey Field Analyzer (HFA III)(Zeiss Meditec Inc, Jena, Germany) utilising 30-2 testing modality (Okimoto et al., 2015). The evaluations were carried out on all eyes, excluding those that were unreliable (fixation loss < 20%; false-positive and false-negative, <15%). Abnormal visual field was defined by the presence of at least one abnormal hemifield (Yohannan et al., 2017).

Fundus examinations were done using SS-OCT (DRI Triton, Topcon, Nagoya, Japan). The morphological features of optic disc, macular retinal ganglion cell layer and RNFL were measured using specific modality of SS-OCT. For optic nerve head measurements (rim area, disc area, vertical cup-to-disc ratio and cup volume) 3D Disc 6.0×6.0 mm mode was used and for macula area measurements 3D Macula 7.0×7.0 mm mode was used (Wichrowska et al., 2022). All procedures were completed within the same day and the diagnosis was confirmed by a senior consultant ophthalmologist. All data were presented as mean and standard deviation. The normality of the data was analysed using Shapiro-Wilk test. Differences in parameters between two groups then were compared by using independent t-tests. The alpha significance level was set at $P < 0.05$. All statistical analyses were performed using IBM SPSS (Predictive analytics software) (version 12, SPSS Inc., Chicago, IL, USA).

RESULTS

This study included 100 eyes of 50 glaucomatous participants and 50 non-glaucomatous. All data were normally distributed. The mean age and SER for both glaucomatous and non-glaucomatous were comparable with 25.5 ± 5.34 years and 23.2 ± 6.53 years respectively (P = 0.766), while the SER was -2.55 ± 1.34 D and -2.42 ± 1.29 D respectively (P = 0.453). In light of the intended parameters, this study found no significant difference in all parameters (Disc area, Rim area, Vertical CDR, Cup volume, Macular ganglion cell, total RNFL thickness).

For the optic nerve head parameters, the mean disc area for both glaucomatous and non-glaucomatous group were 1.98 ± 0.43mm^2 and 1.96 ± 0.42mm^2 respectively,P = 0.812). The mean rims area for both glaucomatous and non-glaucomatous group were 1.27 ± 0.26mm^2 and 1.28 ± 0.23mm^2 respectively, P = 0.844). Meanwhile for mean vertical CDR for both glaucomatous and non-glaucomatous group were 0.54 ± 0.14 and 0.52 ± 0.13 respectively, P = 0.566). And lastly, the mean cup volume for both glaucomatous and non-glaucomatous group were (0.20±0.12 mm^3 and 0.15±0.15mm^3 respectively, P=0.081). For the retinal layer parameters, the mean macular ganglion cell layer for both glaucomatous and non-glaucomatous group were 63.95 ± 3.03µm and 64.84 ± 3.57µm respectively, P = 0.213). Lastly, the mean total retinal nerve fiber layer for both glaucomatous and non-glaucomatous group were 106.41 ± 4.99µm and 108.45 ± 8.47µm respectively, P = 0.171). All findings were summarised in Table 1.

Table 1: Parameters of glaucomatous and non-glaucomatous myopic eyes

Group	Age (years) Mean (SD)	SER (D) Mean (SD)	Disc Area (mm^2) Mean (SD)	Rim Area (mm^2) Mean (SD)	Vertical CDR Mean (SD)	Cup Volume (mm^3) Mean (SD)	MGC layer (µm) Mean (SD)	RNFL thickness (µm) Mean (SD)
Glaucomatous	25.5 (5.34)	-2.55 (1.34)	1.98 (0.43)	1.27 (0.26)	0.54 (0.14)	0.20 (0.12)	63.95 (3.03)	106.41 (4.99)
Nonglaucomatous	23.2 (6.53)	-.2.42 (1.29)	1.96 (0.42)	1.28 (0.23)	0.52 (0.13)	0.15 (0.15)	64.84 (3.57)	108.45 (8.47)
P-value	0.766	0.453	.812	.844	.566	.081	.213	.171

SER: Spherical Equivalent Refraction
SD: Standard deviation
RNFL: Retinal nerve fiber layer
CDR: Cup-to-disc ratio
MGC: Macular ganglion cell

DISCUSSION

The current study intended to compare optic nerve head (disc area, rim area, vertical CDR and cup volume) and retinal layers (MGC layer and RNFL thickness) parameters between glaucomatous and non-glaucomatous myopic eyes using SS-OCT. Based on fundus image obtained, the appearances of the optic nerve head image between glaucomatous and non-glaucomatous eyes were clearly distinct as glaucomatous eye has larger CDR and pale colour compared to non-glaucomatous myopic eye which has normal orange-yellow appearance as in Figure 1 (a) and (b). This study found that there is no significant difference in optic nerve head and retinal layers parameters between glaucomatous and non-glaucomatous myopic eyes. This is in agreement with a previous work (Melo et al., 2006). However, this could be due to the comparison been made based on two different instrument.

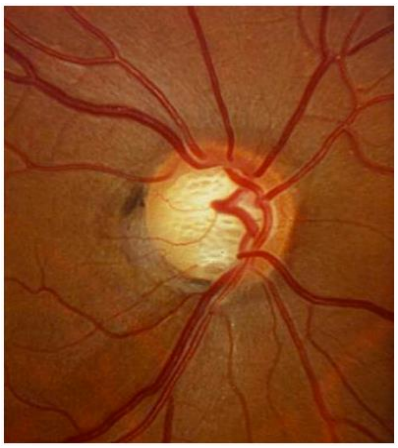

Figure 1 (a) Glaucomatous myopia

Figure 1 (b) Non-glaucomatous myopia

We postulate that these indifferences in our findings could be due to the degree of myopia of the glaucomatous group. Our sample population has lower SER compared to other studies. Previous work (Nakano et al., 2013) had commented that the higher the degree of myopia, more changes in the structural of optic nerve head can be observed. Another possible reason could be this study only comparing the average value of each parameter and not comparing the value in the quadrants. Previous study that take measurements from inferior and superior quadrants reported that peripapillary RNFL values are superior to macular RNFL thickness in giving diagnosis to glaucoma (Sung et al., 2015). This is due to retinal ganglion cell with large axons is more susceptible to damage than the ganglion cell with small axons in macula, however these large axons were commonly seen in the inferior retina (Öztürker et al., 2016; Han et al., 2017). They also reported that the large optic disc or macrodisc can give overestimation of the RNFL thickness as the measurement is taken close to the edge of optic disc, the distance of the scan with the optic disc will be less as it is restricted with the large disc size. Also, they also reported that the true analysis of

RNFL and optic disc could be influenced with axial length variation. However, the current study managed to control this factor by only taken participants that within acceptable refractive error and axial length.

The depth and thickness of lamina cribrosa (LC) are also useful to differentiate between glaucomatous and non-glaucomatous eyes. Previous works (Hata et al. 2014; Yoshikawa et al. 2018) had commented that the depth of LC were deeper, with its thickness were found lesser in glaucomatous compared to non-glaucomatous eyes. This happen could be due to the measurement of LC depth could be including the Bruch membrane opening (BMO) and also influenced by the thickness of choroid. However, in this current study, choroid thickness was not measured. This study found that the macular ganglion cell were comparable between glaucomatous and non-glaucomatous eyes. This is contrary with other studies. Previous study (Rao et al., 2016; Nakano et al, 2013) commented that the difference could be due to lack of sensitivity of the test in differentiating or detecting glaucoma in low myopia, not as in high myopia group. This could reflect limitation in this current study as our study sample were relatively low myopia.

Further investigations are suggested in relation between optic disc morphology and glaucoma with/without myopia. Longitudinal study on the timeline of structural changes in the optic nerve head may help differentiate myopia-related optic disc changes from glaucomatous damage. Age-related differences in optic disc morphology also can be further explored as both aging and myopia influence the optic disc, and age-related changes may exacerbate glaucoma risk. Regional variations in the optic disc and peripapillary area also another area could be worth to explore as certain regions of the optic disc (e.g., inferior-temporal) are more vulnerable to glaucomatous damage.

CONCLUSION

This study found no significant differences in the optic disc parameters and macular ganglion cell layer of glaucomatous and non-glaucomatous myopic eyes.

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ORIGINAL ARTICLE

Impact of Viscosity Variations in Dual-Polymer Artificial Tears on Corneal Regularity and Aberration

Husna Alia Halmi[1], Mohd Radzi Hilmi[1,2,*], Noor Shazana Md Rejab[3], James Stuart Wolffsohn[4]

[1]Department of Optometry and Visual Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]School of Optometry, Faculty of Medicine and Health Sciences, USCI University, Kuala Lumpur.
[3]Ophthalmic Research Group, Aston University, Birmingham, UK

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Corneal aberration; Systane Ultra, Systane Hydration; Tear retention time

ABSTRACT

Background: This study was done to explore the possibility of the usage of different viscosities in artificial tears (Systane Ultra and Hydration) in detecting changes in corneal aberration on dry eye patients. **Methods:** 103 diagnosed dry eyes were observed in this study and two different artificial tears with different viscosities were instilled randomly in each eye. Corneal aberration measurement with Fourier index (Spherical aberration (SA), trefoil and coma) was then captured for 10 minutes using CASIA with a 1-minute time interval. Normal saline was instilled before the treatment was given (referred to as baseline). Repeated measure analysis of variance (RM ANOVA) and paired sample t-test were used to evaluate the effects of artificial tears after instillation and comparison between each specific time interval respectively. The P-value of 0.05 was set as the level of significance. **Results:** Corneal aberration with artificial tears was then compared to normal saline and the results showed that there was no significant difference between artificial tears in terms of retention time after 10 minutes ($p>0.05$) in dry eye participants. Both groups demonstrated significant improvements from baseline and there was a significant difference from baseline ($p<0.05$). **Conclusion:** Instillation of high viscous artificial tear produce better uniformity of the corneal surface resulting in lower corneal aberration.

INTRODUCTION

The tear film acts as a protective barrier for the ocular surface, shielding it from mechanical damage and environmental elements to maintain comfort. It is composed of lipid, aqueous, and mucin layers, each component serves specialized roles dictated by its unique composition. The equilibrium and robustness of the tear film hinge upon coordinated processes such as tear generation, evaporation, absorption, and drainage. Disruption of these processes or impairment of the tear film layer can precipitate the onset of dry eye syndrome (Kopacz et al., 2021).

* *Corresponding author.*
E-mail address: mohdradzihilmi@iium.edu.my

Dry eye disease (DED) is a multifactorial disorder characterized by symptoms including dry eyes, blurred vision, tear film integrity, and degeneration of the ocular surface. Dryness, grittiness, and burning sensations also increase over time. Other typical symptoms include crusty eyelids, stringy discharge, watery eyes, ocular tiredness, discomfort, and temporary vision loss. According to the Dry Eye Workshop of the Tear Film & Ocular Surface Society (TFOS DEWS II 2017 Report), dry eye is "a multifactorial disease of the ocular surface characterized by a loss of tear film homeostasis, accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles" (Craig et al., 2017). The precorneal tear film plays a critical role in maintaining the optical clarity of the eye. Tear film, which serves as the foremost refractive surface of the eye, deteriorates, it causes irregularities on the optical surface. This breakdown can introduce additional aberrations into the eye's optical system. Several research works support the notion that dry eye conditions lead to heightened irregularity and

fluctuation in the tear film, resulting in increased optical aberrations compared to healthy eyes. These changes have been linked to compromised visual acuity and diminished optical quality (Lu et al., 2016; Koh, 2018; Koh et al., 2018).

Corneal wavefront aberrations were found to vary a lot from person to person, and these differences can cause the Zernike aberrations to change over time. Several studies have shown that spherical aberration (SA) changes quickly after blinking, with a significant shift happening about 10 seconds after blinking. This suggests that desiccated tear film can affect the optical quality (Koh et al., 2008; Ferrer-Blasco et al., 2010; Xu et al., 2011). The change in SA could lead to central cornea been evaporated faster than peripheral cornea. Moreover, the corneal surface may shift towards oblate, thus indirectly increasing SA. Previous work had commented that impact of SA on quality of vision is worse than coma and trefoil (Yıldırım et al., 2020). It is an established fact that the usage of artificial tears could increase tears retention time, improving tears stability and reduce corneal irregularities (Che Arif et al., 2020; Che Arif et al., 2021; Che Arif, Hilmi & Kamal, 2023). Currently, there is limited evidence on the impact of instillation of artificial tears on improvement in corneal aberration. Hence, this study aimed to evaluate the changes in aberration on the corneal surface using two dual polymer artificial tears with varied viscosity.

MATERIALS AND METHODS

This study was conducted at IIUM Optometry Clinic, Kuliyyah of Allied Health Sciences, IIUM Kuantan, Pahang. During the study, a total of 103 eyes were recruited in this prospective study. All participants were briefed and informed about all procedures and their consent obtained prior to data acquisition. in accordance was conducted in accordance with the tenets of the Declaration of Helsinki and approved by the institution ethical board (IREC 2023-KAHS/DOVS2). All procedures were conducted in the same examination room, with temperature and humidity kept constant at 20°C-24°C (Carracedo et al., 2019) and 40%-50%, respectively (Torkildsen et al., 2017). Both participant and optometrist conducting the procedures were blinded to the ophthalmic solutions used at each visit. Inclusion criteria set for this study include university students aged 20-26 years old, scotopic pupil size ≤ 6 .5 mm (Md Rejab et al., 2023), having one or more of the following symptoms present: dry eyes, burning, foreign body sensation, blurred vision, and other associated symptoms of dry eye (Yildirim et al., 2021), tear breakup time (TBUT) for each eye was ≤ 6 seconds (Stein et al., 2006), and OSDI score > 13 (Paugh et al., 2008; Che Arif et al., 2023). Participants will be excluded from the study if there is presence of ocular surface abnormalities or diseases such as superficial punctate keratitis, recurrent pterygium, corneal opacity or irregularity (Hilmi et al., 2020; Jais et al., 2021). Participants that are regularly wearing contact lens and currently using artificial tears also were excluded (Hilmi et al., 2019). A condition in which corneal topography could not provide reproducible measurement due to obstruction of the central cornea by pterygium were also excluded. (Che Azemin et al., 2016; Mohd Radzi et al., 2019; Yildrim et al., 2020).

Three ophthalmic solutions were used in this study, which were two dual-polymers artificial tears; Systane® hydration (SH) (Alcon Laboratories Inc, Fort Worth, TX, USA) and Systane® Ultra (SU) (Alcon Laboratories Inc, Fort Worth, TX, USA), and one control solution; Opticare Normal saline solution (Excel Pharmaceutical Sdn. Bhd., Selangor, Malaysia). The viscosity of SH and SU were 26.70 cP and 12.40 cP respectively, based on our previous work (Che Arif et al., 2020). Research randomizer software (https://www.randomizer.org/) was used to randomise the sequence of solutions to be used at each visit, and the sequence and ophthalmic drops was masked from the observer.

TBUT was observed on each participant. A fluorescein strip was applied to the inferior fornix as the participant looked upward. Then, the participant was required to blink several times to ensure that the dye was evenly distributed throughout the cornea. The time required under cobalt blue light until the first black spot appears on the corneal surface is considered break-up time (Abdullah, Ithnin & Hilmi, 2019). The test was performed using a video camera mounted on digital high-definition slit-lamp biomicroscopy (Model SL 990, SLB Mega Digital Vision HR, Costruzione Strumenti Oftalmici, Italy). Measurements of TBUT were done three times, and the average of the results were used for analysis. Anterior segment imaging was done with a swept-source ocular coherence tomography (SS-OCT) (CASIA-2; Tomey Corporation, Nagoya, Japan), which utilise 1,310 nm laser wavelength and a speed of 30,000 A-scans per second. In this study, Zernike polynomials are used to describe wavefront aberrations of the cornea or lens from an ideal spherical shape, which result in refractive errors. Then, from Zernike analysis, it is transformed into a three-dimensional model of the anterior cornea. The loaded ray tracking program was used to compute corneal aberration. The built-in software automatically calculates the anterior corneal surface's 3rd, 4th, and

5th aberrations, SA (Z4, 0), trefoil (Z3, −3), and coma (Z3, −1), using Zernike polynomials translated from corneal data (Lu et al., 2016).

Prior to corneal aberration measurements with CASIA, each participant was instilled with Opticare Normal saline solution (Excel Pharmaceutical Sdn. Bhd., Selangor, Malaysia) in both eyes and instructed to blink several times. The corneal aberrations measurement will be taken immediately following the blink to prevent tear evaporation. This test was performed in a normal lit room and the participant was required to focus on the illuminated target. The first measurement taken was referred to as the baseline. Following the saline application, the first artificial tear was instilled, and the corneal aberration result was captured immediately one minute after the instillation of the artificial tear and after 10 minutes (Montés-Micó, Cáliz & Alió, 2004; Lee et al., 2024). After that, a few drops of saline were instilled for washout period which was set at 60 minutes to avoid the cross-over effect of the previous artificial tears which could affect the aberration reading (Markoulli et al., 2018). All data were analysed using IBM SPSS Statistics for Windows, Version 20 (IBM Corp., Armonk, N.Y., USA). Normality of all the data was assessed using Shapiro-Wik test.

The differences in all variables pre- and post-instillation (Baseline vs. 1 min, Baseline vs. 5 min, Baseline vs. 10 min) were examined using paired sample T-test. Repeated measure analysis of variance (RM ANOVA) and paired sample t-test was used to determine the differences in spherical aberration (SA), trefoil and coma between groups at specific time intervals. The significance level was set at $P < 0.05$.

Table 1: Descriptive analysis for spherical aberration (SA), trefoil and coma

Artificial tear	Time interval (Min)	Aberration			P-value	
		SA (mean ± SD)(μm)	Trefoil (mean ± SD)(μm)	Coma (mean ± SD)(μm)	RM-ANOVA	Paired T-Test
Systane® hydration	Baseline	0.36 ± 0.56	0.18 ± 0.44	0.37 ± 0.24		
	one-minute	0.14 ± 0.34	0.08 ± 0.12	0.17 ± 0.12	< 0.001 for all aberration	*P = 0.55
	10-minute	0.27 ± 0.24	0.12 ± 0.23	0.33 ± 0.14		
Systane® Ultra	Baseline	0.35 ± 0.46	0.17 ± 0.36	0.36 ± 0.16		
	one-minute	0.18 ± 0.32	0.12 ± 0.45	0.19 ± 0.23	< 0.001 for all aberration	*P = 0.63
	10-minute	0.29 ± 0.14	0.15 ± 0.25	0.28 ± 0.14		

Mean ± SD: Mean and standard deviation
Min: Minutes
RM-ANOVA: Repeated measure analysis of variance
*Paired T-test: comparison between baseline and 10-minutes

RESULTS

Based on Shapiro-Wilk test, all data were normally distributed. Based on descriptive analysis, for SH group at baseline the mean and standard deviation (mean ± SD) for spherical aberration (SA), trefoil and coma were 0.36 ± 0.56, 0.18 ± 0.44 and 0.37 ± 0.24 respectively. At one-minute post-instillation, we found steep reduction in all parameters with 0.14 ± 0.34, 0.08 ± 0.12 and 0.17 ±0.12 respectively. At 10-minutes post instillation, there was slight increment with 0.27 ± 0.24, 0.12 ± 0.23 and 0.33 ± 0.14 respectively compared to one-minute interval. For SU group, at baseline the mean ± SD for spherical aberration (SA), trefoil and coma were 0.35 ± 0.46, 0.17 ± 0.36 and 0.36 ± 0.16 respectively. At one-minute post-instillation, we found steep reduction in all parameters with 0.18 ± 0.32, 0.12 ± 0.45 and 0.19 ± 0.23 respectively.

At 10-minutes post instillation, there were slight increment with 0.29 ± 0.14, 0.15 ± 0.25 and 0.28 ± 0.14 respectively compared to one-minute interval. The descriptive analysis is summarised in Table 1 below.

For SH group, RM-ANOVA findings revealed statistically significant changes in SA, trefoil and coma between baseline and 10 minutes observation period. Post hoc comparisons using the Tukey HSD test indicated that SA, trefoil and coma between baseline, one-minute and 10-minutes time interval was significantly different.

However, this study found no significant difference (Paired T-test, $P = 0.55$). Likewise for SU group, RM-ANOVA findings revealed statistically significant changes in SA, trefoil and coma between baseline and 10 minutes observation period. Post hoc comparisons using the Tukey HSD test indicated that SA, trefoil and coma between baseline, one-minute and 10-minutes time interval was significantly different (all $P < 0.001$). However, this study found no significant difference (Paired T-test, $P = 0.63$) between baseline and at 10-minutes instillation. The RM-ANOVA and post hoc findings were summarised in Table 1.

DISCUSSION

In this study, we compared the different viscosities of artificial tears and evaluated their effects on the corneal aberration measurement. Our findings showed that both artificial tears produced reduction in corneal aberration at post one-minute instillation and increased slightly at 10-minutes towards baseline. However, the decrement at one-minute post-instillation showed high viscosity artificial tear produce more reduction compared to medium viscosity artificial tears. This findings in agreement (Röggla et al., 2021). And at 10-minutes, both artificial tears showed an increase of corneal aberration compared to one-minute post-instillation, however it was still lower than baseline. Thus, our study showed that higher viscosity artificial tears provide additional benefits while improving the corneal regularity and last longer on the ocular surface, as previously reported (Pavlopoulos, Horn & Feldman, 1995; Liu & Pflugfelder, 1999; Huang et al., 2002; Wolffsohn et al., 2023).

Although the usage of artificial tears seems to improve the corneal regularity, it is with to note the impact on the quality of vision. Improvement of corneal aberration with the usage of artificial tears should be prudently examined. It needs to be looked upon from the perspective of just-noticeable differences (JND) for each corneal aberration parameter. For SH group, reduction of SA, trefoil and coma between baseline and one-minute interval were 0.22 µm, 0.1 µm and 0.2 µm respectively. Meanwhile for SU group, reduction for SA, trefoil and coma between baseline and one-minute interval were slightly smaller than SH group with 0.17 µm, 0.05 µm and 0.17 µm respectively. Even though the magnitude changes in all parameters were statistically significant (All $P < 0.05$), we postulate that these differences were clinically insignificant. This could happen due to these changes being lesser or just approximately reaching the JND for each aberration. Numerous works had suggested the JND for each aberration are varies with SA approximately 0.15 to 0.25 diopters (D), trefoil in ranges of 0.10 to 0.15 microns and coma at approximately 0.10 microns (He et al., 1998; Oshika et al., 1999; Thibos et al., 2002; Applegate et al., 2003; Marsack, Thibos & Applegate, 2004; Jungnickel et al., 2013). These indicate that the impact of aberration on visual quality varies depending on the types and magnitude of each aberration. Thus, these could suggest the reason why not all patients reported visual disturbance or discomfort due to aberration.

With advancement in artificial tears formulation, high viscous are no longer being used for overnight treatment purposes as it would induce temporary blurred vision. Lievens et al. (2019) reported no differences between high and mid-viscosity eye drops with regards to immediate experiences such as "no blurring or visual interference" upon application and "clear and comfortable vision" within days. Recent study has postulated that the differences in initial eye comfort and visual interference shortly after application could be due to presence of lubricant in its formulation (Weisenberger, Fogt & Swingle Fogt, 2021). In general, the high viscosity lubricant eye drop was well tolerated and proved effective in alleviating signs and symptoms

of dry eyes (Saad & Brings, 2023). Previous studies have demonstrated that viscosity plays a crucial role in maintaining tears on the surface of the eye (Paugh et al., 2008; Che Arif et al., 2020; Kaido & Arita, 2024). Similarly, the findings of this study indicate that both types of artificial tears exhibit shear-thinning behaviour, in which viscosity is higher under low shear stress and vice versa. This suggests that higher viscosity may enhance the effectiveness of artificial tears in maintaining moisture on the ocular surface during periods of minimal shear, such as when the eye is open, thereby reducing evaporation rates (Che Arif et al., 2020). However, in lower viscosity, at higher shear rates, such as during blinking, it may improve ocular comfort and minimise ocular surface friction (Aragona et al., 2019).

There are several limitations which are worth noting. We only recruited participants with mild dry eyes based on the signs and symptoms from OSDI and TBUT measurements. Thus, for future research, it is suggested to include moderate to severe dry eye participants to evaluate if there are any significant differences in corneal aberration. This study only focuses on the observation and measurement of corneal aberration right after artificial tears application. The long-term effects of usage of these artificial tears, alongside multiple instillations, also need further investigation. The selection of age as participant should cover a wider range. This is because tear production tends to diminish as age increases, thus posed higher risk of getting dry eye in older patients. It is suggested that different levels of severity and types of dry eyes with additional factors such as with and without using artificial tears can be included for further research.

CONCLUSION

Instillation of high viscous artificial tear produces better uniformity of the corneal surface resulting in lower corneal aberration.

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ORIGINAL ARTICLE

Microbial Contamination and Biofilm Formation in Ophthalmic Solutions and Ophthalmic Instruments at Optometry Practice

Aina Balqis Abd Karim[1], Hanani Ahmad Yusof[2], Aisyah Saad Al Saadoun[1], Muhammad Afzam Shah Abdul Rahim[1, 4], Noor Halilah Buari[3], Firdaus Yusof[1,4,*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Centre for Optometry Studies, Faculty of Health Sciences, Universiti Teknologi MARA, Puncak Alam Campus, Selangor, Malaysia
[4]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

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ABSTRACT

Background: Maintaining sterility and preventing microbial contamination are critical in optometry, where multiple surfaces, devices, and solutions contact the patient's eyes, posing an infection risk. Contamination, especially from biofilm-forming pathogens, can occur from airborne droplets, surface contact, and improper disinfection. This study investigates microbial contamination and biofilm formation in solutions and on the surface of ophthalmic instruments commonly used in optometry practices. **Methodology:** Samples were collected from a university-affiliated optometry practice deemed a centre for clinical practice, teaching, and research. Samples were obtained from the dropper tip's ophthalmic bottles and the bulk solution, repeated for both newly opened bottles and after one month of use. One-time samples from various ophthalmic instruments (slit lamps, trial frames, trial lenses, and occluders) were also collected after clinical usage. Contact lens containers were also sampled from the outer edge of the bottles. All samples were placed on Congo Red Agar (CRA) for microbial analysis. **Results:** Microbial contamination was observed from the dropper tips of newly opened bottles but not in the solutions. After one month of use, microbial contamination increased from dropper tips but remained absent in solutions. No biofilm formation was recorded before and after one month of use. Ophthalmic instruments exhibited substantial contamination after use, with some showing biofilm formation. Contact lens containers showed contamination without biofilm formation. **Conclusion:** This study shows bacterial presence on the ophthalmic instruments and solution packaging used in the study location. The most common contamination occurs at the dropper tip while the solution remains pristine. Microbial biofilm observed on ophthalmic tools underscores the importance of diligent sanitation procedures for optometrists.

INTRODUCTION

Maintaining sterility and preventing microbial contamination are critical concerns in optometry, where practitioners routinely handle delicate ophthalmic instruments and administer various solutions to patients. The numerous surfaces, devices, and solutions that come into contact with a patient's eyes and mucous membranes create ample opportunities for transmitting pathogenic microorganisms. Contamination can arise through direct contact between individuals and contact with contaminated objects or surfaces (Lau et al., 2024). Microbial transmission may occur via airborne droplets, surface contact, and improper disinfection practices (Lian et al., 2017). Consequently, microbial contamination that produces biofilms can lead to ocular infections, exacerbating existing conditions and compromising patient well-being (Kyei et al., 2019).

Several studies have investigated the prevalence of microbial contamination in ophthalmic instruments and solutions used in clinical settings (Mohapatra, 2017; Tsegaw et al., 2017; Rutala & Weber, 2016). These findings highlight the need for robust decontamination protocols and adherence to best practices to minimise healthcare-associated infection risks. Contamination in ophthalmic solutions risks infection transmission and diminishes the quality and stability of these solutions, undermining treatment efficacy (Noor et al., 2015). A study assessing the sterility of opened multi-dose ophthalmic medications found that 50% of containers tested positive for bacterial or fungal contamination (Tamer et al., 1994). This underscores the importance of properly labelling and storing opened multi-dose containers to maintain sterility (Tamer et al., 1994).

Decontaminating ophthalmic instruments is crucial, as they can quickly become contaminated when used on patients' eyes or mucous membranes (Mohapatra, 2017; Rutala & Weber, 2016). Contaminated medical devices have been linked to outbreaks and infections within healthcare settings, emphasising the need for rigorous

* *Corresponding author.*
E-mail address: yfirdaus@iium.edu.my

sterilisation and disinfection protocols (Infectious Control Unit, 2019). Inadequate cleaning can lead to healthcare-associated infections (Graham et al., 2008). Thus, microbial contamination in ophthalmic instruments and solutions necessitates strict adherence to best practices for patient safety (Hart et al., 2021). Nonetheless, an established disinfection guideline for high-risk ophthalmic instruments remains elusive, leading clinics to create protocols based on limited evidence and manufacturer advice (Dart et al., 1995).

Although studies on microbial contamination are prevalent, biofilm formation is often overlooked. Biofilm-producing microorganisms are particularly concerning due to their heightened resistance to antimicrobial agents, including antibiotics and disinfectants (Navon-Venezia et al., 2017; Khatoon et al., 2018; Lajhar et al., 2018). Biofilms consist of microbial communities that adhere to surfaces and form protective matrices, shielding them from environmental stresses and the immune system (Shree et al., 2023; Muhammad et al., 2020; Gunn et al., 2016). This facilitates chronic infections and complicates treatment, as biofilm-associated bacteria are significantly more resistant than their planktonic counterparts (Sahoo & Meshram, 2024). Addressing biofilm contamination is essential to improve health outcomes in optometry practices, necessitating targeted strategies for monitoring and controlling biofilm formation in instruments and solutions.

This study investigated the direct contamination of solutions and containers usually used in optometry practices and the indirect contamination of ophthalmic instruments commonly used in optometry practices, particularly the presence of biofilm producers.

MATERIALS AND METHODS

Ophthalmic solution sampling

Samples were obtained from seven bottles of ophthalmic solutions: normal saline solutions (sodium chloride 0.9%, 500ml bottle; Bottle-1, Bottle-2, Bottle-3), cycloplegic agent (cyclopentolate hydrochloride 1% with benzalkonium chloride 0.01% preservative, 15ml bottle; Bottle-4) and anesthetic agent (proparacaine hydrochloride 0.5% with benzalkonium chloride 0.01% preservative, 15ml bottle; Bottle-5, Bottle-6, Bottle-7). Due to a manufacturing issue that led to supply shortages, samples were taken from only one bottle of cycloplegic agent.

Samples were taken from the dropper tip (Figure 1) and the solution inside the bottles. Samples from the dropper tips were taken using damp sterile swab sticks (sticks were dipped into sterile distilled water). A damp swab stick enhances the attachment of bacteria compared to a dry swab stick (Pichon et al., 2019). Samples from the dropper tips were placed in sterile plastic containers before laboratory analysis.

Ophthalmic solutions were sampled directly by placing a drop on Congo Red Agar (CRA). To avoid contamination from tips to solutions, each dropper tip was decontaminated using an alcohol swab (70% isopropyl alcohol) before sampling the solution. Care was taken to ensure the alcohol did not enter bottles. The decontaminated tip was left to dry for one minute before sampling.

Sampling was repeated twice: on a newly opened bottle and again one month after the opening date. The usage of the ophthalmic solutions was recorded. The sampling of each ophthalmic solution was triplicated to enhance the validity of the test.

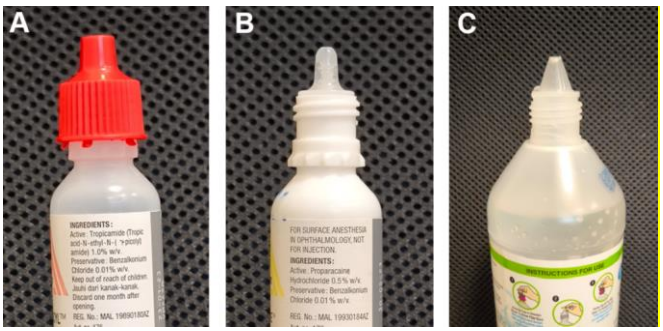

Figure 1: The bottle's tips: (A) shows a 15ml capped bottle of a cycloplegic agent, (B) shows a 15ml uncapped bottle of an anesthetic agent, and (C) shows a 500ml uncapped normal saline bottle. Samples were taken from uncapped bottle tips

Ophthalmic instruments sampling

Ophthalmic instruments from three optometry cubicles (Cubicle-1, Cubicle-2, Cubicle-3) in a university-affiliated optometry practice were chosen for sampling. Samples were collected immediately after a clinic session using the same procedure in sampling ophthalmic solution dropper tips elaborated previously. Samples were taken on slit lamps (SL) in three areas, including the joystick, headrest, and chin rest. Samples were also taken on trial frames, trial lenses, and occluders.

Contact lens (CL) container sampling

Six containers of CL were sampled. The CLs were randomly selected from the available CLs in the optometry practice. Samples were taken from the outer edge of the contact lens bottles. The technique used for collecting the samples

was the same as that used for collecting samples from the dropper tips.

Microbial analysis

Preparation of Congo Red Agar (CRA) plate

The CRA was utilised to differentiate biofilm-producing bacteria while also indicating the presence of contamination by non-biofilm producers. Biofilm is observed as black colonies on CRA, whereas non-biofilm is observed as red colonies (Melo et al., 2013). In preparing the CRA, a mixture of Brain Heart Infusion Agar (23.5g), Agar Technical No.2 (5.0g), glucose (2.5g), and Congo red dye (0.4g) were infused into 500ml of distilled water. The mixture was then shaken thoroughly and sterilised in the autoclave machine at 121°C for 15 minutes. The mixture was then poured into Petri dishes and solidified at room temperature. Two plates from each manufacturing batch were placed in the incubator overnight as control plates to ensure no contamination, while the remaining plates were stored at 2°C to 8°C.

Bacterial isolates on CRA plate

Samples from swabs were streaked on the CRA plates. Ophthalmic solution samples directly placed on the CRA plates were streaked using an inoculating loop strictly under aseptic conditions, using the quadratic streaking technique (Tantray et al., 2023). The cultures were then incubated in 5% carbon dioxide (CO2) at 37ºC for at least three days. They were monitored daily until day five of incubation for bacterial growth and the presence of black colonies. Streptococcus mutans, a biofilm producer, was used as the positive control strain.

RESULTS

Samples from unused (newly opened) ophthalmic solutions showed that two dropper tips were contaminated. The contamination was found at the dropper tip of the normal saline Bottle-3 and anesthetic agent Bottle-6. No biofilm was observed from the contaminated dropper tip samples. No contamination was recorded in all ophthalmic solutions (Table 1). Taking the negative contamination in all solutions, they were deemed safe for study after ensuring proper disinfection of the dropper tip.

Table 2 lists the usage of various ophthalmic solutions in one month, with an average of 10.4 usage per month. Microbial contaminations were observed after one month of usage on the dropper tip of normal saline Bottle-2 and -3 (66% of samples), cycloplegic agent Bottle-4 (100%), and anesthetic agent Bottle-6 and -7 (66%) (Table 3). No biofilm was observed from the contaminated dropper tip samples. None of the solutions, however, were observed to have positive contamination.

Table 1: Baseline data of newly opened bottles of various ophthalmic solutions. Samples were taken and analysed from the dropper tips and ophthalmic solution contents

Ophthalmic solution	DTC	BPT	SC	BPS
Normal saline (3 samples)	Bottle-3	-ve	ND	-ve
Cycloplegia (1 sample)	ND	-ve	ND	-ve
Anesthesia **(3 samples)**	Bottle-6	-ve	ND	-ve

DTC: Dropper Tip Contamination
BPT: Biofilm Presence from Tip
SC: Solution Contamination
BPS: Biofilm Presence from Solution
-ve: Negative
ND: Not Detected

Table 2: The usage record of various ophthalmic solutions in one month

Bottle Number	Number of usage
Normal Saline Bottle-1	11
Normal Saline Bottle-2	12
Normal Saline Bottle-3	12
Cycloplegic Agent Bottle-4	7
Anesthetic Agent Bottle-5	10
Anesthetic Agent Bottle-6	10
Anesthetic Agent Bottle-7	11

Table 3: Bacterial contamination of various ophthalmic solutions after one month of open bottle. Samples were taken and analysed from the dropper tips and ophthalmic solution contents

Ophthalmic solution	DTC	BPT	SC	BPS
Normal saline (3 samples)	Bottle-2, Bottle-3	-ve	ND	-ve
Cycloplegia (1 sample)	Bottle-4	-ve	ND	-ve
Anesthesia **(3 samples)**	2 (67%) Bottle-6, Bottle-7	-ve	ND	-ve

DTC: Dropper Tip Contamination
BPT: Biofilm Presence from Tip
SC: Solution Contamination
BPS: Biofilm Presence from Solution
-ve: Negative
ND: Not Detected

The ophthalmic instruments observed various contaminations after usage (Table 4). The trial frames in all optometry cubicles were contaminated, but there were no observable biofilms. The trial lens in Cubicle-2 was deemed contaminated, but no biofilm was presented. The occluders in Cubicle-1 and -2 were observed to have

bacterial contamination, with Cubicle-2 showing the formation of biofilms. Contaminations were positive from various parts of SL: Cubicle-1 and -3 on SL's joystick, Cubicle-2 and -3 on SL's headrest, and Cubicle-1 and -2 on SL's chinrest. Biofilm was found on the SL's headrest of Cubicle-2.

Two CL containers were deemed contaminated (Table 5). No biofilm was presented from the contaminated CL containers.

Table 4: Bacterial contamination of various ophthalmic instruments from three optometry cubicles after a clinical session

Sampling area	Location of contamination	Biofilm presence
Slit lamp's joystick	Cubicle-1, -3	-ve
Slit lamp's headrest	Cubicle-2, -3	Cubicle-2
Slit lamp's chin rest	Cubicle-1, -2	-ve
Trial frame	Cubicle-1, -2, -3	-ve
Trial lenses	Cubicle-2	-ve
Occluders	Cubicle-1, -2	Cubicle-2

-ve: Negative

Table 5: Bacterial contamination of contact lens containers

No. of contact lens containers tested	Contaminated	Biofilm
6	2	-ve

-ve: Negative

DISCUSSION

The issue of microbial contamination in optometry practices is a significant concern that warrants careful consideration. Ophthalmic solutions, such as diagnostic agents, eye drops, and other topical medications, can serve as potential vectors for the transmission of harmful microorganisms, posing a risk to patients' ocular health and overall well-being (Zilliox et al., 2020; Chua et al., 2021; Kyei et al., 2019). This study investigated three types of ophthalmic solutions, including normal saline, cycloplegic, and anesthetic agents, considering their frequent usage in a typical optometry practice. Both cycloplegic and anesthetic agents contain benzalkonium chloride 0.01% as a preservative, while the normal saline was deemed preservative-free. Preservatives in ophthalmic solutions help maintain sterility and prevent microbial contamination, especially in multi-dose solutions, which are susceptible to repeated use. Preservatives help to inhibit bacteria and other microorganisms, ensuring the product's safety and efficacy (Chua et al., 2021; Bachewar et al., 2018). The current study found no contamination at baseline or after one month of use. This was also true for preservative-free normal saline. However, some studies have questioned the efficacy of certain preservatives in ophthalmic solutions, suggesting the need for better methods to eliminate microbial contamination (Jayant & Halami, 2020).

Microbial contaminations in this current study were spawned from the dropper tip without the formation of biofilm. Contamination was also detected on dropper tips in an unused normal saline and anesthetic agent without compromising the solution. A similar observation was reported by Tsegaw et al. (2017), who observed that 11% of their samples were contaminated at the dropper tip without compromising the residual content. They even found contaminations in samples used for less than seven days. Nevertheless, solutions of more than seven days dominated the reported incidence. In contrast, a study by Chua et al. (2021) reported an average contamination rate of 25% from the dropper tip, 17% in residual content, and 8% of both dropper tip and residual content over 14 and 30 days of preserved ophthalmic drugs (POD) usage. Interestingly, Chua et al. (2021) also reported contamination in nine unused PODs they tested, similar to the current findings of bottle tip contamination on one unused normal saline and anesthetic agent. To reverberate, the current study also observed contamination of CL storage containers. Unfortunately, the solution residue in the containers was not sampled to provide a more conclusive finding.

Existing research has identified several key risk factors for microbial contamination of ophthalmic solutions. Certain therapeutic classes, such as steroid-containing anti-inflammatory solutions, appear more susceptible to contamination than others (Zilliox et al., 2020; Chua et al., 2021). The duration of product use is also a critical factor, with more extended periods of use increasing the likelihood of contamination (Chua et al., 2021). Additionally, the physical appearance of the bottle, such as signs of tampering or cloudiness, can serve as visual cues for potential contamination.

The sources of contamination can arise from various routes, including improper handling by optometrists, inadequate disinfection of equipment and surfaces, and even the intrinsic formulation of the solutions themselves (Chua et al., 2021). The impact of such contamination on patient health can be severe, leading to the development of ocular infections, corneal ulcers, and other sight-threatening complications (Zilliox et al., 2020; Kyei et al.,

2019). Certain microorganisms, such as Gram-negative rod bacteria and Micrococcus species, have been frequently isolated from contaminated ophthalmic solutions, underscoring the potential for serious clinical consequences (Chua et al., 2021).

The current study observed substantial contaminations of the ophthalmic tools in all tested cubicles. All trial frames were deemed contaminated (100% contamination rate) where inoculation occurred after a clinical session, emphasising the need for thorough disinfecting procedures in optometry practices. Viegas et al. (2017) reported that the trial lens was the most contaminated item in their study location. In the current study, a similar observation was made for occluders, with one occluder contamination developing biofilm. A typical disinfection norm after a clinical session focuses on surfaces in contact with patients, and smaller optometry paraphernalia such as trial frames, trial lenses, and occluders may have been neglected. Sivaraj et al. (2004) tested contamination on non-contact handheld lenses and reported an 81% contamination rate, mostly from skin flora. They tested the same lenses after cleaning with detergent, which saw a reduction of contamination rate to 15%. They recommended that regular lens cleaning should be conducted to reduce the risk of cross-infection.

Moosavi et al. (2005) conducted an analysis of various SL components in an emergency room and outpatient clinic of a hospital. They reported that microbial contamination on SLs increases with usage during clinical sessions. They recommended disinfection of SLs prior to use to eliminate potential machine-patient cross-infection. The same study showed a contamination rate of 52.9% for the headrest, 70.5% for the chinrest, and 17.6% for the transformer switches. In another study, where samples were collected from a SL's headrest and joystick, Sobolewska et al. (2018) reported a contamination rate of 65% on their samples. These findings suggest that SLs are a potential source for the transmission of microorganisms. The same observation was found in the current study, where microbial biofilm was identified from the headrest. This underscores the importance of sanitisation procedures, in which vigorous cleaning using alcohol swabs eliminates bacterial contamination (Graham et al., 2008).

Biofilm is a group of bacteria adhering to surfaces and bound together by a matrix called extracellular polymeric substances (EPS), protecting the bacteria against external factors (Muhammad et al., 2020; Gunn et al., 2016). Over time, the EPS matrix strengthens cell adhesion and cohesion, resulting in a densely packed and firmly attached biofilm. Once formed, biofilms become highly resistant to removal or eradication (Zheng et al., 2021). In its early stages, a biofilm is typically invisible to the naked eye because it consists of a thin layer with minimal microorganisms embedded in the EPS matrix. As the biofilm matures, it becomes more noticeable, often appearing as a slimy film on the surface (Ben-Ari, 1999; Sauer, 2017). The development of biofilms plays a crucial role in the survival of microorganisms by facilitating bacterial growth and serving as a protective barrier, shielding the implanted microorganisms from environmental hazards and antimicrobial treatments (Lebeaux et al., 2014). The ability of certain bacterial species to adhere to various fomite surfaces, including ophthalmic equipment, plays a critical role in contamination. For example, the hydrophobic surface properties of Pseudomonas aeruginosa enhance its tendency to adhere to contact lenses. As a well-known biofilm producer, *Pseudomonas aeruginosa* contamination on contact lenses can significantly increase users' risk of biofilm infections (Bruinsma et al., 2001).

Although the current study observed minimal biofilm formation on contaminated apparatus and solutions in ophthalmic settings, the presence of microbial contaminants, especially species with a high biofilm-forming capacity, can still pose a risk of biofilm-related infections with prolonged exposure. To mitigate the risks associated with microbial contamination, particularly biofilm-producers, optometry practices must implement robust infection control measures, adhere to best practices in handling and administering ophthalmic solutions (Chua et al., 2021), and establish rigorous disinfection protocols for all reusable equipment. This includes frequently cleaning and sterilising instruments between patients using appropriate disinfectants and following manufacturer guidelines. Proper tool handling and storage also help prevent the spread of pathogens and reduce cross-contamination risks. Comprehensive disinfection practices ensure patient safety, especially for those with compromised immune systems.

Limitation

Sample contamination can occur when external substances, such as microorganisms, chemicals, or particles, accidentally enter the sample (Group et al., 2023). These particles can be transmitted through the air or by cross-contamination. To reduce the possibility of airborne cross-contamination, the sample swabbing method onto the CRA was conducted near the Bunsen burner (Bykowski & Stevenson, 2020). However, cross-contamination may occur when handling equipment and samples or when using gloves on the samples.

CONCLUSION

This study shows bacterial presence on the ophthalmic instruments and solution packaging used in the study location. The most common contamination occurs at the dropper tip while the solution remains pristine. Microbial biofilm observed on ophthalmic tools underscores the importance of diligent sanitation procedures for optometrists. The finding highlights the potential of microbial contamination on various ophthalmic solutions and instruments, particularly after extended use. The findings implicate the importance of regular cleaning and sterilisation, adherence to best cleaning practices, and appropriate storage of solutions, which are essential to ensure patient safety and mitigate the risk of infections.

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ORIGINAL ARTICLE

Comparing Eye Tracking Technology in Reading Performance Assessment with Conventional Method

Fatin Amalina Che Arif[1], Noor Wafirah Shafee[1], Mohd Zulfaezal Che Azemin[1], Norsham Ahmad[1*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
reading performance; reading speed; fixation duration; eye tracking

ABSTRACT

Background: Reading is one of the most essential skills for academic and social development. It greatly affects one's quality of life, making the assessment of reading performance essential and should be considered in clinical practice. The purpose of this study was to compare the reading speed recorded using eye tracking technology (Tobii Pro Fusion 120-Hz eye tracker and Tobii Pro Lab software) with the reading speed measured using conventional evaluation method. The number of fixations and total fixation duration acquired from the eye tracking data were analysed as potential indicators for reading performance. **Methods:** Seventeen healthy participants (aged 21 to 38) with optimum vision were recruited in this study. All participants were instructed to read aloud from two different reading materials, which were selected in random sequences. During the reading task, the eye tracker automatically captured and computed the reading duration, number of fixations and total fixation duration. As for the conventional evaluation method, the time taken to complete the reading task was manually measured for each participant using a stopwatch. Reading speed was quantified as words per minute (wpm). **Results:** The paired t-test revealed no significant difference in reading speed measurement between conventional evaluation method and eye tracking recording (p=0.986). The Bland-Altman plot demonstrated good agreement between the reading speed measured using the two methods. Regarding the analysis of fixation data, the Pearson correlation showed a negative correlation between reading speed and both total fixation duration (r=-0.515, p=0.035) and number of fixations (r=-0.585, p=0.014), suggesting that participants with lower reading speed (slow reader) tended to have higher number of fixations and longer total fixation duration. These findings imply that fixation data may be a useful measure for assessing reading performance. **Conclusion:** This study highlights the potential of Tobii Pro Fusion 120-Hz eye tracker as a valuable tool for enhancing the assessment of reading performance as it offers a more precise and dynamic approach to assess reading performance compared to conventional methods.

INTRODUCTION

Reading is a fundamental skill involving the ability to understand any information from written or printed stimuli (Frey, 2020). Proficient and efficient reading involves multiple factors including linguistic and cognitive skills such as understanding the auditory and visual elements of word and the meaning of the word itself (McBride et al., 2022). Reading proficiency is a critical skill and significantly affects individual's quality of life especially in term of academic achievement and cognitive development (Kelly et al., 2017; Kugathasan et al., 2019; Narayanasamy et al., 2015).

Traditionally, reading performance usually being evaluated by measuring the reading speed, accuracy and comprehension (Buczkowska & Miskowiak, 2017; Lee et al., 2020). However, the disadvantage of these convensional methods is that these approaches mainly focused on outcome-based assessment, without accounting for the detailed process involved in reading which possibly affect the reading performance such as eye movements, specifically saccades and fixations. These components are critical in understanding the visuomotor behaviour during reading and information processing, especially among individuals with specific visual conditions such as amblyopia and anisometropia (Niechwiej-szwedo et al., 2019; Quaid & Simpson, 2013; Vinuela-Navarro et al., 2017).

One of the promising tools for investigating eye movement behavior during reading tasks is eye tracking technology. Eye tracking is a method used to investigate eye movements by analysing participants' visual attention, cognitive processes and visual behavior. It has been widely used in various research fields including reading and language, psychology, neuroscience, and is currently of great interest for exploring biomarkers in clinical research

* Corresponding author
E-mail address: ansham@iium.edu.my

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(Holmqvist et al., 2023).

In reading research, other than offering detailed analysis of visual performance during reading, eye tracking provides objective measurements of reading behavior such as text processing and duration of visual attention at specific phrase, word or even character level (Tobii AB, 2022). In contrast to conventional methods, eye tracker records the eye movement in real time throughout the reading task, which reflects the way readers engage with the text. This information provides better knowledge on reading behaviors, especially in terms of visual attention and fixation, instead of examining the common elements of reading assessments.

As eye tracker has emerged as a promising tool for analysing eye movement, this study aimed to explore the potential of eye tracking technology in enhancing the assessment of reading performance, offering potential benefits through its objective outcome measures. Specifically, this study aimed to compare the reading speed recorded using Tobii Pro Fusion 120-Hz eye tracker, with the reading speed obtained through conventional evaluation method in order to ensure the accuracy of the eye tracker for clinical applications. Besides, the total fixation duration and the number of fixations obtained from Tobii Pro Lab software were analysed as potential indicators for reading performance.

MATERIALS AND METHODS

This study adhered to the tenets of the Declaration of Helsinki and the study protocols were approved by the International Islamic University Malaysia (IIUM) Research Ethics Committee (IREC 2023-144). Seventeen participants aged between 21 and 38 years volunteered to participate in this study. The number of participants was determined based on previous eye movement study by Shafee (2021). Besides, as this study fall under psychophysics experiment involving the relationship between stimuli and perception among normal population, small sample size was acceptable considering the adequate control of external factors (Marszalek et al., 2011). Written consent was obtained from all participants prior to study procedures.

Participants

All participants underwent a comprehensive eye examination before the data collection process and the participants who met the inclusion criteria were included for data collection. The inclusion criteria for this study were good ocular and general health, age between 20-40 years old, distance best corrected visual acuity of 0.00 logMAR or better in each eye, near best corrected visual acuity of 0.00 logMAR in each eye, able to fluently read Malay reading material and have no known metabolic disorders or serious medical conditions that could affect eye movement.

Reading materials

Two sets of validated reading materials (Omar et al., 2015) were utilized in this study. Both reading materials consist of 50 words, with 6 sentences for each text. As for conventional method, the reading materials were printed in 100% contrast on A4-sized white paper. The font typeface used was 'Arial' as the font was easier to read (Taylor et al., 2020) and made of straight, simple lines without any serifs, which could minimise the crowding effect to the readers (Beier & Oderkerk, 2021). Meanwhile for eye tracker recording, the letter sizes in the reading materials were precisely calculated for 600mm viewing distance, ensuring the visual angle matched that of the conventional method (Eq. 1). Figure 1 illustrates the differences in letter sizes for both conventional method and eye tracking.

$$\text{Visual angle } (\theta) = 2 \cdot \tan^{-1}\left(\frac{S}{2D}\right) \quad (1)$$

where, θ = visual angle
S = height of letter in reading material for conventional method
D = distance between participant's eyes and reading material

Visual angle (ϑ) for conventional reading material

$$\Theta = 2 \cdot \tan^{-1}\left(\frac{5}{2(400)}\right)$$
$$= 2 \cdot \tan^{-1}(0.00625)$$
$$= 0.72°$$

Letter height for eye tracking reading material

$$0.72° = 2 \cdot \tan^{-1}\left(\frac{S}{2(600)}\right)$$
$$S = 2 \cdot 600 \cdot \tan^{-1}\left(\frac{0.72}{2}\right)$$
$$= 7.5\text{mm}$$

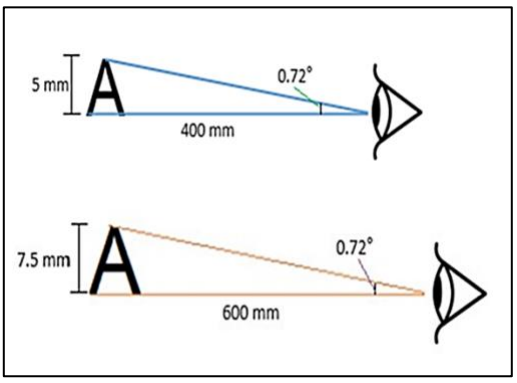

Figure 1: Letter height for conventional method (top) and eye

tracking (bottom).

Reading assessment using conventional method

With their best-corrected visual acuity, the participants were instructed to read the sentences on the Malay reading material (randomly chosen) aloud, as accurately as possible, with the speed as they normally read any reading materials. The reading material was placed 400mm from the participants' eyes. Time taken to complete the reading task was manually timed for each participant using a stopwatch and recorded to the nearest 0.1s (Buari et al., 2015). Reading speed was then calculated in words per minute (wpm), as shown in Eq. (2).

$$\text{Reading speed} = \frac{Number\ of\ words\ in\ text}{Time\ taken\ to\ read\ all\ the\ words\ (\text{sec})} \quad (2)$$

Reading assessment using eye tracking (Tobii Pro Lab Software)

Reading assessment was conducted using Tobii Pro Fusion 120-Hz eye tracker, which mounted on a display monitor positioned 600mm from the participant (Figure 2). During the reading task, all data were recorded on a HP Pavilion laptop equipped with Tobii Pro Lab Software.

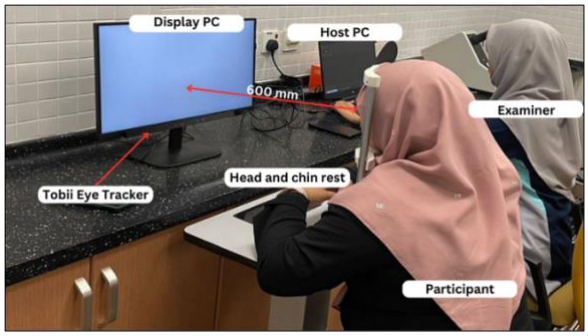

Figure 2: Participant set-up during reading assessment

Prior to reading assessment, eye tracking calibration using a 5-point calibration technique was conducted (Ozer & Ozdemir, 2021). The calibration accuracy and precision thresholds were set at 0.5° and 0.2°, respectively, as recommended by the manufacturer (Tobii AB, 2022). After a successful calibration, reading material (different set as the one used for conventional method) was presented on the display monitor. The participants were instructed to read the reading material and the eye tracker automatically recorded and calculated reading duration, total fixation duration (duration of the eyes fixate inside the texts during the recording period) and number of fixations (the number of fixations occurring within the texts during the recording period) during the reading task.

Data analysis

Statistical analysis was conducted using the Statistical Package for Social Science Software (version 28, Statistical Package for Social Sciences; SPSS Inc., IBM Corp., Armonk, NY, USA). Normality testing was examined using the skewness and kurtosis tests (Kim, 2013). A paired sample t-test was employed to compare the reading speed measured using conventional method and eye tracking technology. Bland Altman analysis was tested to evaluate the limit of agreement between the two methods in assessing the reading speed. Besides, the correlation between; (1) reading speed (measured using eye tracking) and total fixation duration, and (2) reading speed (measured using eye tracking) and number of fixations during reading task were examined using the Pearson correlation .

RESULTS

Reading speed measured using conventional method vs. eye tracking

As presented in Table 1, the paired sample t-test analysis showed a non-significant difference (p=0.986) in reading speed measured using conventional method and eye tracking. The result showed that the Tobii Pro Fusion 120-Hz eye tracker is an accurate device for assessing reading performance, as it produced results comparable to the conventional method.

Table 1: Comparing the mean of reading speed measured using conventional method and eye tracking technology

Parameter	Conventional method Mean ± SD	Eye tracking Mean ± SD	p-value*
Reading speed (wpm)[†]	135.68 ± 11.02	135.69 ± 11.87	0.986

[†] wpm= words per minute
*p-value analysed using Paired sample *t*-test

Furthermore, by using the eye tracker, additional parameters (i.e. total fixation duration and number of fixations) were measured to provide a more comprehensive assessment of reading performance, as shown in Figure 3 and 4.

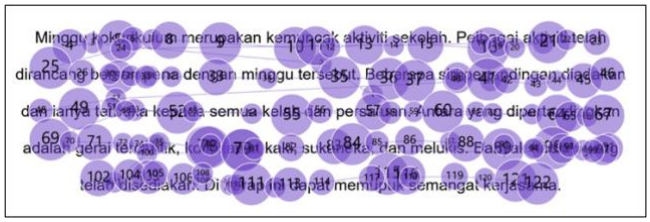

Figure 3: Participant's gaze pattern during the reading experiment. The size of the circle corresponds to the fixation duration. The number in the circle is the rank of fixation. The

lines represent saccades.

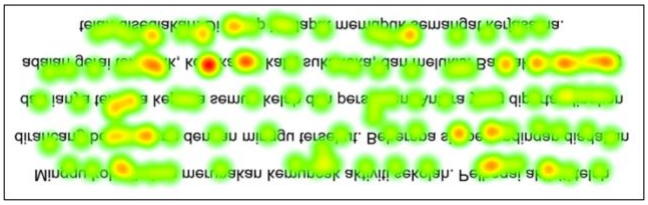

Figure 4: Heat maps visualization of reading material. Red/dark shade indicates high density of fixations and green/light shade indicates low density of fixation.

Agreement of reading speed measured using conventional method vs. eye tracking

The Bland-Altman test showed a bias of -0.01 (95% CI: -0.96 to 0.95) with all data occupied the upper and lower limit of agreement (3.93,-3.95) as illustrated in Figure 5, indicating no proposional bias. The results suggested that while there was a small average difference in reading speed measurement, the two methods were comparable to be used in clinical applications.

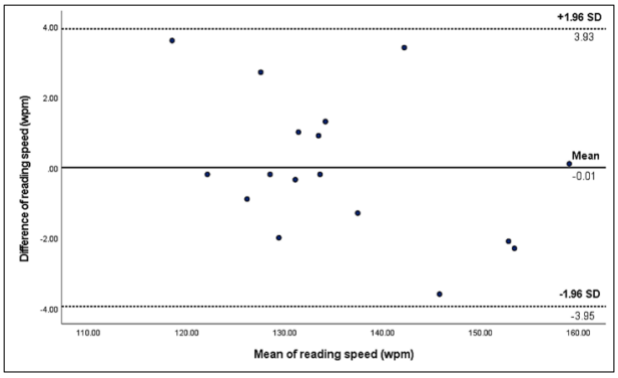

Figure 5: Limit of Agreement (LoA) of reading speed measured using conventional and eye tracking method.

Correlation between reading speed and fixation data during the reading task

The Pearson's correlation analysis showed a negative correlation between reading speed and both total fixation duration and number of fixations, suggesting that as the reading speed increases (in the case of fluent reader), both total fixation duration and number of fixations tend to decrease. Table 2 specifies the Pearson's correlation coefficient (r) and statistical significance for each pair of variables.

Table 2: Correlation between reading speed measured using eye tracker and total fixation duration, and number of fixations during reading task

Variables	r	p-value*
Reading speed (wpm)ᵻ Total fixation duration (ms)#	-0.515	0.035
Reading speed (wpm) Number of fixations	-0.585	0.014

ᵻwpm= words per minute, #ms= milliseconds
*p-value analysed using Pearson correlation

DISCUSSION

The findings suggested that the eye tracking method produced valid measurements regarding reading speed, comparable to those measured using conventional method. Insignificant difference in reading speed measurements (p=0.986) with good agreement between the two methods suggested that eye tracker technology provides comparable and reliable results in assessing reading speed.

As eye tracking technology enables a more detailed analysis on reading assessment, this study included another two parameters for reading performance indicators: total fixation duration and number of fixations. Fixation in reading experiment can be defined as a small pause between saccades, occurred in order to gather sufficient information in analysing the text viewed during reading (Dambacher et al., 2013; Justino & Kolinsky, 2023).Previous studies have reported that eye movement behavior, including fixations were differ between proficient and novice readers (Justino & Kolinsky, 2023; Vinuela-Navarro et al., 2017), indicating the advantages of including these parameters to be included during the assessment.

In this study, the analysis of fixation data revealed a negative correlation between reading speed and both total fixation duration and number of fixations. It can be inferred that slower readers may make a greater number of fixations and have longer fixation durations to gather the necessary information and process the text they are reading. These findings were in line with previous literature which reported higher reading rate resulted in fewer and shorter fixation when measured using Visagraph software (Spichtig et al., 2017).

The consistency in results between the current study and previous research indicates that the eye tracker, specifically Tobii Pro Fusion 120-Hz is a viable tool for assessing reading performance in clinical practice. The potential implications of this study extend beyond the scope of healthy individuals, as it may benefit future investigations, especially among children with learning disabilities. This is because children with visual dysfunction were reported to underperform in academics due to deficits in reading ability, resulting in poorer overall academic outcomes (Kugathasan et al., 2019; McBride et al., 2022).

Thus, it is recommended for future study to evaluate the

effectiveness of eye tracking technology as an early diagnostic tool for children with learning literacy. Besides, it is also highly recommended for future study to explore on other reading metrics available in Tobii Pro Lab software, such as saccades, progression-regression and re-reading duration to provide more comprehensive evaluation of the reading performance using the eye tracking.

CONCLUSION

Eye tracking technology can accurately analysing participants' reading performance in terms of reading speed, total fixation duration and number of fixations, making it a potential alternative to conventional evaluation method. Although conventional evaluation method remains relevant for their cost-effectiveness, incorporating eye tracking technology enhances accuracy and provide valuable insights into reading behavior through the fixation data analysis, leading to better diagnostic and therapeutic approaches.

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ORIGINAL ARTICLE

Coloured Contact Lens Impact on Visual Function and Ocular Surface Integrity: Legit vs Non-Legit Sources Contact Lenses

Zaidatul Khadijah Zaman[1], Mohd Hanif Hajar Maidin[1,2], Firdaus Yusof[1,3], Noor Ezailina Badarudin[4], Ilyanoon Zahari[1,3,*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Ophthalmic Science Research Group (OSReG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[4]Faculty of Health and Life Sciences, Management and Science University, Selangor, Malaysia

Keywords:
contact lenses; online; safety; ocular surface

ABSTRACT

Background: The popularity of purchasing coloured contact lenses (CLs) from non-optometry sources, such as night markets and online platforms, has risen due to cosmetic appeal. The rapid growth of e-commerce platforms that lack regulatory oversight is a concern to the safety, effectiveness, and quality control of these lenses to the wearers. Therefore, this article aims to investigate the changes in visual function, including visual acuity (VA) and contrast sensitivity (CS), as well as ocular surface integrity, encompassing corneal topography, corneal endothe0m, and central corneal thickness (CCT), in wearers of coloured CLs purchased from either optometry or non-optometry sources. **Methods:** A pilot study with five participants meeting the inclusion criteria were enrolled in this study. Preliminary assessments were conducted per the usual contact lenses clinic routine in the IIUM Optometry Clinic. The CL fit on the eyes was observed and noted. A double-masked crossover approach was used to reduce bias and enhance validity. Participants were randomly assigned to wear each type of coloured CL for one month, with a two-week washout in between. Measurements of VA, CS, mean K-reading, corneal endothelial cell density (ECD), and CCT were taken before lens usage, after one week, and after one month. A comparison of these parameters between the two types of CLs was made. **Results:** There were no significant differences in any measurements between lenses from optometry and non-optometry sources across all three time periods ($p>0.05$).**Conclusion:** The pilot study's findings suggest comparable effects on visual function and ocular surface integrity between coloured CLs obtained from optometry and non-optometry sources worn daily for a month.

INTRODUCTION

Coloured or cosmetic CLs alter eye appearance and enhance eye colour to achieve specific looks and enhance beauty. Their popularity is rising, especially among younger individuals (Thiraviam et al., 2022).

In Malaysia, the regulation and distribution of contact lenses (CLs), including coloured CLs, are governed by the Optical Act 1991. According to this act, CLs are classified as medical devices, and their prescription and fitting must be performed by registered optometrists or opticians with contact lens permits only (Optical Act, 1991). Following this act, a "Guideline for Online Sale of Optical Appliances and Contact Lenses" was published by the Malaysian Optical Council, Ministry of Health, a professional body that regulates optometry practices in Malaysia (Malaysian Optical Council, n.d.). According to the guidelines, only CLs registered with Malaysia's Medical Device Authority (MDA), Ministry of Health Malaysia can be displayed and sold in-store and on a website with strict criteria. The CLs must meet the safety and quality standards before being approved for the market (Medical Device Act, 2012).

However, a significant regulatory gap exists due to the lack of effective enforcement of these regulations. This enforcement challenge has led to the alarming proliferation of unauthorised sales of CLs, especially coloured lenses, by non-practitioners through various channels such as online platforms, beauty shops, and even night markets. This enforcement challenge has inadvertently facilitated a growing trend among consumers to purchase CLs without proper professional guidance, often influenced by social media and online

* *Corresponding author.*
E-mail address: ilya@iium.edu.my

influencers. The increasing popularity of these easily accessible sources raises significant concerns about potential impacts on visual function, ocular surface safety, and overall eye health among CLs wearers in Malaysia.

Improper prescription or fitting of coloured CLs can lead to severe complications, including infectious keratitis, a serious vision-threatening condition (Singh et al., 2012). Studies highlight the risks associated with coloured CLs, particularly those obtained from unauthorised sources, which can result in severe infections and inflammation (Steinemann et al., 2003, 2005). Research further emphasises that individuals acquiring CLs from unlicensed vendors face increased risks of ocular complications and are less likely to receive proper usage and care instructions, elevating the risk of complications (Gaiser et al., 2017).

With the surging popularity of coloured CLs from non-authorised sources, the safety of these lenses is questionable. Therefore, this study aimed to investigate whether coloured CLs purchased from optometry practices and those obtained from non-optometry sources available in the Malaysian market, such as unauthorised e-commerce platforms and the night market, affect the visual function and ocular surface integrity of the wearers.

MATERIALS AND METHODS

Study Design

This cross-sectional study enrolled five undergraduate students from the International Islamic University Malaysia (IIUM) Kuantan campus who met the inclusion criteria of a healthy ocular surface and normal visual function.

This study adhered to the Tenets of the Declaration of Helsinki for research involving human subjects and received ethical approval from the IIUM Research Ethics Committee (IREC 2023-KAHS/DOVS12). The participants gave their written informed consent, agreeing to participate in this study. Participants were warned to discontinue CL wear and notify the researcher if they experienced any discomfort or changes to the eye and vision, as explained during the CL delivery session.

For this pilot study, five participants were recruited to fit the standard soft contact lens parameters of 14.2 lens diameter and 8.6 base curve. Two types of coloured CLs were used. One type was sourced from an optometry practice with FDA approval, while the other was purchased from night markets and e-commerce platforms. These were monthly disposable CLs for daily wear. A double-masked approach was used in the study. A randomisation sheet determined the order in which participants wore the CLs, either those obtained from optometry practices or non-optometry sources. The allocation was known only by a third researcher who was not involved in the data collection stage, ensuring both the participants and the researchers were unaware of the lens type during the study period.

Participants underwent preliminary examinations before the study. For the initial month, each participant wore one type of CL (either from optometry practices or non-optometry sources) binocularly. Following the first month, a two-week washout was given, during which participants did not wear any CL. After the washout period, participants switched to the other type of CL and wore it for another month. This method allowed a direct comparison of how each participant responded to both types of lenses.

Subsequently, after the CLs were delivered and worn for 8 to a maximum of 10 hours daily for 6 days/ week, aftercare examinations were conducted at two specific time points: one week and one month. These examinations involved a comprehensive assessment of various ocular parameters, including VA measured with the LogMAR chart, CS evaluated using the Pelli-Robson chart, CCT measured with the Oculus PARK 1 (Oculus GmbH, Wetzlar, Germany), mean K-reading obtained with the Oculus Keratograph 5M (Oculus GmbH, Wetzlar, Germany), and ECD assessed using specular microscope (NIDEK CEM 530, NIDEK Co., Ltd., Gamagori, Japan).

Statistical Analysis

All data collected was analyzed using the Statistical Package for Social Science Software (SPSS) (version 29 for Windows, SPSS, Inc., Chicago, IL, USA). The normality of the data was analyzed using Shapiro-Wilk, skewness and coefficient of variation. All the data were normally distributed, and the Analysis of Variance (ANOVA) was used to compare VA, CS, CCT, mean K-reading and ECD for the respective lenses from optometry and non-optometry sources across all three time periods (before lens usage, one week after, and one month after wearing the lenses) to observe for any differences. Only data for either eye was included in the analysis (Armstrong, 2013).

RESULTS

The study compared optometry and non-optometry CLs across three time periods, evaluating changes in VA, CS, CCT, mean K-reading, and ECD. Table 1 shows the mean values at each time point and the significance levels for all parameters in this study. Repeated measures Analysis

Table 1: Comparison of visual function and ocular surface parameters in optometry and non-optometry sources CLs across three time periods (n=5)

Parameters	Baseline (Mean ± SD)	1 Week (Mean ± SD)	1 Month (Mean ± SD)	p-value
Optometry CL				
VA (LogMAR)	-0.17 ± 0.07	-0.07 ± 0.14	0.05 ± 0.22	0.263
CS (log contrast sensitivity)	1.95 ± 0.00	1.95 ± 0.00	1.89 ± 0.08	0.178
CCT (µm)	542.20 ± 14.26	545.20 ± 14.20	544.80 ± 21.53	0.746
Mean K-reading (Dioptre)	43.81 ± 0.77	43.96 ± 0.76	43.79 ± 0.74	0.703
ECD (cells/ mm^2)	2803.60 ± 261.50	2938.00 ± 331.96	2884.00 ± 261.21	0.091
Non-Optometry CL				
VA (LogMAR)	-0.17 ± 0.07	-0.05 ± 0.12	-0.04 ± 0.15	0.397
CS (log contrast sensitivity)	1.95 ± 0.00	1.92 ± 0.07	1.92 ± 0.07	0.465
CCT (µm)	542.20 ± 14.26	554.00 ± 21.30	549.00 ± 20.58	0.220
Mean K-reading (Dioptre)	43.81 ± 0.77	43.72 ± 0.75	43.77 ± 0.65	0.592
ECD (cells/ mm^2)	2803.60 ± 261.50	2835.40 ± 315.05	2805.80 ± 255.78	0.602

showed no significant differences across the three time periods for the measured parameters (>0.05).

Both CL types showed a trend towards a slight VA decline over time. For optometry CLs, mean VA changed from -0.17 ± 0.07 at baseline to 0.05 ± 0.22 after one month, a decline of 0.22 logMAR units. For non-optometry CLs, the mean VA changed from -0.17 ± 0.07 to -0.04 ± 0.15, a decline of 0.13 logMAR units. These changes were not statistically significant (p=0.263 for optometry, p=0.397 for non-optometry CLs). While the optometry CL group change exceeds 0.1 logMAR units (equivalent to one line on a standard acuity chart), the high variability (as indicated by the standard deviation) and lack of statistical significance suggest caution in interpreting this as a clinically meaningful change. Contrast Sensitivity (CS) remained largely stable for both CL types. Non-optometry lenses showed a slight decrease from 1.95 to 1.92 (p=0.465), while optometry lenses decreased from 1.95 to 1.89 in one month (p=0.178).

Neither CL type significantly affects the CCT. Non-optometry lenses showed a slight increase and decrease (542.20 to 549.00 µm, p=0.220), while optometry lenses had a slight, stable increase (542.20 to 544.80 µm, p=0.746). The corneal power remained relatively stable for both CL types. Non-optometry lenses showed minor fluctuations (43.81 to 43.77 D, p=0.592), as did optometry lenses (43.81 to 43.79 D, p=0.703). Both changes were not statistically significant. For non-optometry CLs, ECD showed minimal changes (2803.60 to 2805.80 cells/ mm^2, p=0.602). Optometry lenses demonstrated a trend towards increased ECD (2803.60 to 2884.00 cells/ mm^2), but this was not statistically significant (p=0.091).

DISCUSSION

This study found that neither type of contact lens notably affects the visual function and ocular surface integrity of the participants. Visual acuity (VA) did not show significant changes with either non-optometry or optometry lenses. These findings differ from previous research suggesting that CLs from unauthorised sources may cause ocular issues, impacting VA and refractive errors (Gaiser et al.,

2017). This discrepancy might be due to several factors, such as the controlled wear schedule implemented in our study, or potentially higher quality standards of non-optometry lenses in the Malaysian market compared to those examined in previous studies. Another explanation is that the participants of this study were carefully selected based on the suitability of the CL base curve.

Central corneal thickness (CCT) was not significantly affected by either type of lens, supporting the notion that short-term use of CLs does not alter corneal thickness, aligning with findings by Ramakrishnan et al. (2016). This stability in CCT suggests that both optometry and non-optometry-sourced coloured CLs, when used for a short duration, may not cause significant corneal swelling. However, other studies have reported higher CCT values with CL wear (Noya-Padin et al., 2022). This discrepancy might be due to differences in study duration, as this study was limited to one month.

Similarly, the corneal power remained stable, indicating no adverse effects on corneal curvature from either CL source, consistent with Yeniad et al. (2003). However, other studies reported increased corneal curvature with contact lens usage (Ramakrishnan et al., 2016; Badawi, 2015; Liu & Pflugfelder, 2000). The difference might be attributed to the short duration of the study, as changes in corneal power occur over longer periods of lens wear. Additionally, the specific design and material of the lenses used in the study may have contributed to the lack of observed changes in corneal power.

Corneal endothelial cell density (ECD) was not significantly affected by either type of lens, supporting the safety of short-term use of coloured CLs from both sources, as also observed by Badawi (2015). This is particularly important as the corneal endothelium is indispensable in sustaining corneal transparency (DelMonte & Kim, 2011) and cannot regenerate (Van den Bogerd et al., 2018). However, it is important to note that the study's short duration may not reveal potential long-term effects on ECD since all participants followed the recommended wearing hours and did not exceed its monthly modality. An otherwise outcome may be seen if the lens is worn for three months. Some studies have suggested that long-term CL wear may affect endothelial cell morphology (Mohd-Ali & Chen, 2021).

In this study, contrast sensitivity (CS) results showed no notable difference between the two sources of CLs, suggesting stability in CS regardless of the source. This finding aligns with previous studies indicating stable CS with CL use (Sapkota et al., 2020). On the contrary, research by Briggs (1998), Mahjoob & Heydarian (2021), and Ozkagnici et al. (2003), observed lower CS among CL wearers than their controlled subjects of non-CL wearers. This difference might be attributed to improvements in lens materials and manufacturing processes over time or the specific brands of lenses used in the study. Additionally, the participants' knowledge of lens care as optometry students may have contributed to better lens maintenance, potentially mitigating negative effects on CS.

Approximately 18% of individuals obtain CLs from friends and family, while around 24% make purchases online (Gaiser et al., 2017). Most unauthorised sellers revealed that they did not follow proper protocols for selling CLs or provide adequate instructions on lens wear and care, potentially increasing the risk of contact lens-related complications (Gaiser et al., 2017). Wearing CLs from unauthorised sources can lead to corneal complications, visual impairment, and severe eye damage (Steinemann et al., 2003).

This study had limitations, including not accounting for potential long-term effects, and the lack of information about manufacturing standards for CLs from non-optometry sources, both of which could have influenced the results. Additionally, the small sample size and short study duration may limit the generalisability of these findings. A notable limitation was that all participants were final-year Optometry students, who may have exercised more caution in CL care and wear than the public. This specialised knowledge and training could have influenced the results, potentially minimising differences between the two lens types that might be more apparent in a broader, less informed population.

For upcoming research, studies should aim to cover longer periods and include more participants to understand the lasting effects and improve the reliability of the findings. Additionally, future investigations should examine the manufacturing standards and safety protocols of non-optometry sources and compare several types of coloured CLs from various sources. This comprehensive approach would provide a clearer understanding of how different sources and production processes impact ocular health and visual function over extended periods of use.

CONCLUSION

The findings of this study suggest that coloured CLs obtained from both optometry and non-optometry sources have comparable effects on visual function and ocular surface integrity. This indicates potential safety and efficacy across both types of lenses. However, it is crucial to note that this study does not endorse using coloured CLs from non-optometry sources.

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ORIGINAL ARTICLE

Development, Validity, and Reliability of Challenges and Attitudes to Practice Primary Eye Care (CAPEC) Questionnaire Among Malaysian Private Sector Optometrists

Nurul Ain Yahaya[1,2,*], Noor Azlina A. Rahman[3]

[1]Department of Optometry and Visual Sience, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[3]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
primary eye care (PEC); private sector optometrists; questionnaire validation; challenges toward PEC; attitudes toward PE

ABSTRACT

Background: Primary Eye Care (PEC) is vital in preventing visual impairment, yet private sector optometrists in Malaysia face barriers that hinder its implementation. This study aimed to develop and validate the Challenges and Attitudes to Practice Primary Eye Care (CAPEC) questionnaire to assess the barriers and attitudes of optometrists in the Malaysian private sector toward implementing PEC services. **Methods*:*** The CAPEC questionnaire was developed based on qualitative insights and thematic analysis from initial interviews with optometrists. The instrument underwent rigorous content validation by experts using the Content Validity Index (CVI) and exploratory factor analysis (EFA) for construct validity. A pilot study tested reliability and readability, and the finalized questionnaire was distributed to a sample of private sector optometrists. **Results*:*** The validated CAPEC questionnaire consists of 34 items within four domains addressing challenges (working environment, support and recognition, self-sufficiency, and customer influence) and two domains on attitudes (motivation and sense of responsibility). Results from the pilot study confirmed the questionnaire's reliability, with high internal consistency (Cronbach's alpha scores above 0.7 for all domains). **Conclusion*:*** The CAPEC questionnaire is a valid and reliable tool for assessing challenges and attitudes in PEC practice among optometrists. Its use may support further research and efforts to enhance PEC implementation in private optometry settings in Malaysia.

INTRODUCTION

PEC plays a crucial role in preventing visual impairment and blindness, providing essential services such as refraction, early detection of eye diseases, and patient education. The World Health Organization (WHO) has emphasised the importance of integrating PEC into primary health systems to address the global rise in preventable visual impairment and blindness (WHO, 2019). In Malaysia, while PEC services are accessible in public healthcare facilities, the role of private-sector optometrists in delivering PEC remains underutilised, despite evidence suggesting that these professionals are well-positioned to contribute significantly to PEC (Abd Aziz et al., 2020; Chew et al., 2018).

Despite the demand for comprehensive eye care services, private optometrists in Malaysia often face constraints, including limited resources, lack of formal recognition, and the influence of customer expectations. These challenges can impact their ability and willingness to expand their role beyond refractive services to include PEC (George et al., 2019). Understanding these barriers and optometrists' attitudes toward PEC may provide valuable insights for strengthening eye care services in Malaysia.

This study developed and validated the *Challenges and Attitudes to Practice Primary Eye Care (CAPEC)* questionnaire, designed to evaluate the specific challenges private-sector optometrists face in implementing PEC services and to assess their attitudes toward adopting these practices. The CAPEC questionnaire's development aimed to produce a reliable tool to inform efforts that could enhance PEC adoption in Malaysia's private optometry sector.

MATERIALS AND METHODS

This study followed a structured, multi-phase approach to develop and validate the CAPEC questionnaire. The process included initial qualitative research to inform item development, expert content validation, pre-testing for clarity, and a pilot study to assess construct validity and reliability. The main steps and results involved in the development, validation, and reliability of the questionnaire are summarized in Figure 1.

* *Corresponding author.*
E-mail address: nurulainyahaya@iium.edu.my

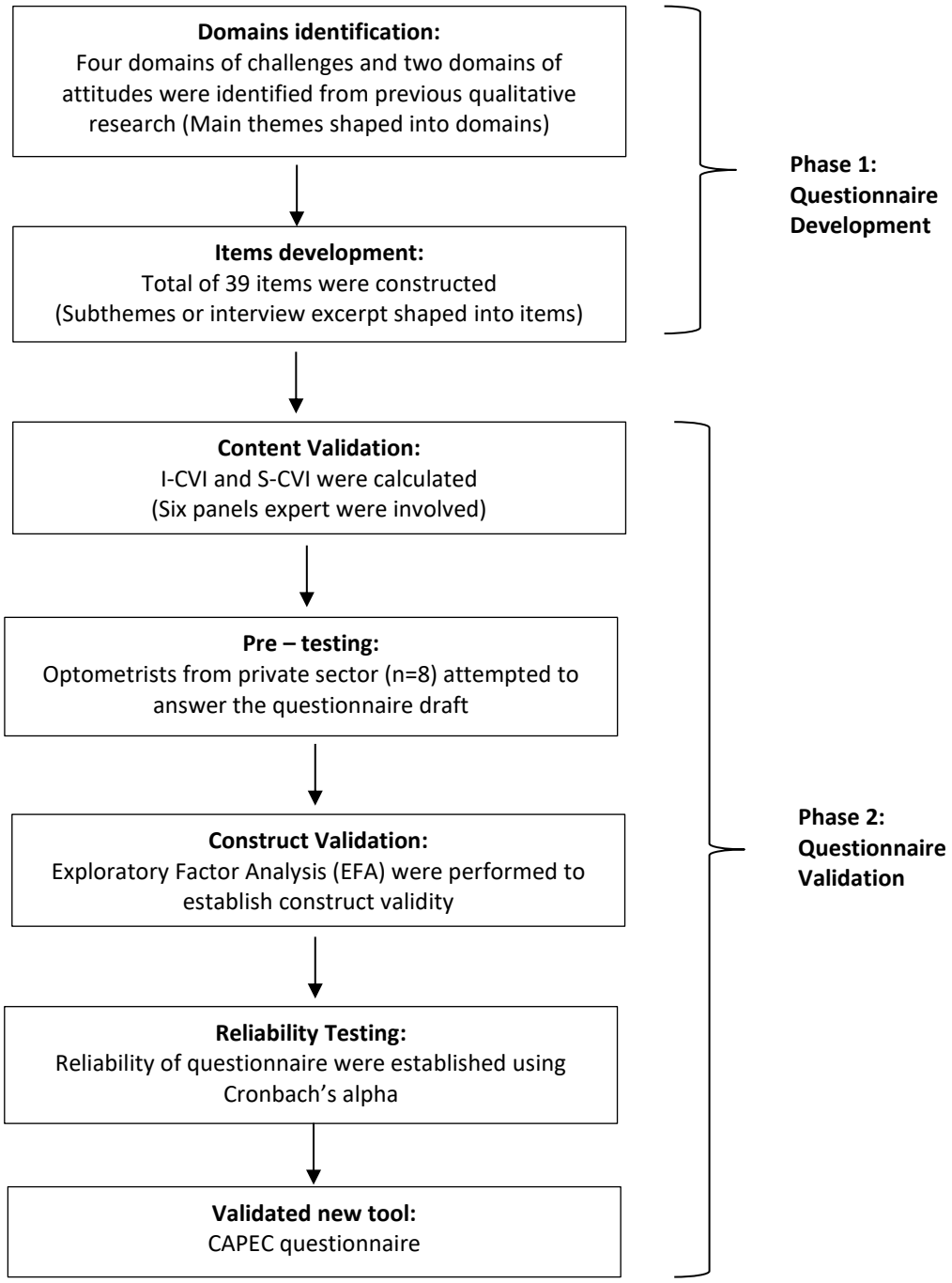

Figure 1: Flowchart of construction, validation, and reliability of the questionnaire.
CAPEC: Challenges and Attitudes to Practice Primary Eye Care; I-CVI: item-level content validity index; S-CVI: scale content validity *index*

Phase 1: Questionnaire Development

The development phase consists of two stages; domains identification and items development. Prior to the development, the CAPEC questionnaire was structured into three sections: demographics, challenges, and attitudes. The demographic section gathered essential participant information, including age, gender, race, location of practice, type of practice, ownership status, years of experience, and graduating university. These demographic factors aimed to identify potential associations with the respondents' perspectives on the challenges and attitudes toward PEC. Meanwhile , the challenges and attitudes sections comprised of items relevant to the areas being studied.

Domains identification

This study is a part of exploratory sequential mixed-methods design, whereby the development of the

questionnaire was based on the result of previous qualitative findings (Yahaya et al., 2023). These findings informed the construction of the challenges and attitudes domains, resulting in four challenge domains (working environment, lack of support and recognition, self-sufficiency, and customer influence) and two attitude domains (motivation and sense of responsibility). This framework guided the questionnaire's structure, ensuring alignment with the specific challenges and attitudes relevant to private-sector optometrists in Malaysia.

Items development

After identifying the domains, item development began using qualitative findings (Yahaya et al., 2023; Boateng et al., 2018). Key themes from the qualitative analysis shaped the domains, while subthemes or interview extracts informed specific items, ensuring relevance to the target population—optometrists in Malaysia's private sector (Creswell & Clark, 2018). Throughout this process, literature-based guidelines were applied, with frequent reviews of the research questions to maintain relevance (Rattray & Jones, 2007). Items were carefully drafted to avoid complex terminology, double negatives, and leading questions, thereby reducing potential response bias (Boateng et al., 2018; Robinson, 2018).

A five-point Likert scale was selected for responses, providing simplicity and high data quality (Rattray & Jones, 2007; Boateng et al., 2018). Responses ranged from 'strongly disagree' to 'strongly agree,' coded from 1 to 5. To allow flexibility in later stages, a preliminary item pool larger than the final required survey was initially constructed, comprising 39 items across domains: five for working environment, eight for support and recognition, seven for self-sufficiency, seven for customer influence, and twelve for attitudes (seven for motivation and five for sense of responsibility) (Artino et al., 2014; Robinson, 2018).

Phase 2: Questionnaire Validation

The questionnaire underwent multiple testing phases to ensure its validity and reliability. Developing a quantitative tool with strong psychometric properties is essential to support the validity of study findings (Devon et al., 2007; McKenzie et al., 1999). In this study, validity is defined as the instrument's ability to accurately measure the attributes of the construct under investigation (Devon et al., 2007). While validity encompasses several types—face, content, construct, and criterion validity (Cook & Beckman, 2006; McKenzie et al., 1999)—we focused specifically on assessing content and construct validity to ensure the precision and relevance of the instrument for this research.

Content validation

During content validation, a panel of six experts specializing in optometry and PEC reviewed the item pool. This panel included two academicians, two experienced public-sector optometrists serving as board members of the Association of Malaysian Optometrists (AMO), and two board members from the Malaysian Optical Council (MOC). The experts assessed each item for relevance, clarity, and simplicity of the constructs. Items were rated using a 4-point Likert scale, and the Content Validity Index (CVI) was calculated to quantify agreement among the experts (Polit & Beck, 2006). The recommended minimum values are 0.78 for I-CVI, 0.90 for S-CVI/Ave, and 0.75 for modified kappa statistic (Lynn, 1986; Polit & Beck, 2006; Polit et al., 2007).

Pre-Testing

A pre-test was conducted with eight optometrists to assess the questionnaire's readability, feasibility, and clarity from the respondents' perspective. Participants completed the draft questionnaire and were encouraged to give feedback on any ambiguous or confusing items. This process resulted in minor wording adjustments to enhance clarity, ensuring that all items were clearly understood as intended for the target audience (Lynn, 1986).

Construct Validation and Reliability

To assess the questionnaire's construct validity and reliability, a pilot study was conducted with a sample of 38 optometrists from the private sector. The pilot data were analysed using exploratory factor analysis (EFA) to determine the underlying factor structure and confirm the thematic domains identified in the qualitative phase. The extraction method was principal component analysis with an oblique (Varimax with Kaiser Normalization) rotation. Factors were retained based on eigenvalues greater than 1.0 and factor loadings above 0.40 (Fabrigar & Wegener, 2012).

The internal consistency reliability of the CAPEC questionnaire was measured using Cronbach's alpha. All domains achieved alpha values above 0.70, which is generally considered acceptable for psychological and educational assessments (George & Mallery, 2003).

Ethical Considerations

Ethical approval for this study was obtained from the International Islamic University Malaysia Research Ethics Committee (IREC), approval number (IREC 2020-153). All participants provided written informed consent, and their confidentiality was maintained throughout the study.

RESULTS

This section presents the findings from each phase of the CAPEC questionnaire's development and validation, including content validity, pre-test feedback, exploratory factor analysis, and reliability assessment.

Content Validity

Content validation involved six expert reviewers who rated each item for relevance, clarity, and simplicity. Items with an item-level I-CVI below 0.78 and scales with S-CVI below 0.90, were revised per Lynn's (1986) guidelines.

As shown in Tables 1, the I-CVI scores for each item and overall items were excellent (Polit & Beck, 2006; Yusoff, 2019). This result was further supported by high S-CVI scores at the scale level, with S-CVI/Ave values ranging from 0.93 to 1 (Davis, 1992; Polit & Beck, 2006). Additionally, the modified kappa statistic for each item was satisfactory, with a minimum value of 0.81.

Table 1: Content validity index (CVI) of CAPEC questionnaire items

Items No.	S-CVI/Ave	I-CVI/ Ave	I-CVI Interpretation	Modified kappa	Interpretation
Working environment	0.93				Excellent
Item 1		1	Appropriate	1	Excellent
Item 2		0.83	Appropriate	0.81	Good
Item 3		0.83	Appropriate	0.81	Good
Item 4		1	Appropriate	1	Excellent
Item 5		1	Appropriate	1	Excellent
Support and Recognition	0.98				Excellent
Item 6		1	Appropriate	1	Excellent
Item 7		1	Appropriate	1	Excellent
Item 8		0.83	Appropriate	0.81	Good
Item 9		1	Appropriate	1	Excellent
Item 10		1	Appropriate	1	Excellent
Item 11		1	Appropriate	1	Excellent
Item 12		1	Appropriate	1	Excellent
Item 13		1	Appropriate	1	Excellent
Self-sufficiency	0.93				Excellent
Item 14		1	Appropriate	1	Excellent
Item 15		1	Appropriate	1	Excellent
Item 16		0.83	Appropriate	0.81	Good
Item 17		0.83	Appropriate	0.81	Good
Item 18		0.83	Appropriate	0.81	Good
Item 19		1	Appropriate	1	Excellent
Item 20		1	Appropriate	1	Excellent
Customer Influence	0.93				Excellent
Item 21		0.83	Appropriate	0.81	Good
Item 22		0.83	Appropriate	0.81	Good
Item 23		1	Appropriate	1	Excellent
Item 24		1	Appropriate	1	Excellent
Item 25		0.83	Appropriate	0.81	Good
Item 26		1	Appropriate	1	Excellent
Item 27		1	Appropriate	1	Excellent
Motivation	0.95				Excellent
Item 1		0.83	Appropriate	0.81	Good
Item 2		0.83	Appropriate	0.81	Good
Item 3		1	Appropriate	1	Excellent
Item 4		1	Appropriate	1	Excellent
Item 5		1	Appropriate	1	Excellent
Item 6		1	Appropriate	1	Excellent
Item 7		1	Appropriate	1	Excellent

Sense of Responsibility	1				Excellent
Item 8		1	Appropriate	1	?
Item 9		1	Appropriate	1	Excellent
Item 10		1	Appropriate	1	Excellent
Item 11		1	Appropriate	1	Excellent
Item 12		1	Appropriate	1	Excellent

Pre-Test Feedback

A pre-test with eight optometrists assessed the CAPEC questionnaire's clarity and readability. Using a Yes/No scale (Ventkitachalam, 2015), participants rated items on readability, feasibility, and word clarity, with scores over 90% considered acceptable. High scores were achieved; 99.7% for readability, 99.0% for feasibility, and 99.4% for word clarity. Participants completed the questionnaire in 15 to 25 minutes, finding all items clear, though minor adjustments were made for clarity. The pre-test confirmed the questionnaire's relevance and ease of interpretation for the target audience.

Construct Validation

The pilot study involved a sample of 38 optometrists and was used to perform exploratory factor analysis (EFA) to confirm the questionnaire's structure. Six factors were identified, aligning with the thematic domains from the qualitative phase. Table 2 and 3 presents the factor loadings for each domain, supporting the construct validity of the CAPEC questionnaire.

Table 2: Factor loading of challenges items in the CAPEC Questionnaire

CAPEC item	**Factor loading**			
	1	**2**	**3**	**4**
Factor 1: Working Environment				
Item 1	0.66			
Item 2	0.70		0.29	
Item 3	0.83			0.21
Item 4	0.60			0.21
Item 5	0.65			
Factor 2: Support and Recognition				
Item 6	0.22	0.37	0.23	
Item 7		0.41		
Item 8		0.65	0.26	0.24
Item 9		0.66	0.39	
Item 10		0.77		
Item 11		0.69		
Item 12		0.72		
Item 13		0.66		0.34
Factor 3: Self-sufficiency				
Item 14			0.72	
Item 15			0.69	
Item 16			0.31	
Item 17			0.61	
Item 18			0.67	
Item 19			0.71	
Item 20			0.61	
Factor 4: Customer Influence				
Item 21				0.51
Item 22				0.51
Item 23				0.50
Item 24				0.76
Item 25				0.76
Item 26				0.47
Item 27				0.30

Table 3: Factor loading of attitudes items in the CAPEC questionnaire

CAPEC item	Factor loading	
	1	2
Factor 1: Motivation		
Item 1	0.77	0.39
Item 2	0.74	0.36
Item 3	0.71	0.36
Item 4	0.69	
Item 5	0.56	0.44
Item 6	0.53	
Item 7	0.51	
Factor 2: Sense of Responsibility		
Item 8		0.83
Item 9	0.37	0.72
Item 10		0.71
Item 11		0.67
Item 12	0.46	0.55

Reliability Assessment

The internal consistency reliability of each domain was evaluated using Cronbach's alpha. All domains exceeded the commonly accepted threshold of 0.70, indicating good reliability (George & Mallery, 2003). Specifically, the domains of 'support and recognition' and 'sense of responsibility' demonstrated the highest reliability, with Cronbach's alpha values of 0.803 and 0.816, respectively. Table 4 summarises the Cronbach's alpha values for each domain.

Table 4: The internal consistency reliability (ICR) of the challenges and attitudes domains

Domain	No. of items	ICR[a]	
		Corrected ITC[b]	Cronbach's Alpha
Challenges			
Working environment	5	0.507 - 0.714	0.798
Support and recognition	8	0.369 - 0.766	0.803
Self-sufficiency	5	0.308 - 0.716	0.727
Customer Influence	4	0.285 - 0.763	0.713
Attitudes			
Motivation	7	0.505 - 0.767	0.746
Sense of Responsibility	5	0.671 - 0.829	0.816

Note. ITC[b]= Item total correlation

Five items were removed either due to low EFA or low Cronbach's alpha value. The final validated questionnaire consists of 34 items with four domains of challenges ('working environment,' 'support and recognition,' 'self-sufficiency,' and 'customer influence') and two domains of attitudes ('motivation' and 'sense of responsibility').

Summary of Findings

The CAPEC questionnaire demonstrated high content validity, construct validity, and internal consistency reliability across all domains. These results indicate that the CAPEC questionnaire is a robust tool for assessing challenges and attitudes toward PEC among private-sector optometrists in Malaysia.

DISCUSSION

This study developed and validated the CAPEC questionnaire, specifically designed to assess the challenges and attitudes of optometrists in the Malaysian private sector toward implementing PEC. The CAPEC questionnaire exhibited high validity through thorough psychometric evaluations, demonstrating that it is a valid and reliable tool with strong content and construct validity and high internal consistency across all domains.

The content validity of the CAPEC questionnaire was assessed using the Index I-CVI and S-CVI/Ave, both confirming the validity of the items and overall scale. Content validation typically involves three to ten experts (Davis, 1992; Lynn, 1986; Yusoff, 2019), and this study employed a panel of six professionals: two academics, two board members AMO, and two from the MOC. An I-CVI score of 0.78 or above is considered excellent, and all CAPEC items achieved I-CVIs ranging from 0.83 to 1.00. The S-CVI values, measuring the questionnaire's overall relevance, were between 0.93 and 1.00, indicating strong content validity. Additionally, all modified kappa values exceeded 0.75, showing high expert agreement beyond chance. These results confirmed the relevance of all items,

so none were removed during content validation. However, some minimal revisions to the items' structure and grammar were made in response to expert comments.

These were followed with pre-testing of the questionnaire. Pre-testing is essential in questionnaire development to assess face validity and identify potential issues before broader distribution (Boateng et al., 2018). In this study, the questionnaire was pre-tested with a convenience sample of eight private-sector optometrists to gauge its effectiveness and minimize misunderstandings and measurement errors (Boateng et al., 2018; Reynolds et al., 2017). For this study, the pre-testing results were excellent and all participants also indicated that all items were clear and understandable, hence further revision was not needed.

The construct validity of the CAPEC questionnaire was assessed using exploratory factor analysis (EFA). Most items in the challenges domain demonstrated satisfactory factor loadings, aligning well within their respective domains. These acceptable factor loadings provide strong evidence of the CAPEC questionnaire's construct validity, supporting the conclusion that its individual items are both important and relevant for measuring the challenges and attitudes of private-sector optometrists in implementing PEC.

Reliability analysis of the CAPEC questionnaire, conducted using corrected Item-Total Correlations (ITC) and Cronbach's Alpha, confirmed its robustness. Five items with low corrected ITC were removed from the challenges section, leaving 22 items with strong reliability scores. As these removed items were not essential to the domain content, their exclusion did not impact the integrity of the domains. The attitudes section displayed corrected ITC values above 0.3 and Cronbach's Alpha values exceeding 0.7, affirming the questionnaire's reliability for assessing private-sector optometrists' challenges and attitudes toward implementing PEC.

The CAPEC questionnaire distinguishes itself from existing tools such as the Perceptions of Primary Eye Care Questionnaire (Thite et al., 2014) and the Optometric Practice Attitudes Scale (Smith et al., 2017), which also measure perceptions and attitudes in PEC settings. Unlike these tools, CAPEC has been specifically tailored to address the unique challenges faced by Malaysian private-sector optometrists, including cultural and systemic barriers. Its structure and design allow for contextualized assessment, making it highly adaptable for use in other cultural or healthcare settings with appropriate modifications. For instance, CAPEC could be validated and adapted for other Southeast Asian countries where optometrists face similar underutilisation of PEC due to resource constraints and role ambiguity (World Health Organization, 2019). Additionally, in developed healthcare systems, the tool could help uncover residual attitudinal barriers to PEC implementation, providing valuable insights for policy and professional development. Future research should consider cross-cultural validation of the CAPEC questionnaire to enhance its applicability and impact globally.

Study Limitation

This study offers important insights into the development and validation of the CAPEC questionnaire but also identified a few limitations to be addressed in future research. While the sample size was adequate for content and face validation, it may not entirely represent the diversity of the population. Future studies should include more varied geographic locations and account for differences in cultural and socioeconomic backgrounds. Expanding the sample size in subsequent validations would also enhance the generalisability of the findings.

CONCLUSION

This study developed and validated the CAPEC questionnaire as a reliable tool for assessing the challenges and attitudes of Malaysian private-sector optometrists toward implementing PEC. Extensive psychometric testing confirmed high content and construct validity, as well as internal consistency across all domains. The final CAPEC questionnaire, consisting of 22 items in four challenge domains and 12 items in two attitude domains, was reviewed by expert panels, pre-tested for clarity, and analysed through factor analysis to confirm its relevance and accuracy. Although the CAPEC is culturally specific to Malaysia, future research could enhance its applicability by expanding the sample size and incorporating more diverse geographic, cultural, and socioeconomic perspectives.

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ORIGINAL ARTICLE

Evaluating Objective Smooth Pursuit Eye Movements with Tobii Eye Tracker: Normative Data and Clinical Applications

Siti Nur Jannatul Ajilah Hashim[1], Fatin Amalina Che Arif[1], Ilyanoon Zahari[1,2], Noor Wafirah Shafee[1,2,*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Background: Smooth pursuit eye movements (SPEMs) are essential for stabilizing vision during the tracking of moving objects, ensuring continuous alignment on the fovea. This study aims to establish normative data for SPEMs within a clinical context using the Tobii eye tracker, enhancing diagnostic assessments of eye movement abnormalities. **Methods:** Thirty participants, aged 20 to 24 years, from the International Islamic University Malaysia community, were selected according to strict inclusion criteria to minimize confounding factors that could affect eye movement performance. Participants' SPEM performance was assessed using key metrics: root mean square error (RMSE) and pursuit gain, which evaluate tracking accuracy and synchronization with target movement. The data generated served as a normative baseline for comparison with patient data. **Results:** The study generated normative data, revealing an average RMSE of 0.63 ± 0.10 and a pursuit gain of 0.99 ± 0.05, closely aligning with or surpassing existing normative benchmarks. Minor tracking deviations, particularly at peak target velocities, were observed, reflecting expected physiological limitations of smooth pursuit accuracy. **Discussion:** The findings demonstrate the effectiveness of the Tobii eye tracker in providing precise, objective measurements of SPEMs, establishing it as a reliable tool for clinical diagnostics. The normative data offer a valuable reference for clinicians to identify deviations that may indicate neurological or psychiatric disorders. This study highlights the role of eye-tracking technology in improving the diagnostic evaluation of oculomotor dysfunction, supporting its integration into clinical practice for early detection and intervention. **Conclusion:** The established benchmarks serve as a valid reference for clinicians to detect abnormalities in smooth pursuit patterns, aiding in the identification of potential disorders.

Keywords:
smooth pursuit; eye tracking; pursuit gain; root mean square error

INTRODUCTION

Smooth pursuit eye movements (SPEMs) are crucial components of the human oculomotor system, allowing the eyes to track and maintain the image of a moving object on the fovea, where visual acuity is highest. These movements are essential for daily activities, such as reading, driving, and sports, that require precise visual tracking of moving objects. Functionally, SPEMs serve to minimize retinal motion blur and maintain a stable image during dynamic visual tasks, supporting clearer and more accurate visual perception (Barnes, 2008; Leigh & Zee, 2015).

Role of SPEMs in Diagnostic Assessment

Abnormalities in SPEMs can be early indicators of various neurological and psychiatric conditions (Benson et al., 2012). For example, patients with Parkinson's disease often exhibit impaired smooth pursuit, characterized by reduced gain and increased position error relative to healthy controls (Lencer & Trillenberg, 2008). Schizophrenia and other psychiatric conditions are also associated with specific SPEM deficits, such as lower gain and more frequent saccadic intrusions (Benson et al., 2012; Hutton et al., 1998). SPEMs have similarly shown diagnostic value in developmental disorders, where children with ADHD, for instance, demonstrate reduced smooth pursuit gain and accuracy, which may serve as potential biomarkers for the condition (Caldani et al., 2020). These observations underscore the clinical importance of SPEM assessment as a non-invasive, accessible means of identifying early-stage or progressive impairments across diverse patient groups.

* *Corresponding author.*
E-mail address: wafirah@iium.edu.my

Advances in Eye-Tracking Technology for SPEMs

In clinical practice, SPEMs is evaluated through tests such as the ocular motility test (OMT), in which a penlight is smoothly moved across various gaze positions to assess eye movement balance and detect any overshoot or undershoot. However, this method relies on patient cooperation and clinician expertise, and subtle eye movement abnormalities may go undetected, potentially delaying urgent referrals for serious underlying conditions (Shafee, 2021). However, recent advances in eye tracking technology have significantly enhanced the precision, accessibility, and versatility of SPEMs measurement. Modern eye trackers, such as the Tobii eye tracker used in this study, offer non-invasive tracking of eye movements and provide detailed, objective data that supports both research and clinical diagnostics across various fields. The Tobii eye tracker, specifically, has been extensively utilized in studies on cognitive function, neurology, and human-computer interaction, showcasing its versatility and value as a tool in both research and clinical settings (Brunyé et al., 2019).

Current Gaps and Objectives

While normative data for SPEMs exist, they often differ due to variations in testing paradigms. Although extensive research on age-related eye movement norms using video eye tracking has been conducted, these methods can yield inconsistent results (Liversedge, S. et al., 2011). Therefore, establishing normative data is essential before comparing eye movement anomalies across new eye movement recording paradigms.

This study aims to fill this gap by establishing normative data for SPEMs in young adults within the IIUM community, using the Tobii eye tracker. By providing reliable normative benchmarks, we seek to assist clinicians and researchers in accurately identifying SPEM abnormalities and enhancing the diagnostic utility of eye-tracking technology in detecting oculomotor dysfunctions.

MATERIALS AND METHODS

Study Design and Ethical Approval

This cross-sectional study was conducted in accordance with the principles of the Declaration of Helsinki and received ethical approval from the IIUM Research Ethics Committee (IREC 2023-KAHS/DOVS10). The study aims to establish normative data for SPEMs in a population of young adults at IIUM, using the Tobii eye tracker for accurate and objective measurement.

Participants

Thirty participants (six males and twenty-four females), aged between 20 and 24 years, were recruited for this study. All participants met the following inclusion criteria: (1) absence of any ocular or systemic disease, (2) not on any medication that could affect eye movements, (3) best-corrected distance visual acuity of 0.2 logMAR or better in each eye, and (4) ability to maintain focus on a moving target (Shafee, 2021). Exclusion criteria included individuals with high myopia, strabismus, nystagmus, or any ocular motility deficit, as these could confound smooth pursuit measurements.

All participants provided informed consent after receiving a detailed explanation of the study's purpose and procedures. They were assured of the right to withdraw at any stage without any consequences.

Participant and Display set-up

Figure 1 shows the setup for the experiment, where participants were positioned comfortably in a quiet, controlled environment with standard room lighting. A chin and forehead rest were used to minimize head movements, ensuring stable and consistent measurements during the test. The chin rest was disinfected with alcohol wipes between participants. Each participant was seated at a standardized distance of 60 cm from the computer screen. The study setup utilising two computers: one laptop dedicated to gathering data from the Tobii eye tracker, and a separate display monitor used to present stimuli to participants.

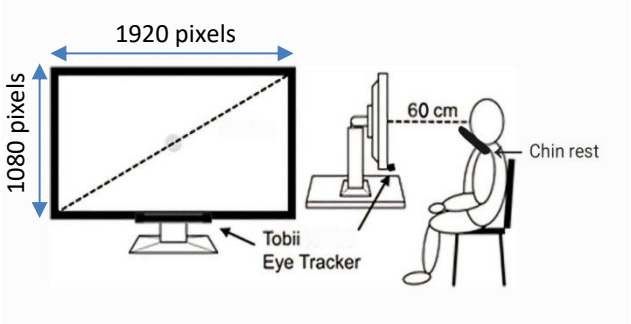

Figure 1: Participant positioning during eye tracking. The participant was seated with a chin rest, at a distance of 60 cm away from the display monitor. The Tobii Eye Tracker was mounted at the bottom edge of the monitor to record eye movements accurately.

Pre-Test Procedures and Participant Preparation

Upon arrival, each participant's visual acuity was verified, and a comprehensive history was taken to confirm adherence to inclusion criteria. Visual acuity testing was conducted to ensure that only those with 0.2 logMAR or better would proceed. A cover test and OMT were also performed to exclude participants with strabismus, nystagmus, or other motility disorders.

Eye Tracker Calibration and Validation

In this study, Tobii Pro Fusion eye tracker (Tobii Pro AB, Danderyd, Sweden) with 120 Hz sampling frequency was utilized to record the eye movements. The eye tracker was attached to the display monitor, AOC (Model: 22B2HN) with refresh rate of 75 Hz.

Prior to each test, the Tobii eye tracker was calibrated to enhance accuracy. The calibration process involved presenting a stationary target at five predetermined points on the monitor, which the participant fixated upon to set baseline eye position measurements. This calibration was immediately followed by a validation phase with the same five points to confirm the precision of calibration. Optimal calibration was achieved when the numerical feedback values met the tracker's accuracy threshold.

Stimulus of the SPEMs

The Tobii eye tracker was used to assess the smooth pursuit eye movements (SPEMs) of each participant. The stimulus presented was a black cross with a diameter of 2.5 mm. It moved horizontally across the monitor in a smooth, sinusoidal path, oscillating with a fixed amplitude of ±10°. The stimulus was designed using MATLAB (The MathWorks, Inc., Natick, Massachusetts, US).

During testing, participants were instructed to maintain precise fixation at the center of the black cross and to follow its movement while ensuring their gaze always remained fixed on the stimulus's center. To ensure data consistency and reliability, each participant completed four trials.

SPEMs Testing Protocol

The testing room was maintained at a quiet and consistent ambient light level to prevent distractions. Participants were instructed to maintain focus on the moving target with minimal head movement and were given brief breaks between trials to prevent fatigue.

Data Collection and Analysis

The primary SPEMs parameters measured were root mean square error (RMSE) and pursuit gain. RMSE indicates the average error between the target and the actual gaze position, providing a measure of tracking accuracy. Pursuit gain represents the ratio of eye velocity to target velocity, with an ideal gain value close to 1.0 indicating accurate tracking of the target's movement.

Data from all four trials were recorded for each participant, and the average values of RMSE and pursuit gain were calculated. Data analysis was conducted using Statistical Package for Social Sciences (SPSS, version 12 for Windows, SPSS Inc., Chicago, IL, USA). Normality of the data was tested to determine the appropriate statistical tests. One-sample t-tests were used to compare the average pursuit gain and RMSE against established benchmarks from previous studies. Statistical significance was set at $p < 0.05$.

RESULTS

A total of 30 participants aged between 21 and 24 years (mean age = 22.3 ± 1.1) met the inclusion criteria and successfully completed the study. The main parameters analyzed were pursuit gain and RMSE, both of which provide key insights into SPEMs accuracy and stability.

SPEMs Outcomes

The mean SPEMs gain for the sample was 0.99 ± 0.05, which indicates a high degree of synchronization between the eye and target velocities, aligning with the ideal gain of 1.0. The RMSE, averaging 0.63 ± 0.10, indicated minimal deviation between gaze and target positions.

Comparison with Prior Normative Data

To assess the validity of our findings, we compared our pursuit gain and RMSE values with those reported in previous studies (Shafee, 2021). The t-test for pursuit gain and RMSE showed statistically significant differences, suggesting that our sample had slightly higher pursuit gain and RMSE compared to previously documented values, as summarized in Table 1. These findings may reflect specific demographic or methodological factors and underscore the need for establishing population-specific norms.

Table 1: Table shows the result on SPEMs

SPEMs Parameters	Test value	Mean ± SD	p-value
Gain	0.89	0.99 ± 0.05	0.03
RMSE	0.56	0.63 ± 0.10	0.04

Graphical Analysis of SPEMs in Relation to Stimulus

Figure 2 illustrates a time-series comparison of the stimulus and the actual pursuit eye movement of the right eye and the left eye. The x-axis represents timestamps in seconds, while the y-axis displays the normalized eye position ranging from 0 to 1.

The eye trajectories closely match the sinusoidal stimulus, with minor deviations observed at the peak positions. These deviations, although subtle, are expected due to the increased difficulty in maintaining smooth pursuit at the extreme edges and during directional changes of the target. At these points, small catch-up saccades may occur as the eye adjusts to realign with the moving target.

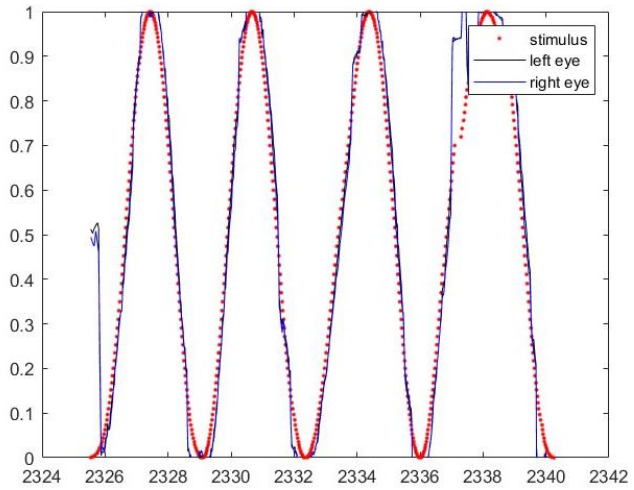

Figure 2: Graph shows comparison of stimulus trajectory and SPEMs. Stimulus trajectory = sinusoidal red dotted line, left eye = blue line and right eye = black line.

DICUSSION

This study aimed to establish normative data for SPEMs in a young adult population using the Tobii eye tracker, a device suitable for objective eye movement assessments. Our findings provide valuable normative benchmarks that can serve as a reference in clinical settings, enhancing diagnostic capabilities for conditions associated with abnormal eye movements.

Comparison with Prior Studies

The mean pursuit gain and RMSE observed in our sample were comparable to previously reported values in similar populations, with our mean pursuit gain of 0.99 closely aligning with prior studies that reported a gain of approximately 0.96 (Shafee, 2021). Minor discrepancies between studies may be attributed to variations in instrument used, testing strategies, sample size, or specific characteristics of the population. Such consistency across studies underscores the reliability and clinical utility of Tobii eye tracker measurements for SPEMs, validating our findings as robust and suitable for clinical application.

Graphical Analysis of Eye Movements

The graphical analysis of eye movements confirmed that participants' smooth pursuit motions closely followed the sinusoidal stimulus trajectory, with minimal deviations observed at the peaks and troughs. These minor deviations likely reflect physiological constraints of the smooth pursuit system or inherent limitations in the response time of the eye-tracking technology. The high degree of synchronization between the eye movements and the stimulus supports the Tobii eye tracker's capacity for precise measurement, further affirming its utility in clinical and research settings.

Clinical Implications

The normative data generated from this study holds significant potential for enhancing clinical assessments of eye movement disorders. Clinicians can utilize this reference to determine if a patient's SPEM performance falls within the typical range or exhibits deviations indicative of underlying neurological, psychiatric, or developmental conditions. For instance, abnormalities in pursuit gain or increased RMSE have been observed in patients with conditions like Parkinson's disease, schizophrenia, and attention-deficit/hyperactivity disorder (ADHD), where decreased gain and higher tracking errors often serve as early indicators of dysfunction (Caldani et al., 2020; Hutton et al., 1998). By providing a normative baseline, this study enables early detection of these anomalies, facilitating timely intervention and potentially improving patient outcomes.

Methodological Considerations

Although the normality test indicated a slight skew in the average gain distribution, we employed parametric tests based on the Central Limit Theorem, as the sample size (N = 30) is sufficient for such analyses. This approach is consistent with established statistical guidelines and ensures that our findings remain statistically valid. Additionally, the high level of consistency in pursuit gain across trials underscores the reliability of the Tobii Eye Tracker for repeated measures in smooth pursuit assessment, supporting its adoption in clinical environments.

Limitations and Recommendations for Future Research

While our study provides foundational normative data, the sample size and focus on young adults aged 20-24 limit the generalizability of these findings. Future studies should expand the sample to include diverse age groups to better capture age-related variations in SPEMs, which would enhance the applicability of these norms across a broader demographic spectrum. Furthermore, our study did not account for potential confounding factors, such as cognitive load or attention, both of which are known to influence smooth pursuit performance. Previous studies have shown that higher attentional demands, such as working memory tasks, can disrupt smooth pursuit by increasing phase lag and positional errors, highlighting the need to control for these factors in future research (Stubbs et al., 2019).

To strengthen the clinical applicability of these findings, future research should aim to (1) expand normative datasets across age groups, as previous studies have reported a decrease in smooth pursuit gain with aging (Moschner & Baloh, 1994), (2) examine the impact of cognitive and attentional factors on SPEMs performance, and (3) explore the use of Tobii and similar technologies in longitudinal studies to assess changes in SPEMs over time.

Technological Advancements in Eye Tracking

This study highlights the capabilities of modern eye-tracking technology, particularly the Tobii eye tracker, in facilitating precise, non-invasive assessments of SPEMs. The device's ease of use, coupled with its high accuracy, offers significant advantages for clinical adoption, particularly in settings requiring reliable and efficient diagnostics. By enabling objective and reproducible measurement of eye movements, the Tobii eye tracker bridges a critical gap in clinical practice, offering optometrists and other eye care professionals a practical tool for detecting and managing eye movement disorders. As eye tracking technology continues to advance, its applications may expand to include more sophisticated analyses, such as differentiating between subtle neurocognitive conditions based on unique SPEM patterns.

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ORIGINAL ARTICLE

IIUM Optometry Clinic Patient's Satisfaction Survey

Nurnadzura Ellyna Ahmad Razalli[1], Siti Idayu Zulkifle[1], Noor Wafirah Shafee[1,2], Ilyanoon Zahari [1,2,*]

[1]Department of Optometry and Visual Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Integrated Omics Research Group (IORG), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
patient satisfaction; optometry clinic; eyecare services; service quality

ABSTRACT

Background: Understanding patient or client satisfaction and their experience with medical care is pivotal for healthcare providers. Since its establishment in 2006, the IIUM Optometry Clinic has provided various specialized eye care services. Consequently, like other healthcare facilities, gaining insights into the clients' experiences is invaluable for continuous improvement. While clinic authorities have developed paper surveys, there has not been a dedicated study conducted at our clinic that analyses factors affecting the patients' satisfaction levels. This research intends to analyse and assess patient satisfaction with the healthcare services offered by the IIUM Optometry Clinic, focusing on identifying key factors influencing the satisfaction level. This study also aims to identify the clinic's strengths and overcome its weaknesses by proposing strategies to increase IIUM Optometry Clinic's standard of care. **Methods:** 164 respondents participated in this study, providing feedback on the clinic's performance through the existing client satisfaction survey forms distributed by examiners after each eye checkup session. Elements rated include the appointment set up, waiting time, quality of services, variety of services available, service by the clinic staff, clinic facilities, service charges, and ambiance. **Results:** 96% of the patients expressed satisfaction with the quality of services provided by the excellent staff of IIUM Optometry Clinic. **Conclusion:** Our results suggest that patients' satisfaction levels are mostly affected by the quality of services and the excellence of the staff. Client feedback also highlighted recommendations for improving the clinic, including maintenance of the machines and expansion of the network infrastructure.

INTRODUCTION

Established in 2006, the IIUM Optometry Clinic has been dedicated to providing a diverse array of specialised eye care services in Kuantan. The services offered include primary optometry and further specialised clinics such as contact lens fitting and care, binocular vision and paediatric. Other services available are colour vision and low vision management. Being the only Optometry school on the East Coast of Malaysia Peninsular that provides such eyecare services with advanced optical instruments, it attracts the surrounding community and potentially benefits them.

After almost 20 years of providing various eyecare services, it is important to measure the satisfaction of the clients or in our setting, the patients. Various methodologies exist for gathering customer feedback, ranging from innovative approaches like photovoice and in-depth interviews to traditional methods such as focus groups and paper surveys. Among these, paper surveys stand out as the preferred method in healthcare facilities for their easy administration. They are often distributed during post-services to promptly capture patient perspectives on the quality of treatment received (De Silva, 2013).

Feedback from the services provided is important for continuous improvement and as a check and balance, especially after a long period. A tertiary hospital providing eyecare services in India assessed their patient satisfaction in a 9-month study (Sudhan et al., 2011). A standardised close-end questionnaire was answered by 320 patients, who responded on waiting time, facilities, treatment, the staff's attitude, and willingness to come again. The results showed that 97% of respondents were satisfied with the services received and were committed to using the clinic's services for the rest of their lives. It is believed that a satisfied customer will help attract others (Sudhan et al., 2011).

* *Corresponding author.*
E-mail address: ilya@iium.edu.my

In another similar tertiary eyecare service located centrally in Malaysia Peninsular, UiTM Puncak Alam's Vision Care Clinic conducted a 3-month cross-sectional study to evaluate patients' satisfaction regarding eye examinations performed by clinical optometry students. A 30-question survey is divided into three sections: patient's demographics, treatment received and overall experience. They found that 96% of patients expressed satisfaction due to the excellent care provided during examinations and student-patient consultations. This study concluded that strong interpersonal skills contribute to improved compliance and positive outcomes in any examination (Zainodin and Mohd Nor Azmi, 2019).

At the nearby location, a patient satisfaction survey was conducted by the IIUM Family Health Clinic (FHC), Kuantan using Patient Satisfaction Questionnaire 18 (PSQ-18). Their investigation primarily assessed interpersonal manners, treatment duration, and service charges. The findings indicated an overall satisfaction score of 78.6%, with the highest satisfaction in interpersonal interactions (Mohammad et al., 2021). However, some patients expressed dissatisfaction with the duration of treatment at the family health clinic.

Apart from the state-of-the-art facilities that the IIUM Optometry Clinic offers, we lack information on how satisfied the patients are with the services received. Therefore, this study aims to identify patient satisfaction with the services provided by the IIUM Optometry Clinic. This would be an important measure of the Clinic's performance, enhancing the services to stay relevant within this locality continuously.

MATERIALS AND METHODS

This descriptive cross-sectional study applied a quantitative research method. Patients attending the IIUM Optometry Clinic were selected as the study population. A paper survey was conducted to collect the responses. A total of 164 respondents' feedback was collected from Semester 1 2023/2024 and Semester 2 2023/2024 clinic sessions between October 2023 and April 2024. This study has been approved by the IIUM Research Ethics Committee (IREC) (approval number: IREC 2023-KAHS/DOVS16).

All new patients who consented to participate in the study were included as survey respondents. For minors, defined as patients below 18 years old, the survey was answered by their guardians. For follow-up cases, the survey was given for the annual follow-ups per the guidelines for services evaluation produced in association with the National Health Services (NHS) United Kingdom. De Silva (2013) noted that it is uncommon to survey patients repeatedly unless they receive continuous treatment. Therefore, only patients returning for follow-up cases from one year onwards were given the survey form.

The study employed a pre-existing clinic survey form to evaluate the factors influencing patient satisfaction. The questionnaires were revised and validated internally by the clinic administrators via group discussion. It was structured into multiple categories to comprehensively assess various aspects: scheduling appointments, waiting times, quality of services, variety of services available, service by the clinic staff, clinical facilities, service charges, and ambiance.

Data Collection Process

During every clinical session, the examiners attending to their patients collected all the clinic's forms together with the additional survey form. The researcher and clinic administrators consistently reminded the examiners to distribute the survey form to their patients at the end of the clinical session with the respective patients attended.

Once the patient was seated in the examination room, the examiner requested them to complete the form of their details as part of the usual clinic routine. On that page, the patient was also asked for consent that the data collected could be used anonymously for academic and research purposes. This step will determine the patient's eligibility for inclusion in the study. As all the examinations are completed, the patient is briefed about the survey. The examiner informed the patient that this survey is crucial for improving the clinical services at the IIUM Optometry Clinic in the future. The survey was given only when the patient agreed to answer it. Data from the questionnaires were gathered weekly every Friday in Microsoft Excel (2013) and subsequently analysed using the Statistical Package for Social Science Software (SPSS) (version 20.0 for Windows, SPSS, Inc., Chicago, IL, USA).

RESULTS

Demographic characteristics of patients and details of services received

Surveys were distributed after each clinic session over two semesters, from October 2023 to April 2024. A total of 164 respondents, consisting of 125 females and 39 males, completed the questionnaire, and their demographic data, as well as the services they received, were documented. Most of the patients were university students aged 18 to 24 years old, primarily receiving services from the Primary Optometry Clinic (POC). Table 1 provides a summary of the

Table 1: Summary of patients' demographic data and services received

	Frequency	Percentage (%)
Gender		
Male	39	23.8
Female	125	76.2
Occupation		
IIUM Staff	4	2.4
University student	104	63.4
Public staff	27	16.5
School student	29	17.7
Age		
Less than 18	30	18.3
18 to 24	103	62.8
25 to 54	20	12.2
More than 55	11	6.7
Services*		
POC	126	77
CL	25	15
BV	6	4
PAEDS	6	4
CV	1	1

patient's gender, occupation, age, and the services they received. Furthermore, the percentage distribution of the services received is illustrated in the pie chart shown in Figure 1.

*POC: Primary Optometry Clinic, CL: Contact Lens Clinic, BV: Binocular Vision Clinic, Paeds: Paediatric Clinic, CV: Colour Vision Clinic

University students (63.4%) are frequent clients of IIUM Optometry Clinic, drawn to its status as a teaching institution where optometry students often invite their peers or post advertisements through social media (e.g., residential college groups, associations, and friends group chat) for complimentary eye checkups. School students (17.7%) aged less than 18 years old also frequently attend the optometry clinic, especially to receive treatment from the pediatrics and binocular vision clinics. Public staff make up another significant group of clients, whereas IIUM staff were the least frequent clients, with 16.5% and 2.4%, respectively.

The Primary Optometry Clinic (POC) was the most sought-after service, followed by contact lens consultations with 77% and 15% respectively. These can be due to the increasing interest in the community in getting eye checkups and the popular demand for contact lenses. Binocular vision (BV) and pediatrics (PAEDS) clinics together account for 4% of the total visits. Interestingly, only one case of colour vision (CV) was recorded throughout the semesters. The low number of respondents for specialized clinics (Pediatrics and Binocular Vision) may be caused by improper preparation or poor time allocation by the examiners. In addition, most of the time the patients are restless younger kids and the parents/ guardians are unable to stay and respond to the survey upon completing their clinic's session.

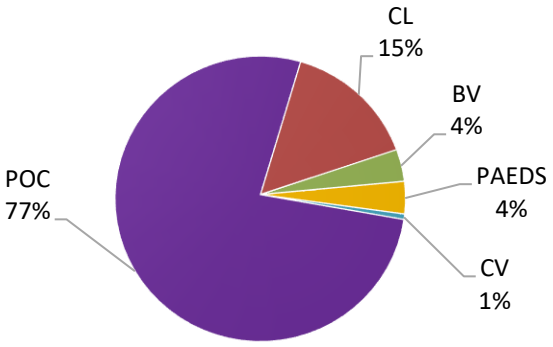

Figure 1: Distribution of services attended

Patient satisfaction ratings

There were eight factors assessed by the patients in the survey; appointment setup; waiting time; quality of services; variety of services available; service by clinic staff; clinic facilities; service charges; and ambience. Most of the respondents rated it as either good or excellent. The detailed ratings for these factors are provided in Table 2, highlighting the overall positive feedback received from the patients.

DISCUSSION

Key Factors Affecting Patients' Satisfaction with IIUM Optometry Clinic's Services

Our findings showed that patients' satisfaction at the IIUM Optometry Clinic was predominantly influenced by the quality of service received and the excellence of the examiners in conducting eye care examinations, which included both Optometry students and staff as there was no demarcation made. Interestingly, service charges were the lowest-rated aspect in the questionnaire, with a satisfaction rate of 90.2%. Despite this, the data indicates that the clinic excels in both service quality and the performance of the clinic's personnel. Patients consistently reported high levels of satisfaction with the care provided, highlighting the clinic's dedication to excellence. The positive feedback concerning professionalism and the quality of services underscores the clinic's success in delivering superior patient-centred care. This strong performance in key areas demonstrates the clinic's ability to meet and exceed patient expectations, fostering a high level of trust and satisfaction among its clients.

Feedback And Strategies Proposed in Improving the Clinic's Quality of Services

Among the surveys collected, several patients offered valuable feedback for enhancing the clinic's services. This feedback highlighted specific areas where the IIUM Optometry Clinic can improve, particularly in expanding its network infrastructure and maintaining equipment. Patients claimed that they need a broad internet connection while in the clinic as it can provide smooth and fast cashless transactions for billing. This is also applicable during specialisation clinics (BV and PAEDS) when sometimes an app needs to be installed on mobile devices for vision therapy purposes. In addition, some patients recommended maintenance machines and clinical equipment such as fixing non-adjustable patient chairs. While patients generally appreciate the quality of care and the professionalism of the staff, some suggest that improving the clinic's technological capabilities and ensuring regular maintenance of equipment would significantly enhance their overall experience. Addressing these recommendations will not only help in elevating the overall service quality but also ensure that the clinic remains a reliable and advanced provider of optometric care.

CONCLUSION

The study revealed that patients' satisfaction with the IIUM Optometry Clinic is primarily influenced by the quality of service and excellent service provided by the personnel. Our client also suggested improvements such as equipment maintenance and expanding the clinic's network infrastructure. These findings have the potential to foster continuous enhancement of the clinic's performance and services, promoting a more patient-centred approach to care. The research provided valuable insights into patients' perceptions of the clinic's performance. Furthermore, it contributed to raising the clinic's standard of care by identifying areas of strength to maintain and weaknesses to address effectively. Additionally, enhancing patient satisfaction can positively impact the clinic's financial performance, as satisfied patients are more likely to adhere to treatment recommendations and recommend the IIUM Optometry Clinic to their families and acquaintances.

Table 2: Eight factors rated by the patients

	Frequency	Percentage (%)
Appointment setup		
Good	13	7.9
Excellent	151	92.1
Waiting time		
Good	10	6.1
Excellent	154	93.9
Quality of services		
Good	7	4.3
Excellent	157	95.7
Variety of services available		
Good	12	7.3
Excellent	152	92.7
Service by the clinic staffs		
Good	9	5.5
Excellent	155	94.5
Clinic facilities		
Good	10	6.1
Excellent	154	93.9
Service charges		
Good	16	9.8
Excellent	148	90.2
Ambience		
Good	11	6.7
Excellent	153	93.3

Addressing this issue is essential for accurately assessing patient satisfaction at the IIUM Optometry Clinic. If the recommendations are not taken seriously and the problem is not resolved, the clinic may continue to repeat mistakes and fail to operate efficiently. This lack of understanding of patient preferences can result in financial losses and an inability to meet patient expectations. Consequently, both the clinic and the optometry department could face significant repercussions. Therefore, resolving this issue is of utmost importance for enhancing overall clinic performance and patient care outcomes. By doing so, the clinic can ensure a higher level of service, avoid financial pitfalls, and better fulfil the needs and expectations of its patients, thereby securing a more successful and sustainable future for both the clinic and the department.

The research findings have provided essential insights that could lead to the development of new perspectives and objectives focused on enhancing community eye healthcare. The potential applications of these findings are substantial, especially for clinical settings such as the IIUM Optometry Clinic, where they can be implemented to improve patient care and better meet patient expectations. For the Ummah, this study has proven to be a valuable resource for clinical facilities striving to deliver optimal patient care and support the needs of the community. By integrating these findings into practice, clinics can ensure they are providing the highest level of service and care to their patients, ultimately benefiting the wider community.

ACKNOWLEDGEMENT

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APPENDIX: The survey form

PATIENT SATISFACTION SURVEY FORM/
BORANG SOAL SELIDIK KAJIAN KEPUASAN PELANGGAN
IIUM OPTOMETRY CLINIC/ *KLINIK OPTOMETRI UIAM*

Please tick √ to the related box. ***Tandakan √ pada kotak yang berkenaan.***

1. Customer profile/ *Profil pelanggan*:

☐ New ☐ Follow-up

IIUM Staff/ Kakitangan UIAM		University students/ Pelajar universiti	
Public staff / Kakitangan Awam		School students/ Pelajar sekolah	

2. Gender/ *Jantina*: ☐ Male ☐ Female
3. Date/ *Tarikh*: _____ Example/ *Contoh*: January 7, 2023
4. Time/ *Masa*: _____ Example/ *Contoh*: 8.30am
5. Age/ *Umur*: ☐ < 18 y.o ☐ 18 – 24 y.o ☐ 25 – 54 y.o ☐ >55 y.o
6. Information source about our clinic/ *Sumber informasi tentang klinik kami*:
   - ☐ Social media/ *Media sosial* (e.g Facebook, Tik Tok, Google)
   - ☐ Family/ *Ahli keluarga*
   - ☐ Friends/ *Kawan-kawan*
   - ☐ Others (please state)/ *Lain-lain (sila nyatakan)*:

     _____
7. Service received today:
   Perkhidmatan yang diterima pada hari ini:

Primary Optometry Clinic		Colour Vision Clinic	
Contact Lens Clinic		Ophthalmic Dispensary	
Binocular Vision Clinic		Myopia Management Clinic	
Paediatric Optometry Clinic		Dry Eye Clinic	
Low Vision Clinic			

Version 3, 3/3/2023

Page 1 of the front page of the survey

8. Rate your satisfaction with the scale provided.
Nilaikan tahap kepuasan anda mengikut skala berikut.

4	*3*	*2*	*1*
Excellent *Cemerlang*	**Good** *Baik*	**Satisfactory** *Memuaskan*	**Unsatisfactory** *Tidak memuaskan*

No.	Matters/ *Perkara*	1	2	3	4
1	Setting your appointment. *Penetapan tarikh temujanji.*				
2	Waiting time. *Masa menunggu.*				
3	Quality of services. *Kualiti perkhidmatan.*				
4	Variety of services available. *Kepelbagaian perkhidmatan yang disediakan.*				
5	Service by the clinic staff. *Layanan daripada staf klinik.*				
6	Clinic facilities. *Kemudahan klinik.*				
7	Service charges. *Caj perkhidmatan.*				
8	Ambience. *Suasana persekitaran.*				

9. Additional feedback/ *Komen atau cadangan penambahbaikan.*

Thank you for your feedback. *Terima kasih atas maklum balas anda.*

Version 3, 3/3/2023

Page 2 of the back page of the survey

ORIGINAL ARTICLE

ASSOCIATION BETWEEN NECK PAIN AND DEPRESSION, ANXIETY, AND STRESS AMONG IIUM KUANTAN STUDENTS

NUR ARIEFAH BINTI MOHD ZAIDI[1], MOHD YUSOF BIN MOHAMAD[2,*]

[12]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Neck pain, depression, anxiety, stress, IIUM Kuantan students

ABSTRACT

Background: Neck pain is a common disorder worldwide due to degenerative changes in facet joints and the collapse of intervertebral discs. The incidence of neck discomfort is significantly higher in older people. Psychological distress refers to generic stress, anxiety, and depression symptoms. High levels of psychological distress indicate poor mental health and may be indicative of prevalent mental disorders. The main objective of this study was to evaluate the association between neck pain and psychological distress among International Islamic University Malaysia (IIUM) Kuantan students. **Methods**: 83 subjects were selected through the convenience sampling method following the inclusion and exclusion criteria. Neck Disability Index (NDI) and the Depression Anxiety Stress Scales 21 (DASS-21) were used to determine the level of neck pain, depression, anxiety, and stress, respectively. Descriptive statistics and the Chi-square test of independence were applied to analyse the data**. Result**: 68.6% of the students suffered from mild to moderate neck disability. More than half of the students suffered from depression, anxiety, and stress, with the percentage of 59.1%, 79.0% and 43.5%, respectively. The result showed a significant association between neck pain and depression (*p*=0.006), anxiety (p=0.023), and stress (p=0.023). **Conclusion**: IIUM students demonstrated mild to moderate neck pain and high levels of depression, anxiety, and stress with a significant association between them. It is hoped that this study brings awareness of maintaining good physical and mental health among students and how it correlates with each other.

INTRODUCTION

Poor posture, sedentary lifestyle and academic stress are among the factors that are associated with neck pain and psychological stress among students. Although the burden of neck pain has not increased significantly from 1990 to 2019, its high prevalence means that it affects a significant number of people around the world. Psychological factors contribute to the onset of neck discomfort (Kazeminasab et al, 2022). According to Al-Ghamdi et al. (2022), the combination of neck pain with psychological issues was substantially associated with the population. In other studies, there is evidence that adolescents' high levels of psychological distress contribute to their musculoskeletal complaints (Liu et al., 2018).

Awareness campaigns and initiatives aimed at enhancing mental health have been carried out during the preceding years. It is common knowledge that keeping excellent mental health helps reduce the likelihood of developing musculoskeletal diseases like neck pain. This is one of the reasons why many of us are aware of the benefits of doing so. Having many assignments and remaining focused while working on a laptop, on the other hand, can contribute to an increased likelihood of experiencing stress, depression, and anxious feelings, as well as increasing the level of neck pain. As a result, it is essential to acquire knowledge concerning depression, anxiety, and stress levels to enhance one's physical health and avoid developing neck pain. Indirectly, we can assert that there is a significant association between pain in the neck and psychological distress.

Therefore, the study intended to address the level of depression, stress, and anxiety among IIUM Kuantan students and its association with the level of neck pain. It is vital to accomplish this goal because it can give students the ability to control their mental health as well as prevent the development of musculoskeletal diseases such as neck pain.

* *Corresponding author.*
E-mail address: yusofkahs@iium.edu.my

MATERIALS AND METHODS

Study Design

The study was using a cross-sectional study design and information gathered from specific populations in a specific period.

Subjects

The study was conducted at the International Islamic University Malaysia (IIUM), Kuantan Campus. The questionnaires were distributed online using Google Forms. The targeted population was students at IIUM Kuantan. The study's inclusion criteria were undergraduate IIUM Kuantan students aged 18 to 30 who understand the English language. Students with pathological conditions associated with the neck and who are taking drugs for anxiety, depression, or stress are excluded from this study.

Ethical Consideration

The study obtained approval from the Kulliyyah Postgraduate and Research Committee (KPGRC) (Reference Number: IIUM/310/14/11/2 ID Number: KAHS 92/23). The respondents were informed about the study's objectives and consented to participate.

Sample Size Calculation

The sample size was calculated using a single proportion formula, with a confidence interval of 95% and a precision of 10%. Participants' withdrawal from the study is expected, and an additional 10% for incomplete data is added to the sample size. From the sample size calculation, the sample size for this study was about 82 students.

Sampling Method

The samples were collected using convenience sampling. The subject's demographic data, including Kulliyyah, Year of Study, Age and Gender, were recorded. The subject must meet all the inclusion and exclusion criteria of the study to proceed. Then, the subjects needed to answer a set of questionnaires consisting of three parts: demographic data, a Neck Disability Index (NDI) by Vernon (2008) and the Depression Anxiety Stress Scales 21 (DASS-21) by Lovibond & Lovibond (1995). NDI is used to analyse the level of neck pain. A total of ten inquiries pertaining to neck pain were presented. The severity of neck pain can be assessed by combining the cumulative scores. The total scores of the NDI accumulated to 50. The levels of NDI encompass a range of disability severity, including no disability, mild disability, moderate disability, severe disability, and complete impairment. DASS-21 is a collection of three self-report measures specifically developed to assess individuals, levels of three psychological distress, including depression, anxiety, and stress. It consists of seven items per scale; in total, there will be 21 questionnaires. The scoring for DASS-21 can be calculated by summing up the score for each category. There were five different labels of severity of depression, anxiety and stress, which are normal, mild, moderate, severe, and extremely severe.

Statistical Analysis

The statistical analysis data was done by using the Statistical Package for Social Science (SPSS) version 27 for Windows. Demographic data was analysed by using descriptive statistics. Both levels of neck pain and depression, anxiety and stress were reported using descriptive statistics. The level of neck pain can be divided into no disability, mild disability, moderate disability, and severe disability. The score is calculated by summing up the score for each question. The level of anxiety was determined by calculating the sum of the questions of numbers 2, 4, 7, 9, 14, 19 and 20 in DASS-21 and was categorised into normal, mild, moderate, severe and extremely severe. For anxiety, a total score of 0-3 is classified as normal level, scores 4-5 are classified as mild anxiety, scores 6-7 are classified as moderate anxiety, scores 8-9 are classified as severe anxiety and extremely severe anxiety when the total score is 10 and above. The level of depression was determined by calculating the sum of the questions of numbers 3, 5, 10, 13, 16, 17 and 21 in DASS-21, and was categorised into normal, mild, moderate, severe and extremely severe. For depression, a total score of 0-4 is classified as normal level, scores 5-6 are classified as mild depression, scores 7-10 are classified as moderate depression, and scores 11-13 are classified as severe depression and for extremely severe depression when the total score is 14 and above. For the association of neck pain and depression, anxiety and stress were demonstrated using the Chi-Square test of independence.

RESULTS AND DISCUSSION

Demographic data

The study comprised 83 respondents who provided consent and participated, consisting of 12 males (14.5%) and 71 females (85.5%). Most of the respondents were within the age range of 21-23 years old. Approximately 41.0% of the participants were in the 18-20 age group, with an additional 2.4% representing the 24-26 age group. Among the six Kulliyyah at IIUM Kuantan, only five participated in the study. KAHS got the highest response rate at 39.8%, followed by KOS (24.1%), KOM (20.5%), KOD (10.8%), and lastly, KON (4.8%).

The most represented academic year was Year 4, with 38.6% of the respondents. Years 2 and Year 1 shared almost similar percentages, each at 24.1% and 22.9%, respectively. Year 3 secured the fourth position with 12%, while Year 5 occupied the last position with 2.4%. Table 4.1

presents a summary of the characteristics of the respondents according to each variable.

Table 1 Characteristics of the respondents (n=83)

Variable	Frequency	Percentage (%)
Gender:		
Male	12	14.5
Female	71	85.5
Age:		
18-20	34	41.0
21-23	47	56.6
24-26	2	2.4
Kulliyyah:		
KAHS	33	39.8
KOS	20	24.1
KOM	17	20.5
KOD	9	10.8
KON	4	4.8
Year of Study:		
Year 1	19	22.9
Year 2	20	24.1
Year 3	10	12.0
Year 4	32	38.6
Year 5	2	2.4

Level of Neck Pain

The results show that 49 students had a mild disability in the neck (59.0%), followed by no disability with 26 students (31.3%), and moderate disability in the neck with eight students (9.6%). Figure 1 summarises the level of neck pain among IIUM Kuantan students.

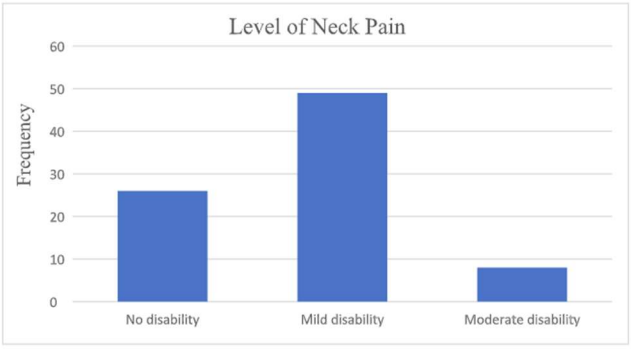

Figure 1 Level of Neck Pain among IIUM Kuantan students (n=83)

Level of Depression

In terms of depression level, most of the respondents had a normal level of depression, with 34 students (41.0%), followed by moderate depression with 17 students (20.5%), mild depression with 13 students (15.7%), extremely severe depression with 11 students (13.3%) and severe depression with 8 students (9.6%). Figure 2 shows the level of depression among IIUM Kuantan students.

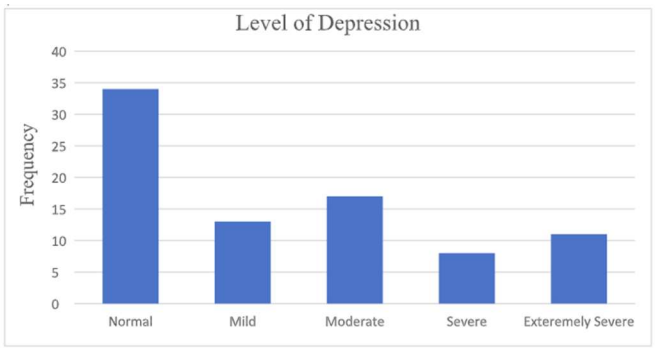

Figure 2 Level of Depression among IIUM Kuantan students (n=83)

Level of Anxiety

In terms of anxiety level, most of the respondents had extremely severe anxiety with 22 students (26.5%) followed by normal level with 21 students (25.3%), mild anxiety with 18 students (21.7%), moderate anxiety with 15 students (18.1%) and severe anxiety with 7 students (8.4%). Figure 3 shows the level of anxiety among IIUM Kuantan students.

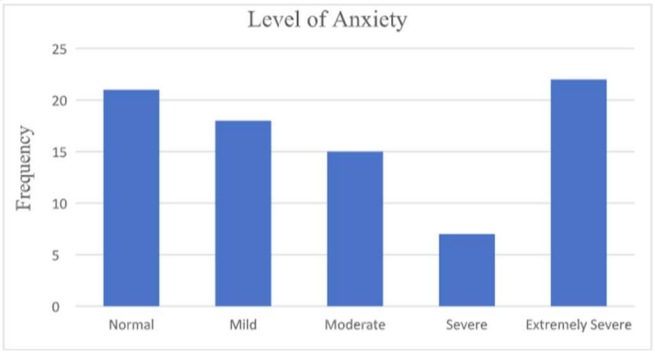

Figure 3 Level of Anxiety among IIUM Kuantan students (n=83)

Level of Stress

In terms of stress level, most of the respondents had a normal level of stress, with 47 students (56.6%), followed by severe stress with 13 students (15.7%); mild stress and moderate stress share the same number of students, 11 students each (13.3%). Only one student has extremely severe stress (1.2%). Figure 4 shows the level of stress among IIUM Kuantan students.

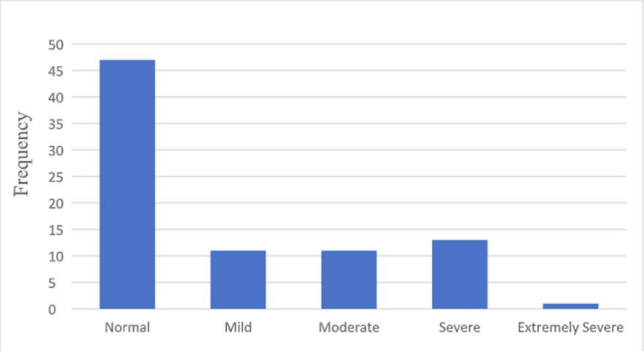

Figure 4 Level of Stress among IIUM Kuantan students (n=83)

Association of Neck Pain and Depression

The association between neck pain and depression was analysed using the Chi-square test for independence. A significant association was found, with a *p*-value lower than α *(p*=0.006).

Table 2: Association of Neck Pain and Depression Level (n=83)

Variable	Level of Neck Pain			Total n (%)	□²	df	*p*-value
	No disability (%)	Mild disability (%)	Moderate disability (%)				
Level of Depression							
Normal	17 (50.0)	17 (50)	0 (0.0)	34 (100)			
Mild	2 (15.4)	10 (76.9)	1 (7.7)	13 (100)			
Moderate	5 (29.4)	9 (52.9)	3 (17.6)	17 (100)	18.793	8	0.006
Severe	1 (12.5)	4 (50.0)	3 (37.5)	8 (100)			
Extremely Severe	1 (9.1)	9 (81.8)	1 (9.1)	11 (100)			
Total	26	49	8				

Association of Neck Pain and Anxiety

On the association of neck pain and anxiety, the statistical analysis is shown in Table 3. There is a significant association found between neck pain and anxiety level, with a p-value lower than α (*p*=0.023).

Table 3: Association of Neck Pain and Anxiety Level (n=83)

Variable	Level of Neck Pain			Total n (%)	□²	df	*p*-value
	No disability (%)	Mild disability (%)	Moderate disability (%)				
Level of Anxiety							
Normal	9 (42.9)	12 (57.1)	0 (0.0)	21 (100)			
Mild	8 (44.4)	10 (55.6)	0 (0.0)	18 (100)			
Moderate	5 (33.3)	9 (60.0)	1 (6.7)	15 (100)	16.473	8	0.023
Severe	2 (28.6)	3 (42.9)	2 (28.6)	7 (100)			
Extremely Severe	2 (9.1)	15 (68.2)	5 (22.7)	22 (100)			
Total	26	49	8				

Association of Neck Pain and Stress

On the association of neck pain and stress, the statistical analysis is shown in Table 4 for a confidence level of 95%, the p-value was compared with the significance level (α) of 0.05. Therefore, there is a significant association found between neck pain and stress level, with a *p*-value lower than α (*p*=0.023).

Table 4: Association of Neck Pain and Stress Level (n=83)

Variable	Level of Neck Pain			Total n (%)	□²	df	*p*-value
	No disability (%)	Mild disability (%)	Moderate disability (%)				
Level of Stress							
Normal	20 (42.6)	26 (55.3)	1 (2.1)	47 (100)	15.688	8	0.023
Mild	2 (18.2)	8 (72.7)	1 (9.1)	11 (100)			
Moderate	3 (27.3)	6 (54.5)	2 (18.2)	11 (100)			
Severe	1 (7.7)	8 (61.5)	4 (30.8)	13 (100)			
Extremely Severe	0 (0.0)	1 (100)	0 (0.0)	1 (100)			
Total	26	49	8				

According to Chan et al. (2020), in the study, 60% of 1003 respondents consisting of undergraduate students in Hong Kong reportedly had neck pain. The statement from that study was parallel to the outcome found in IIUM Kuantan students where 68.6% of undergraduate students combined had mild and moderate disability of the neck. Several factors, including prolonged use of smartphones, sports injuries, study hours and mental health levels, can cause neck pain in students. A study from China reported that study time of more than six hours, flexed neck posture of more than 20 degrees, static duration posture of more than two hours and psychological distress are independent factors for neck pain in female students (Zheng et al., 2022). One of the categories of neck pain is mechanical neck pain. Mechanical pain originates in the spine or its supporting structures, such as ligaments and muscles (Cohen, 2015). Common examples of mechanical pain include pain arising from the facet joints, discogenic pain, and myofascial pain. Gull et al. (2021) concluded that university students have a higher risk of developing mechanical neck pain.

The term depression describes a wide range of emotional lows, from mere sadness to a pathological suicidal state (Naushad et al., 2014). People with this mental illness often have a lot of stress in their daily lives. For depressed people, their sadness or unhappiness lasts for a very long time because they are unable to find the real reason why they should be happy. The person may stop their social activities and be more likely to be alone. However, people who are mentally stable, will get better with sadness for a suitable amount of time and continue life as usual. Depression in young individuals frequently accompanies other mental diseases, including anxiety, disruptive behaviour, or substance addiction disorders (Weissman et al., 1999 as cited in Naushad et al., 2014). Among 83 students, the prevalence of depression was found to be 59.1%. As compared to the other study conducted in Borneo, their study found that 82% of the students struggle with depression (Zulkafli et al, 2022). A study conducted in Selangor found that 53.9% of the students

had moderate to severe depression (Wong et al., 2023). Students were more likely to have depression as the previous studies shared similar results with the current study. Students tend to develop depression due to low self-esteem, peer problems and traumatic events (WHO, 2023). Traumatic events among students can include being scolded by teachers or physically abused by friends. The most common types of depression found in this study were moderate depression (20.5%), followed by mild depression (15.7%), extremely severe depression (13.3%) and severe depression (9.6%). A cross-sectional study conducted in Malaysia in 2011 found that moderate depression was the most common one found among Malaysian students (Shamsuddin et al., 2011).

Anxiety is characterised by persistent intrusive thoughts and concerns that result in perpetual worry and tension. In a similar fashion, anxiety has also been described as having a disproportionate amount of worry and fear relative to everyday situations, which leads to adverse thoughts and predictions about future events (Tan et al., 2023). In university, especially for those who studied far from their hometown, their anxiety will be increased due to financial factors, and challenges in meeting new environments and people. 79.0% of students had anxiety in this present study. This was higher compared to the study conducted among 16 universities in Malaysia, the prevalence risk was recorded at 29% where 529 out of 1821 students had anxiety (Mohamad et al., 2021). According to the authors, the academic year, getting money for the study, drinking alcohol, getting bad sleep, body mass index (BMI), having a good friend at university, unsure future, being involved in society, and having a problem with other students and lecturer were all found to be significantly linked to and indicate the risk of anxiety in that study. Most of the respondents who have anxiety had extremely severe anxiety (26.5%), followed by mild anxiety (21.7%), moderate anxiety (18.1%) and severe anxiety (8.4%). The study found that university students in Selangor, Malaysia, showed the same trend as the current study, with extremely severe anxiety (32.7%) being the highest among people who have anxiety (Wong et al., 2023).

Stress can arise from various factors in daily life, such as work, personal, social, and financial factors. It is a state of emotional instability that impairs someone's capacity to consistently focus and perform successfully. It reduces a student's efficiency in doing tasks and learning new knowledge. they encounter significant and demanding difficulties during their academic journey and youthful activities (Qamar et al., 2015). Studies showed that academic stress is the most common factor of stress among college students (Pozos-Radillo et al., 2014). Half of the respondents in the study had stress (43.5%). Students tend to develop stress due to assignments, presentations, and examinations. A study conducted among Malaysian students at university showed that the prevalence rate of perceived stress among undergraduate students was 37.7% (Jia & Loo, 2018). The other study conducted in Selangor found that 44.6% of university students had moderate to severe stress (Wong et al., 2023). It can be concluded that Malaysians suffer from stress, especially among university students, as the other study shared almost similar results from current study. A current study shows most students who have stress have severe stress (15.7%). Mild and moderate levels of stress shared the same number of respondents which are 11 each (13.3%), then followed by extremely severe stress (1.2%). Severe stress can affect academic performance. However, medical students in top universities in Malaysia showed that their academic performance is not affected by stress as the medical school trains the students to face everyday challenges and manage stress well (Siraj et al., 2014). Therefore, it is necessary for educational institutions to conduct programmes related to stress management.

There was a significant association between neck pain and depression, anxiety, and stress. This finding was consistent with other studies that have reported anxiety and depression were found to be major contributors to neck pain among students in Saudi Arabia (Alghamdi et al., 2023). The study did not specify if stress can contribute to neck pain or not. Another study found a strong link between stress and neck disability during the COVID-19 lockdown period among students, with stressed individuals having a significantly higher relation of suffering moderate to severe neck pain limitations (Daher & Halperin, 2021). High amounts of stress can significantly affect the neck as stress will strain the muscles around it. In another study conducted in Pakistan, they found that neck pain is associated with depression and stress (Batool et al., 2022). Individuals in Germany with symptoms of depression or anxiety were found to have a strong association with experiencing severe neck pain (Blozik et al., 2009).

From all the previous studies, depression was consistently the contributor to neck pain. In the meta-analysis study, out of 33 risk factors of neck pain, 11 risk factors have been listed as the main risk factors, including emotional issues (Gao et al., 2023). It shows that there is an association between neck pain and depression, stress and anxiety, as many other studies share similar results. There was a little study about the relationship between neck pain and depression, anxiety and stress in the Malaysian community. A previous study found that psychological distress was associated with musculoskeletal pain such as shoulder, hip, wrist and knee among students in Selangor

(Sabri et al., 2023). The study did not find that psychological distress is associated with neck pain but is associated with other physical pain. Other studies conducted among teachers in Malaysia showed that there is an increase in the trend of experiencing neck pain when the scores of self-reported questionnaires for depression and anxiety increase (Zamri et al., 2017).

The study concludes that teachers with high depression and anxiety are more prone to have neck pain. This study design did not draw any conclusions about the direction of the relationship between emotional distress and pain. People with chronic pain are significantly more likely to develop depression or anxiety (Gerrits et al., 2014). However, it is believed that psychological distress can contribute to the onset of acute neck pain, especially in adolescence, as this current study asks the respondents questions related to neck pain and psychological distress in the same time frame, which is in the past 7 days. Considering the high number of students suffering from depression, anxiety and stress, the counselling department needs to overcome these problems by conducting more programs to improve mental wellbeing. Students should be educated about psychological problems because they can cost a life. The promotion of good physical health also can be organised to achieve physical well-being. Neck pain is better treated during the acute stage before it becomes chronic. Prevention is better than cure.

CONCLUSION

This study showed that 66.2% of the students suffered from mild to moderate disability of the neck. Depression, anxiety and stress affect quite a number of students, with 59.1%, 79.0% and 43.5%, respectively. Lastly, there was an association between neck pain and depression (p=0.006), anxiety (p=0.023), and stress (p=0.023) among IIUM Kuantan students.

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ORIGINAL ARTICLE

In Vivo Evaluation of a Nanoantibiotic-Integrated Collagen-Chitosan Scaffold for Bone Regeneration in a Critical-Size Rat Defect Model

Nora Azirah Mohd Zayi[1], Muhammad Lutfi Mohamed Halim[1], Ahmad Fahmi Harun Ismail[1,5], Mohd Hafiz Arzmi[2,3,5], Pram Kumar A/L Subramaniam[4] , Mohd Yusof Mohamad[1,5,*]

[1]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Department of Fundamental Dental and Medical Science, Kulliyyah of Dentistry, International Islamic University Malaysia, Pahang, Malaysia
[3]Melbourne Dental School, The University of Melbourne, Victoria, Australia
[4]Department of Oral Maxillofacial Surgery and Oral Diagnosis, Kulliyyah of Dentistry, International Islamic University Malaysia, Pahang, Malaysia.
[5]Cluster of Cancer Research Initiative IIUM (COCRII), International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Bone regeneration; Periodontal disease, Biodegradable scaffold; collagen-chitosan scaffold; metronidazole nonantibiotics

ABSTRACT

Background: Bone loss due to periodontal disease, trauma, or anatomical factors is a significant challenge in periodontology. Guided Bone Regeneration (GBR) scaffolds, which provide a 3D structure for cell attachment and tissue regeneration, have shown promise in treating bone defects. However, non-biodegradable scaffolds require secondary surgery for removal, which can increase the risk of infection and hinder bone regeneration. Biodegradable scaffolds with antibacterial properties offer a solution to reduce infection risk and promote healing.The use of antibiotic-loaded scaffolds, such as metronidazole nanoparticle-loaded (MNP) scaffolds, can address the issue of prolonged antibiotic use and associated risks like resistance and side effects. Previous studies have demonstrated the potential of MNP-loaded scaffolds in periodontal regeneration. This study aims to evaluate the effectiveness of a collagen-chitosan scaffold loaded with metronidazole nanoparticles, focusing on its in vivo biocompatibility and potential toxicity. **Materials and Methods**: A sample of 18 rats was chosen based on the Resource Equation Method, ensuring an adequate sample with a 20% attrition rate, in line with animal testing ethics (3Rs: replacement, reduction, refinement). Male Sprague-Dawley rats (8 weeks, 250-300g) were divided into three groups: CC-MNP scaffold, CC scaffold, and no scaffold (control). Anaesthesia was given intraperitoneally using ketamine (80 mg/kg) and xylazine (10 mg/kg). A 5 mm skull defect was created surgically, and the respective scaffold treatment was placed. The surgical site was closed, and post-operative monitoring focused on pain and healing for four weeks, after which X-ray imaging assessed bone healing at the defect site. Radiographic images were analyzed using Image J, measuring new bone formation percentage as a function of the original defect size. Bone regeneration was quantified by defect closure area based on ROI measurements. Histological analysis on decalcified tissue sections stained with hematoxylin and eosin (H&E) was conducted to evaluate new bone morphology. **Results**: The CC-MNP scaffold group demonstrated significantly higher rates of bone organisation compared to the CC scaffold and control groups. Histological analysis showed denser and more compact bone regeneration within the defect area, suggesting that the MNP-infused scaffold promotes cellular activity and tissue integration. This study underscores the potential of a biodegradable, antibiotic-loaded scaffold to support bone regeneration in critical defects, reducing the need for secondary surgeries and offering a sustainable solution potentially suitable for clinical use in periodontal applications.

INTRODUCTION

Bone loss resulting from periodontal disease, trauma, or anatomical factors poses a common therapeutic challenge in the field of periodontology (Donos et al., 2015). To promote bone regeneration in various types of bone defects under different systemic conditions, a range of bone grafts, bone substitutes, biomaterials, or combined regenerative procedures have been employed. Guided Bone Regeneration (GBR) scaffolds, which provide a three-dimensional (3D) structure for cell attachment, growth, and tissue regeneration, have been widely studied for the treatment of periodontal disease (Lim et al., 2019).

One of the common challenges with GBR application is the use of non-biodegradable scaffolds, which do not degrade naturally within the body over time. As a result, a second surgical procedure is often required to remove the scaffold once bone regeneration is complete. After scaffold removal, the site becomes exposed, creating a favourable environment for bacterial colonisation and an increased risk of infection. This bacterial colonisation can hinder the natural bone regeneration process by causing inflammation and tissue damage. To address these limitations, biodegradable scaffolds with antibacterial properties have been developed.

These scaffolds aim to reduce the risk of infection, promote a more conducive environment for bone regeneration, and ultimately improve the outcomes of GBR treatments. Biodegradable scaffolds are commercially available; however, the halal status of these commercially available scaffolds remains uncertain, particularly regarding the materials and their source. As tissue engineering for bone regeneration continues to grow, it is crucial that scaffolds meet halal standards for Muslim populations while also reducing the risk of infection.

Prolonged use of antibiotics can increase the risk of systemic side effects, including antibiotic resistance, potentially compromising the success of GBR procedures. A promising approach to overcome this issue is the development of scaffolds loaded with antibiotic nanoparticles, such as metronidazole nanoparticle-loaded (MNP) scaffolds. Previous studies have demonstrated the potential of MNP loaded scaffolds, particularly their ability to provide controlled and sustained drug release at the site of infection, minimising the risks associated with systemic antibiotic use, such as resistance and side effect. For instance, a study by Zayi et al. (2023) developed a fish-derived collagen scaffold incorporated with metronidazole nanoparticles, demonstrating favorable physical characteristics, biodegradability, and swelling ability, which shown potential for their application in periodontal bone regeneration. In this study, we further evaluate the suitability and effectiveness of a collagen-chitosan scaffold loaded with metronidazole nanoparticles for periodontal regeneration, focusing specifically on the biomaterial's *in vivo* biocompatibility and potential toxicity.

MATERIALS AND METHODS

Development of Collagen-Chitosan Scaffold loaded with Metronidazole

The fabrication of collagen-chitosan scaffolds loaded with metronidazole nanoparticles (CC-MNP) followed the protocol outlined in a previous study. Certified halal fish collagen derived from Tilapia mossambica (Eva Chemicals, Kuala Lumpur, Malaysia) was utilised. A 30:70 collagen-to-chitosan ratio was prepared by dissolving the materials in a 1% glacial acetic acid solution (w/v). Glycerin (20%) was added as a plasticiser and stirred at room temperature for one hour. Neutralisation was achieved using 5% sodium bicarbonate ($NaHCO_3$), and MNP at concentrations (30 wt%) were incorporated into the mixture. The blend was transferred to 96-well moulds, subjected to slow freezing at temperatures between −20°C and −80°C overnight, and subsequently freeze-dried for 24 hours. The lyophilised scaffolds were crosslinked through dehydrothermal treatment (DHT) at 105°C for 24 hours.

Experimental Design and Procedure

The Sprague-Dawley rat skull defect model was used in this study, with sample size calculated based on the Resource Equation Method by Charan & Kantharia (2013). A total of 18 animals, male Sprague-Dawley rats, approximately eight weeks old and weighing between 250 and 300 grams, were divided into three groups for examination on the 4th weeks post-surgery, as shown in **Table 1.** In total, 18 animals were allocated across three groups, inclusive of a 20% attrition rate.

The study design involved three groups, each to be evaluated at 4 weeks post-surgery:

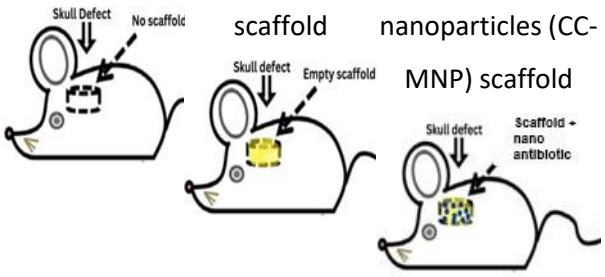
Group A: Rats with skull defects left untreated, serving as the control group to evaluate the natural healing process without any scaffold.

Group B: Rats with skull defects implanted with a collagen-chitosan (CC) scaffold. This group was used to assess the potential of a biodegradable scaffold for promoting bone regeneration without the addition of metronidazole nanoparticles.

Group C: Rats with skull defects implanted with a collagen-chitosan scaffold loaded with metronidazole nanoparticles (CC-MNP). This group was included to evaluate the combined effects of the scaffold and the localized antibiotic delivery system for enhanced bone regeneration and infection prevention.

Table 1: Study design

Groups	A	B	C
(n = 6)	Rats' skull defect without any scaffold implantation	Rats' skull defect implanted with collagen-chitosan (CC) scaffold	Rats' skull defect implanted with collagen-chitosan loaded with metronidazole nanoparticles (CC-MNP) scaffold



Anaesthesia and Surgical Procedure

Anesthesia was administered using ketamine (80 mg/kg) and xylazine (10 mg/kg) to ensure deep sedation without pain responses. After shaving and disinfecting the animals' skulls with 10% polyvinylpyrrolidone (PVP), a 4 cm incision was made along the midline of the scalp to expose the skull. A 5 mm diameter defect was drilled into the skull using a trephine bur. A hydrated scaffold was then placed over the defect, and the surgical site was sutured with absorbable sutures according to the protocol by Carlos et al. (2020). Each animal was housed individually with free access to food and water. The procedure is approved by the IIUM Institutional Animal Care and Use Committee (I-ACUC) (IACUC 2023-013).

Post-operative Observation

Rats were observed every 12 hours for the first 48 hours post-surgery and every other day afterwards. The pain was assessed based on guidelines from the University of Michigan's Unit for Laboratory Animal Medicine and the IACUC-IIUM Code of Practice, paying special attention to signs like arching, twitching, and aggression. The surgical wound was examined for signs of infection, including haemorrhage, scabbing, discharge, and swelling (Grant, 2009; Lansdown & Rowe, 2001).

Animal Sacrifice

Euthanasia was performed using CO_2 gas in a chamber pre-filled to a 20-30% concentration, gradually increased to 70-100% to ensure humane termination (Moody et al., 2014). Mortality was confirmed by the absence of vital signs, after which skull samples were fixed in 10% formalin for further examination.

***In vivo* X-ray**

At the end of the 4th week, rats were euthanised and underwent X-ray imaging to assess scaffold efficacy in promoting defect healing. Imaging parameters were set for small animals (mFX-1000, FUJIFILM, Tokyo, Japan) with images focusing on the defect site. Bone regeneration was measured using Image J software, calculating new bone formation as a percentage of the initial defect area:

$$\% \text{ Bone Regeneration} = (\text{Initial ROI area} - \text{Final ROI area}) / (\text{Initial ROI area}) \times 100 \quad (1)$$

Histological Analysis

Following X-ray analysis, tissue samples were processed for histological evaluation. The skull defects were decalcified in 17% EDTA, dehydrated, and embedded in paraffin. Sections approximately 5µm thick were stained with hematoxylin and eosin (H&E) and examined microscopically (Carlos et al., 2020; Ma et al., 2016).

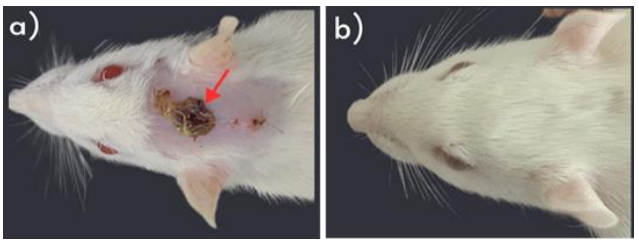
RESULTS AND DISCUSSION

The critical size defect (CSD) is a fundamental concept when creating bone defect models, as it represents a bone defect that cannot heal spontaneously and instead forms fibrous connective tissue. CSDs require the application of a bone graft or substitute material to facilitate healing (Mukherjee et al., 2022; Zain & Hamdan, 2021). The term was first defined by Schmitz and Hollinger (1986) as "the smallest size intraosseous wound in a particular bone and animal species that will not naturally heal during the lifetime of the animal." In rat calvarial defects, a CSD of 5-8 mm is frequently used, allowing for successful regeneration within four weeks with intervention (Schmitz et al., 2018; Spicer et al., 2012; Ma et al., 2016).

This study utilized a 5 mm CSD in the rat calvarium, with no bone regeneration observed within the defect area in the absence of intervention, as shown in Figures 3a and 4a. This observation establishes a clear baseline for evaluating the effectiveness of the biomaterials used in this study.

Post-operative observation & Wound Healing

No behavioural differences were observed between the control and experimental groups, showing effective post-operative care. By week 2, healing varied: the control group displayed redness and swelling, while scaffold-treated groups showed wound closure without inflammation. The accelerated healing in scaffold-treated groups is credited to metronidazole nanoparticles, which acted as antimicrobials, reducing infection and promoting recovery (El-Shanshory et al., 2022). By week 4, the redness had diminished across all groups, and fur regrowth indicated successful skin and epidermal layer healing, signalling to restore normal skin function as depicted in **Figure 1.** Scab formation is crucial in wound healing, controlled bleeding, blocking contamination, and protecting underlying tissues. In the final proliferative phase (lasting from days 4 to 14), new granulation tissue and extracellular matrix formed, supporting skin regeneration (Desmiaty et al., 2024).



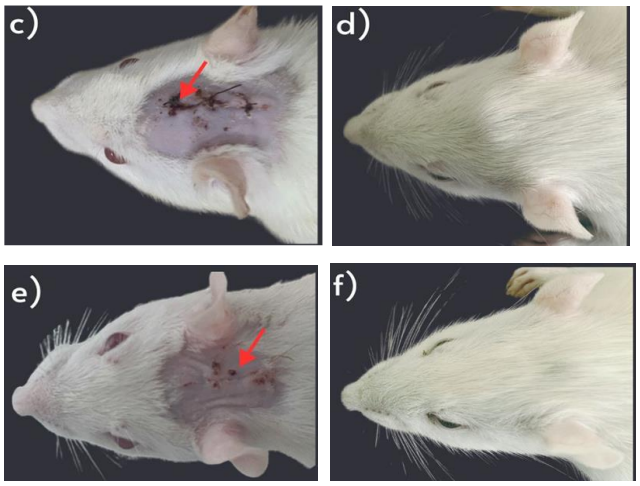


Figure 1: Photographs showing the wound area in all groups; non-implanted (a-b), implanted with CC-scaffold (c-d), and implanted with CC-MNP scaffold (e-f) at the week 2 and week 4.

Table 2: Analysis of Skin Abnormalities

Groups	Week 2	Week 4
Non-implanted	Large scab covering wound (red arrow) Visible inflammation and tissue damage Slow/incomplete healing	- Wound mostly healed - No scab visible - Fur regrowth observed in the wound area
Implanted with CC scaffold	- Partial wound closure - Smaller scab than non-implanted - - No inflammation	- Complete wound closure - Minimal signs of wound - Fur regrowth observed
Implanted with CC-MNP scaffold	- Wound nearly healed - No scab and inflammation - Accelerated healing compared to other groups	Complete wound closure No scab or inflammation - Fur regrowth observed, suggesting full recovery

Table 2 presents the analysis of skin abnormalities at weeks 2 and 4. At week 2, the non-implanted group displayed a large scab covering the wound with visible inflammation and slow, incomplete healing. In contrast, rats implanted with the CC scaffold showed partial wound closure and smaller scabs with no inflammation. The CC-MNP scaffold group exhibited the most advanced healing, with nearly healed wounds and no scab or inflammation. By week 4, the control group showed minimal scab presence, with fur regrowth indicating that the wound was mostly healed. The CC scaffold group achieved complete wound closure, with minimal signs of a wound, and fur regrowth observed. The CC-MNP scaffold group demonstrated complete wound closure, no scab or inflammation, and fur regrowth, suggesting full recovery.

Fur regrowth across all groups indicated significant healing, with the CC-MNP scaffold group demonstrating the fastest recovery, especially at week 2. This improvement is attributed to the metronidazole nanoparticles, which functioned as antimicrobials, inhibiting microbial growth and promoting an environment conducive to tissue regeneration. These findings are consistent with previous studies where metronidazole-loaded nanofibrous scaffolds enhanced wound healing by reducing microbial activity and supporting granulation tissue formation (El-Shanshory et al., 2022), as depicted in Figure 1e. In contrast, the non-implanted control group exhibited thicker scabs and residual debris, characteristic of early-phase wound healing (Choudhary et al., 2024), as shown in Figure 1a.

Radiological Observation

The study assessed the percentage of bone regeneration under various conditions, as illustrated in **Figure 2**. The control group without scaffold implantation exhibited minimal bone regeneration (16.79% ± 2.99), consistent with previous research, which suggests that natural healing is limited without biomaterial support (Togari et al., 2012). The defect in the control group remained largely unhealed, highlighting the body's limitations in repairing large bone defects without structural support. By contrast, groups receiving scaffold implants showed significantly improved outcomes, underscoring the necessity of a structural matrix for effective tissue regeneration (Daei-farshbaf et al., 2014; Hatakeyama et al., 2013; Kashte et al., 2021). The CC scaffold group achieved nearly complete regeneration (97.45% ± 0.51), indicating that even a simple scaffold framework can support the natural healing process by providing a structure for cellular infiltration and tissue development. Prior studies support that biodegradable scaffolds facilitate bone growth and defect closure (Suvarnapathaki et al., 2022). Additionally, the CC-MNP scaffold group demonstrated nearly full bone regeneration (99.08% ± 0.76), highlighting the role of bioactive nanoparticles in enhancing healing. **Figure 3** presents X-ray images of the bone defects. The control group's defect area remained largely unhealed, while the CC scaffold and CC-MNP scaffold groups showed

progressive bone formation, filling the entire defect area in the CC-MNP group. **Figure 4** shows ROI (Region of Interest) images, visually confirming these differences, with the CC-MNP scaffold group demonstrating near-total defect closure. The enhanced osteogenesis observed in the CC-MNP scaffolds likely due to the nanoparticles influencing cellular behaviours such as proliferation and differentiation, thus providing both mechanical support and the potential for therapeutic agent delivery.

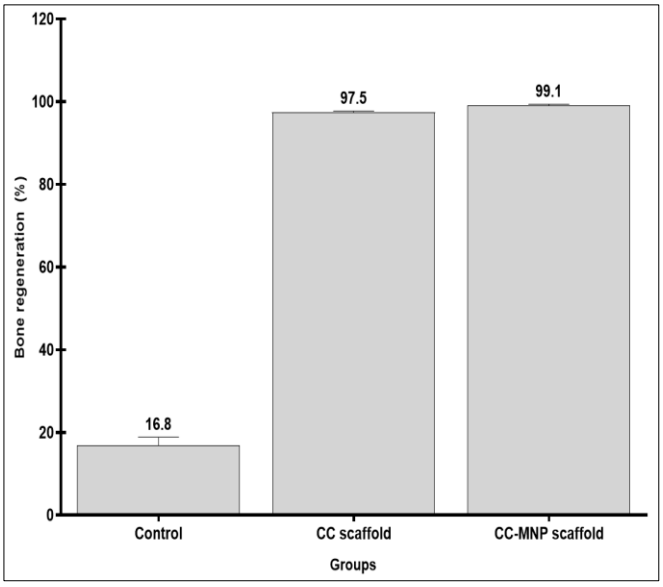


Figure 2: Percentage of bone regeneration in the rat skull defect area for the control group (no scaffold implantation) and groups implanted with scaffolds, without and with metronidazole (CC empty and CC-MNP scaffolds).

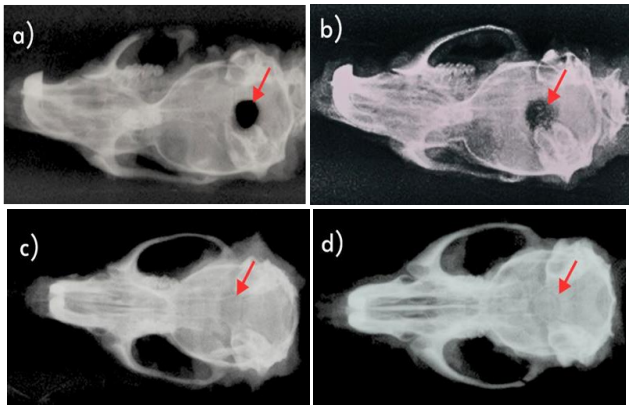


Figure 3: Error signs highlight the X-ray images of the defect area. (a) Baseline of the bone defect prior to treatment, (b) X-ray of the bone defect in a rat without any implantation, (c) newly formed bone at the defect closure in rats implanted with CC scaffold, and (d) newly formed bone at the defect closure in rats implanted with the CC-MNP scaffold

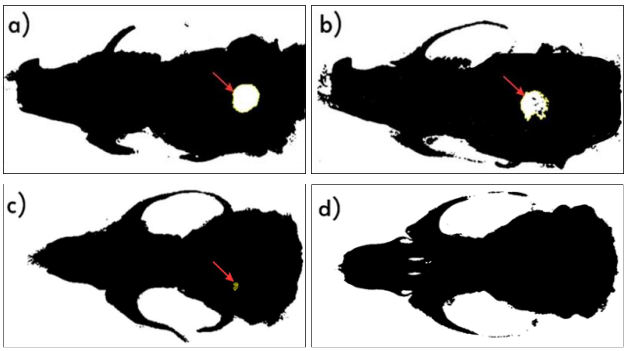


Figure 4: Error signs highlight the ROI images of the defect area using ImageJ. (a) Baseline of the bone defect, (b) the rat without any implantation, (c) newly formed bone at defect closure in rats implanted with an CC scaffold and (d) CC-MNP scaffold

Histological analysis

The histological analysis in **Figures 5** and **6** illustrates bone regeneration across experimental groups. Rats with CC-MNP scaffolds, CC scaffolds, and without any scaffold were examined using haematoxylin and eosin (H&E) staining. Comparing baseline, control, CC scaffold, and CC-MNP scaffold groups highlighted the scaffolds' role in enhancing bone healing. In the baseline **(Figure 5a),** no new bone formed, and the defect remained largely unfilled, marked only by old bone (OB) on each side. By the 4th week, the control group **(Figure 5b)** showed fibrous tissue (FT) but no new bone (NB), consistent with X-ray findings and prior studies (Ono et al., 2014; Sun et al., 2018). This result aligns with earlier findings where natural healing without scaffolds was limited to soft tissue infiltration rather than bone regeneration (Chen et al., 2013), indicating that critical-size defects require scaffolds or bioactive agents for effective healing (Zhou & Lee, 2016).

In contrast, both scaffold-treated groups demonstrated notable bone formation. The CC scaffold provided a framework for new bone growth, facilitating the natural healing process by offering structural support and cellular infiltration space, as shown in previous studies (Sato et al., 2020). By week four, the CC-MNP scaffold group exhibited a more organised, dense new bone structure **(Figure 5d),** compared to the less organised bone in the Cc scaffold group **(Figure 5c).** Histological images showed NB formation, with a well-organised matrix and increased cell density. OB integrated seamlessly with NB, indicating active remodelling, similar to prior studies (Farazin & Mahjoubi, 2024).

Histological images at four weeks post-implantation

(Figure 6) further confirm these findings, revealing evidence of active remodelling. This is consistent with studies involving poly (L-lactic acid)-hydroxyapatite-gelatin scaffolds that similarly promoted osteogenesis and remodelling through osteoblast proliferation and osteoid matrix formation (Kashte et al., 2021). Previous studies have shown bacterial infections can hinder bone repair due to inflammation, often requiring prolonged antibiotic treatment or multiple surgeries. The nano-antibiotics in the scaffold may have reduced bacterial colonisation at the defect site, creating a favourable environment for bone healing (Farazin & Mahjoubi, 2024). The bioactive nanoparticles in the scaffold promoted mineralised matrix formation, accelerating regeneration and producing superior bone formation (Dasari et al., 2022).

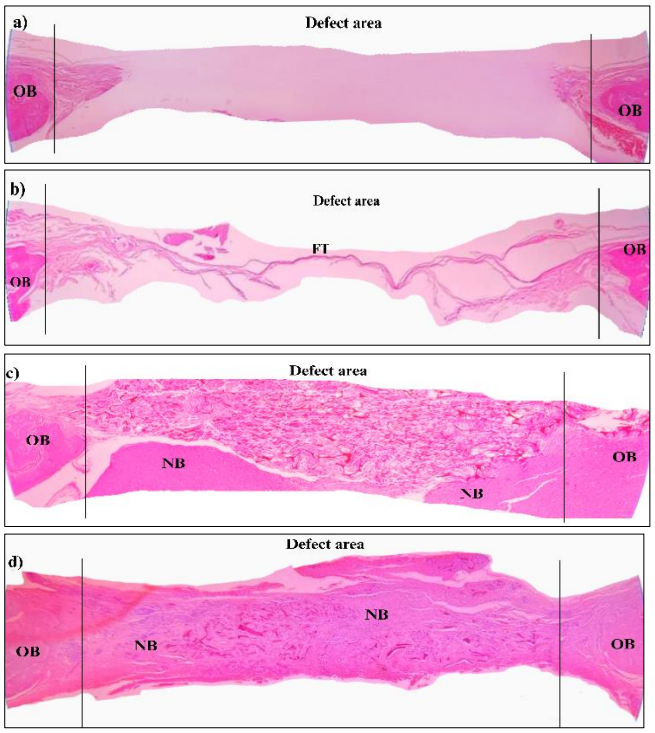


Figure 5: Histological images showing bone regeneration in rat skull defect areas under different conditions (a) shows the control group at baseline (0 weeks), with the presence of old bone (OB) and fibrous tissue (FT). (b) shows the same control group at 4 weeks, highlighting OB and FT. (c) displays rats implanted with a CC scaffold at 4 weeks, showing the presence of old bone (OB) and new bone (NB) in the defect area. (d) shows rats implanted with a CC-MNP scaffold at 4 weeks, demonstrating extensive new bone (NB) formation alongside old bone (OB) in the defect area (4x magnification).

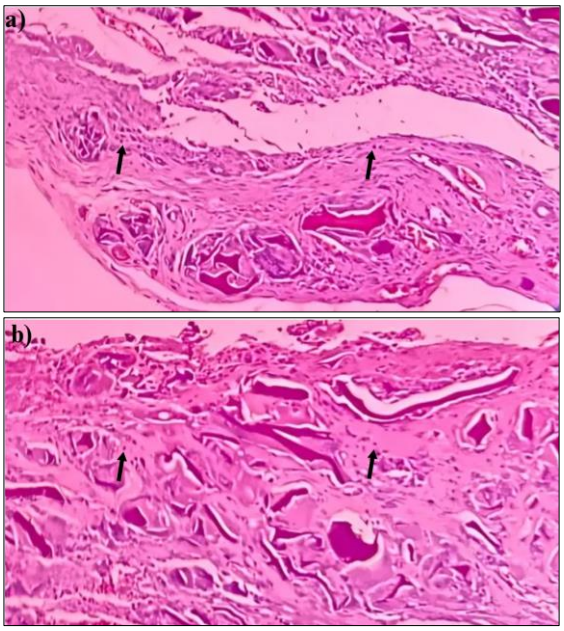


Figure 6: Histological images of rat bone sections at 4 weeks post-implantation. (a) CC scaffold group; (b) CC-MNP scaffold group. Arrows indicate osteocytes within the bone matrix at 100x magnification.

CONCLUSION

The study highlighted significant bone healing improvements when using CC-MNP scaffolds compared to CC scaffolds. Although X-rays showed no major difference in bone healing between scaffold types, detailed analysis indicated denser and more organised bone growth in MNP-loaded scaffolds, suggesting that MNP supports enhanced cellular activity and bone quality. Minimal bone growth in the non-scaffold group underscores the importance of scaffolds in repairing larger bone defects. These findings suggest that the incorporation of MNP into scaffolds can improve structural integrity and cellular response, making MNP-loaded scaffolds a promising option for bone tissue repair.

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REVIEW ARTICLE

Phytochemicals Constituents of Malay Traditional Medicinal Plants as Potential Remedies for Breast Cancer: A Review

Raja Siti Syazana Raja Soh[1], Mohammad Syaiful Bahari Abdull Rasad [1,*]

[1]Department of Biomedical Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Malay traditional medicinal plants; phytochemical; anti-breast cancer; remedies

ABSTRACT

Background: Breast cancer is the most prominent cancer in Malaysia, followed by lung, nasopharyngeal, colorectal, and liver cancers. Data from the World Health Organisation (2020) support the nation's high incidence of breast cancer. Studies have shown that phytochemicals, or secondary plant metabolites, have a promising future as adjuvants for a number of current medicines. The aim of this research is to provide an overview of the phytochemical components identified in traditional Malay medicinal plants that may be used to treat breast cancer in Malaysian women. **Methods**: The most prominent phytochemicals found Malay traditional medicinal plants with anticancer activities against breast cancer are identified and compiled using a scoping review technique. Scopus, ScienceDirect, and PubMed were the three databases used in the study to search for papers that fit the inclusion and exclusion criteria. The screening approach concentrates on English papers from January 2015 to April 2023, utilising keywords such as the scientific names of the 45 identified plants, "phytochemical," and "breast cancer". **Results**: Out of 702 screened articles, only 23 met the predetermined criteria and were included in the study. The analysis reveals that 13 Malay traditional medicinal plants show positive outcomes against breast cancer, primarily due to the presence of phenolic compounds in their extract. **Conclusions**: The study identifies 13 out of 45 selected Malay traditional medicinal plants that exhibit positive outcomes against breast cancer. These plants contain significant phytochemicals such as phenolic compounds, alkaloids, terpenoids, and others, highlighting their potential as therapeutic agents. This comprehensive review is expected to assist researchers in embarking on pre-clinical studies focused on potential Malay traditional plants for breast cancer treatment and further elucidating the pharmacology of these phytomedicines.

INTRODUCTION

According to the World Health Organization, breast cancer recorded the highest number of new cases in 2020 at approximately 2.26 million cases, followed by lung, colon and rectum cancer and prostate cancer. In addition, breast cancer statistics worldwide also indicate quite a high number of cancer mortality rates in 2020. Additionally, breast cancer is the most prevalent type of cancer in Malaysia, followed by colorectal, lung, nasopharyngeal, and liver cancers (WHO, 2020). One of the leading causes of mortality for cancer-stricken Malaysian women is breast cancer, followed by cervical cancer. Various types of therapies, such as chemotherapy, immunotherapy, and radiation therapy, are used in treating cancer accompanied by severe side effects for the patients who undergo it (Iqbal et al., 2017). Due to its known long-term adverse effects on the patient, a new approach was made for a safer chemotherapeutic design.

Iqbal et al. (2017) expressed that plant-derived products are eco-friendly, safer, affordable, and less hazardous compared to allopathic medicine or mainstream medicine. Research into phytochemicals, especially phenolic compounds and flavonoids, reveals their potential in combating oxidative stress and preventing cancer, underscoring the importance of exploring these natural compounds for safer, more effective breast cancer therapiesas reported by Mainasara et al. (2018).Several published articles also suggested the potential of phenolic compounds as antioxidants against oxidative stress disease in humans (Kikuchi et al., 2019; Luna-Guevara et al., 2018; Younas et al., 2018). For instance, a review by Younas et al. (2018) that focuses on phytochemical compounds, especially the flavonoid groups, gives a vital knowledge of the mechanisms for each compound in breast cancer chemoprevention. Phytochemicals such as curcumin, resveratrol, epigallocatechin gallate (ECGCG), silibinin, benzyl isothiocyanate, genistein, kaempferol and quercetin have been shown to restrict breast cancer in a few mechanisms of action.

A compilation of 45 Malay traditional medicinal plants is listed in supplementary materials. The list is mainly

* *Corresponding author.*
E-mail address: syaiful@iium.edu.my

extracted from Abuga et al. (2022). The list was adopted for a more thorough scoping assessment in this study on the effectiveness of anticancer against breast cancer. Zakaria (2010) mentioned that Malay traditional medicine passed on information about treatments and supplies verbally and via memory. As a result, knowledge of Malay traditional medicine that has high nutritional and health benefits to humans must be documented to ensure its validity and preservation (Zakaria, 2010).

The objective of this review is to assess the anticancer potential of specific phytochemicals found in these plants through a comprehensive analysis of peer-reviewed scientific literature. Compiling these phytochemicals provides valuable insights into their potential anticancer properties against breast cancer.

MATERIALS AND METHODS

Study design

This scoping review was accomplished based on the Population, Intervention, Comparison, Outcomes (PICO) design, as shown in Table 1, which was used to compose the eligibility criteria in the scoping review and as a framework to develop research questions. In addition, a flow diagram for Preferred Reporting Items for Systematic and Meta-analyses extension for Scoping Review, PRISMA-ScR by Tricco et al. (2018) was adopted, which consists of identification, screening, eligibility, and the included article (Figure 1).

Table 1: PICO framework

Criteria	Determinants
Problem	Breast cancer and Malay traditional medicinal plants.
Interest	Anticancer activity and phytochemicals.
Comparison	Not applicable.
Outcomes	**Primary outcome**: Identification of Malay traditional medicinal plants as anti-breast cancer. **Secondary outcome**: List of phytochemicals in selected Malay traditional medicinal plants.

Identifying the research question

The review questions were: (1) Which plants among the published list of 45 Malay traditional medicinal plants from Abuga et al. 2022 have sufficient published reports of anticancer activity against breast cancer? (2) What are the phytochemicals found in the selected plants that have breast anticancer?

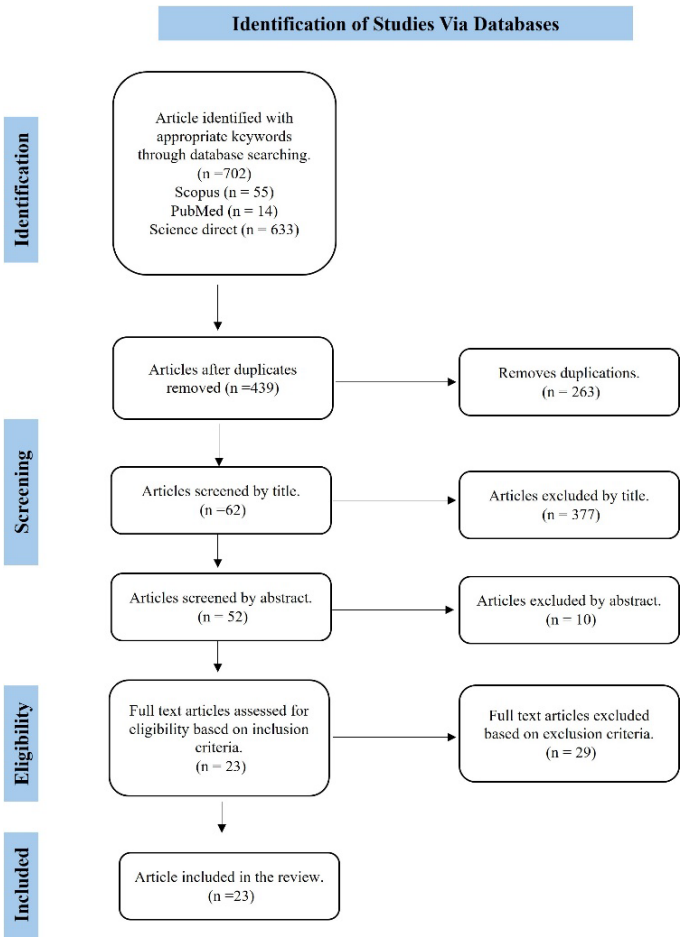

Figure 1: Flow diagram of study selection

Search strategy

Scopus, Science Direct, and PubMed databases wereutilized and screened for the related articles that matched the keywords and studies reported from December 2022 until April 2023. The keywords used were "name of scientific plants", "phytochemical" and "breast cancer". The Boolean terms 'AND' are used to combine the keywords. For instance, "*Adenosterma viscosum*" AND "Breast cancer" AND "phytochemical".

Data selection and collection

Inclusion and exclusion criteria in selecting the article throughout the research project are listed in Table 2.

Charting the data

The findings are summarized based on the authors' names, publication year, plant names, plant parts, extraction solvent, extraction method, *in vivo* or *in vitro* studies, pure compounds or crude extracts, specific phytochemical compounds, human breast cell lines used, and positive outcomes on breast cancer as shown in Table 3.

Table 2: Inclusion and exclusion criteria

Inclusion	Exclusion
• Article from 2015 onwards. • The language uses English. • Full text accessible. • Qualitative and quantitative study for all breast cancer types, pure compound, and crude extract. • Experimental study for both *in vivo* and *in vitro.* • Index paper.	• Review study, discussion, book chapter, survey, questionnaire and others. • Chemically synthesized phytochemical.

RESULTS

Overview of identified articles

Initially, 702 items matching the criteria were found in three databases: 55 articles in Scopus, 14 in PubMed, and 633 in Science Direct, as shown in Figure 1. The articles were subsequently uploaded into Mendeley to be reviewed and duplicated between the three databases removed. 263 duplicate articles were deleted, and the remaining 439 were screened further based on their title. Following the removal of 377 articles, 62 articles were reviewed based on their abstracts. After examining the abstract, 52 papers were left. To choose the 23 included articles, full-text accessibility and eligibility based on inclusion and exclusion criteria were utilized.

Phytochemical as anticancer

A list of phytochemicals from 13 selected Malay traditional medicinal plants was tabulated in Table 4 to achieve the primary objective of this study.

Table 4: List of phytochemicals found in Malay traditional medicinal plants that exhibited anticancer properties against the breast.

Scientific name of plants	Phytochemicals
Allium sativum	• Thiosulfonate • Flavonoids • Terpenoids • Alkaloids • Allicin
Cinnamomum verum	• Benzoic acid, cinnamic acid, flavonoid • Oxygenated monoterpenes • Sesquiterpene hydrocarbons • Oxygenated sesquiterpenes • Phenylpropanoids
Curcuma longa	• Phenolic, flavonoid, condensed tannin, hydrolysable tannin • Curcumin, quercetin, epicatechin
Lagerstroemia speciosa	• Flavonoids • (Gallic acid, quercetin)
Momordica charantia	• 3β,7β,25-trihydroxycucurbita-5,23(E)-dien-19-al (TCD) • 10% alkaloid • 4% phenols • 7% tannins • 1% flavonoid • 6% saponin
Murraya koenigii	• Alkaloids • Triterpenoids • Flavonoids • Tannins • Phenols • Mahanine (MH)
Ocimum basilicum	• Linalool • Eugenol • Geraniol • Methyl-chavicol • Phenolics • Flavonoids
Phyllanthus emblica	• Alkaloids • Phenol • Flavonoids • Saponins
Psidium guajava	• Guajadial • Triterpenoids • Flavonoids • Psidial A
Punica granatum	• Octadecatrienoic acid • Sterols • Steroids (17-α Estradiol, tocol, γ-tocopherol) • Terpenes, Sesquiterpenes • Polyphenolic, flavonoids, tannic acid and gallic acid derivatives • Fatty acid (punicic acid highest)
Quercus infectoria	• Terpenoids • Phenols • Alkaloids
Tamarindus indica	• Phenols (flavonoid)
Zingiber officinale	• 6-shagoal • [10]-gingerol • [8]-gingerol • [6]-gingerol

Table 3: Extraction data from the accepted article that match the inclusion criteria (n=23).

Authors' name & year	Name plants	Parts of plants	Extraction solvent	Extraction method	*In vivo/ in vitro*	Pure compound/ crude extract	Phytochemical compound	Human breast cell line/ animal model	Positive outcome
(Bai et al., 2016)	*Momordica charantia*	Whole parts	-	-	*In vitro*	Pure	3β,7β,25-trihydroxycucurbita-5,23(E)-dien-19-al (TCD)	• MCF-7 • MDA-MB-231	• Suppress the antiproliferative of breast cancer lines. • HDAC inhibition. • Induce apoptosis through ROS generation. • Downregulation of Akt-NF-kB signalling • Activation of p53 phosphorylation
(Kilcar et al., 2020)	*Momordica charantia*	Seeds	80% ethanol	Reflux extraction	*In vitro*	Crude	10% alkaloid 4% phenols 7% tannins 1% flavonoid 6% saponin	• MCF-7 (ER+) • MDA-MB-231 (ER-)	• Incubation of cells with bitter melon extract (BME) raised paclitaxel (PAC) IC_{50} value.
(Al-Zereini et al., 2022)	*Cinnamomum verum*	Bark	Distilled water	Hydro-distilled	*In vitro*	Crude essential oils (EO)	Oxygenated monoterpenes Sesquiterpene hydrocarbons Oxygenated sesquiterpenes Phenylpropanoid Others	• MDA-MB-231	• Inhibit tumour cells proliferation with IC_{50} 0.14µl/mL
(Guneidy et al., 2022)	*Curcuma longa* *Zingiber officinale* *Syzygium aromaticum* *Tamarindus indica* *Cinnamomum verum* *Punica granatum*	Rhizome Rhizome Seed Seed Bark Seed	70% of solvent (acetone / ethanol)		*In vitro*	Crude	Phenolic, flavonoid, condensed tannin, hydrolysable tannin Benzoic acid, cinnamic acid, flavonoid Phenolic, flavonoid, condensed tannin, hydrolysable tannin, anthocyanins	• MCF-7	• Only *Tamarindus indica* and *Cinnamomum verum* showed cytotoxicity effects.

(Ali et al., 2022)	*Zingiber officinale Rosc*	Rhizomes	Petroleum ether (PE) and chloroform: methanol (CM)	maceration	*In vitro*	Pure	6-gingerol 6-shogaol	• MCF-7	• Cytotoxicity effect.
(Meysami et al., 2021)	*Zingiber officinale Roscoe*	Rhizomes	70% ethanol	maceration	*In vivo*	Pure	6- gingerol	• Mice, inject with 4T1	• Downregulated of specific oncogenes (MMP-13)
(Lucci et al., 2015)	*Punica granatum*	Whole seed	Absolute ethanol	-	*In vitro*	Crude	Phenolic compound Fatty acid (punicic acid highest)	• MCF-7	• Promising antiproliferative activity with IC_{50} value 26.5 μg/ml.
(Nadaf et al., 2020)	*Murraya koenigii*	Seed	Methanol	Soxhlet	*In vitro*	Crude	Alkaloids Triterpenoids Flavonoids Tannins Phenols	• MCF-7	• Cell viability significantly reduced compared to control
(Bazioli et al., 2020)	*Psidium guajava*	leaves	Dichloromethane	-	*In vitro* *In vivo*- hollow fiber assay	Crude	Flavonoids Triterpenoids Phenolics Meroterpenoids-Guajadial (49%) Psidial A	• MCF-7 • MCF-7 BUS • Swiss female mice, Balb-C female mice, Wistar female mice	• Successive fractionation shows potent antiproliferative activity on MCF-7, MVF-7 BUS • Tumour inhibition through estrogen receptors (*in vivo)*
(Alkhateeb et al., 2021)	*Ocimum basilicum*	Fresh blossoms	Water	Aqueous extract	*In vitro*	Crude	Phenolic Flavonoids	• MCF-7	• Restrains development and multiplication of breast cancer through apoptotic.
(Durgawale & Datkhile, 2016)	*Punica granatum*	Flowers	Methanol	Maceration	*In vitro*	Crude	Polyphenolic Flavonoids Tannic acid and gallic acid derivatives	• MCF-7	• Positive anti-cancer activity on MTT anti proliferative assay
(Wan Yusof & Abdullah, 2020)	*Quercus infectoria*	Galls	n-hexane ethyl acetate methanol	maceration	*In vitro*	Crude	Tannins Alkaloids Saponin Terpenes Flavonoids Glycosides Phenolic compound	• MCF-7 • MDA-MB-231	• High toxicity for MCF-7 on ethyl acetate extract with the lowest IC_{50} value. • Methanolic extract of *Quercus infectoria* has high cytotoxicity on MDA-MB-231.

(Sai Saraswathi, Rajaguru, et al., 2017)	*Lagerstroemia speciosa*	Leaves	Acetone Methanolic	Soxhlet	*In vitro*	Crude	Gallic acid (check use HPTLC) Flavonoids	• MCF-7	• Acetone extract displayed significant cytotoxicity activity on breast cells.
(Yang et al., 2020)	*Curcuma longaz*	Rhizomes	Ethanol (80%)	Ultrasonic assisted extraction (UAE) Conventional solvent extraction (CSE)	*In vitro*	Crude	Phenolic compounds (Curcumin, quercetin, epicatechin, etc.)	• MCF-7 • MDA-MB-231	• UAE showed higher phenolic compound and cytotoxicity activity on breast cancer lines.
(Sai Saraswathi, Saravanan, et al., 2017)	*Lagerstroemia speciosa*	Leaves	Methanolic	Soxhlet	*In vitro*	Pure Crude	Quercetin (isolated using HPLC)	• MCF-7	• Pure compound quercetin showed higher cytotoxicity and cell viability than methanolic crude extract.
Elgndi et al., 2017	*Ocimum basilicum*	Leaves	Carbon dioxide	Supercritical fluid extraction (SFE) Hydro distillation (essential oil)	*In vitro*	Crude	Linalool Eugenol Geraniol Methyl-chavicol	• MDA-MB-453	• Antioxidant and antiproliferative activity of EO and CO_2 extract but significantly higher antioxidant activity in EO.
(Das et al., 2019)	*Murraya koenigii*	Leaves	Methanol	Cold maceration	*In vitro* *In vivo*	Pure	Mahanine (isolated using HPLC)	• MCF-7 • MDA-MB-231 • N-methyl-N-nitrosourea (MNU) induced rat	• Reduce proliferation through apoptosis both on MCF-7 and MDA-MB-231. • Reduced mammary tumour weight in MNU induced rat.
(Zheng et al., 2018)	*Phyllanthus acidus*	Stems and roots	Methanol	Reflux	*In vitro*	Pure	Cleistanthane diterpenoids; phyllaciduloids A-D	• MCF-7	• No obvious activity at a concentration of 40μM.
(Talib, 2017)	*Allium sativum*	Bulbs	Aqueous	-	*In vivo*	Crude	Thiosulfonate Flavonoids Terpenoids Alkaloids Allicin	• Balb/c female mice	• 60% undetectable tumours were reported for mice treated with garlic extract, but the combination of garlic and lemon was reported for 80%.

(Mónica et al., 2020)	*Punica granatum*	Seeds and peels	Ethanol Chloroform Hexane	-	*In vitro*	Crude	Terpenes, Sesquiterpenes Flavonoids Steroid	• MDA-MB-231	• Seed extract showed cytotoxicity activity.
(Patel et al., 2022)	*Phyllanthus emblica*	Fruits	Chloroform Ethyl acetate Methanol Ethanol Distilled water	Series extraction method	*In vitro*	Crude	Alkaloids Phenol Flavonoids Saponins	• MCF-7	• Aqueous extract reported decreased cell viability as concentration increased.
(Mandal et al., 2015)	*Punica granatum*	Seed oil and aqueous extract (PE emulsion)	-	-	*In vivo*	Crude	Octadecatrienoic acid Sterols Steroids (17-α Estradiol, tocol, y-tocopherol)	• 7,12-dimethylbenz[α]anthracene (DMBA) induced rats	• Decrease ER- α and ER- β expression in mammary tumour.
(Bernard et al., 2017)	*Zingiber officinale*		-	-	*In vitro*	Pure	[10]-gingerol [8]-gingerol [6]-gingerol	• MDA-MB-231 • MDA-MB-468	• Inhibitory of TNBC growth.

Notes: CM, chloroform methanol; DMBA, 7,12-dimethylbenz[α]anthracene; ECGC, epigallocatechin gallate; ER, estrogen receptor; HT116, colon adenocarcinoma; HeLa, human cervical cancer cell line; HepG2, human hepatoma; HPLC, high performance liquid chromatography; HT29, colon adenocarcinoma; MH, mahanine; MCF-7, human mammary cancer cells; MDA-MB-231, triple-negative breast cancer cell line; MNU, N-methyl-N-nitrosourea; PE, petroleum ether.

In earlier studies, it was discovered that the traditional Malay remedies reported had antioxidant and anticancer characteristics that extended beyond breast cancer. For instance, mahanine (MH) a compound extracted from *Murraya koenigii* has lately gained attention as a possible candidate to prevent several cancers, including leukemia, pancreas, cervix, lungs, colorectal, prostate, and glioma (Das et al., 2019).

Besides that, the cytotoxicity impact of C*urcuma longa* extract on a few cancer cell lines (MCF7, MDA-MB-231, HCT116, HT29, HepG2, HeLa) was also reported by Yang et al. (2020) research, demonstrating its anticancer properties. Meanwhile, Monica et al. (2020) studies demonstrated *Punica granatum's* anticancer properties as the ethanolic seed extract had a cytotoxic effect on the cancer cell lines MDA-MB231 and HT29. Furthermore, Durgawale & Datkhile (2016) revealed that the methanolic flower extract of *Punica granatum* had anti-proliferative effects against all three cancer cell lines they studied, which were derived from breast, liver, and cervical cancer types. According to Ali et al. (2022), the HT29, HCT116, and MCF-7 cancer cell lines were all sensitive to ginger rhizome petroleum ether (PE) and chloroform; methanol (CM) extracts, with CM extract having the most significant cytotoxicity effect.

Both *Curcuma longa,* and *Punica granatum* extract consist of phenolic compounds that act as anticancer on MCF-7 cell lines. However, secondary metabolites in *Curcuma longa* extract, curcumin, also have anticancer activity, as reported by Yang et al. (2020). On the other hand, a pure extract of mahanine from *Murraya koenigii* has a significant effect as an anticancer in both *in vitro* and *in vivo*. A pure extract from the rhizome of *Zingiber officinale* also proved its anticancer activity due to the presence of 6-gingerol and 6-shagoal.

In summary, extracts from *Curcuma longa, Punica granatum, Murraya koenigii,* and *Zingiber officinale* contain phenolic compounds and secondary metabolites with notable anticancer effects on various human cancer cell lines, including MCF-7. Curcumin in *Curcuma longa*, mahanine in *Murraya koenigii*, and 6-gingerol and 6-shogaol in *Zingiber officinale* have each shown potent anticancer properties in both *in vitro* and *in vivo* studies. Further research into these phytochemicals, especially their effects on specific cancer types, could enhance drug development efforts by identifying promising candidates for targeted anticancer therapies.

Plant extract effect on breast cancer

According to Table 3, *Punica granatum* was the plant that was mentioned in relation to breast cancer the most often out of the 23 papers that were accepted (Lucci et al., 2021; Durgawale & Datkhile, 2016; Monica et al., 2020; Mandal et al., 2015). In all breast cancer investigations, anti-proliferative activity was shown to be promising on MCF-7 (Lucci et al., 2021), anti-proliferative in 7,12-dimethylbenz[α]anthracene (DMBA) rats (Mandal et al., 2015), and seed extract showed cytotoxicity impact (Monica et al., 2020; Durgawale & Datkhile, 2016). However, *Zingiber officinale,* the second-most frequently suggested plant, reported a pure product of 6-gingerol, and 6-shagoal from rhizome extract (Ali et al., 2022). The efficacy of [10]-gingerol, [8]-gingerol, and [6]-gingerol to suppress the growth of human and mouse mammary cancer cells was compared by Bernard et al. (2017).

In addition, according to extraction data, all plants were evaluated on human cancer cell lines aside from *Psidium guajava* and *Murraya koenigii*, which were examined on both cell lines and animal models. According to Bazioli et al. (2020), *Psidium guajava* (guajadial, terpenoid, polyphenol) has substantial antiproliferative activity on MCF-7, MCF-7 BUS, and tumor inhibition via estrogen receptors. It also exhibited beneficial results in both *in vivo* and *in vitro* experiments. Due to polyphenolic components and terpenoids in the crude extract, *Murraya koenigii* methanolic extract also favorably affected MCF-7 (Nadaf et al., 2020). The *in vivo* and *in vitro* results of investigations utilizing the MCF-7, MDA-MB-231, and N-methyl-N-nitrosourea (MNU) rat strains of pure extracted mahanine by HPLC were favorable (Das et al., 2019).

DISCUSSION

Mechanism of action of phytochemicals from various plant extracts

Punica granatum

After an extensive literature review, this study highlights the findings of Mandal et al. (2015), which demonstrated positive outcomes in breast cancer treatment using pomegranate emulsion (PE). The chemical analysis of pomegranate formulation revealed that the lipid phase contained mixed octadecatrienoic acids, sterols, and steroids, particularly 17-α-estradiol, as well as tocol and γ-tocopherol, and the aqueous phase contained caffeic acid, corilagin, ellagic acid, ferulic acid, gallic acid, 5-hydroxymethylfurfural, protocatechuic acid, punicalagin alpha and punicalagin beta. Mandal et al. (2015) proposed that pomegranate emulsion (PE) inhibited cell proliferation, induced apoptosis, upregulated proapoptotic protein Bax, and downregulated antiapoptotic protein Bcl-2 in mammary tumors in DMBA-

initiated rats. These effects were associated with decreased incidence, total burden, and average weight of mammary tumors. Not only that, in Mandal et al. (2015) investigation, the author also looked at the expression of ER-α and ER-β in rats given PE therapy and DMBA-induced mammary tumours.

The findings show that ER-α and ER-β are expressed significantly in mammary tumours eradicated in DMBA control animals. The findings are intriguingly consistent with a prior study that showed that a methanolic extract of pomegranate pericarp (peel) prevented estradiol binding to ER, downregulated the ER-α gene, and decreased the growth and proliferation of ER-positive MCF-7 breast cancer cells (Sreeja et al., 2012).

Additionally, a recent review study from Moga et al. (2021) explored the anticancer mechanism and molecular targets of *Punica granatum*, focusing on the main phenolic chemicals detected in the peels, juice and seeds extract, demonstrating that pomegranates are a possible therapy option for breast cancer. Furthermore, ellagic acid, punicic acid, ellagitannins, anthocyanins and anthocyanidins, flavones, flavonoids, and estrogenic flavonols are the most prominent therapeutically active polyphenols from pomegranates.

Murraya koenigii

Nadaf et al. (2020) concluded that the methanolic extract of Murraya koenigii seeds (MEMS) displayed an antiproliferative impact primarily by inducing apoptosis, which included depolarizing the mitochondrial membrane and activating caspase. It has the antioxidant capacity to demonstrate cytotoxicity by acting as an oxidant scavenger and lowering oxidative stress. Furthermore, it was discovered that MEMS activated caspase activity in a concentration-dependent way. A further dosage form design requires thorough investigation.

On the other hand, mahanine, a pure substance from *Murraya koenigii*, has already demonstrated its promise as a cervical, lung, prostate, and glioma inhibitor (Samanta et al., 2018). Therefore, it piques interest to learn more about its anticancer effects on breast cancer. It was confirmed by Samanta et al. (2016) that administering MH at a dose of 50 mg/kg body weight three times per week for four weeks has the capacity to completely eliminate tumour incidence and mammary tumour volume. The current study's findings from Das et al. (2019) also demonstrated that the naturally occurring carbazole alkaloid MH is highly efficient at lowering breast cancer subtypes independent of cell proliferation through inhibition of breast cancer stem cell (bCSC) population and *in vivo* suppression of mammary tumour burden in MNU-induced breast cancer.

Therefore, the methanolic extract of *Murraya koenigii* seeds (MEMS) shows strong antiproliferative and antioxidant properties by promoting apoptosis and reducing oxidative stress. Additionally, MEMS activates caspase in a concentration-dependent manner, suggesting further investigation into optimized dosage forms. Furthermore, mahanine, a pure compound from *Murraya koenigii*, has shown promise in inhibiting various cancers, including breast cancer. Studies demonstrate that mahanine effectively reduces breast cancer cell populations and tumor burden, emphasizing the potential of *Murraya koenigii* in both its crude and purified forms as an anti-breast cancer agent.

Momordica charantia

Cucurbitane-type triterpenoids, cucurbitane-type triterpene glycosides, phenolic acids, flavonoids, essential oils, fatty acids, amino acids, lectins, sterols, saponin (goyasaponins I, II, and III) constituents, as well as some proteins present in fruits, seeds, roots, leaves, and vines, are the main chemical components of bitter melon that give it biological activity (Dandawate et al., 2016).

The triterpenoid 3β,7β,25-trihydroxycucurbita-5,23(E)-dien-19-al (TCD) inhibited the growth of MCF-7 and MDA-MB-231 breast cancer cells in a PPARγ-independent manner, with IC_{50} values at 72 hours of 19 and 23 M, respectively. TCD-induced cell apoptosis, along with a variety of biological modifications, such as the inhibition of histone deacetylase protein expression, downregulation of Akt-NF-B signalling, upregulation of p38 mitogen-activated protein kinase and p53, and cytoprotective autophagy (Bai et al., 2016). Moreover, a study by Sur et al. (2020) recorded the bitter melon as a promising cancer prevention and therapeutic agent for several types of cancer. The therapeutic effect of the phytochemicals extracted from the bitter melon was recorded in Table 5. *Punica granatum* was discussed because it was frequently mentioned in four of 23 accepted articles. Meanwhile, pure compounds from *Murraya koenigii* and *Momordica charantia* were also discussed. However, the other ten plants, whose mechanisms of action were not discussed, also have potential remedies for breast cancer.

CONCLUSION

The study indicates that several Malay traditional medicinal plants have anti-breast cancer effects. *Allium sativum, Cinnamomum verum, Curcuma longa, Lagerstroemia speciosa, Momordica charantia, Murraya koenigii, Ocimum basilicum, Phyllanthus emblica, Psidium*

Table 5: Bitter melon compound therapeutic effect on breast cancer (Source: Sur et al. 2020)

Cancer	Bitter melon extract/compound	Therapeutic effect
Breast	Water extract of fruit, dried extract and isolated compounds 3β,7β,25-trihydroxycucurbita-5,23(E)-dien-19-al (TCD), eleostearic acid, RNase MC2, MAP30	Inhibited breast cancer cells growth, induced apoptosis and autophagy Inhibited syngenic tumor, xenograft tumor and spontaneous mammary tumorigenesis in SHN virgin mice

guajava, Punica granatum, Quercus infectoria, Tamarindus indica, and *Zingiber officinale* are among the notable plants. This study also discovered that these 13 Malay traditional medicinal plants contain a variety of phytochemicals, including mahanine (MH), guajadial, 6-gingerol, 6-shogaol, and other polyphenolic compounds, alkaloids, terpenoids, and sterols. The anticancer capabilities of these substances have been proven in earlier studies using breast cancer cell lines and animal models.

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REVIEW ARTICLE

The Impact of Electromagnetic Fields on Female Fertility: A Scoping Review of Research Designs and Study Limitations

Suzanah Abdul Rahman[1*], Nur Ilma A'isyah Azrul[1], Zafri Azran Abdul Majid[2], Wan Azdie Mohd. Abu Bakar[3]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia (IIUM), Kuantan, Pahang, Malaysia [2]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia (IIUM), Kuantan, Pahang, Malaysia
[3]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia (IIUM), Kuantan, Pahang, Malaysia

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ABSTRACT

Background: The modern lifestyle has heightened exposure risks to various forms of electromagnetic fields (EMFs). Exposure to EMF has been shown to impair cellular homeostasis, endocrine function, reproductive function, and foetal development in animal models. To assess the reproductive risks of EMFs in human, it is crucial to examine the research methodology used, in order to provide the most reliable risk estimations. This review paper evaluates the study designs employed to investigate the impact of EMFs on female fertility and addresses the limitations of the research methodologies. **Methods:** This review follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Extension for Scoping Review (PRISMA-SCR) guidelines. Seven electronic databases were utilised to access recent cohort studies published between the years 2013 to 2023. **Results:** A total of 33 articles reporting on EMFs and fertility were analysed. Majority of the studies employed animal study design (n= 15), followed by 9 observational studies, 4 case-control, 3 in vitro studies and 2 interventional studies. Thematic analysis identified five main themes addressing the methodological limitations; (i) operationalisation, (ii) measurement and instrumentation, (iii) contextual constraints, (iv) practical constraints, and (v) analytical constraints. **Conclusion:** This review identifies several key limitations on the current research methodologies that can be incorporated into future studies to support the development of empirical study designs.

INTRODUCTION

Electromagnetic fields (EMFs) are invisible areas of energy that are categorised into non-ionising EMFs, which are typically harmless, and ionising EMFs, which have the potential to cause cellular and DNA damage (National Cancer Institute, 2022). The waves of EMFs are emitted by a diverse range of devices and technologies essential for modern life, facilitating communication, transportation, healthcare, and more. It encompasses a broad spectrum, ranging from extremely low frequency (ELF) waves produced by power lines to radiofrequency (RF) waves generated by mobile phones and microwaves (Gye & Park, 2012).

While these technologies offer significant benefits, concerns have been raised regarding their potential impacts on human health. Humans in modern society should be aware of the risks associated with EMFs, as exposure to diverse forms of EMFs is unavoidable in domestic and professional environments. Through *in vitro* and *in vivo* studies, EMF exposure adversely affects embryonic and foetal development (Pourlis, 2009), modifies endocrine hormones (Rodriguez et al., 2004), and disrupts gonadal functions (Guney et al., 2007; Kaur et al. 2023). The potential threats associated with EMFs exposure are contingent upon the intensity, wave type, duration, and frequency. Nevertheless, the findings regarding the hazards of EMF on human health remain uncertain due to the contradictory results, which could be attributed to the non-standardised methodologies and assessment tools. Furthermore, present studies primarily focused on epidemiology, and risk assessment, with insufficient data addressing study designs and their limitations.

Therefore, the main focus of this review is to evaluate the types of study designs employed to investigate the impact of EMFs exposure on female fertility and further analyse the limitations of the research methodologies from the selected studies. This review is based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Extension for Scoping Review (PRISMA-SCR) guidelines. Unlike traditional systematic reviews, which address specific research questions, a scoping review aims to provide a broad overview of the literature, sources of evidence, and knowledge gaps.

To the best of the authors' knowledge, this is the first scoping review that provides analytical data on study designs, and limitations concerning the reproductive risks associated with low and high frequencies of EMF exposure in females. The findings from this review can assist policy makers and public health authorities in addressing

*Corresponding author.
E-mail address: arsuzanah@iium.edu.my

potential risks concerning the use of EMF-emitting devices. This review will be beneficial for new authors to refine their knowledge and develop new research ideas by considering the limitations identified in this study. Above all, it is hoped to add to the existing body of knowledge and fills the gap in the current EMF literature.

MATERIALS AND METHODS

The Preferred Reporting Items for Systematic Review and Meta-Analysis Extension for Scoping Review (PRISMA-SCR) 2018 guidelines was employed throughout this review, comprising twenty essential reporting items and two optional items (Tricco et al., 2018). The protocol of this review was approved by the approving committee for the undergraduate research project (AHBS 3612) course of Department of Biomedical Science, Kulliyyah of Allied Health Sciences, IIUM.

Eligibility Criteria

Inclusion

i. Studies that evaluate the effects of EMF on general health and female infertility
ii. Studies published between 2013 and 2023.
iii. Studies that include qualitative and quantitative analyses.
iv. Studies that include experimental and observational designs.
v. Studies written in the English language.

Exclusion

Non-original articles, such as conference proceedings, abstracts, systematic reviews and meta-analyses.

Information Sources

A comprehensive literature search was conducted using the following electronic databases; PubMed, Google Scholar, ScienceDirect, Wiley Online Library, ProQuest, Cochrane and Scopus.

Search

The search in the databases was carried out using the following keywords search strategy: “electromagnetic fields”, “EMF”, “fertility”, “infertility”, “female infertility”, “health effects”, “reproduction”, “pregnancy”, “abortion” and “oocyte”. The Boolean terms (AND and OR) were also used to specify and separate each keyword, widening the search result and ensuring the keywords were present in the articles.

Study Selection and Data Collection Process

Two reviewers independently screened the titles and abstracts in accordance with the inclusion criteria. Following that, the full-text articles were further accessed for eligibility. Data from studies that meet all the eligibility criteria were recorded and analysed in the excel spreadsheet. Disagreements were resolved by discussion.

Data Items

Data extracted from each study include: (i) the study characteristics, (ii) the types of study design used, and (iii) study limitations. Thematic analysis was utilised to generate themes pertaining to the study limitations identified in the reviewed articles. The data was clustered as themes and subthemes according to the common pattern.

Methodological Quality Assessment

The quality of the selected articles in this review was assessed by two authors to ensure the validity and reliability of the research papers. However, a formal quality assessment using tool such as the Crowe Critical Appraisal Tool (CCAT) was not conducted, as it is not within the scope of the scoping review methodology (Pham et al., 2014). While this step is beneficial, it is optional in a scoping review since a detailed critical appraisal of study quality is often not the primary focus.

RESULTS

Study Selection

A total of 157 articles were identified for this review via seven electronic databases. Following the removal of 47 duplicates, 110 articles were selected for the screening process. The first screening phase involved evaluation of the titles, resulting in the exclusion of 4 articles. In the second phase, the titles and abstracts were screened and a total of 73 articles were excluded as they did not meet the inclusion criteria. In total, 33studies were identified as being eligible for full text evaluation (Figure 1).

Study Characteristics

Articles selected were published within the last ten years, from 2013 to 2023. The majority of the articles (n= 15) involved animal studies (Poulletier de Gannes et al., 2013; Hafizi et al., 2014; Bakacak et al., 2015; Qi et al., 2015; Ahmadi et al., 2016; Alchalabi et al., 2016a; Alchalabi et al., 2016b; Khaki et al., 2016; Shirai et al., 2017; Woelders et al., 2017; Papoyan et al., 2018; Saygin et al., 2018; Ruan et al., 2019; Burcu et al., 2020; Wang et al., 2022). A total of 9 studies conducted observational studies which included retrospective, prospective, longitudinal cohort and cross-sectional designs (de Vocht et al., 2014; de Vocht & Lee, 2014 secondary data; Abad et al., 2016; Xu et al., 2016; Li et al., 2017; Migault et al., 2018; Auger et al., 2019; Ingle et al., 2020; Tokinobu et al., 2021). Four studies collected data via case-control design (Mahmoudabadi et al., 2013; Mahmoudabadi et al., 2015; Sadeghi et al., 2017;

Esmailzadeh et al., 2019). Interventional study was performed in 2 studies (Rad et al., 2014; Dias et al., 2023), while in-vitro experimental study was conducted in 3 studies (Suzuki et al., 2017; Chen et al., 2021; Kozlowska et al., 2021). The study characteristics of the reviewed articles are presented in the Supplementary Table 1.

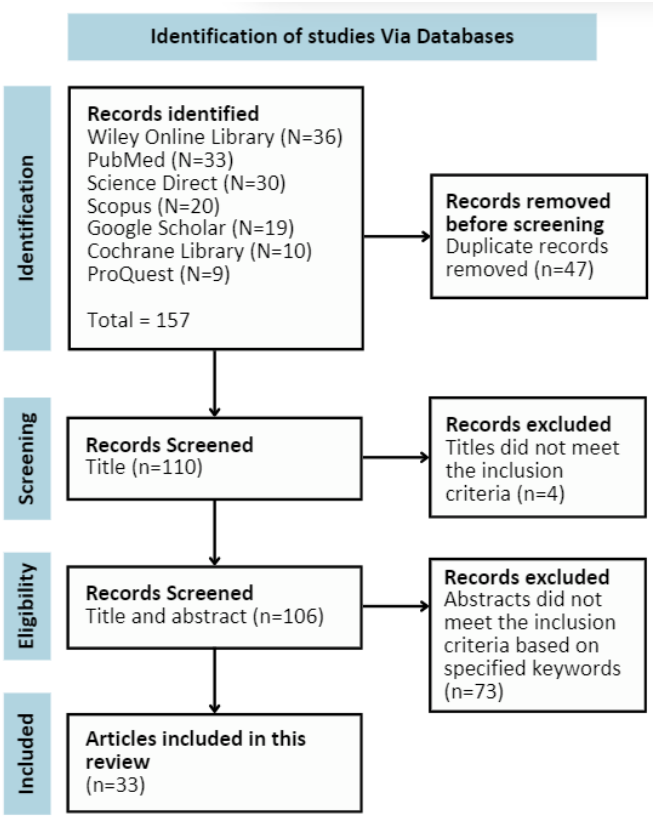

Figure 1: PRISMA flow diagram

Thematic Analysis

Based on the research question "*What are the study limitations identified in the selected studies*?", thematic analysis of the reviewed papers revealed five main themes addressing the methodological limitations of various study designs employed; (i) operationalisation, (ii) measurement and instrumentation, (iii) contextual constraint, (iv) practical constraint, and (v) analytical constraint (See Supplementary Table 1). The theme operationalisation implied three subthemes: (a) sample size, (b) duration of exposure, and (c) risk of bias. Measurement and instrumentation yielded two subthemes: (a) validity threats, and (b) limitations/variations in measurement methods. The contextual constraint mainly pertained to the applicability of findings in humans. Practical constraint was mainly related to resource constraints, which include lack of data availability and limited technical expertise. The analytical constraints were primarily related to the limitations of statistical analysis and the significance of the findings.

Theme 1: Operationalisation

Sample size

This review noted that all the study designs employed in the selected studies showed limitation of small sample size, which limits the generalisability of their findings to broader population or different context; such as interventional study design by Rad et al. (2014), and Dias et al., 2023; animal studies by Hafizi et al. (2014), Bakacak et al. (2015), Qi et al. (2015), Ahmadi et al. (2016), Khaki et al. (2016), Papoyan et al. (2018) and Saygin et al. (2018); and observational studies by Xu et al. (2016), Ingle et al. (2020) and Abad et al. (2016).

Duration of exposure

Three articles examining the impacts of EMF exposure on female fertility were identified using *in vitro* experimental study design. All three studies emphasised on the short-term EMF exposure, with a lack of long-term effects data. In a study by Suzuki et al. (2017), the short EMF exposure time may inadequately reflect the possible impacts on fertilisation and early embryonic development. Moreover, concentrating exclusively on early embryonic development renders the long-term consequences of EMF exposure during subsequent stages uncertain. Similarly, Chen et al. (2021) did not investigate the long-term effects of EMF exposure on fertility or reproductive outcomes beyond embryonic development. The short exposure time to EMF in the study by Kozlowska et al. (2021) resulted in insufficient long-term evidence on the effects of EMF exposure on endometrial function and overall fertility. In an interventional study conducted by de Vocht & Lee (2014), the exposure duration was 1 to 3 months, which may not adequately represent long-term effects. The majority of the animal studies focused on short-term impacts without addressing potential long-term or cumulative effects of EMF exposure (Poulletier de Gannes et al., 2013; Hafizi et al., 2014; Qi et al., 2015; Ahmadi et al., 2016; Alchalabi et al., 2016b; Khaki et al., 2016).

Risk of bias

Selection bias was identified in a prospective observational study by Tokinobu et al. (2021) due to unknown participation rate, while attrition bias was identified in a retrospective observational study by de Vocht et al. (2014) due to missing data on the residential addresses and maternal smoking status. Reporting bias was noted in two observational studies (Xu et al., 2016; Tokinobu et al., 2021) due to the high possibility of recall bias in self-reported questionnaires.

Theme 2: Measurement and instrumentation

Validity threats

According to Kozlowska et al. (2021), *in vitro* study was susceptible to inconsistent responses to EMF exposure

due to the variations in the sensitivity of different genes and proteins towards EMF radiation. Meanwhile, interventional study by Vocht & Lee (2014) addressed the limitation of maintaining comparable conditions between the control and experimental groups, as confounding factors may still affect the results. A case-control study conducted by Sadeghi et al. (2017) omitted various confounding risk factors that could influence preterm birth, suggesting that the study's findings may not be generalisable to other populations or geographies. Mahmoudabadi et al. (2015) performed a case-control study to investigate the association between mobile phone usage during pregnancy and the risk of spontaneous abortion. Nonetheless, potential confounding variables, such as risk factors for spontaneous abortions, including balanced chromosomal abnormalities were not evaluated, and data on spontaneous abortions at very early stages were not recorded. Animal study by Woelders et al. (2017) observed differences among exposure units for certain measured parameters, which indicated that even small deviations in local climate conditions or mechanical factors can influence experimental outcomes. Residual confounding factors were identified as one of the primary limitations in retrospective, prospective and longitudinal observational studies (de Vocht et al., 2014; de Vocht & Lee, 2014 secondary data; Migault et al., 2018; Auger et al., 2019; Ingle et al., 2020; Tokinobu et al., 2021).

Limitations/variations in measurement methods

Several limitations with regards to the measurement methods were observed in the reviewed studies. In an interventional study conducted by Dias et al. (2023), participants' pregnancy and implantation rates were not evaluated, and gene expression analysis was limited. A case-control study by Sadeghi et al. (2017) investigating preterm birth in women residing within 600 meters of high voltage power lines had notable limitation, particularly in its measurement methodology. The study employed geographical information systems (GIS) to estimate proximity to power lines but failed to consider all sources of magnetic fields within the domestic setting. Furthermore, this study was unable to randomly allocate pregnant women to reside in proximity to or at a distance from the power lines. Mahmoudabadi et al. (2013) conducted a case-control study utilising a measurement device for ELF-EMF that encompassed a limited frequency range of 30 Hz to 3 kHz, possibly overlooking additional significant frequencies. In a case-control study conducted by Esmailzadeh et al. (2019) examining the correlation between exposure to EMFs from high voltage overhead power lines and female infertility, the EMF intensity in residential areas was not directly quantified using a low-frequency gauss meter; rather, the evaluation relied on the proximity to power lines.

Several animal studies mentioned limitations due to variability in experimental design across studies, such as differences in Specific Absorption Rate (SAR) values, frequencies, duration of exposure, and controlled environments, making it difficult to draw definitive conclusions (Poulletier de Gannes et al., 2013; Alchalabi et al., 2016b; Papoyan et al., 2018). Meanwhile, Saygin et al., 2018 faced variability in the oestrous cycle of animal models, affecting the determination of the exact stage of the cycle and influencing results. Other animal studies showed a limited scope of measurements; for example, (i) Wang et al. (2022) only investigated the effects of a single 60-minute exposure to 16 T HiSMF with 700 MHz RF-EMF, leaving out the effects of repeated or chronic exposure and acoustic noise effects, (ii) Burcu et al. (2020) did not examine the mechanisms that induce tissue-inducible nitric oxide synthase (iNOS) activity, (iii) Ruan et al. (2019) assessed only partial fertility parameters and (iv) Alchalabi et al. (2016a) did not fully elucidate the underlying mechanisms by which oxidative stress contributes to tissue damage, focusing instead on specific biochemical markers and histopathological changes without assessing other potential biomarkers or pathways.

Three studies employing retrospective and prospective observational designs exhibited methodological limitations resulting from misclassification of exposures and measures (de Vocht et al., 2014; de Vocht & Lee, 2014 secondary data; Li et al., 2017; Auger et al., 2019).

Theme 3: Contextual constraint

Applicability of findings

Three types of study design were found to have limitation with regards to applicability of the findings in humans. The use of porcine oocytes as a model in the *in vitro* study by Chen et al. (2021) may not fully represent human oocyte physiology and not fully mimic the complex interactions of the female reproductive system. According to two studies that conducted intervention study design using animal models (de Vocht & Lee, 2014; Rad et al., 2014), direct applications to humans are limited since animal models may not accurately depict human physiology and responses to electromagnetic fields. Similarly, three studies that conducted animal study designs addressed the limitation of applying findings to human fertility as laboratory conditions may not mimic natural environment (Ahmadi et al., 2016; Papoyan et al., 2018). Bakacak et al. (2015) further highlighted on the ethical concern that impedes the conduct of comparable experiments in humans.

Theme 4: Practical constraint

Resource constraint

Dias et al. (2023) conducted a prospective intervention

study on the potential effects of EMF in women with diminished ovarian reserve undergoing assisted reproductive technology (ART) via clinical trials. However, there was lack of pregnancy outcome data, necessitating further research using a larger and randomised cohort. Meanwhile, interventional study by Rad et al. (2014) and animal study by Bakacak et al. (2015) highlighted the technical limitations that prevented the determination of ovarian follicle counts, as well as the lack of analysis on the destruction and apoptosis in harvested ovarian tissues.

Theme 5: Analytical constraint

Animal study by Woelders et al. (2017) included multiple comparison and interactions which could increase the likehood of false positives. Moreover, the dependence on parameters, such as initial egg weight influencing embryo weight, further complicated the interpretation of results. Three observational studies highlighted the analytical limitations, which include insufficient statistical power to detect associations (Tokinobu et al., 2021), failure to meet statistical test assumptions (Abad et al., 2016) and potential underpowering to detect associations with high exposure levels due to low prevalence of high exposures in the study population.

DISCUSSION

Planning a study design requires a thoughtful attention to various elements to ensure it is best suited the objectives of the study. This scoping review identified five prominent study designs utilised by researchers to assess the impact of EMFs on female fertility over the past 10 years: animal model, observational, interventional, case-control and *in vitro* studies. Given the influence that variations in research methodologies can have on the study outcomes, this review analysed the limitations of each study design via thematic analysis.

With regards to the operational limitation of various study designs, this review reported that short study duration and small sample size were the most frequently stated factor impacting the generalisability of the study findings. Previous studies have demonstrated that short study periods, particularly in longitudinal cohort studies, might have a negative impact on the statistical power and precision of regression coefficient estimations (Raudenbush & Xiao-Feng, 2001; Moerbeek, 2008). Therefore, a longer study period is beneficial for evaluating the long-term effects and gaining a more comprehensive understanding of the outcomes, as well as for identifying potential delayed effects (Collins & Graham, 2002). Nevertheless, increasing the length of the study period can be costly in terms of resources, finances, and time, while also imposing a considerable strain on participants about their prolonged commitment, potentially resulting in response fatigue. Furthermore, prolonged study duration may lead to higher participant attrition bias due to illness, death or loss of interest to continue participation (Raudenbush & Xiao-Feng, 2001; Collins & Graham, 2002; Moerbeek, 2008). Loss of participants to follow-up will subsequently reduce the sample size, introduce selection bias, and adversely affect the statistical power of the study (Kristman et al., 2003).

The articles reviewed in this study showed that the translation from animal studies to humans is the main limitation in study designs that involved animal model. Even though the use of animal research is necessary, particularly in testing the safety and effectiveness of new drugs before clinical trials (Sibbald, 2000), its use has been controversial. The applicability of animal experiment results to humans is debated mainly due to biological disparities between species, and poor methodological designs, conduct and analysis. According to Perel et al. (2007), diverse animal species and strains exhibit a range of metabolic pathways and drug metabolites, resulting in variability in efficacy and toxicity. Moreover, variations in drug dosing schedules, regimens and follow-up duration are of uncertain relevance to the human condition. The differences in laboratory techniques can influence outcomes, and small experimental groups result in insufficient statistical power.

Confounding factors were also observed as the main limitation in the majority of the study design reviewed. It is one of the common forms of bias present in observational studies evaluating the safety and effectiveness of treatments (Assimon, 2021). Confounding is described as a 'mixing effect' in which the effects of exposure being studied are conflated with those of surrounding factors, leading to a misinterpretation of the true relationship. The existence of confounding variables may mask an actual association making it difficult to establish a definitive causal relationship between treatment and the outcome (Skelly et al., 2012). Recognising potential confounding factors and mitigating their impact is essential for the study's credibility.

The diverse methodological parameters and measurement instruments utilised by researchers to evaluate the impact of EMF exposure on female fertility in the reviewed studies further posed an additional challenge for quality assessment. Heterogeneity in research methods may complicate the interpretation of results and hinder the replication of study designs in various contexts. In animal research, the implementation of standardised frequencies, intensities, and durations of exposure will enhance comparability across studies. Bleich et al. (2020) assert

that the refinement and development of model-specific methodologies for evaluating impacts of treatments in animal studies, along with minimal or non-invasive monitoring and imaging techniques, can enhance data quality and improve ethical considerations.

Several limitations were identified across the reviewed studies. First, there was scarcity of research papers that specifically addressed the relationship between EMF exposure and female fertility, as opposed to those that addressed male fertility. Therefore, the inclusion criteria for the publication years spanned over a decade, from 2013 to 2023. Second, the screening process was impeded by the inability to access full text articles for several papers, affecting the comprehensiveness of the scoping review. Lastly, several relevant papers were excluded from the analysis due to their publication in languages other than English.

Future studies may conduct comparable research using more unified assessment criteria and a standardise definition of EMF exposure to enable replication of the study design and facilitate easier interpretation of findings. Well-designed *in vitro* or *in vivo* studies using animal models are essential to study the mechanisms and the effects that have been suggested in literature. Long-term EMF exposure and larger cohort studies are necessary to examine the detrimental effects emitted by the waves on female reproductive health, in order to enhance understanding of safety levels and the effectiveness of intervention strategies. Inclusion of diverse demographic groups and possible confounding factors will mitigate research bias, enhance the evaluation of EMF exposure implications, and improve the generalisability of the study findings. In addition, adequate financing and resources are essential for conducting extensive and long-term research.

CONCLUSION

This scoping review elucidates the present research designs and their prevalent methodological limitations in studies assessing the reproductive risks associated with low and high frequencies of EMFs. It is essential to recognise and address these limitations in order to preserve the credibility and integrity of research findings. Prospective cohort studies with comprehensive exposure assessments may represent the best research design for investigating the impact of EMF on female fertility. Such studies would enable the measurement of EMF exposure during aetiologically relevant periods and allow for the control of confounding factors while maintaining a longitudinal perspective on fertility outcomes. This review can serve as a guide for future researchers in developing effective intervention models by effectively navigating common limitations and enhancing the robustness and applicability of their contributions by adopting transparent reporting practices and implementing mitigation strategies.

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CONFLICT OF INTEREST

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Supplementary Table 1

Characteristics of articles reviewed: Types of study designs and study limitations

No.	Title	Author/s (Year)	Type of study design/Study duration/n	Study limitations
1.	Ozone sauna therapy and pulsed electromagnetic field therapy could potentially improve outcome in women with diminished ovarian reserve undergoing assisted reproductive technology	Dias et al. (2023)	Prospective interventional study/Each participant underwent two IVF cycles: Cycle 1 was performed before treatment with OST + PEMF, followed by 3 weeks of treatment (OST + PEMF twice a week). Cycle 2 was conducted after the treatment period./ 50 women (aged 39.7 ± 1.1 years) with Diminished Ovarian Reserve (DOR).	Generalizability Issues • Small sample size Duration and Scope • Lack of pregnancy outcome data • Limited assessment of gene expression • Need for further research with larger cohort and randomised trials
2.	Effect of low-frequency electromagnetic field exposure on oocyte differentiation and follicular development	Rad et al. (2024)	Interventional research (experimental study)/21 days of EMF exposure/ 30 pregnant female mice, which were divided into two groups of 15 mice each (experimental and control).	Generalizability Issues • Limited sample size of animals examined. • Animal experiment, limiting direct applicability to humans. Technical or Analytical Limitations • Technical limitations prevented determination of ovarian follicle numbers before the study. Measurement and Exposure Assessment Limitations • Destruction and apoptosis were not analysed in the extracted ovarian tissues. • Lack of detailed understanding of the underlying molecular mechanisms.
3.	Influence of Radiofrequency Electromagnetic Waves From 3rd-Generation Cellular Phones on Fertilization and Embryo Development in Mice	Suzuki et al. (2017)	In vitro experimental study/60 minutes exposure to RF-EMW/male and female B6D2F1 mice	Generalizability Issues • Short exposure time. Measurement and Exposure Assessment Limitations • Only investigates early embryonic development, and post-implantation development of embryos was not investigated. • Potential effects on oxidative stress and antioxidants
4.	Effects of electromagnetic field (EMF) radiation on androgen synthesis	Kozlowska et al. (2021)	In vitro experimental study/Gilts slaughtered on	Generalizability Issues • Short-term EMF exposure. Technical or Analytical Limitations

	and release from the pig endometrium during the fetal peri-implantation period		days 15–16 of pregnancy. Endometrial slices were pre-incubated for 2 hours and then exposed to EMF treatments for 2 or 4 hours/5 post-pubertal gilts (Sus scrofa f. domestica)	• Does not provide data on long-term effects of EMF exposure on endometrial function and overall fertility. • Inconsistent response to EMF exposure, indicating potential variability in the sensitivity of different genes and proteins to EMF radiation.
5.	Effects of electromagnetic waves on oocyte maturation and embryonic development in pigs	Chen et al. (2021)	In vitro experimental study/in vitro maturation (IVM) period of 42–44 hours for the oocytes/pre-pubertal gilts	Measurement and Exposure Assessment Limitations • Use of porcine oocytes as a model may not fully represent human oocyte physiology. • Not fully mimic the complex in vivo environment of the female reproductive system. Duration and Scope • Did not investigate the long-term effects of EMF exposure on fertility or reproductive outcomes beyond embryonic development.
6.	Maternal Proximity to extremely low frequency electromagnetic fields and risk of birth defects	Auger et al. (2019)	Observational study (Retrospective cohort study)/ 1989 to 2016 / 2,164,246 live-born infants in hospitals in Quebec, Canada	Measurement and Exposure Assessment Limitations • Inconsistent exposure assessment and misclassification of exposure. Confounding Factors and Bias • Presence of residual confounding factor. Generalizability Issues • Generalisability of the result. Measurement and Exposure Assessment Limitations • The biological plausibility of extremely low frequency electromagnetic fields as a cause of birth defects is uncertain.
7.	Maternal Residential Proximity to Sources of Extremely Low-Frequency Electromagnetic Fields and Adverse Birth Outcomes in a UK Cohort	de Vocht et al. (2014)	Observational study (Retrospective)/ from 1990 to 2009 (data analysis from 2004 to 2008) /265,926 singleton live births.	Measurement and Exposure Assessment Limitations • Exposure misclassification measurement. Confounding Factors and Bias • Bias due to missing data residential addresses and maternal smoking status for a portion of the population. • Residual confounding from socioeconomic factors, as well as other environmental exposures correlated with distance to EMF sources. • Lack residential history during the full pregnancy period. Generalizability Issues • Prevalence of women living close to ELF-EMF sources was low, limiting the generalizability of the findings to populations with similar exposure patterns.
8.	Maternal Use of Induction Heating Cookers During Pregnancy and Birth	Tokinobu et al. (2021)	Observational study (prospective cohort study)/	Confounding Factors and Bias • Selection bias due to participation rate is unknown.

	Outcomes: The Kyushu Okinawa Maternal and Child Health Study		April 2007 to March 2008/1,565 mother–child pairs.	• Participants was assessed via self-reported questionnaires, which may be subject to recall bias or misclassification of exposure. • Other confounding factors that were not accounted for. Technical or Analytical Limitations • Insufficient statistical power to detect associations.
9.	Residential proximity to electromagnetic field sources and birth weight: Minimizing residual confounding using multiple imputation and propensity score matching	de Vocht & Lee (2014)	Observational study (secondary data)/ 2004 to 2008/140,356 live singleton births	Confounding Factors and Bias • Residual confounding exists due to unmeasured or incomplete measured confounding factors. Measurement and Exposure Assessment Limitations • Exposure misclarification. • Use of postal code centroids to estimate residential proximity to EMF sources may introduce measurement error. Generalizability Issues • Limit the generalisability of the findings to other populations or time periods.
10.	Association of personal exposure to power-frequency magnetic fields with pregnancy outcomes among women seeking fertility treatment in a longitudinal cohort study	Ingle et al. (2020)	Observational study (Longitudinal cohort study)/2012 to 2018/119 women	Generalizability Issues • Small sample size. • Limit the generalisability of findings to the general population due to this cohort comprised subfertile women seeking fertility treatment at an academic clinic only. Confounding Factors and Bias • Possible confounding factors.
11.	Association between electromagnetic field exposure and abortion in pregnant women living in Tehran	Abad et al. (2016)	Observational study (Longitudinal study design)/ during pregnancy, with data collected across three trimesters/413 pregnant women	Generalizability Issues • Small sample size. Technical or Analytical Limitations • Variation in magnetic field (MF) level and daily activity patterns of participants not fully accounted. • Statistical tests assumptions not met. Confounding Factors and Bias • Lack of information on other potential confounding factors (age, familial marriage, and interpersonal conflicts).
12.	Health Effects of Electromagnetic Fields on Reproductive-Age Female Operators of Plastic Welding Machines in Fuzhou, China	Xu et al. (2016)	Observational study (cross-sectional study design)/does not specify the exact time period for data collection/529 participants aged 18 to 40 years	Confounding Factors and Bias • Potential for recall bias in self-reported symptoms and medical history. Generalizability Issues • Limited generalisability beyond Chinese female workers in shoe factories. • Hormone levels may vary due to diurnal and menstrual cycle variations, affecting interpretation of results. • Cross-sectional study limit interpretation of causal relationships. Measurement and Exposure Assessment Limitations • Exposure assessment based on single workday measurements may not reflect true cumulative exposures.

13.	Maternal cumulative exposure to extremely low frequency electromagnetic fields and pregnancy outcomes in the Elfe cohort	Migault et al. (2018)	Observational study (prospective birth cohort study)/ This cohort study will follow the children until they reach 20 years of age/ 18,040 families and 18,329 children enrolled	Generalizability Issues • Inability to consider exposure to other occupational hazardous factors due to lack of accurate data. Technical or Analytical Limitations • Limited ability to modify exposure estimates individually based on specific exposure characteristics. • Potential underpowering to detect associations with high exposure levels due to low prevalence of high exposures in study population. • Lack of individual exposure measurements; exposure assessment based on job characteristics and duration of work during pregnancy. • Berkson error introduced by use of group average exposure in place of individual values in exposure assessment. Confounding Factors and Bias • Potential for residual confounding despite inclusion of known confounders in analysis.
14.	Exposure to Magnetic Field Non-Ionizing Radiation and the Risk of Miscarriage: A Prospective Cohort Study	Li et al. (2017)	Observational study (prospective cohort study)/ duration of the study was based on the participants' pregnancies, with the primary focus being on miscarriage before 20 weeks of gestation/913 pregnant women	Measurement and Exposure Assessment Limitations • Challenges in accurately measuring Magnetic Fields (MF) exposure levels. Technical or Analytical Limitations • Difficulty in ascertaining MF exposure long after the relevant window of exposure has passed. • Prospective study design required to capture MF exposure during an etiologically relevant period. Measurement and Exposure Assessment Limitations • Misclassification of MF exposure possible if measurements not conducted on a typical day. • Use of subjective or surrogate measures for MF exposure in past studies may have led to misclassification and null findings. • Focus on studying MF effects on cancer in past studies may have exacerbated the problem of inaccurate exposure assessment. Confounding Factors and Bias • Lack of dose-response relationship observed for MF exposure levels above 2.5 mG, possibly due to a threshold effect.
15.	Preterm birth among women living within 600 meters of high voltage overhead Power	Sadeghi et al. (2017)	Case-control study/ February 2013 to December 2014/135 cases of singleton live spontaneous preterm birth	Measurement and Exposure Assessment Limitations • The measurement method used to measure distance to power lines using geographical information systems (GIS) that may not capture all sources of magnetic fields in the residence and distance of pregnant women living from the power lines. Confounding Factors and Bias

				• Other confounding factors that might influence preterm birth. Generalizability Issues • The findings may not be generalized to other populations or locations.
16.	Exposure to extremely low frequency electromagnetic fields during pregnancy and the risk of spontaneous abortion: a case-control study	Mahmoudabadi et al. (2013)	Case-control study/2012/ 116 participants	Measurement and Exposure Assessment Limitations • Covers a limited frequency range.
17.	Exposure to Electromagnetic Fields of High Voltage Overhead Power Lines and Female Infertility	Esmailzadeh et al. (2019)	Case-control study/February 2014 to December 2016/ 471 participants with no history of infertility	Generalizability Issues • Findings may be partly subjective as electromagnetic field strength in residential areas was not directly measured with a low-frequency gauss meter. The assessment was primarily based on distance from power lines. • Cross-sectional nature study design did not permit assessment of the temporal and thus potentially causal relation of the exposure and infertility.
18.	Use of mobile phone during pregnancy and the risk of spontaneous abortion	Mahmoudabadi et al. (2015)	Case-control study/Study duration is not explicitly stated/ 600 participants (292 cases + 308 controls).	Confounding Factors and Bias • Unknown risk factors for spontaneous abortions, such as balanced chromosomal abnormalities, not assessed. • Data about unknown spontaneous abortions at very early stages not collected. • Potential confounding factors not fully adjusted for, despite adjustments in logistic regression analyses. Technical or Analytical Limitations • Mechanisms underlying the effects of EMF on the risk of spontaneous abortions not well understood. • Cell phones may not be the only source of electromagnetic fields (EMF). Generalizability Issues • Case-control nature of the study implies caution in causal interpretations.
19.	Study of Potential Health Effects of Electromagnetic Fields of Telephone and Wi-Fi, Using Chicken Embryo Development as Animal Model	Woelders et al. (2017)	Animal study	Technical or Analytical Limitations • Differences observed among exposure units for certain measured parameters. This indicates that even small deviations in local climate conditions or mechanical factors can influence experimental outcomes. • Some measured parameters were not independent of each other, which could complicate the interpretation of results. • The statistical analysis includes multiple comparisons and interactions, which could increase the likelihood of false positives.
20.	Influence of Low-Intensity Electromagnetic Field on Some Biological Parameters of	Papoyan et al. (2018)	Animal study/ Spanned six rounds, with each incubation lasting 22	Generalizability Issues • Limited sample size number. • Observations limited to parental generation and three subsequent generations only. Duration and Scope

	Freshwater Crustaceans Daphnia magna Straus		days/900 chicken eggs incubated and studied	• Limited scope of EMF frequency, intensities or durations. Measurement and Exposure Assessment Limitations • Conducted under laboratory conditions that may not perfectly mimic natural environments.
21.	Evaluating the biological safety on mice at 16 T static magnetic field with 700 MHz radio-frequency electromagnetic field	Wang et al. (2022)	Animal study/14 days/ 48 male C57BL/6 mice (8 weeks old)	Duration and Scope • The study only examined the effects of a single 60-minute exposure to 16 T HiSMF with 700 MHz RF-EMF. It did not explore the effects of repeated or chronic exposure. • The study did not investigate the potential effects of acoustic noise generated during MRI scanning on mice, which is a known issue at high magnetic field strengths. • The paper suggests that further research is needed to assess the impact of 16 T MRI on the reproductive system, implying that this area was not covered in the current study. Generalizability Issues • The study exclusively used male mice, and therefore, the results might not be directly applicable to female mice.
22.	Histopathological changes associated with oxidative stress induced by electromagnetic waves in rats' ovarian and uterine tissues	Alchalabi et al. (2016a)	Animal study/ Two groups exposed to 1,800 MHz GSM-like RF for 30 days and 60 days/30 female Sprague Dawley rats (3 months old, 180 g).	Technical or Analytical Limitations • The study identifies oxidative stress as a contributor to tissue damage but does not fully elucidate the underlying mechanisms of DNA damage and follicular atresia. • The study focuses on specific biochemical markers (MDA, GSH-PX, MT) and histopathological changes, but does not investigate other potential biomarkers or pathways that could be involved in the observed effects.
23.	The effect of non-ionizing electromagnetic field with a frequency of 50 Hz in Rat ovary: A transmission electron microscopy study	Khaki et al. (2016)	Animal study/ The study duration is: Experiment 1: 8 weeks (3 weeks intrauterine + 5 weeks post-birth). Experiment 2: 13 weeks (3 weeks intrauterine + 10 weeks post-birth)/ 30 Wistar rats (300 ± 30 g, 3 months old).	Generalizability Issues • Limited sample size. Duration and Scope • Lack of Long-term Exposure Analysis.
24.	The impact of electromagnetic radiation (2.45 GHz,	Saygin et al. (2018)	Animal study/30 days (1 hour/day)/ 18	Generalizability Issues • Limited sample size.

	Wi-Fi) on the female reproductive system: The role of vitamin C		female Sprague Dawley rats	Measurement and Exposure Assessment Limitations • Short and variable oestrous cycle in rats was noted as a challenge in determining the exact stage of the cycle, which could affect the results.
25.	Different periods of intrauterine exposure to electromagnetic field: Influence on female rats' fertility, prenatal and postnatal development	Alchalabi et al. (2016b)	Animal study/3 weeks exposure duration/ 60 virgin female Sprague-Dawley rats	Measurement and Exposure Assessment Limitations • The lack of consistency across different studies in terms of SAR values, frequencies, duration of exposure, and whether the exposure was short-term or long-term. Technical or Analytical Limitations • Limited understanding of precise biological mechanism. Generalizability Issues • Controlled environment may not fully replicate real-world scenarios of EMF exposure.
26.	The Effect of Extremely Low Frequency Pulsed Electromagnetic Field on In Vitro Fertilization Success Rate in NMRI Mice	Hafizi et al. (2014)	Animal study/The main experimental exposure (ELF-PEMF) lasted 5 hours. The entire process, from hCG injection to fertilization assessment, spanned 3 days/ 10 female and 2 male NMRI mice	Generalizability Issues • Small sample size used. Duration and Scope • Lack of long-term assessment.
27.	Rat fertility and embryo fetal development: Influence of exposure to the Wi-Fi signal	Poulletier de Gannes et al. (2013)	Animal study/ Male and female rats were exposed for a total of 6 and 5 weeks, respectively/ 12 pairs of animals per group (12 males and 12 females for each exposure condition).	Measurement and Exposure Assessment Limitations • Short exposure duration. • Only specific SAR levels used.
28.	The effects of prenatal and postnatal exposure to electromagnetic field on rat ovarian tissue	Burcu et al. (2020)	Animal study/ 9 weeks/8 pregnant Sprague-Dawley rats	Technical or Analytical Limitations • Does not examine the mechanisms that induce iNOS activity and how these mechanisms function. • The relationship between oxidative stress, the proinflammatory system, and iNOS activation due to EMF exposure was not thoroughly explored. Measurement and Exposure Assessment Limitations

				• Other potential impacts or compare with different EMF strengths and durations were not fully explored.
29.	Power-frequency magnetic fields at 50 Hz do not affect fertility and development in rats and mice	Ruan et al. (2019)	Animal study/rats were exposed for 24 weeks to PF-MF and mice were exposed for 12 weeks in the PF-MF/ 120 adult Sprague-Dawley rats and 64 C57BL/6J mice	Measurement and Exposure Assessment Limitations • Only assess partial fertility parameters.
30.	Effects of extremely low-frequency electromagnetic fields (ELF-EMF) exposure on B6C3F1 mice	Qi et al. (2015)	Animal study/15.5 months/Exposed Group: 10 pregnant females, resulting in 66 offspring (24 males, 42 females). Control Group: 10 pregnant females, resulting in 62 offspring (30 males, 32 females).	Generalizability Issues • Small sample size. • Primarily relies on observational analysis of outcomes in exposed and control groups of mice. It cannot establish causation or elucidate underlying mechanisms. Measurement and Exposure Assessment Limitations • Limited Duration of exposure.
31.	No adverse effects detected for simultaneous whole-body exposure to multiple-frequency radiofrequency electromagnetic fields for rats in the intrauterine and pre- and post-weaning periods	Shirai et al. (2017)	Animal study/ 8 weeks/ 14 pregnant Sprague-Dawley (SD) rats	Generalizability Issues • Primarily relied on observational analysis of outcomes in exposed and control groups. Confounding Factors and Bias • Functional development, water-maze, and behavioural tests were conducted after RF EMF exposure rather than in real-time exposure, which may introduce confounding variables.
32.	Effect of non-ionizing electromagnetic field on the alteration of ovarian follicles in rats	Ahmadi et al. (2016)	Animal study/ 8 weeks (Group 1: 3 weeks intrauterine + 5 weeks ectopic) or 13 weeks (Group 2: 3 weeks intrauterine + 10 weeks ectopic)/30 rats	Generalizability Issues • Animal model used may not fully represent human physiology and response to EMF exposure. • Limited sample size and duration of exposure. • Findings may not be directly applicable to human reproductive health. Measurement and Exposure Assessment Limitations • Lack of direct measurement of physiological parameters related to fertility. Confounding Factors and Bias • Potential confounding factors not fully controlled.

33.	The effects of electromagnetic fields on the number of ovarian primordial follicles: An experimental study	Bakacak et al. (2015)	Animal study/15 days /16 female Wistar-Hannover albino rats	Technical or Analytical Limitations • Technical difficulties prevented determination of ovarian follicle numbers before the study. • Destruction and apoptosis were not analysed in the extracted ovarian tissues. Generalizability Issues • Small sample size of rats examined. • Ethical concerns prevent conducting similar experiments in humans. Confounding Factors and Bias • Lack of pre-intervention ovarian primordial follicle (PF) numbers in experimental objects.

REVIEW ARTICLE

Unlocking Early Detection: The Role of DNA Methylation Biomarkers in Colorectal Cancer Tumorigenesis – A Systematic Review

Nurul Izzati Mohd Shukri[1], Mohd Arifin Kaderi[1], Adel Alhabbal[2], Norafiza Zainuddin[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Bandar Indera Mahkota, Jalan Sultan Haji Ahmad Shah, 25200 Kuantan, Pahang, Malaysia
[2]Department of Microbiology & Biochemistry, Faculty of Pharmacy Arab Private University for Science and Technology, 2Q85+R2Q, Hama, Syria

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ABSTRACT

Background: DNA methylation is an epigenetic mechanism that holds promise for improving disease detection, particularly in the early stages of neoplastic transformation. Although colonoscopy is currently the most effective method for detecting colorectal cancer (CRC) due to its high sensitivity, patient compliance is often hindered by its invasive nature, high cost, and inconvenient preparation process. This systematic review aims to systematically identify DNA methylation-based biomarkers used in early-stage CRC detection and to systematically compile evidence on the roles of DNA methylation-based biomarkers in CRC tumorigenesis. **Methods:** Data were collected via electronic searches for relevant citations from 2018 to 2023 in PubMed, Scopus, and Cochrane Library, using relevant and specific keywords for the search strategy. The selection of relevant articles is associated with the inclusion and exclusion criteria. The quality of the articles was assessed using the Crowe Critical Appraisal Tool (CCAT). **Results:** From an initial pool of 121 articles, 14 articles were selected based on the inclusion criteria and PRISMA guidelines. This systematic review successfully identified relevant DNA methylation-based biomarkers that have potential in early-stage CRC detection which are SDC2, KCNQ5, C9orf50, CLIP4, a combination of SEPT9 and SDC2, and a combination of GALNT9 and UPF3A. These biomarkers have been shown to have high accuracy and can be identified in a non-invasive approach such as stool and blood, demonstrating their potential as an effective tool for early CRC detection. Additionally, DNA methylation biomarkers were shown to be involved in key processes of CRC tumorigenesis, including cell proliferation, migration, transformation, metastasis, and angiogenesis. **Conclusion:** This systematic review highlights the promising role of DNA methylation-based biomarkers in the early detection of CRC, offering a non-invasive approach and highly accurate alternative to traditional methods.

INTRODUCTION

Colorectal cancer (CRC) is one of the most common cancers worldwide and the second leading cause of cancer-related deaths, according to the World Health Organization (2023). It ranks third among cancers in men and second in women after breast cancer (WHO, 2023). CRC risk increases with age, but healthier lifestyles and regular screening have contributed to decreasing incidence rates in some countries (Miller et al., 2019). In line with this, The American Cancer Society (2024) stated that the mortality rates of CRC have been declining for some decades among males and females due to the reason for getting a screening. Getting a screening could increase the identification and removal of colorectal polyps before they develop into cancer and facilitate more accessible treatment for CRC.

Colorectal cancer often arises due to a combination of genetic and epigenetic modifications (Ye et al., 2024) . One of the most common epigenetic modifications linked to CRC is DNA methylation. Changes in DNA methylation pattern which leads to aberrant methylation can serve as cancer biomarkers (Yuan, 2024). This aberrant methylation manifests in the initial phase of cancer progression, making them potentially valuable for screening purposes (Locke et al., 2019).

Various CRC screening methods exist, each with strengths and weaknesses. The current gold standard for CRC detection is colonoscopy, which significantly reduces CRC mortality by 67% (Doubeni et al., 2016). Despite its high accuracy, colonoscopy's invasive nature, cost, and preparation process often deter patients from getting screened (Pontone et al., 2022). Non-invasive stool-based tests like the guaiac-based fecal occult blood test (gFOBT) and fecal immunochemical test (FIT) are easier to use but have limited sensitivity, particularly for early-stage CRC (Zhang et al., 2023).

Given these limitations, there is a need for more effective, non-invasive screening methods. DNA methylation-based biomarkers show promise for early CRC detection. Changes in DNA methylation patterns occur early in cancer progression and could serve as reliable biomarkers. These biomarkers could improve detection accuracy and patient

*Corresponding author.
E-mail address: znorafiza@iium.edu.my

compliance, complementing existing CRC screening methods.

MATERIALS AND METHODS

Materials and methods

Protocol and registration

This systematic review was conducted according to a protocol registered in the International Prospective Register of Systematic Reviews (PROSPERO—https://www.crd.york.ac.uk/PROSPERO/) under registration number CRD42024487883. This study closely adhered to the guidelines provided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-P) 2020.

Selection Procedure

The articles have been reviewed by evaluating their titles, objectives, abstracts, discussions, and research designs to assess their relevance to the research subject. Furthermore, any duplicates present in the list of relevant articles were identified and removed. Additionally, each article was evaluated based on the inclusion and exclusion criteria. The authenticity of articles was then ultimately verified by quality evaluation.

Systematic Review Process

Identification

Articles were retrieved from the chosen databases which are PubMed, Scopus, and Cochrane Library using specified keywords, including colorectal cancer, DNA methylation, biomarker, and early screening. The search strategy design involved integrating text words (keywords) and MeSH terms. All possible variations of the terms were considered and combined with Boolean operators (AND, OR) and truncated search terms according to the PubMed User Guide. In PubMed, the truncation symbol is represented by an asterisk (*) where this truncation retrieves all terms that contain the root which is the base part of the word.

Screening

The articles retrieved from the databases were further screened for any presence of duplications, and those that were identified were excluded from inclusion. Subsequently, the titles and abstracts of the remaining articles were thoroughly assessed, and any articles that were found unrelated to the research objectives were excluded.

Eligibility

After the initial screening of articles, the inclusion and exclusion criteria were applied to determine the eligibility of the remaining full-text articles (Table 1). Only articles that satisfied all the criteria were included in this study.

Inclusion

Data analysis was conducted on the remaining selected articles that met all the criteria and previous assessments.

Table 1: Inclusion and exclusion criteria for systematic review

Inclusion criteria	Exclusion criteria
• Studies published in English.	• Studies published in other languages.
• Studies published in 2018-2023.	• Studies published before 2018 and after 2024.
• Randomized controlled trials, clinical trials, validation studies, observational studies (cohort, cross-sectional and case-control studies), prospective studies, prospective-retrospective studies, and multicentred studies.	• Unpublished studies, hand-searched articles or grey literature, technical reports, web-based guidelines, letters, editorials, reviews (systematic, scoping, narrative reviews), and meta-analysis.
• Must contain samples from CRC patients.	• Studies on patients with adenoma, precancerous polyps, or other types of cancer.
• Studies conducted on humans.	• Studies conducted on animals.

Data Extraction

Data from the final full-text publications were assessed, summarized, and presented in the form of tables to enhance readability. Besides, the main findings were retrieved from the articles that discuss on DNA methylation-based biomarkers used in CRC detection and their roles in CRC tumorigenesis. Data was also retrieved in a pre-defined form including the specimen type, sensitivity, specificity, and analysis method. The extracted effect measures are restricted to the area under the receiver operating curve (AUC), sensitivity and specificity.

Quality Assessment

For quality assessment, the Crowe Critical Appraisal Tool (CCAT) (Crowe, 2015) version 1.4 has been used to systematically assess research papers' reliability, validity, and overall quality. The CCAT comprises a form and a user guide that must be used together to ensure the scores obtained are valid and reliable. To ensure that the systematic review includes only high-quality publications, a quality score of 75% or higher is only included in this systematic review. Any discrepancies during the assessment of the risk of bias process were resolved by discussion and consensus among all reviewers.

RESULTS

Literature Search

121 articles in total were identified through database searching on PubMed, Scopus, and Cochrane Library. Six duplicate articles were identified and removed, leaving 115 articles for further assessment. Subsequently, these articles underwent a screening process based on the titles, which led to the removal of 22 articles. The remaining 93 articles underwent abstract screening, resulting in 51 of the articles being excluded. 42 articles from the abstract screening underwent an eligibility process which involved predefined inclusion and exclusion criteria. Eight articles did not meet the criteria and have been removed, resulting in 34 articles. These articles were then assessed for their quality by using CCAT tools. Of 34 articles, 14 of the articles were qualified and included in this systematic review. Figure 1 shows the comprehensive view of the selection procedure in a PRISMA flow diagram.

Data Selection and Study Characteristics

The primary author, publication year, journal, study title, study design, study population, and country were extracted, summarized, and tabulated based on the 14 eligible full-text articles (Supplementary Data). Furthermore, the DNA methylation-based biomarkers used in early-stage CRC detection, the biomarkers' performance, and the roles of biomarkers were analyzed and extracted. This study exclusively focused on articles written in English and published in 5 years from 2018 to 2023.

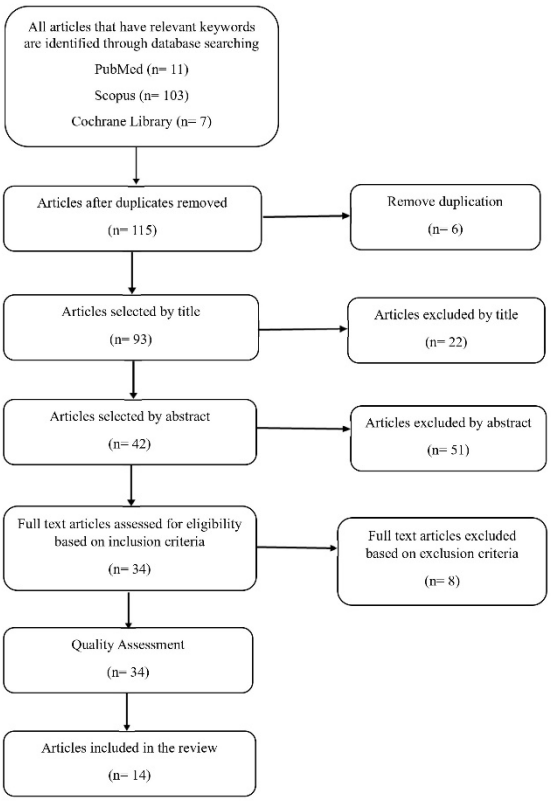

Figure 1: Flow diagram based on PRISMA 2020

Main Findings

DNA methylation-based biomarkers in early-stage CRC detection

DNA methylation which serves as a biomarker for CRC detection was identified from the included studies, comprising of single gene and panel gene biomarkers. The sample used, detection method, and early-stage detection status of DNA methylation biomarkers were extracted and tabulated (Table 2), and the performance of biomarkers in terms of sensitivity, specificity, and AUC value, were extracted (Table 3). Among the included studies, several potential biomarkers for early-stage CRC detection were identified such as *SDC2*, *KCNQ5*, *C9orf50*, combination of *SEPT9* and *SDC2*, *CLIP4*, and combination of *GALNT9* and *UPF3A* (from Study no. 2, 3, 7, 8, 9, and 12).

Role of DNA methylation biomarkers

DNA methylation-based biomarkers play important roles in the progression of CRC. Table 4 demonstrates the findings on the role of DNA methylation biomarkers which influence various processes in CRC tumorigenesis such as proliferation, migration, cell transformation, metastasis, and angiogenesis (from Studies no. 1, 5, 6, 11 and 14).

Table 2: DNA methylation-based biomarkers used in early-stage CRC

Study no.	Gene (s)	Sample/ Material	Method to detect methylation	Early-stage sensitivity for CRC detection
1.	*SM22α*	Tissue	Methylation-specific Polymerase chain reaction	-
2.	*SDC2*	Stool	Linear target enrichment-quantitative methylation-specific real-time PCR using me*SDC2* LTE-qMSP	- In stage 0-II: 89.1%
3.	*SDC2*	Stool	Real-time quantitative methylation specific PCR using sDNA test	- In stage 0-II: 87.0% sensitivity
4.	*SMAD3*	Tissue Plasma	Quantitative methylation-specific polymerase chain reaction	-
5.	*TMEM240*	Tissue Plasma	Quantitative methylation-specific polymerase chain reaction	-
6.	*WIF1* *NPY*	Tissue Plasma	Crystal Digital PCR™	-
7.	*KCNQ5* *C9orf50*	Stool	Methylation-specific quantitative PCR	- For *KCNQ5,* in stage 0:84.4%, stage I: 82.8%, stage II: 69.5% - For C9orf50, in stage 0: 90.6%, stage I: 87.9%, stage II: 84.7%
8.	*SEPT 9/SDC2*	Plasma	Quantitative real-time PCR using ColoDefense test	- In stage 0-II: 81.8% using ColoDefense test
9.	*CLIP4*	Stool	Quantitative real-time PCR using m*CLIP4* test	- In stage I: 96.2% and stage II: 83.1%
10.	*SDC2*	Whole blood	Methylation quantification endonuclease-resistant DNA	-
11.	*LINC00473*	Plasma	Quantitative methylation-specific PCR and droplet digital PCR	-
12.	*GALNT9* *UPF3A* *WARS* *LBD2*	Serum	Bisulfite pyrosequencing	-In stage I: 54.2% and stage II: 75.0% detection If *GALNT9*/*UPF3A*: 87.5% stage I detection and 100% stage II detection
13.	*SEPT9* *BMP3*	Plasma	Droplet digital PCR	-
14.	*FOXF1*	Plasma	MethyLight PCR	-

Table 3: Screening accuracy and AUC value of the biomarkers used in CRC

Study no.	Gene (s)	Sensitivity	Specificity	AUC value
2.	*SDC2*	90.2% (stage 0-IV) 89.1% (stage 0-II)	90.2%	0.90
3.	*SDC2*	83.8% (stage 0-IV) 87.0% (stage 0-II)	98.0%	0.95
4.	*SMAD3*	78.5%	-	-
6.	*WIF1/NPY*	95.5%	100%	0.94 0.98
7.	*KCNQ5* *C9orf50* *KCNQ5/C9orf50*	77.3% 85.9% 88.4%	91.5% 95.0% 89.4%	0.85 0.90 0.89
8.	*SEPT9* *SDC2* *SEPT9/SDC2*	75.8% 60.4% 85.7%	94.7% 86.8% 86.8%	0.86 0.80 0.97
9.	*CLIP4*	90.3%	88.4%	0.96
10.	*SDC2*	81.5%	69.2%	0.85
11.	*LINC00473*	81.0% 90.0%	100% 63.0%	0.88 0.83
12.	*GALNT9/UPF3A/WARS/LBD2* *GALNT9/UPF3A*	62.1% 78.8%	97.4% 100%	0.86 0.90
13.	*SEPT9* *BMP3* *SEPT9/BMP3*	50.0% 40.0% 65.0%	90.0% 90.0% 86.0%	0.68 0.58 0.77
14.	*FOXF1*	78.0%	89.5%	-

Table 4: Roles of the identified DNA methylation-based biomarkers

Study no.	Gene	Original function	Role in tumorigenesis	References
1.	*SM22α*	• Act as a tumor suppressor. • May decrease proliferation and invasion and increase apoptosis in colorectal carcinoma cells. • May prevent the metastasis of CRC	-	Liu Y. et al. (2018)
5.	*TMEM240*	• May repress cell growth, migration, and induce cell cycle arrest in colon cancer cells.	-	Chang S. et al. (2020)
6.	*WIF1*	• A tumor suppressor gene.	• Repression of *WIF1* leads to an overexpression of the Wnt signaling pathway thus promoting cell transformation.	Overs A. et al. (2021)
11.	*LINC00473*	• Able to sponge endogenous miR574-5p or miR15b-5p, inhibit cell proliferation and colony formation capacity, and induce cell apoptosis by activating the APAF1 CASP9-CASP3 pathway.	• Downregulation of pro-apoptotic tumor suppressor properties in CRC.	Ruiz-Bañobre, J. et al. (2022)
14.	*FOXF1*	-	• Associated with angiogenesis in CRC	Dastafkan, Z. et al. (2023)

DISCUSSION

This systematic review focuses on a comprehensive review of DNA methylation biomarkers that hold the potential for early-stage detection of colorectal cancer (CRC). This study includes fourteen articles pertinent to the study objectives, which are to systematically identify DNA methylation-based biomarkers used in early-stage CRC detection and to compile evidence on the roles of DNA methylation-based biomarkers. Every single study that was considered for inclusion had an article quality score of 75% or higher. The countries where the studies were conducted include China, South Korea, France, Iran, Spain, and Brazil. Notably, half of the included studies were accounted for in China. Han et al. (2024) reported a rising incidence of CRC in China, which ranks among the top five causes of cancer mortality in the country. Studies in China were also overrepresented as they have a broader target population. Apart from that, most of the included studies employed observational study design and involved human subjects. This focus on human studies can enhance the relevance and applicability of the findings to clinical settings.

Identifying early-stage biomarkers is essential to improve early detection and treatment of CRC. DNA methylation biomarkers can be utilized in molecular diagnostic blood- and stool-based assays, a non-invasive method feasible in early CRC detection. Employing these samples is more convenient and encourages higher patient compliance. The compilation of findings from 14 studies utilized various biological samples of participants for CRC detection, such as plasma, stool, whole blood, serum, and tissue.

Among the included studies, plasma samples were mostly employed in the identification of DNA methylation biomarkers. These biomarkers include *SMAD3*, *TMEM240*, *WIF1* and *NPY*, *SEPT9* and *SDC2*, *LINC00473*, *SEPT9* and *BMP3,* and *FOXF1*. Higher levels of these methylated genes at the promoter regions have been found in plasma samples from CRC patients compared to healthy individuals, except for the *SMAD3* gene, where a decrease in methylation was detected in 86.6% of plasma CRC patients, as mentioned in Study 4 (Ansar et al., 2020). The hypermethylation and hypomethylation of the studied genes correspond to increased and decreased expression, respectively. Plasma samples consist of cell-free DNA (cfDNA), which can be a promising non-invasive approach for CRC detection. Cell-free DNA refers to the release of DNA fragments into the bloodstream from cancer cells (Canzoniero & Park, 2016). According to Chen et al. (2021), screening tests utilizing plasma rather than whole blood is often suggested since blood cells would introduce an overabundance of genetic material. This could reduce the accuracy of the screening test itself in detecting any changes associated with the disease. However, contradictory to this, whole blood was used as a sample to assess the methylation status of the *SDC2* gene in Study 10, where a substantial difference was identified between CRC and control samples (AUC: 0.85), with 81.5% sensitivity and 68.2% specificity. This suggests that *SDC2* methylation can be a promising CRC biomarker in whole blood samples.

Biomarkers such as *SEPT9* and *SDC2* seem to be the best for early detection in plasma samples because the combination of these biomarkers has been reported in Study 8 to have 81.8% positive methylation in CRC stages 0 to II. In this context, a gene panel is used to detect CRC from the plasma ColoDefense test, resulting in higher sensitivity and specificity of 85.7% and 86.8%, respectively. Also, the AUC value is 0.97, demonstrating better discrimination ability between the CRC and control groups. In comparison, when single gene was used, the resulting sensitivity and specificity were slightly lower, where sensitivity and specificity for *SEPT9* alone were 75.8% and 94.7%, and sensitivity and specificity for *SDC2* alone were 60.4% and 86.8%, respectively. This suggests that combined promoter methylation analysis in a gene panel may increase the accuracy of biomarkers in CRC detection, particularly in early-stage detection compared to single gene analysis.

Other than that, the included studies have also indicated the feasibility of using serum samples for identifying DNA methylation biomarkers. This can be demonstrated by Study 12 where the combination of *GALNT9* and *UPF3A* was utilized and demonstrated good capability in detecting CRC early-stage. The positive methylation in stage I and stage II for the combined gene are high enough which are 87.5% and 100%, respectively. However, when all combined genes from Study 12 were used with the combination of *GALNT9*, *UPF3A*, *WARS*, and *LBD2*, the resulting positive methylation for stage I and stage II was slightly lower. Hence, the used of combined *GALNT9* and *UPF3A* using serum samples has potential in early-stage CRC detection due to its high accuracy in detecting CRC stages I and II.

Besides plasma, serum and whole blood, stool offers a valuable medium in CRC detection due to the natural shedding of cancer cells into the colonic lumen. Based on the findings, several methylated genes were found in stool samples, namely *SDC2*, *CLIP4*, *KCNQ5* and *C9orf50*. The shedding of the tumor cells into the stool occurs before the invasion of blood vessels during CRC development (Ahlquist et al., 2012). Also, the concentration of ctDNA in stool samples is much higher than in plasma due to the dispersion of ctDNA throughout the total blood volume when it is introduced into the circulation (Cao et al., 2021). This results in higher sensitivity for detecting abnormal DNA methylation, making stool feasible for early detection

of CRC. The differences in the performance of methylated genes between different samples can be observed in the *SDC2* gene between Studies 3 and 8. Using stool samples, *SDC2* identified malignancy with higher sensitivity (83.8%) and specificity (98.0%), and AUC of 0.95 in detecting all CRC stages compared to plasma samples in Study 8 with slightly lower sensitivity (60.4%) and specificity (86.8%), and AUC of 0.80.

SDC2 is the most reported methylated gene in stool samples, as reported in Studies 2 and 3. Based on the results, both studies revealed a higher sensitivity and specificity to detect early-stage CRC, but Study 2 outperforms Study 3 in this case. Owing to this, the sensitivity of *SDC2* to detect stages 0 to II in Study 2 is 89.1%, meanwhile, for Study 3 is 87.0%. Additionally, the specificity of this biomarker in both studies is significantly greater, ranging from 90.2% to 98.0%, with an AUC of 0.90 to 0.95. This demonstrates that *SDC2* is a feasible biomarker with the potential to be a single precise biomarker in early CRC detection using stool samples.

Other than that, according to the findings in Study 7, *KCNQ5* and *C9orf50* can be considered as promising biomarkers in identifying early-stage CRC in stool samples. This is due to the high positive methylation in detecting stages 0, I, and II among CRC patients. For *KCNQ5*, the positive methylation in detecting stages 0, I, and II is 84.4%, 82.8% and 69.5%, respectively. Meanwhile, for *C9orf50*, the positive methylation in detecting stages 0, I and II is slightly higher than *KCNQ5* which is 90.6%, 87.9% and 84.7%, respectively. The study also highlighted that methylation of *C9orf50* alone is high enough rather than a combination of *KCNQ5* and *C9orf50* because *C9orf50* alone exhibits higher sensitivity and specificity to detect all stages, making it a good candidate for a single biomarker. Furthermore, the AUC value of *C9orf50* alone (0.90) is excellent in distinguishing CRC from non-CRC patients.

Besides *SDC2*, *KCNQ5* and *C9orf50*, *CLIP4* shows potential in early-stage CRC detection, as depicted in findings from Study 9. The reason for this is that it can identify stage I with an accuracy of 96.2% and stage II with an accuracy of 83.1%. All stool biomarkers from Studies 2, 3, 7, and 9 demonstrated immense potential in early-stage CRC detection. Among these biomarkers, *CLIP4* has the greatest accuracy with the highest sensitivity and AUC values of 90.3% and 0.96, respectively, making it a valuable biomarker with a strong ability for disease detection.

Overall, it can be concluded that *SDC2*, *KCNQ5*, *C9orf50*, *CLIP4*, the combination of *SEPT9* and *SDC2*, and the combination of *GALNT9* and *UPF3A* (from Studies 2, 3, 7, 8, 9, and 12) show promise as reliable DNA methylation biomarkers for early-stage CRC detection. Pooled data revealed that these biomarkers perform well, with specificity over 80% and sensitivity over 70%, and an AUC range of 0.85 to 0.97, indicating strong discriminatory ability. On the other hand, Studies 1, 4, 5, 6, 10, 11, 13, and 14 lacked information regarding early-stage detection status, hence it cannot be confirmed if the biomarkers from these studies are potential for early detection. However, certain biomarkers from these studies demonstrated good accuracy and could be further validated for their potential in early-stage CRC detection.

Apart from that, the evidence on the role of DNA methylation biomarkers was gathered and analysed from the selected studies. Findings from Studies 1, 5, 6, 11, and 14 indicate that DNA methylation-based biomarkers contribute to multiple aspects of CRC progression by influencing key processes in tumor development, such as proliferation, migration, cell transformation, metastasis, and angiogenesis.

DNA methylation is a crucial mechanism that is strongly associated with the expression of tumor suppressor genes. Alterations in DNA methylation patterns can lead to the silencing of these genes, thereby contributing to tumorigenesis (Jin et al., 2011). Study 1 highlighted the role of *SM22α* as a tumor suppressor. It has been reported that *SM22α* can inhibit cell proliferation and invasion, promote cell death, and potentially prevent metastasis of CRC cells. When this gene is aberrantly methylated, its tumor-suppressing functions are disrupted, which can promote CRC tumorigenesis. The study reported the downregulation of *SM22α* in CRC tissue rather than in the adjacent normal tissue of the CRC patient (Liu et al., 2018). Therefore, this study highlights the role of *SM22α*, indicating that its downregulation can enhance cell proliferation and metastasis in CRC.

Besides that, *WIF1* is a tumor suppressor gene mentioned in Study 6. The downregulation of this gene due to hypermethylation has been associated with promoting CRC tumorigenesis. According to the study, the repression of the *WIF1* gene results in the activation of Wnt signalling pathway, which is known to be crucial in cell transformation and cancer progression (Overs et al., 2021). Hence, this underlines the role of *WIF1* gene in cell transformation which potentially contributes to CRC progression.

Other than that, *TMEM240* is a gene reported to have a role in CRC tumorigenesis by influencing CRC cell growth and migration. Study 5 demonstrated that *TMEM240* may repress cell proliferation. This was revealed when overexpression of *TMEM240* suppressed the development of DLD-1 cells, which are known as CRC cells (Chang et al., 2020). Conversely, when *TMEM240* is silenced, the growth

of CRC cells increases, and the cells actively proliferate. Additionally, increased expression of *TMEM240* has been reported to suppress the migration of CRC cells. Therefore, alterations of *TMEM240* which causes its silencing, can have a substantial impact on the development of CRC in terms of cell growth and migration.

Furthermore, *LINC00473* which is known as long noncoding RNA, was found to be downregulated in CRC, as reported in Study 11. This gene can suppress cell proliferation and prevent the colonies formation by accumulating endogenous miR574-5p or miR15b-5p (Ruiz-Bañobre et al., 2022). However, when *LINC00473* is downregulated, its tumor suppressor capabilities which can promote cell apoptosis, are reduced. Hence, it is explained that *LINC00473* plays a significant role in CRC cell initiation and progression.

On the other hand, *FOXF1* is a crucial element in CRC progression as its increased expression is linked to the angiogenesis process in CRC, as stated in Study 14. It has been implicated that overexpression of the *FOXF1* gene results in increased epithelial-mesenchymal transition (EMT) gene signatures (Dastafkan et al., 2023). This underscores its role in promoting metastasis through EMT induction, making it a significant element in CRC progression. The findings on the role of DNA methylation-based biomarkers in CRC progression can imply the need for further interventions to enhance the diagnosis of CRC.

CONCLUSION

In conclusion, this systematic review underscores the potential of DNA methylation-based biomarkers in early-stage colorectal cancer (CRC) detection. Several promising biomarkers, including *SDC2*, *KCNQ5*, *C9orf50*, *CLIP4*, a combination of *SEPT9* and *SDC2*, and a combination of *GALNT9* and *UPF3A*, have been identified for their potential in early-stage CRC detection. Since these biomarkers exhibit high performance in terms of sensitivity, specificity, and AUC value, and can be identified in a non-invasive method, these findings support the use of DNA methylation biomarkers as effective tools for CRC detection. Beyond detection, DNA methylation biomarkers are also implicated in key aspects of CRC tumorigenesis such as cell proliferation, migration, transformation, metastasis, and angiogenesis. Understanding these roles can provide crucial insights into the early molecular events that lead to CRC. This knowledge can drive the development of highly sensitive and specific screening tools, improving the diagnosis of CRC.

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SUPPLEMENTARY DATA

Annexure 1: Characteristics of Included Studies

Study No	Author and Publication Year	Journal of Publications	Title of Study	Study Design	Study Population	Country
1.	Liu, Y. et al. (2018)	*Oncology Letters*	Downregulation of *SM22α* protein by hypermethylation of its promoter in colorectal cancer	-	78	China
2.	Han, Y. D. et al. (2019)	*Clinical Epigenetics*	Early detection of colorectal cancer based on presence of methylated syndecan-2 (*SDC2*) in stool DNA	Retrospective case and prospective control study	585	South Korea
3.	Wang, J. et al. (2020)	*Clinical Epigenetics*	Robust performance of a novel stool DNA test of methylated *SDC2* for colorectal cancer detection: a multicenter clinical study	Multicenter clinical study	1110	China
4.	Ansar, M. et al. (2020)	*International Journal of Molecular Sciences*	*SMAD3* hypomethylation as a biomarker for early prediction of colorectal cancer	-	548	China
5.	Chang, S. et al. (2020)	*Clinical Epigenetics*	Hypermethylation and decreased expression of *TMEM240* are potential early-onset biomarkers for colorectal cancer detection, poor prognosis, and early recurrence prediction	Case-control study	556	China
6.	Overs, A. et al. (2021)	*BMC Cancer*	The detection of specific hypermethylated *WIF1* and *NPY* genes in circulating DNA by crystal digital PCR™ is a powerful new tool for colorectal cancer diagnosis and screening	Cohort study	45	France
7.	Cao, Y. et al. (2021)	*Frontiers in Oncology*	*KCNQ5* and *C9orf50* methylation in stool DNA for early detection of colorectal cancer	-	460	China

Annexure 1: (Cont.)

8.	Chen, Z. et al. (2021)	*Journal of Cancer*	Blood leukocytes methylation levels analysis indicate methylated plasma test is a promising tool for colorectal cancer early detection	Validation cohort study	213	China
9.	Cao, Y. et al. (2021)	*Frontiers in Oncology*	Feasibility of methylated *CLIP4* in stool for early detection of colorectal cancer: a training study in chinese population	Case-control study	321	China
10.	Siri, G. et al. (2022)	*Journal of Cancer Research and Therapeutics*	Analysis of *SDC2* gene promoter methylation in whole blood for noninvasive early detection of colorectal cancer	Case-control study	130	Iran
11.	Ruiz-Bañobre, J. et al. (2022)	*Clinical Epigenetics*	Noninvasive early detection of colorectal cancer by hypermethylation of the *LINC00473* promoter in plasma cell-free DNA	Retrospective cohort study	868	Spain
12.	Gallardo-Gómez, M. et al. (2023)	*Clinical Epigenetics*	Serum methylation of *GALNT9*, *UPF3A*, *WARS*, and LDB2 as noninvasive biomarkers for the early detection of colorectal cancer and advanced adenomas	Multicenter cohort study	433	Spain
13.	Lima, A. B. et al. (2023)	*Cancer Medicine*	Combined *SEPT9* and *BMP3* methylation in plasma for colorectal cancer early detection and screening in a Brazilian population	-	262	Brazil
14.	Dastafkan, Z. et al. (2023)	*The International Journal of Biological Markers*	Diagnostic value of *FOXF1* gene promoter-methylated DNA in the plasma samples of patients with colorectal cancer	Case-control study	100	Iran

REVIEW ARTICLE

The Prognostic Power of Blood Biomarkers in Ischemic Stroke: A Systematic Review

Nur Ain Assila Husna Che Husin[1], Mohd Arifin Kaderi[1], Mohd Basri Mat Nor[2], Norafiza Zainuddin[1]*

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Department of Anaesthesiology and Intensive Care, Kulliyyah of Medicine, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Blood biomarkers; ischemic stroke; prognosis; outcomes; accuracy

ABSTRACT

Background: Blood biomarkers have emerged as potential indicators of poor outcomes following ischemic stroke, helping to monitor the onset of stroke-related processes. Identifying reliable and accessible biomarkers for assessing the prognosis of ischemic stroke patients remains a significant clinical challenge. One of the most difficult areas of research in cerebrovascular disease is the discovery and validation of dependable biomarkers to track the clinical progression of ischemic stroke and predict patient outcomes. Therefore, this article aims to systematically compile evidence on blood-based biomarkers for ischemic stroke prognosis and their clinical outcomes. **Methods:** Three electronic search engines PubMed, Scopus and Cochrane Library used to search for articles related to the study by following PRISMA-P guidelines using specific keywords covering from January 2018 to December 2023. Seventeen studies were selected from 545 articles based on specific inclusion and exclusion criteria, and their quality was assessed using the Crowe Critical Appraisal Tool (CCAT). **Results:** A total of 545 articles were screened and 17 full-text articles were evaluated. The pathophysiological mechanism(s) involved in ischemic stroke are inflammation marker, angiogenesis marker, oxidative stress marker, neurofilament light chain marker and glial fibrillary acidic protein marker. The clinical outcomes of the biomarkers for ischemic stroke prognosis depend much on the performance of diagnostic accuracy. The study also highlights the importance of the timing of biomarker measurements post-event such as within 24 hours after stroke which is crucial for accurate prognosis. The clinical factors also contribute to the progress of prognostication of ischemic stroke such as age, medical history, particularly hypertension and diabetes which could impact stroke outcomes. **Conclusion:** Blood biomarkers alongside clinical factors, offer valuable insights into ischemic stroke outcomes. This review emphasizes their potential to improve stroke prognosis and management.

INTRODUCTION

Biomarkers are important in supplementing the established prognostic factors and improving outcome prediction of ischemic stroke patients (Whiteley et al., 2009 & Uphaus et al., 2022). Biomarkers in ischemic strokes can provide valuable information about the severity of the stroke, potential complications, and the likelihood of recovery. Identification of reliable and accessible biomarkers to characterize ischemic stroke patients' prognosis remains a clinical challenge. According to Ferrari et al. (2023), one of the most challenging research fields in cerebrovascular disease is to identify and validate reliable biomarkers to characterize the clinical evolution of ischemic stroke and patients' prognosis. They mentioned that ischemic stroke has high inter-individual variability as regards clinical presentation, etiology, infarct size and cerebral localization.

Blood biomarkers have the advantage of being minimally invasive, rapidly obtainable, quantitative and reproducible. Montellano et al. (2021) found that blood-based biomarkers might provide additional information to established prognostic factors. According to Angioni et al. (2022), new blood-based markers have the potential to be accurate. It is also conveniently accessible and cost-effective for extensive clinical applications. Besides, it may help with timely diagnosis and could be employed as pharmacodynamic indicators to determine direct target engagement and disease-modifying effects. Katan and Elkind (2018) mentioned that any measurable substance that evaluates the appearance of a stroke-related process in the context of an acute ischemic stroke might be considered a blood biomarker. Thus, blood biomarkers are used as potential indicators in ischemic stroke prognosis and outcome prediction for the patients.

* *Corresponding author.*
E-mail address: znorafiza@iium.edu.my

Besides that, according to Ishida and Cucchiara (2022), some blood biomarkers have been evaluated for association with stroke outcomes. The prediction of outcome could support decision-making processes in ischemic stroke to tailor management and inform patients and relatives (Montellano et al., 2021). As for that, numerous blood-based ischemic stroke biomarkers have been found and appear to be promising in the treatment of ischemic stroke. The use of biomarkers offers essential insights into the extent of the stroke, possible complications, and prognosis for ischemic stroke patients. Hence, this review goal is to systematically gather information regarding the roles of blood-based biomarkers for ischemic stroke prognosis and their clinical outcomes information.

MATERIALS AND METHODS

This systematic review followed guidelines from Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA-P) 2020 (Page et al., 2021) and was conducted according to a protocol registered in the International Prospective Register of Systematic Reviews, PROSPERO under registration number CRD42024558197. A comprehensive literature search was conducted utilizing the open-access online databases available through the International Islamic University of Malaysia (IIUM) subscriptions, including PubMed, Scopus, and the Cochrane Library.

Articles were retrieved from the databases of the chosen search engines using specified keywords. The search strategy was applied for each database (PubMed, Scopus and Cochrane Library) to obtain more accurate results for this review. The study employed a study design search method that utilized a combination of words and included MeSH terms as synonyms. All potential variations of these terms were considered. The variations of keywords used were ischemic stroke, prognosis, biomarker, and blood biomarkers.

The articles were evaluated by reviewing the full texts and filtered based on the inclusion and exclusion criteria. Studies were included if they met the following conditions: (1) published in English, (2) released between January 2018 and December 2023, (3) classified as case reports, clinical studies, multicenter studies, randomized controlled trials, evaluation studies, observational studies, prospective studies, or prospective-retrospective studies, and (4) focused on primary human research involving blood biomarkers in patients with ischemic stroke. Studies involving patients diagnosed with transient ischemic attacks or hemorrhagic stroke were excluded from this review.

The quality of the articles was evaluated using the Crowe Critical Appraisal Tool (CCAT) (Crowe, M., 2013) version 1.4 checklist. Only studies that achieved a score of over 75 percent were deemed to be of sufficiently high quality for inclusion in this systematic review.

RESULTS

Data Analysis

According to Figure 1, a total of 545 articles were initially identified for this study using the specified keywords across multiple databases (PubMed, Scopus, and Cochrane Library). After removing 24 duplicate articles, 521 articles remained. These were first screened by title, reducing the number to 256 articles. Further screening based on the abstracts led to the exclusion of 126 articles. The remaining 130 articles were then carefully assessed through full-text reading and filtered according to the inclusion and exclusion criteria, resulting in the removal of 71 irrelevant articles. Ultimately, 59 full-text articles underwent a quality assessment using the CCAT, and only 17 articles met the required quality standards.

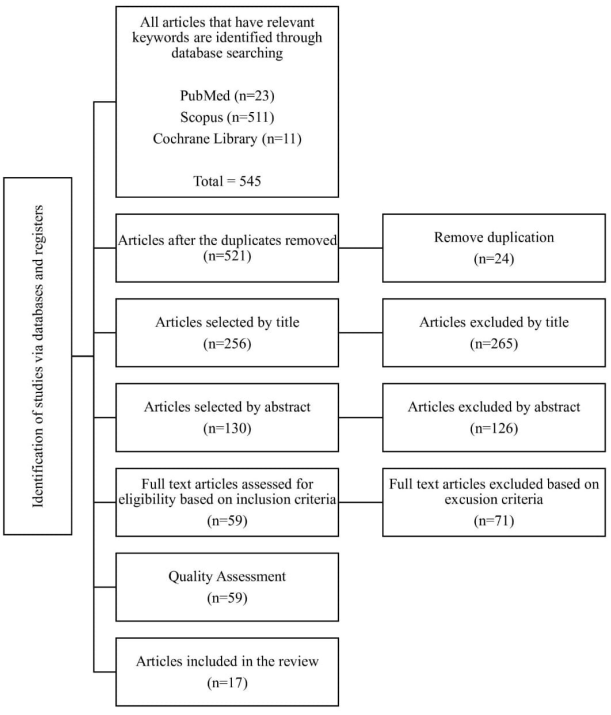

Figure 1: PRISMA 2020 flow diagram

Study Characteristics

The author, study title, country, sample size, study design, and age were extracted and compiled under the study's characteristics based on seventeen relevant full-text articles (Table 2; supplementary data). The review's

included publications, whose sample sizes ranged from 36 to 15,166 patients, were published between 2018 and 2023. The patients' ages ranged from 55 to 68 years old on average. China, Egypt, Italy, and Uzbekistan were the included study countries.

Roles of Blood Biomarkers

All 17 articles published over the past five years (2018-2023) met the inclusion criteria, identifying 17 biomarkers associated with the prognosis of ischemic stroke. Notable roles discussed in this review include markers of inflammation, neuronal injury, glial injury, and anti-inflammatory responses (Table 3; supplementary data).

Blood Biomarkers and the Predicted Outcomes

The seventeen identified blood biomarkers were systematically compiled to determine their predicted outcomes, with all relevant information presented in Table 1. The table includes data on the prognostic outcomes of the biomarkers, along with their diagnostic accuracy in terms of sensitivity, specificity, and area under the curve (AUC). In the context of ischemic stroke prognosis, the timing of blood biomarker measurement post-event is critical, as it affects the accuracy and relevance of the predicted outcomes. Additionally, clinical factors such as age, sex, medical history, smoking habits, and alcohol consumption were also documented.

Table 1: Blood-based biomarkers and the prognosis/predicted clinical outcomes

Biomarker	Clinical Factors	Time measured, post-event	Sensitivity	Specificity	AUC	Prognosis/Clinical outcome
Thioredoxin	Age, sex, smoking, DM, hypertension, dyslipidemia, and carotid stenosis ≥50%.	Within 24 hours from the onset	88%	64%	0.75	A statistically positive correlation between thioredoxin level and clinical outcome after 3 months was measured by mRS.
Copeptin	Age, Sex, DM, hypertension, dyslipidemia, cardiac diseases, carotid stenosis.	Onset within 24 hours	62.2%	84.4%	0.769	Copeptin level was significantly higher in patients with severe stroke (NIHSS > 16) and in patients with unfavorable outcome (mRS 3–6).
Free Triiodothyronine (FT3)	Age, smoking, alcohol consumption, history of stroke, hypertension.	Onset within 48 hours	62.70%	72.03%	0.713	Low FT3 levels at admission are independently associated with poor outcomes in patients with acute ischemic stroke after 3 months.
Serum adiponectin	Age, sex, smoking hypertension, hypercholesterolemia, coronary heart disease, atrial fibrillation, DM	Symptom onset within 48 hours	63.6%	62.4%	0.65	High adiponectin are associated with stroke severity and support the hypothesis that adiponectin can be serve as a biomarker of poor outcome after stroke.

Calprotectin	Age, sex, smoking, medical history (hypertension, hyperlipidemia, hypercholesteremi, atrial fibrillation, DM, family history of stroke).	Within 24 hours after symptom onset	2 weeks after AIS onset (65.63%) During 2 weeks follow-up (81.82%)	2 weeks after AIS onset (66.67%) During 2 weeks follow-up (61.67%)	2 weeks after AIS onset (0.705) During 2 weeks follow-up (0.753)	This study identified calprotectin as a short-term prognostic biomarker of AIS.
Plasma Neurofilament light chain (pNfL)	Age, sex, hyperlipidemia, diabetes, hypertension.	2 days, 7 days and 6 months	2 days (64.3%) 7 days (64.3%) 6 months (82.1%)	2 days (84.6%) 7 days (93%) 6months (54%)	2 days (0.746) 7 days (0.812) 6 months (0.694)	Patients with poor functional outcomes within 6 months after stroke showed have higher pNfL concentration at admission than those with good outcomes.
Serum albumin to globulin ratio (A/G)	Age, sex, smoking, alcohol consumption, medical history (hypertension, dyslipidemia, DM, CHD, atrial fibrillation, family history of stroke).	Within 7 days of the index event of IS or TIA	3 months follow up (53.55%) 1 year follow up (48.56%)	3 months follow up (69.14%) 1 year follow up (69.38%)	3 months follow up (0.6438) 1 year follow up (0.6119)	Lower serum A/G levels were associated with poor functional outcomes and all- cause mortality at 3 months and 1-year follow-up in patients with AIS.
Intercellular adhesion molecule-1 (ICAM-1) and C reactive protein (CRP)	Age, sex, alcohol consumption, medical history (hypertension, DM, CHD, atrial fibrillation, family history of stroke).	Within 24 hours	NA	NA	ICAM (0.829) Hs-CRP (0.748)	Serum concentrations of ICAM-1 and hs-CRP at ED admission could be useful markers for predicting neurological recovery at 3 months after stroke.
Angiopoietin-like protein 4 (ANGPTL-4)	Age, sex, medical history (hypertension, hyperlipidemia, DM, family history of stroke).	Within 48 hours of symptom onset	NA	NA	NA	Increased plasma ANGPTL- 4 concentrations at admission were associated with poor prognosis in ischemic stroke patients.
C1q tumor necrosis factor (TNF)-related protein 9 (CTRP9)	Age, sex, smoking, alcohol consumption, medical history (hypertension, hyperlipidemia, DM).	Within 48 hours of symptom onset	NA	NA	NA	The serum CTRP9 concentration and ratios of CTRP9 to lipids could be promising blood-derived early evaluative biomarkers and a useful tool to predict prognosis in patients with IS at admission.

Eosinophil-to-monocyte ratio (EMR)	Age, sex, medical history of (hyperlipidemia, previous stroke, atrial fibrillation).	The time from the onset of stroke to hospitalization was less than 24 hours	NA	NA	NA	Lower EMR on admission was associated with higher risk of 3-month poor functional outcome, indicating that EMR may be a potential prognostic biomarker for AIS (NIHSS score < 4).
Neurofilament light chain (NfL) and glial fibrillary acidic protein (GFAP)	Gender, age, hypertension, smoking habit.	Within 24 hours .	NA	NA	NA	Both biomarkers correlate not only with stroke severity but also with patients' functional recovery assessed through specific motor and disability scales over a 3-month follow-up.
Serum Netrin-1	Age, sex, smoking, alcohol consumption, dyslipidemia, medical history of hypertension.	Within 48 hours of onset	NA	NA	NA	Elevated serum netrin-1 levels were associated with improved prognosis at 3 months after ischemic stroke, suggesting that serum netrin- 1 may be a potential prognostic biomarker for ischemic stroke.
Soluble triggering receptor expressed on myeloid cells (sTREM2)	Age, sex, smoking, alcohol consumption, medical history (hypertension, hyperlipidemia, DM, CHD, family history of stroke)	Within 48 hours	NA	NA	NA	Higher plasma sTREM2 concentrations in the acute phase of ischemic stroke were associated with greater risk of death and cardiovascular events.
Serum Complement C3	Age, sex, smoking, alcohol consumption, medical history (hypertension, DM, hyperlipidemia, family history of stroke)	Within 48 hours of symptom onset	NA	NA	NA	Elevated serum complement C3 levels were associated with increased risks of adverse clinical outcomes among patients with ischemic stroke.

Serum hepatocyte growth factor (HGF)	Age, sex, smoking, alcohol consumption, medical history (hypertension, DM, CHD, family history of stroke)	Within 48 hours of symptom onset	NA	NA	NA	Serum HGF levels were higher in more severe stroke at baseline, and elevated HGF levels were probably associated with 3-month poor prognosis independently of stroke severity among ischemic stroke patients.
Serum Brain-Derived Neurotrophic Factor (BDNF)	Age, sex, smoking, alcohol consumption, medical history (hypertension, hyperlipidemia, DM, CHD, family history of stroke)	Within 48 hours of onset	NA	NA	NA	Elevated serum BDNF levels at baseline are associated with better prognosis at 3 months among Chinese ischemic stroke patients, suggesting that serum BDNF may be a potential biomarker for prognosis after ischemic stroke.

AIS= acute ischemic stroke, AUC= area under curve, CHD= chronic heart disease, DM= Diabetes mellitus, ED= emergency departments, Ischemic stroke, mRS= modified Rankin Scale, NA= Data not available, NIHSS= National Institutes of Health Stroke Scale

DISCUSSIONS

Today's clinical settings depend heavily on blood indicators of ischemic stroke prognosis. Therefore, this review highlights systematically compiled evidence on the potential roles blood biomarkers may play in assisting established prognostic variables in ischemic stroke patients and their functional outcomes.

Blood Biomarkers that Supplement the Established Ischemic Stroke Prognostic Factors

The most notable role of the blood biomarkers is inflammation which involves the biomarkers thioredoxin, serum albumin to globulin ratio (A/G), copeptin, eosinophil-to-monocyte ratio, free triiodothyronine, intercellular adhesion molecule-1 (ICAM-1) and C reactive protein (CRP), calprotectin, soluble triggering receptor expressed on myeloid cells 2 (sTREM2), and serum complement C3. Inflammatory markers play a significant role in the pathophysiology of ischemic stroke and are closely associated with stroke prognosis. After an ischemic stroke, an inflammatory response is triggered in the brain, contributing to both tissue damage and repair. Several inflammatory biomarkers have been studied for their potential to predict the outcomes of ischemic stroke, including the severity of neurological damage, risk of complications, and long-term recovery.

Another proposed role of blood biomarkers is angiogenesis, involving angiopoietin-like protein 4 (ANGPTL-4) and serum hepatocyte growth factor (HGF). Angiogenesis refers to the formation of new blood vessels around the infarct, which is positively associated with stroke patients' survival rate, survival time, and neurological recovery (Zhu et al., 2021). By promoting the development of new blood vessels, ANGPTL-4 and HGF help restore blood flow, reduce the size of the infarct, and support the brain's repair and regeneration processes.

In addition, neurofilament light chain (NfL) and glial fibrillary acidic protein (GFAP) markers were included in the table. Ferrari et al. (2023) found that GFAP and NfL are brain injury markers detectable in blood using highly sensitive technologies. Among these, sNfL holds a stronger prognostic value, showing better predictive performance compared to sGFAP. Furthermore, elevated blood NfL levels during the acute phase of stroke are associated with a poor prognosis (Wu et al., 2022).

By identifying the roles played by these biomarkers in stroke pathology, a deeper understanding of their contributions can be gained and novel approaches for therapeutic interventions that target the enhancement of their positive effects can be achieved.

Blood Biomarkers and their Clinical Outcomes in Ischemic Stroke Patients

Most of the prognostication outcomes were found to be poor after ischemic stroke. Markers that had poor outcomes were angiopoietin-like protein 4 (ANGPTL-4), serum albumin to globulin ratio, copeptin, eosinophil-to-monocyte ratio, neurofilament light chain (NfL), glial fibrillary acidic protein (GFAP), free triiodothyronine, soluble triggering receptor expressed on myeloid cells 2 (sTREM2), serum adiponectin, serum complement C3, and serum hepatocyte growth factor (HGF). However, serum netrin-1 & serum BDNF were found to be associated with better prognosis which has a higher chance of recovery after an ischemic stroke. The remaining biomarkers such as CTRP9, thioredoxin, ICAM-1 & CRP, and calprotectin, were not specified.

The details gathered also discussed the performance of diagnostic accuracy in terms of biomarker's sensitivity, specificity and area under curve (AUC). The biomarkers that provided information on those are thioredoxin, serum albumin to globulin ratio (A/G), copeptin, fT3, ICAM-1 & CRP, calprotectin, pNfL and serum adiponectin. The data on the remaining biomarkers are not available. Thioredoxin, calprotectin and pNfL (at 6 months after stroke) provided good sensitivity between above 80 percent, showing reliable diagnostic capabilities and making it valuable in confirming non-stroke cases. Similarly, copeptin and pNfL (at 2 days & 7 days after stroke) also showed strong performance with high specificity (84.4% and (84.6% & 93%)) respectively. Moreover, ICAM-1 has been identified as the most promising biomarker, demonstrating the highest AUC, which reflects excellent diagnostic accuracy.

The timeframes for post-stroke biomarker measurements, outlined in Table 1, played a pivotal role in understanding the progression and impact of ischemic stroke. Most of the samples were collected within 24 hours (n=6, 35.29%) and 48 hours (n=9, 52.94%) after stroke onset. Montellano et al. (2021) emphasized the importance of sampling biomarkers early, especially those whose concentrations naturally fluctuate during disease progression or are influenced by early complications, such as post-stroke infections and inflammation. Early sampling ensured accurate and timely monitoring of disease progression and potential complications. By providing prompt prognostic information during the initial clinical evaluation, the predictive value of these biomarkers was significantly enhanced.

Clinical factors also serve as predictive outcomes for ischemic stroke, typically reflecting patient characteristics and medical conditions. This review identified several notable clinical factors, including age over 22 years and medical history of conditions such as hypertension (n=16, 94.12%) and diabetes mellitus (n=13, 76.47%). Increased age heightens the risk of ischemic stroke, as aging leads to harder and thicker arterial walls, which raises the likelihood of blockages. Furthermore, McManus & Liebeskind (2016) noted that up to 84% of patients with acute stroke presented with hypertension, while a smaller percentage exhibited blood pressures below normal during episodes of cerebral ischemia. Additionally, individuals with diabetes mellitus (DM) are at risk of developing early atherosclerosis and plaque instability due to endothelial dysfunction, increased thrombogenesis, and monocyte activation (Olesen et al., 2019). Incorporating clinical factors alongside biomarkers improves the predictive accuracy of functional outcomes, such as disability or mortality.

CONCLUSION

This systematic review highlights the findings on the role of blood biomarkers and their clinical outcomes for ischemic stroke prognosis. These blood biomarkers play various roles in ischemic stroke prognosis which are inflammation marker, angiogenesis marker, oxidative stress marker, neurofilament light chain marker and glial fibrillary acidic protein marker. The functional outcomes of the ischemic stroke much relying on the prognostication outcomes, the performance biomarkers' accuracy in terms of sensitivity, specificity and AUC, the timing of biomarker measurements post-event and the clinical factors. This review underscores the importance of blood biomarkers in advancing the prognostication and management of ischemic stroke, ultimately aiming to improve patient outcomes.

One of the systematic review's limitations is the absence of data regarding the diagnostic accuracy of the biomarkers, which could potentially skew the overall results and render them inconclusive. Besides that, the compiled studies were mostly distributed from China caused the dataset may have limited the generalizability of the results to a broader global context. Furthermore, restricting the study to English-language articles might have excluded relevant studies published in other languages. Thus, further research, validation, and standardization are necessary to ensure the clinical utility and integration into routine practice. Additionally, considering factors such as the timing of biomarker measurement, patient heterogeneity, and variability in stroke etiology will be crucial for developing robust predictive models in ischemic stroke management.

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REVIEW ARTICLE

Fertility Supplements and Their Impact on Reproductive Health in Women with Poor Ovarian Response (POR): A Scoping Review

Putri Nurliyana Zulkafli[1], Azantee Yazmie Abdul Wahab[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Fertility supplements, infertility, poor ovarian response, women, reproductive health

ABSTRACT

Background: Occasionally, infertile women undergoing fertility treatment, particularly those affected by factors such as poor-quality oocytes and poor ovarian response (POR), turn to supplements to enhance their chances of conceiving. However, women with POR represent approximately 10% of this group, making them a minority and limiting their available treatment options. Therefore, this study aims to investigate the most commonly used fertility supplements for women with POR and evaluate their potential effects on reproductive health.. **Methods:** Relevant keywords were used to search three major online databases: PubMed, Scopus, and ScienceDirect. Article selection followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, considering all articles published between 2012 and 2022 that met the inclusion and exclusion criteria. **Results:** A total of 11 articles were selected, demonstrating that fertility supplements have an effect on POR and reproductive health. The findings identified several fertility supplements as effective and suitable for women with poor ovarian response, including dehydroepiandrosterone (DHEA), vitamin D, myo-inositol, and the Ding-Kun Pill (DKP). These supplements have been linked to positive effects on reproductive health, such as increased insulin-like growth factor 1 (IGF-1) levels, healthy follicular growth, and improved oocyte quality and development, which may enhance fertility outcomes. **Conclusion:** This review is significant as it enhances our understanding of the effectiveness fertility supplements for women with impaired ovarian reserves. By offering suitable treatment options, it also fulfills the need for evidence-based knowledge about the reproductive impacts of these supplements.

INTRODUCTION

Fertility supplements, according to Forbes Health (2023), are manufactured products that exist in the form of a capsule, sachet, pill, or tablet. They may contain a range of substances and are frequently mentioned as serving a significant contribution to improving both male and female fertility. Examples include selenium, folic acid, coenzyme Q10, dehydroepiandrosterone (DHEA), and many others. Female fertility supplements assist in conception by providing extra micronutrients into the body, where they aid in the production of high-quality oocytes and the reduction of oxidative stress. The majority of women may benefit from consuming supplements, especially the older population who are more prone to oxidative cell damage as well as those with limited ovarian reserve or poor responses.

According to the United Nations (2015), infertility is a pressing global health issue that affects 20 to 30% of the female reproductive age population in society today. However, the most varying explanations are mostly rooted in the decrease of reproductive potential among females. A multitude of systemic and ovarian diseases, such as polycystic ovarian syndrome (PCOS), endometriosis, premature failure of the ovary, and pelvic inflammatory disease, can also influence the female reproductive system and potentially lead to infertility (Deshpande and Gupta, 2019). Fertility supplements should be addressed as one of the options for restoring fertility and normal reproduction as it can be seen that the reproductive health of poor ovarian responders are significantly compromised.

Approximately 10% of women pursuing fertility treatments have an impaired ovarian reserve where it can affect people of all ages (Greene et al., 2014). Jirge (2016) mentioned that poor ovarian reserve (POR) is a significant limiting element for the effectiveness of any infertility method of treatment. This suggests that women of reproductive age have fewer oocytes of lower quality and quantity. Moreover, the fertility rate of women with POR is also relatively low compared to a control group study, especially for women above 40 who have driven ovarian aging (Zhen et al., 2008). Although POR is a rare condition affecting a minority of women, some cases still involve low ovarian reserves and infertility complications. Consequently, fertility supplements that are suitable, effective, and safe to consume are few and minimal. It is also critical for women to comprehend the implications of fertility supplements on their reproductive health, particularly if they struggle with ovarian reserve issues. Thus, by compiling the available information based on

* *Corresponding author.*
E-mail address: yazmie@iium.edu.my

scientific results, this study provides evidence of various fertility supplements effective for women with POR.

MATERIALS AND METHODS

Study Design

A scoping review study design was chosen to comprehensively examine the available evidence on fertility supplements for infertile females with ovarian reserve complications and their effects on reproductive health. The framework included the development of research objectives aligned with the research problems, the selection of articles that met the review's goals, and a screening process to ensure compliance with the inclusion and exclusion criteria, along with the availability of full-text articles.

Search Method

Relevant research articles were retrieved from three medically and scientifically credible online databases: PubMed, Scopus, and ScienceDirect. The following keywords were used to identify relevant publications: 'fertility supplements', 'poor ovarian response', 'POR', 'diminished ovarian reserve', 'DOR', 'poor ovarian responders', 'women', 'females'. Additionally, in order to further clarify and broaden the search parameters while using databases, Boolean operators (AND, OR) and asterisks (*) were utilized in combination with the search keywords.

Inclusion and Exclusion Criteria

Several criteria were established and considered during the selection of relevant papers for this scoping review. Articles that failed to meet the inclusion criteria outlined in Table 1 were excluded from the analysis

Selection of Studies

The research papers were selected following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews (PRISMA-ScR) standards. These standards provide guidelines for choosing, evaluating, and synthesizing studies in scoping reviews, and the most recent statement incorporates improvements in these approaches (Page et al., 2021). Articles published between 2012 and 2022 were extracted from online databases and screened. After eliminating duplicates from various sources, the remaining articles underwent title and abstract screening to filter out irrelevant studies. Subsequently, the full-text versions of the selected papers were retrieved. Next, the information in those articles was thoroughly examined to analyze the data on fertility supplements for women with POR and their impact on reproductive health. During the screening process, articles that did not meet the inclusion criteria or conformed to the exclusion criteria were excluded. The PRISMA extension for scoping reviews, retrieved from Tricco et al. (2018), is presented in Figure 1.

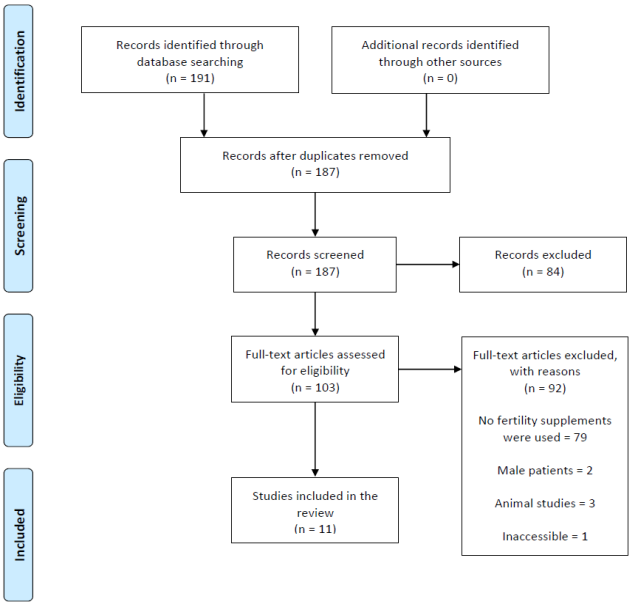

Figure 1: PRISMA flow diagram

Data Extraction

The final phase for methodology is data retrieval from the chosen articles. The findings from the final selection of research articles were extracted, examined, and are presented in Table 3 and Table 4. Here, the characteristics of each study is clearly identified and examined for further discussion.

RESULTS

The selection of articles is summarised in Figure 1. Initially, 191 references were retrieved from the databases (Table 2). After removing duplicates, 187 references remained. These references were screened based on predetermined criteria (Table 1), focusing on infertile women with POR and the use of fertility supplements. A total of 103 articles were eligible for inclusion after excluding conference papers, review articles, case reports, and inaccessible publications. Among the eligible articles, 11 publications specifically mentioned the type of fertility supplements used. Table 3 presents data on the characteristics of the research articles, including the author, title, year of publication, study type, country of origin, participant data, and type of fertility supplements used. Table 4 illustrates the reproductive outcomes associated with fertility supplements in women with POR, providing information on the author, supplement type, ovarian markers, fertilization rate, and pregnancy rate. Out of 11 selected studies, six investigated the use of DHEA in women with POR, two focused on myo-inositol, two on vitamin D, and one study examined the effects of the Ding-Kun Pill (DKP).

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
a) Research articles that are written in English b) Research articles that are published from year 2012 to 2022 c) Research articles that are related to fertility supplements for infertile women POR d) Full-text and peer-reviewed research articles e) Qualitative (eg. case study) and quantitative (eg. descriptive) studies f) The search consists of specific keywords	a) Research articles that are written in languages other than English b) Research articles that are published before year 2012 c) Research articles that are not related to fertility supplements for infertile women with POR d) Research articles that are not in full text e) Conference papers, case reports, grey literatures, review studies, editorials, letters f) Research articles that are irrelevant to the objectives of the study g) Research articles on female medications

Table 2: Total number of hit-searches based on keywords of PubMed, Scopus and ScienceDirect

Online Database	Keywords	Total of References
PubMed	("fertility supplement" AND (women OR female) AND ("poor ovarian response" OR POR OR "diminished ovarian reserve" OR DOR OR "poor ovarian responder") AND infertil*	20
Scopus	"fertility supplement" AND (women OR female) AND ("poor ovarian response" OR "diminished ovarian reserve" OR "poor ovarian responder") AND infertil*	42
ScienceDirect	"fertility supplement" AND (women OR female) AND ("poor ovarian response" OR "diminished ovarian reserve") OR "poor ovarian responder") AND infertility	129
	Total	191

Table 3: Data Extraction on the Common Types of Fertility Supplements for Infertile Women with POR

Author	Title	Year of Publication	Specific of Study Design	Country of Origin	Type of Fertility Supplement	Dose of Supplement	Duration of Supplement
Moawad & Shaeer	Long-term androgen priming by use of dehydroepiandrosterone (DHEA) improves IVF outcome in poor-responder patients. A randomized controlled study	2012	Randomized controlled trial (RCT)	United Arab Emirates	DHEA	25mg	12 weeks
Yeung et al.	A randomized, controlled, pilot trial on the effect of dehydroepiandrosterone on ovarian response markers, ovarian response, and *in vitro* fertilization outcomes in poor responders	2014	RCT	Hong Kong	DHEA	25mg	12 weeks
Zhang et al.	Dehydroepiandrosterone plus climen supplementation shows better effects than dehydroepiandrosterone alone on infertility patients with diminished ovarian reserve of low-FSH level undergoing in-vitro fertilization cycles: a randomized controlled trial	2016	RCT	China	DHEA	25mg	12 weeks
Hu et al.	The effect of dehydroepiandrosterone supplementation on ovarian response is associated with androgen receptor in diminished ovarian reserve women	2017	Prospective chort study	China	DHEA	25mg	8 weeks
Ozcil	Dehydroepiandrosterone supplementation improves ovarian reserve and pregnancy rates in poor responders	2020	Prospective chort study	Turkey	DHEA	50mg	5 months
Nazari et al.	Effect of myo-inositol supplementation on ICSI outcomes among poor ovarian responder patients: A randomized controlled trial	2020	RCT	Iran	Myo-inositol	4g	1 month
Mohammadi et al.	The effect of Myo-inositol on fertility rates in poor ovarian responder in women undergoing assisted reproductive technique: a randomized clinical trial	2021	RCT	Iran	Myo-inositol	4g	12 weeks
Aramesh et al.	Does vitamin D supplementation improve ovarian reserve in women with diminished ovarian reserve and vitamin D deficiency: a before-and-after intervention study	2021	Pre-post intervention study	Iran	Vitamin D	50,000IU	3 months
Song et al.	The Role of Traditional Chinese Formula Ding-Kun Pill (DKP) in Expected Poor Ovarian Response Women (POSEIDON Group 4) Undergoing *In Vitro* Fertilization-Embryo Transfer: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial	2021	RCT	Mainland China	Ding-Kun Pill (DKP)	7g	5-6 weeks
Bacanakgil et al.	Effects of vitamin D supplementation on ovarian reserve markers in infertile women with diminished ovarian reserve	2022	prospective, non-randomized, cross-	Turkey	Vitamin D	300,000IU	2 months

			sectional study				
Hou et al.	DHEA restores mitochondrial dynamics of cumulus cells by regulating PGAM5 expression in poor ovarian responders	2022	nested case-control study	Taiwan	DHEA	25mg	2 months

Table 4: Data Extraction on the Reproductive Impacts of Fertility Supplements on Infertile Women with POR

Author	Title	Type of Fertility Supplement	Ovarian Reserve Markers				Fertilization Rate	Pregnancy Rate
			FSH	AMH	AFC	Estradiol		
Moawad & Shaeer	Long-term androgen priming by use of dehydroepiandrosterone (DHEA) improves IVF outcome in poor-responder patients. A randomized controlled study	DHEA	Decreased	No change	Increased	Increased	Improved	Improved
Yeung et al.	A randomized, controlled, pilot trial on the effect of dehydroepiandrosterone on ovarian response markers, ovarian response, and *in vitro* fertilization outcomes in poor responders	DHEA	Slightly increased	Slightly increased	No change	Slightly increased	Improved	No significant improve-ment
Zhang et al.	Dehydroepiandrosterone plus climen supplementation shows better effects than dehydroepiandrosterone alone on infertility patients with diminished ovarian reserve of low-FSH level undergoing in-vitro fertilization cycles: a randomized controlled trial	DHEA	Decreased	Increased	Increased	Increased	Improved	Improved
Hu et al.	The effect of dehydroepiandrosterone supplementation on ovarian response is associated with androgen receptor in diminished ovarian reserve women	DHEA	Decreased	Increased	Increased	Increased	Improved	Improved
Ozcil	Dehydroepiandrosterone supplementation improves ovarian reserve and pregnancy rates in poor responders	DHEA	Decreased	Slightly increased	Increased	Increased	Improved	Improved
Hou et al.	DHEA restores mitochondrial dynamics of cumulus cells by regulating PGAM5 expression in poor ovarian responders	DHEA	Decreased	Increased	N/A	Slightly increased	Improved	Improved
Nazari et al.	Effect of myo-inositol supplementation on ICSI outcomes among poor ovarian responder patients: A randomized controlled trial	Myo-inositol	Slightly increased	No change	No change	N/A	Improved	No significant improvement
Mohammadi et al.	The effect of Myo-inositol on fertility rates in poor ovarian responder in women undergoing assisted reproductive technique: a randomized clinical trial	Myo-inositol	Slightly increased	Slightly increased	Slightly increased	Slightly increased	Improved	Improved
Aramesh et al.	Does vitamin D supplementation improve ovarian reserve in women with diminished ovarian reserve and vitamin D deficiency: a before-and-after intervention study	Vitamin D	N/A	Increased	No change	N/A	Improved	Improved
Bacanakgil et al.	Effects of vitamin D supplementation on ovarian reserve markers in infertile women with diminished ovarian reserve	Vitamin D	Decreased	Increased	Increased	N/A	Improved	Improved
Song et al.	The Role of Traditional Chinese Formula Ding-Kun Pill (DKP) in Expected Poor Ovarian Response Women (POSEIDON Group 4) Undergoing In Vitro Fertilization-Embryo Transfer: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial	Ding-Kun Pill (DKP)	Slightly increased	Slightly increased	No change	Increased	Improved	No significant improvement

DISCUSSION

Numerous interventions have been explored to improve fertility outcomes in women with poor ovarian response (POR). Various supplements have shown potential in enhancing ovarian function and improving fertility in the management of POR. Among these, certain supplements have gained attention for their ability to support reproductive health. However, the effectiveness of these interventions may vary between individuals. Based on our the findings, the most common fertility supplementations for women with POR and their impacts on reproductive health are DHEA, Myo-inositol, Vitamin D and Ding-Kun Pill (DKP).

The most commonly used fertility supplement for POR is DHEA. DHEA, a common steroid in human blood, acts as a precursor for steroid hormone production in the follicle. Moawad and Shaeer (2012) found that DHEA supplementation improves oocyte yield and pregnancy rates in women with POR. Hou et al. (2022) confirmed that DHEA raises intrafollicular IGF-1 levels, enhancing follicle growth and oocyte quality. A study by Yeung et al. (2021) shows that DHEA boosts androgen levels, which are essential for follicular development and increased sensitivity to FSH. This mechanism, according to Hu et al. (2017), may promote follicle growth in women with diminished ovarian reserve (DOR). Ozcil (2020) also reported that DHEA improves ovarian reserve markers and pregnancy outcomes, particularly in women with secondary infertility. Similarly, Zhang et al. (2016) found that DHEA increases conception rates, boosts anti-Müllerian hormone (AMH) levels, and lowers FSH levels. Studies by Hou et al. (2022) and Hu et al. (2017) further show that DHEA enhances FSH effects and improves mitochondrial function, making it a potential treatment for improving clinical pregnancy rates. The majority of DHEA regimens involve a dose of 25 mg for a duration of 8–12 weeks, with the exception of Ozcil (2020), who utilized a dose of 50 mg over 5 months. Overall, these findings suggest that DHEA treatment has the potential to improve ovarian reserve markers, fertilization rates, and clinical pregnancy outcomes among poor responders.

Myo-inositol, part of the vitamin B complex, has been shown to improve oocyte maturation, reduce androgen production, and lower oxidative stress. Mohammadi et al. (2021) found that myo-inositol reduces the required gonadotropin dose, increases ovarian sensitivity, and improves fertilization rates. These effects may be due to myo-inositol's ability to enhance oocyte responsiveness to calcium oscillations during fertilization, contributing to higher embryo quality and pregnancy rates. Nazari et al. (2020) reported that administering myo-inositol for three months before ovulation in POR patients undergoing ICSI improved reproductive outcomes including fertilization, implantation, and embryo development. However, no statistically significant improvement was observed in the pregnancy rate. The studies utilized a Myo-inositol dose of 4 g, with treatment durations ranging from 4 to 12 weeks.

Vitamin D, a steroid hormone, is essential for bone and calcium metabolism, aiding calcium absorption and supporting bone growth. Studies have revealed an effective association between vitamin D levels in follicular fluid and embryo quality, as well as an increase in AMH and antral follicular count (AFC) levels which led to better treatment outcomes in terms of higher oocyte yield, higher fertilization rates, and increased chances of pregnancy (Aramesh et al., 2021; Bacanakgil et al., 2022). Bacanakgil et al. (2022) also linked vitamin D to reproductive conditions like PCOS and endometriosis, as well as improved outcomes in controlled ovarian stimulation during IVF. The doses of Vitamin D in these studies vary, ranging from 30,000 IU to 50,000 IU, with treatment durations of 2 to 3 months.

Ding-Kun Pill (DKP), a traditional Chinese medicine used since the Qing dynasty, contains ginseng, deer antler, safflower, scutellaria, and other herbs. A study by Song et al. (2021) found that 7g of DKP significantly increased estradiol, slightly increased FSH, and AMH but there is no changes in AFC in patients with reduced ovarian reserve. DKP also improved blastocyst quality and reduced follicle apoptosis by enhancing ovarian sensitivity to gonadotropins, leading to better oocyte development, increase in the fertilization rate along with higher qualities and quantities of blastocysts and endometrial receptivity. However, this supplement did not yield statistically significant improvements in the overall pregnancy rate.

This review has several limitations. Variations in dosages and durations of supplementation across studies make it difficult to determine the optimal regimen. The long-term safety and potential side effects of fertility supplements are not fully understood or adequately assessed. The findings are based on available evidence and may not reflect the most current research. Furthermore, the effectiveness of fertility supplements may vary depending on patient characteristics such as age, fertility status, and health conditions, limiting the applicability of this review to all women with POR. More research, including randomized controlled trials, is needed to establish the efficacy of these supplements.

CONCLUSION

In conclusion, this scoping review highlights the potential benefits of fertility supplementation in infertile women with POR. Fertility supplements such as DHEA, vitamin D, myo-inositol, and DKP have shown positive effects on reproductive health, including improved ovarian response, gonadotropin levels, embryo quality, endometrial receptivity, and fertility rates. These findings suggest that fertility supplementation may be a beneficial treatment option for women with POR.

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REVIEW ARTICLE

Proximity of Maternal Residences to Nuclear Power Plant, Prenatal Exposure to Ionising Radiation and Its Effect on Pregnancy Outcomes: A Systematic Review

Aisyah Sofia Hamzah[1], Norhidayah Ahmad[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, 25200 Kuantan, Pahang, Malaysia

Keywords:
Ionising radiation; industrial activity; nuclear power plant; pregnancy outcomes

ABSTRACT

Background: The radiation issue has long been a subject of controversy and debate, particularly on acceptable exposure levels and the potential health impacts on the public, especially vulnerable groups like pregnant women. The proximity of residency to sources of this physical hazard can significantly contribute to elevated levels of radiation exposure. Therefore, this study aims to systematically review the published articles on the effects of pregnancy outcomes resulting from maternal exposure to ionizing radiation (IR) from nuclear power plants (NPP) or mines and to investigate the relationship between the proximity of maternal residences to NPPs or mines and the associated risk of adverse pregnancy outcomes. **Methods:** This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Articles were sourced from PubMed, ProQuest, and Scopus databases. The inclusion criteria encompassed:(i) articles published in English with full-text availability and (ii) observational studies that reported on IR exposure from industrial areas and its effects on pregnancy. Articles were excluded from this study if they did not report the observed exposure and health outcomes or if they involved a non-human study. The Critical Appraisal Tool (CCAT) version 1.4 was used for the quality assessment. **Results:** 215 articles were screened, with 8 full-text articles selected for final evaluation. Among these, 6 articles examined IR exposure from the NPP, while 2 articles investigated the radiation exposure from uranium plants. The distance between residential homes and the NPPs or uranium plants ranged from 0.8 to 50km. The observed adverse pregnancy outcomes included birth defects, premature birth, pregnancy loss, and low birth weight. 5 articles recorded high quality (score range from 80 – 90%) and only 3 articles recorded acceptable quality (score range from 55- 75%). **Conclusion:** Our findings reveal no association between the proximity of residency to NPP or uranium plants with adverse pregnancy outcomes. This review was able to enhance the understanding of the observed relationship, despite the limited articles to provide a defined conclusive. Future studies are recommended to focus on the effects of radiation on the exposure of specific trimester windows and determine the biological mechanisms underlying the adverse pregnancy outcomes.

INTRODUCTION

Radiation is classified as a physical hazard that can cause detrimental effects to human health by causing chemical changes in human DNA and may result in abnormal cell growth (ILO, 2024). Radiation can be divided into two types, which are non-ionising radiation (NIR) and ionising radiation (IR) (USNRC, 2020). NIR does not have enough energy to remove electrons from atoms and the energy will be accumulated in the materials it passes, such as visible light, microwaves and radio waves. Meanwhile, IR has enough energy to remove electrons from the atom using the accumulated energy such as cosmic rays, x-rays and radiation from radioactive materials (ILO, 2024; USNRC, 2020).

IR has numerous applications across various industries, including energy production, manufacturing, medicine and research (ILO, 2024). People may exposed to radiation, whether from medical procedures, occupational factors or environmental sources. The exposure to radiation to certain vulnerable groups has raised public health concerns. Radiation exposure to pregnant women during the gestational period can jeopardize the health and safety of the developing fetus. The International Commission on Radiological Protection (ICRP 103) recommends a radiation protection limit of 1 mSv/year for pregnant workers to protect the developing fetus, which is the same as the annual limit for public exposure (ICRP, 2007). Maternal exposure to IR during the gestational period may cause adverse pregnancy outcomes, such as spontaneous abortion, intrauterine growth restriction, mental retardation, birth defects and leukaemia (Tsou et al., 2019).

To date, there is limited research available on discussing the effect of pregnancy outcomes due to the radiation generated from industries of nuclear power plants (NPP) or mines (Wang, 2009). The previous literature studied the impact of high-dose of IR on the survivors of the catastrophes of Hiroshima and Nagasaki and the

* *Corresponding author.*
E-mail address: hidayahahmad@iium.edu.my

Chernobyl meltdown, but the health effects of the daily exposure level to IR among humans are limited and only focused on the animal effect (Mangones, 2013). The exposure to radiation from industrialization has become a public health concern as the radiation from these sources may add up to 80% of the yearly dose of radiation level to the nearest population, whereas the remaining 20% comes from various sources such as medical, commercial and industrial activities (World Nuclear Association, 2017). Hence, this study aimed to systematically review the published articles on the effects of pregnancy outcomes resulting from maternal exposure to ionizing radiation (IR) from nuclear power plants (NPP) or mines. It also aims to investigate the relationship between the proximity of maternal residences to NPPs or mines and the associated risk of adverse pregnancy outcomes.

METHODS

Study Design

This study was carried out based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline. There is a 27-item checklist and a four-phase flow diagram (as shown in Figure 1) in the PRISMA Statement (Moher et al., 2009).

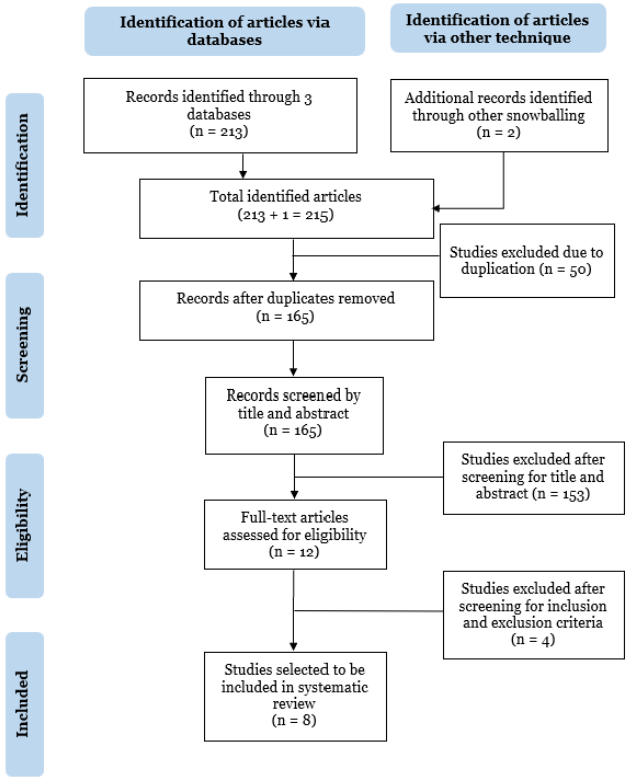

Figure 1: PRISMA Flow Diagram for the selection of articles

Article Search Strategy

The search strategy of the research paper was conducted by referring to three online databases (PubMed, ProQuest and Scopus). The Boolean operators of the connective terms such as AND, OR, and NOT have been used in the search strategy to get comprehensive results. A specific search string was built: (pregnancy OR "pregnant women" OR "pregnant woman" OR fetus OR foetus) AND (mining OR "processing plant" OR "nuclear plant" OR "power plant" OR "nuclear facilities") AND radiation AND (effect OR outcome). Other relevant articles were also manually searched by checking the reference lists of selected articles using the snowballing technique.

Selection Criteria

From the identified articles, studies that met the following eligibility criteria were selected based on; (i) articles published in the English language with full-text access; (ii) human epidemiological studies with several study designs (case-control, cohort and cross-sectional studies) and (iii) studies reported on IR exposure from the NPP or mines and the effect on pregnancy. Retrieved articles that did not meet these criteria were excluded from the list. Only the final shortlisted articles went through the data analysis process and quality assessment procedures.

Article Screening and Data Extraction

The selected articles were evaluated by two independent reviewers for the relevance of the selection and any disagreement between reviewers was discussed. The article selection involves four levels as outlined in the PRISMA guideline.

For the first level of screening, the titles and abstracts of the articles were screened and the duplicates of research articles between databases were removed. The articles that passed the first level of screening were further screened based on the eligibility criteria of inclusion and exclusion. Then, the data from the selected articles were extracted systematically. Study characteristics that comprised the information of the year of study and country, study design, sample size, source of radiation, observed pregnancy outcomes and the major findings were recorded in Table 1.

Article Evaluation and Critical Appraisal

The evaluation of the selected articles was performed with the use of Crowe Critical Appraisal Tool (CCAT)

version 1.4. It has 22 items that are divided into eight categories (preliminaries-title/abstract, introduction, design, sampling, data collection, ethics, results and discussion) to evaluate the quality of the articles. Each category can only be scored as a whole number (from 0 to 5) and the total scores will be converted into a percentage, which the value of percentage can be categorised as; poor (≤ 50%), acceptable (51–79%) and high quality (≥ 80%).

RESULTS

Bibliographic Search

The searches identified 213 potentially relevant articles from three online databases (98 articles from PubMed, 74 articles from Scopus and 41 articles from ProQuest) and only two articles were obtained from snowballing technique. After eliminating the duplicate articles, the articles were screened based on the title and followed by the abstract, which resulted in 153 articles being excluded (irrelevant to the aim and criteria of the study). Only 12 articles were eligible for full-text screening. At this stage, four articles were further excluded as they were not primary studies that explored the exposure of IR in pregnant women. Finally, only eight articles were included in this review.

Overview of the Selected Articles

Characteristics of the selected articles are presented in Table 1. The selected articles have been published from 1992 to 2020. Among eight selected articles, two were case-control studies (Gong et al., 2016; Shields et al., 1992), two were cohort studies (Dummer et al., 1998; Queisser-luft et al., 2011) and four were cross-sectional studies (Wang et al., 2010; Mangones et al., 2013; Jirova et al., 2020; Slama et al., 2008). Out of eight, three articles were conducted in the United States (US) (Gong et al., 2016; Shields et al., 1992; Mangones et al., 2013), one in Taiwan (Wang et al., 2010), one in the United Kingdom (UK) (Dummer et al., 1998), one in Czechia (Jirova et al., 2020), one in Germany (Queisser-luft et al., 2011) and one in France (Slama et al., 2008). All the selected articles involved a large population sample size (n > 1000).

Proximity of Maternal Residences to Nuclear Power Plants or Mines

All selected studies defined the study area as below a 50 km radius from maternal residency to NPP or mines, except only one study that did not specify the distance that they adopted (Slama et al., 2008). Six articles examined the exposure of IR from NPP (Wang et al., 2010; Queisser-luft et al., 2011; Mangones et al., 2013; Dummer et al., 1998; Slama et al., 2008; Gong et al., 2016), whereas two articles assessed the pregnancy outcomes due to exposure to IR from uranium processing plants (mines) (Jirova et al., 2020; Shields et al., 1992).

Effects of Ionising Radiation on Adverse Pregnancy Outcomes

Adverse pregnancy outcomes refer to health complications or unfavourable events affecting the mother, newborn or both during gestation, labor and delivery, or the postpartum period (Tadese et al., 2022). These complications can range from mild to severe and may have short or long-term effects on maternal and neonatal health such as spontaneous abortion, stillbirth, birth defects and intrauterine growth restrictions. In this review, four articles observed multiple adverse pregnancy outcomes such as stillbirth, premature birth, low birth weight (LBW) and birth defects (Wang et al., 2010), birth defects, LBW and prematurity (Mangones et al., 2013), spontaneous abortions and birth defects (Jirova et al., 2020) and miscarriage and LBW (Slama et al., 2008). Meanwhile, four articles only observed single outcomes such as birth defects (Queisser-luft et al., 2011; Shields et al., 1992), stillbirths (Dummer et al., 1998) and LBW (Gong et al., 2016). Seven of the selected articles did not obtain any associations except for Shields et al. (1992) found an association between radiation exposure and birth defects.

Quality of the Selected Articles

The quality assessment (QA) of the selected articles was assessed based on the Crowe Critical Appraisal Tool (CCAT) version 1.4 as shown in Table 2. All the articles clearly described their objective, defined the outcomes, reported results and had conclusions that supported their results. From all the selected studies, the highest percentage of QA was recorded by Slama et al. (2008) at 90%. This is followed by Queisser-luft et al. (2011), Wang et al. (2010), Gong et al. (2016), and Mangones et al. (2013) which recorded the percentage of QA at 85, 83, 80, and 80%, respectively. Meanwhile, the studies by Dummer et al. (1998) and Shields et al. (1992) recorded a percentage between 70 – 79% and the lowest recorded by Jirova et al. (2020) at a percentage of 55%. Despite Jirova et al. (2020) being the lowest figure, this study was still deemed acceptable and included in this review.

Table 1: Characteristics of selected articles on radiation exposure and adverse pregnancy outcomes

No.	Author and year of study; Country	Title of study	Study design; Research data	Source of radiation; Radiation exposure level	Observed outcomes; Sample size	Principal findings
[1]	Jirova et al. (2020); Czechia	Incidence of spontaneous abortions and congenital anomalies in the vicinity of a uranium processing plant	Cross-sectional study; 19 years of medical records (1994 – 2013)	UPP; N/A	Spontaneous abortions and congenital anomalies; Not specified	- Distance from residential regions to the UPP (mines) is within 20 km - Non-significant increment of spontaneous abortions (p>0.05) and birth defects (p = 0.05) in the vicinity
[2]	Gong et al. (2017); US	Maternal residential proximity to nuclear facilities and low birth weight in offspring in Texas	Case-control study; 12 years of medical records (1996 – 2008)	NPP; N/A	Low birth weight; 94,106	- Distance from residential to NPP is within 50 km - No association between the proximity of maternal residential homes to NPP and LBW for group: 40-50 km (95% CI = 0.81, 1.03); 30-40 km (95% CI = 0.84, 1.13); 20-30 km (95% CI = 0.79, 1.15); 10-20 km (95% CI = 0.70, 1.04); 0-10 km (95% CI = 0.59, 1.61)
[3]	Mangones et al. (2013); US	Congenital anomalies, prematurity, and low birth weight rates with nuclear power plant proximity	Cross-sectional study; 9 years of medical records (1992 – 2001)	NPP; N/A	Congenital anomalies, low birth weight and premature birth; 328,124	- Distance from residential to NPP is within a 32.19 km radius - No association between the proximity of maternal residential homes to NPP and birth defects (95% CI = 0.366-0.425)
[4]	Queisser-luft et al. (2011); Germany	Birth defects in the vicinity of nuclear power plants in Germany	Cohort study; 1-year of medical records (2007 – 2008)	NPP; N/A	Birth defects; 5,273	- Distance from residential to NPP is within 10 km - No association between the proximity of maternal residential homes (during the conception phase) to the NPP and birth defects (p = 0.82)
[5]	Wang et al. (2010); Taiwan	Pregnancy outcome of women in the vicinity of nuclear power plants in Taiwan	Cross-sectional study; 3 years of medical records (2001 – 2004)	NPP; < 0.2 µSv/h (1.8 mSv/year)	Stillbirth, premature birth, low birth weight, and congenital anomalies; 5,679	- Distance from residency to the NPP is within 14.23 km - Non-significant associations between distance and stillbirth (95% CI = 0.56-2.56), premature birth (95% CI =0.95-1.53), LBW (95% CI =0.79-1.37), and birth defects (95% CI =0.85-2.93)
[6]	Slama et al. (2008); France	Reproductive life events in the population living in the vicinity of a nuclear waste reprocessing plant	Cross-sectional study; 15 years of medical records (1985 – 2000)	NPP; N/A	Miscarriage and low birth weight; 1,183	- No increased risk of miscarriage (p = 0.70) and LBW (p = 0.80) in the population living in the vicinity of the NPP

[7]	Dummer et al. (1998); UK	Stillbirth rates around the nuclear installation at Sellafield, Northwest England: 1950-1989 (39 years)	Cohort study; 39 years of medical records (1950 – 1989)	NPP; N/A	Stillbirths; 260,100	- The outcome was observed for those who resided within 25 km of the nuclear plant - Distance from NPP did not significantly influence stillbirth (p = 0.30)
[8]	Shield et al. (1992); US	Navajo birth outcomes in the Shiprock uranium mining area	Case-control study; 18 years of medical records (1964 – 1981)	UPP; 1.7 – 5.2 mSv/year	Adverse pregnancy outcomes were grouped into 5 categories (in total 320 kinds of defective congenital conditions); 13,329	- Distance from residency to UPP is within 0.805 km - A statistically significant association was recorded between mothers living near UPP (mines) and the outcome of Group 2** (OR 2.71, p = 0.03). The associations of the observed outcomes were weak and must be interpreted with caution. ***Hip dysplasia and dislocation, cerebral palsy, mental retardation, stillbirths, infection and neoplasm.*

*N/A: No available data; NPP: Nuclear power plants; UPP: Uranium processing plant

Table 2: Checklist for Quality Assessment [Adapted from Crowe (2013)]

No.	Item	Selected articles							
		[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]
1.	Preliminaries - Title (aims and design) - Abstract (key information, balanced, informative) - Text (sufficient detail, clear writing/ table/ diagram/ figure)	5	5	5	5	5	5	5	4
2.	Introduction - Background - Objective	5	5	5	5	5	5	4	4
3.	Design	3	4	4	4	4	5	4	4
4.	Sampling	2	3	3	3	3	5	3	3
5.	Data collection	2	3	2	3	3	5	4	3
6.	Ethical matters	0	3	5	5	3	3	3	3
7.	Results	3	4	3	4	5	5	3	4
8.	Discussion	2	5	5	5	5	3	4	3
9.	Total (%)	55	80	80	85	83	90	75	70

DISCUSSIONS

In this review, we have systematically synthesized the existing evidence on the effects of maternal exposure to ionizing radiation (IR) and its effect on pregnancy outcomes. Our findings highlight the limited number of published articles that examine the studied relationship. The main adverse pregnancy outcomes observed by the selected studies were birth defects, premature birth, miscarriage and LBW. However, based on the findings, only one study found a significant association between the mother's residence near the UPP and the effect on birth defects (Shield et. Al., 1992). Other studies did not find any significant relationship of the observed outcomes, hence the definite conclusive to associate the exposure and the outcome was not able to be obtained.

Maternal exposure to ionizing radiation (IR) from nuclear power plants or mines

The stages of pregnancy (trimester window) and the absorbed radiation dose by the human body are

associated with the severity of radiation effects towards pregnancy outcomes (Shaw et al., 2011). The majority of articles did not measure the individual radiation exposure level, hence we were not able to determine whether the radiation exposure in that area exceeded the dose limit or not. Only minimum information was obtained from Wang et al. (2010) and Shields et al. (1992), in which the IR level was recorded at 1.8 and 1.7 – 5.2 mSv per year, respectively. As reported in BEIR VII, radiation exposure below 100 mSv/year is considered low exposure levels (National Research Council, 2006). In terms of absorbed radiation dose, the radiation level of 50 mSv is the dose limit for the general population where these levels may cause stochastic effects on humans including malformation and mental retardation in the fetus (Streffer et al., 2003). Also, in human studies, it is hard to distinctly observe the effect of radiation on the embryo or fetus with a dose range of less than 100 mSv (Kusama & Ota, 2002).

The results of the selected articles showed that the effects of radiation on pregnancy outcomes are weak and almost have no evidence. Even Shield et al. (1992) have recorded a statistically significant association between mothers living near UPP and the outcome of Group 2 (hip dysplasia and dislocation, cerebral palsy, mental retardation, stillbirths, infection and neoplasm), but the associations of the observed outcomes were weak (OR 2.71, P=0.03, n=113 cases) and must be interpreted with caution due to small study population. The effects of radiation usually are based on long-term exposure, and maybe the exposure during the gestational duration (40 weeks or 280 days) is not sufficient to observe the health effects.

The proximity of maternal residences to nuclear power plants and the risk of adverse pregnancy outcomes

Based on the selected articles, different methods were applied to determine the IR exposure from maternal residency to NPP or UPP (mines). The selected articles have measured the distance between both locations by using a variety of distance thresholds. For example, 32.19 km of the radius was divided into four zones of 8.05 km increments (Mangones et al., 2013), 25 km of the radius was divided by 5 km increments (Dummer et al., 1998) and 50 km was further divided into five equal interval groups using thresholds 10, 20, 30, and 40 km (Gong et al., 2016). However, if the distance thresholds are too small, there would be a very small sample size in that particular area, hence reducing the power of the study (Gong et al., 2016). Therefore, it is recommended that distance thresholds between the areas be defined on an appropriate and consistent scale relative to other thresholds to ensure that each proximity group has a sufficient sample size for the statistical analysis (Gong et al., 2016).

Among all the selected studies, Shield et al. (1992) utilized the shortest distance (<1 km) between the UPP and maternal residency, compared to other studies that used a distance ranging between 10 to 50 km. This closer proximity may explain the significant findings in their study; however, many factors must also need to be considered.

Based on the major findings in this review, it is evident that the distance (within 50 km or less from the source of apportionment) did not result in adverse pregnancy outcomes. A possible explanation for this result may be due to the reduction of radionuclide deposition near the point of source, thereby lowering the exposure radiation level in the nearest areas. In industrial settings, the use of a high chimney stack could contribute to this reduction, as the stack releases the industrial pollutants on an upward trajectory, causing them to disperse away from the source (Lawson & Waller, 1996).

The adverse pregnancy outcomes that have been discussed in the selected articles are subject to some limitations including lower birth rate in the study area and poor access to health care services and facilities. As a result, these contributed to the abortions or underreporting of adverse pregnancy outcomes in that particular location (Mangones et al., 2013). A study conducted by Dummer et al. (2008) found no statistical evidence for an increased risk of stillbirths with closer proximity to NPP. The data of this study showed the increased risk of stillbirths recorded in two areas located within 10-15 km from NPP in the northwest sea and 15-20 km from NPP in the northeast sea. However, the increased risk of stillbirth in both stated locations was not due to the proximity of residency to the NPP, but it is related to the high population in that study area that may cause high chances of getting adverse pregnancy outcomes.

As for the recommendation for future studies, it is suggested that future research also include other contributing factors that can increase the risk of adverse pregnancy outcomes such as maternal factors (smoking, alcohol consumption, nutritional and social status), hereditary factors and external environmental factors (Wang et al., 2009). More future research is needed to find evidence to support the association between IR exposure from NPP or mining activity and adverse pregnancy outcomes because of the severe effect of NPP accidents and widespread radiation exposure in the

population, even though the selected articles did not manage to provide evidence for such association.

CONCLUSION

The finding of this study suggests that maternal exposure to IR from nuclear power plants NPP or mines is unlikely to be associated with adverse pregnancy outcomes. The proximity of maternal residential homes to the industrial area, specifically NPP, was not correlated to adverse pregnancy outcomes such as LBW, stillbirth, spontaneous abortion or birth defects. Overall, the primary strength of this review lies in the large sample sizes across all the selected studies, which contribute to a high level of statistical power. However, this review is limited by a relatively small number of publications addressing this association. Additionally, as a retrospective study, individual radiation exposure levels could not be determined in all selected studies. None of the studies measured the real-time radiation exposure levels, making it impossible to ascertain the actual radiation doses exposed by the populations. Hence, it is recommended that future research emphasize individual exposure levels on specific trimester windows, as well as investigate the biological mechanisms underlying the relationship between radiation exposure during pregnancy and adverse pregnancy outcomes.

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REVIEW ARTICLE

Application of System Theoretic Accident Model and Processes (STAMP) in Healthcare Settings: A Scoping Review

Bisyarah Zamberi[1], Ibrahim Adham Taib[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
System Theoretic Accident Model and Processes; System Theoretic Process Analysis; Causal Analysis based on System Theory; Healthcare

ABSTRACT

The healthcare industry has seen a rise in adverse events and system failures, highlighting the need for comprehensive safety analysis methods. The System Theoretic Accident Model and Processes (STAMP) offers a systems-based approach to understanding and mitigating complex interactions leading to failures. Despite its application in various industries, there is a gap in the literature regarding the extent of its use in healthcare, including its benefits and limitations. This scoping review investigates the application of STAMP in various medical departments, using the PRISMA-ScR methodology, to identify relevant studies in Scopus, PubMed, and ScienceDirect databases. Nine studies from radiology, cardiology, and other departments were identified, they reported the benefits of using STAMP, such as its ability to uncover system flaws and suggest improvements beyond traditional root-cause methods. They also highlighted several disadvantages, including potential biases and limited level of detail about specific failures. The findings offer valuable insights for researchers and healthcare professionals, indicating that STAMP is a valuable tool for enhancing patient safety and system reliability.

INTRODUCTION

Risk assessment methods including Fault Tree Analysis (FTA) and Failure Modes and Effects Analysis (FMEA) have often been used to identify and mitigate hazards and failures in many workplace settings. The application of these methods has enabled the causes and factors of adverse events to be examined, helping prevent such events from reoccurring in the future (Lundberg et al., 2009) However, as systems in many workplaces have become more complex, there is a need for more advanced tools. One such tool is the System Theoretic Accident Model and Processes (STAMP), which uses system theory and thinking to analyse complex interactions that result in failures or loss (Leveson, 2011). Unlike traditional methods that focus on identifying root causes, STAMP takes a broader view by considering accident causation as the result of system-wide interactions, making it suitable for addressing complex systems such as healthcare.

Although other advanced methods such as AcciMap and Safety Occurrence Analysis Methodology (SOAM) have been developed to also address such complexities, STAMP is gaining recognition for use in safety-critical industries like healthcare (Allison et al., 2017). For example, STAMP provides more detailed insights than AcciMap about the interactions within complex systems, including how decisions and controls at different levels contribute to safety (Salmon, Cornelissen, & Trotter, 2012). Similarly, unlike SOAM, STAMP is able to address safety issues associated with emergent phenomena that often involve non-linear interactions between different system components (Arnold, 2019).

Within the healthcare sector, STAMP has been shown to benefit healthcare settings by offering a more comprehensive analysis of systemic factors, leading to more effective interventions (Canham, 2018). Furthermore, STAMP can be useful for ensuring efficient and reliable management of healthcare systems (Yoshida, 2021). However, little is known about the extent to which STAMP has been applied in healthcare and reported in literature, for example which departments have utilised the method, as well as the advantages and disadvantages found. In light of this gap in the literature, a scoping review was carried out with the aim to identify the healthcare departments that have used STAMP and synthesise information about their reported advantages and disadvantages. In doing so, the scoping review would provide valuable insights to researchers and practitioners planning to apply or adopt STAMP.

MATERIALS AND METHODS

To achieve its objective, the scoping review was carried out according to the five-step framework developed by Arksey and O'Malley (2005) and refined by Levac et al. (2010): (i) identifying research questions, (ii) identifying relevant studies, (iii) selection of study, (iv) data charting, and (v) collating, summarizing, and reporting results. Furthermore, the scoping review was reported according

*Corresponding author.
E-mail address: tibrahim@iium.edu.my

to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (Shaw et al., 2021). Relevant peer-reviewed papers were searched from 2004, the year STAMP was first introduced, until 2022, when this study was conducted, using three online databases: Scopus, PubMed, and ScienceDirect. Various search keywords, along with similarly meaning terms and Boolean Operators including AND, OR and parentheses, were used to identify related studies. The keywords used were (application OR utilization OR employment OR practice OR usage OR adoption OR investigation OR integrate) AND ('system theoretic accident model processes' OR 'system theoretic process analysis' OR 'causal analysis based on system theory') AND (healthcare OR hospital OR clinic OR infirmary OR medical centre OR medical OR medicine).

To be included in this scoping review, each article underwent a screening process, starting by reviewing titles and abstracts, followed by a full-text review. Only articles written in English, published in peer-reviewed journals, and utilising STAMP in healthcare were included in this study. On the other hand, review articles such as narrative, scoping, or systematic reviews were excluded, as the aim for this study was limited to original research articles. To ensure the screening reliability, 20 abstracts were independently reviewed by both authors, with only three disagreements in the outcome that were then resolved through consensus. After the full-text review, data was extracted from the selected papers according to the following data items: author, year of publication, medical department, data collection method, reported advantages, and reported disadvantages.

RESULTS

As indicated by the PRISMA-ScR diagram in Figure 1, a total of 980 articles were identified in the initial search: 22 from Scopus, 373 from PubMed, and 585 from ScienceDirect. 463 duplicate articles were removed before the screening process. The remaining 517 articles were screened based on their titles and abstracts; consequently, 501 articles were excluded and 16 articles were included for the next screening process. The full text of the 16 articles were examined according to the inclusion and exclusion criteria. Two articles were excluded due to restricted access or limited institutional resources, while five others were omitted because they only mentioned STAMP briefly without directly applying its theory. Lastly, 9 articles underwent qualitative synthesis, with data extracted and summarised in Table 1.

Data Collection Method

Several methods were utilized in the included articles, with observation being the most frequently applied as it was used in six studies. One possible advantage of using observation over other methods is its ability to capture and describe various aspects of the system, including subjects' behaviours, interactions, and contextual factors. The second most frequently applied method was focus group discussion, followed by document review, interviews, case study, and survey. This may be due to the time required to process survey data, potential low response rates, and the difficulty of using questionnaires to capture the complex, system-wide information required for STAMP analysis (Jones et al., 2013).

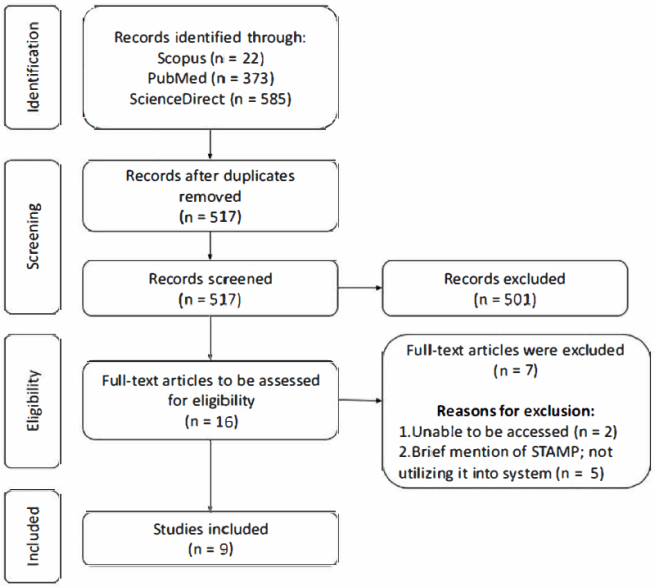

Figure 1: Flow Diagram of Articles Selection based on PRISMA-ScR Flow Diagram

Medical Department Applying STAMP

As indicated in Figure 2, departments applying STAMP to analyse their systems were identified, with Radiology having the highest reported usage, appearing in three articles (33%). This was followed by Anaesthesiology at 22%, while the remaining five departments—Cardiology, Endocrinology, Pharmacy, and Neonatal Intensive Care Unit (NICU)—each had a reported usage rate of 11%.

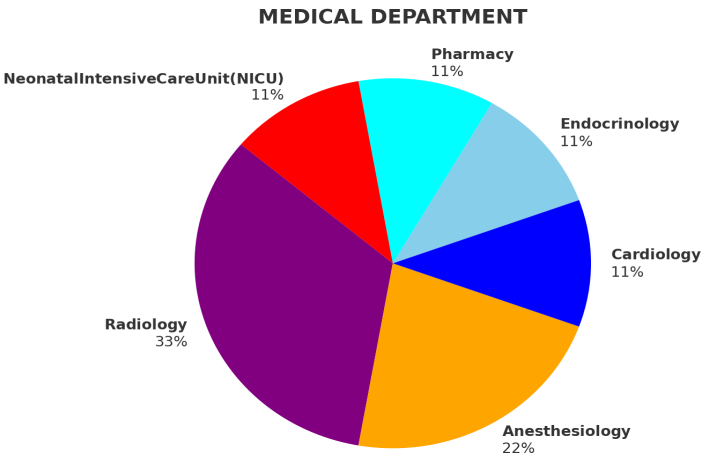

Figure 2: Medical Department Applying STAMP

Table 1: Summary of Advantages and Disadvantages of STAMP Application in Healthcare

No	Author	Year of Publication	Medical Department	Data Collection Method	Reported Advantages	Reported Disadvantages
1	Leveson et al.	2020	Cardiology	Observation	- Able to identify the general weaknesses in the control measures employed at the hospital - Able to generate systemic recommendation that current root cause analysis might sometimes overlook	Not reported
2	Silvis-Cividjian et al.	2020	Radiology	Document review, observation	- Require short time to obtain list of potential hazards - STAMP is better in term of effectiveness than HFMEA - Able to identify subtle and unexplored unsafe conditions	Does not provide a detailed description of hazard
3	Bas	2020	Endocrinology	Observation	- Consider more type of accidents and hazard causes - More effective compared to Fault Tree Analysis (FTA) and Failure Modes and Effect Analysis (FMEA)	Not reported
4	Bargal et al.	2018	Pharmacy	Focus group discussion, survey	- Helped identify important safety risks and recommend controls to mitigate these risks - Focus on system redesign rather than individual blame	- Challenging to understand - Time consuming - Less familiar
5	Patriarca et al.	2019	Anesthesiology	Focus group discussion, interview	- Reveals more hazard and potential failure in system	Mainly applied for academic context only
6	Yamaguchi & Thomas	2019	Radiology	Observation	- More effective to conduct hazard analysis for medical equipment - STAMP identified a potential and broader set of causes compared to FMEA	Not reported
7	Kaya	2021	Neonatal Intensive Care Unit (NICU)	Document review, interview, focus group discussion	- Help identify unsafe control actions and reveal more scenarios - Develop safety recommendations - User friendly and well-structured - STAMP provides a better understanding of the system to be assessed compared to FRAM	- Difficulties when building control structure - Not widely used in healthcare
8	Pawlicki et al.	2016	Radiology	Observation	- STAMP procedures are generalizable to all aspects of radiation oncology for analysing new and existing process	There could be hazards that are unidentified
9	Samost-Williams & Nanji	2020	Anesthesiology	Observation, case study	- Can be used in a variety of settings to help improve patient safety by identifying areas of highest risk to target in quality improvement initiatives	STAMP may be biased

Radiology is one of the most complex hospital departments, operating high-technology machines essential to diagnostic care. Atwal et al. (2017) reported that the workload per radiologist has consistently increased, while the number of radiologists hired has declined. Additionally, Radiology departments often operate 24/7 to meet demand. Although accidents in Radiology are less frequently reported, they do occur. Tarkiainen et al. (2020) highlighted that adult patients represent the highest frequency of cases involving excessive radiation exposure during CT procedures. Researchers have leveraged STAMP to investigate these

issues, applying it to identify root causes and contributing factors.

Meanwhile, STAMP was applied equally across the departments with the least frequent application—NICU, Emergency, Pharmacy, and Endocrinology—each at 10%. Greater consideration is needed for STAMP's application in these departments, particularly in high-risk settings like the Emergency Department (ED). Although only one study examined the ED, Amaniyan et al. (2019) reported that this department carries a high risk of patient safety incidents. The ED is one of the most demanding environments within healthcare institutions, with continuous patient flow, heavy workload, and the need to manage patients with varying conditions and severity levels (Sartini et al., 2022). Ineffective management of these challenges can lead to excessive labour demands, healthcare worker burnout, and a greater likelihood of safety incidents. These factors suggest that future studies could explore STAMP's potential to manage complex safety issues in such critical areas.

Reported Advantages

Six reported advantages were extracted from all included articles, as presented in Table 2. Firstly, STAMP effectively identifies hazards and unsafe control actions (UCAs), along with their causes. The articles highlighted that STAMP is effective for hazard identification and analysis (Bas, 2020; Patriarca et al., 2019; Yamaguchi & Thomas, 2019). Moreover, the articles suggested that STAMP can evaluate and improve control measures (Kaya, 2021; Leveson et al., 2020). These views are also shared by studies in other industries, such as nuclear power and transportation (Ahmad et al., 2021; Jung et al., 2022).

The second reported advantage is that STAMP aids in developing recommendations to reduce accident risks. Identifying UCA is only the first step; actionable solutions are needed to mitigate hazards. The articles suggested that solutions generated by STAMP are more systemic than those from root cause analysis (Leveson et al., 2020). Additionally, STAMP facilitates solutions more likely to target the highest risks for quality improvement (Samost-Williams & Nanji, 2020). This observation was also noted by Hamim et al. (2022) in the context of rail-level crossing accidents, where STAMP produced numerous recommendations when combined with other analysis tools.

Thirdly, STAMP was reported by the articles as being user-friendly and adaptable due to its straightforward design and structure. Kaya (2021) described STAMP as being easy to use due to its structured approach, which highlights its accessibility. Consequently, multidisciplinary teams, including those unfamiliar with advanced risk analysis methodologies, can effectively identify risks and develop safety recommendations. By contrast, Underwood et al. (2016) reported that first-time users from aviation industry faced difficulties using STAMP, this difference possibly due to less training and a less structured guideline than those in Kaya's study.

The fourth reported advantage of STAMP is related to its efficiency. Silvis-Cividjian et al. (2020) suggested that STAMP can be relatively quick in determining the potential hazards in a healthcare system. This means that small teams can conduct efficient and effective hazard analyses in complex settings like healthcare. Furthermore, due to its structured approach, STAMP can be proactively applied in the early phases of system design. However, this would depend on the users' familiarity with STAMP, as indicated by Underwood et al. (2016) in their study with aviation users.

Table 2: Summary of Reported Advantages of STAMP in Healthcare Applications

No	Reported Advantages	Author
1	STAMP is able to identify the UCAs along with its causes	Bargal et al. (2018), Bas (2020), Kaya (2021), Leveson et al. (2020), Patriarca et al. (2019), Samost-Williams & Nanji (2020), Silvis-Cividjian et al. (2020), and Yamaguchi & Thomas (2019)
2	STAMP is able to generate highly effective recommendations to reduce UCA risk	Bargal et al. (2018), Kaya (2021), Leveson et al. (2020), and Samost-Williams and Nanji (2020)
3	STAMP is user-friendly and adaptable	Kaya (2021) and Pawlicki et al. (2016)
4	STAMP requires a short time to obtain a list of potential hazards	Silvis-Cividjian et al. (2020)
5	STAMP does not focus on individual blame	Bargal et al. (2018)
6	STAMP is more effective than other methods in identifying hazards	Bas (2020), Kaya (2021), Silvis-Cividjian et al. (2020), and Yamaguchi and Thomas (2019)

The fifth advantage of STAMP is its focus on system factors rather than blaming individuals. One of the reviewed articles highlighted how STAMP guided users to focus their interventions on healthcare system redesign (Bargal et al., 2018). Similarly, Tonk and Boussif (2024) remarked that STAMP emphasises systemic factors when applied in railway. These findings suggest that STAMP supports a non-blaming approach, which can positively influence safety culture (Bond, 2008).

The sixth advantage identified in this review is the effectiveness of STAMP relative to other established methods. For example, the reviewed articles indicated its superiority over methods such as FRAM, FMEA, HFMEA, and FTA in identifying potential hazards in healthcare (Bas, 2020; Kaya, 2021; Silvis-Cividjian et al., 2020; Yamaguchi & Thomas, 2019). Likewise, a study in the coal mine industry highlighted how STAMP is superior to FRAM in identifying actionable recommendations (Qiao, Li, & Liu, 2019).

Reported Disadvantages

Overall, six papers highlighted several disadvantages, as shown in Table 3. The first disadvantage of STAMP is its limited use outside academic research in healthcare (Kaya, 2021; Patriarca et al., 2019). This may be linked to the second disadvantage, which is its complexity and perceived lack of user-friendliness (Bargal et al., 2018). However, another possibility is that practitioners simply prefer well-established methods (Patriarca et al., 2019), underscoring the need to better highlight STAMP's benefits.

Table 3: Summary of Reported Disadvantages of STAMP in Healthcare Applications

No	Reported Disadvantages	Author
1	STAMP is not widely utilized	Kaya (2021) and Patriarca et al. (2019)
2	STAMP is not user-friendly	Bargal et al. (2018)
3	STAMP does not provide a detailed description of hazard	Silvis-Cividjian et al. (2020)
4	There could be hazards that are not identified by STAMP	Pawlicki et al. (2016)
5	STAMP might include bias	Samost-Williams and Nanji (2020)

The third reported disadvantage is that STAMP does not provide a detailed description of hazards (Silvis-Cividjian et al., 2020), while the fourth is it may overlook some hazards (Pawlicki et al. (2016). Both of these limitations may hinder mitigation measures as information about hazards may not be specific enough or be incomplete. However, while these criticisms may be apparent when comparing tools for hazard analysis, the completeness of such analysis is inherently difficult to ascertain (Pawlicki et al. (2016).

The fifth reported disadvantage is the potential for bias to influence the outcome of analysis, particularly due to the less structured approach for generating causal scenarios in STAMP (Samost-Williams & Nanji, 2020). For example, availability bias may lead to more focus on frontline hazards, like medication errors, while overlooking risks from management, such as poor policies or resource issues. However, the authors noted that such biases can be managed through multidisciplinary input and the structured steps inherent in STAMP to identify unsafe control actions.

CONCLUSION

In conclusion, this study examined the medical departments using STAMP and summarized its advantages and disadvantages in healthcare, according to published studies. The review found that STAMP was most frequently reported in the radiology department (30%), followed by anaesthesiology (20%), and then in the pharmacy, cardiology, endocrinology, emergency, and NICU departments (each at 10%) STAMP's main advantages include its ability to identify potential hazards and unsafe actions, as well as generate recommendations to reduce risks. On the other hand, its limitations include underuse, difficulty of use, and potential bias. Overall, this review may help healthcare facilities consider STAMP as a tool to build safer systems.

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REVIEW ARTICLE

Radionuclide Contamination in Soil and Radiological Hazard Assessment from Industrial Areas: A Systematic Review

Supiah Abd Bahar[1] and Noor Fatihah Mohammad Fandi[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Radionuclides exposure; radiological hazard assessment; soil; industrial areas

ABSTRACT

Background: The production of radionuclides as industrial by-products such as radium (^{226}Ra), thorium (^{232}Th), potassium(^{40}K), and uranium (^{238}U) might contaminate the soil and harm the health of nearby populations for long-term. Due to the limited evidence of the associated relation and lack of public awareness of the potential risk, people tend to ignore this concerning issue. Therefore, this study aims to review the activity concentrations of the aforementioned radionuclides in the soil's nearest industrial vicinity and to assess their radiological hazard presented in the existing literature. **Method:** This systematic review was conducted using Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA 2009) on online databases such as PubMed, SpringerLink, Scopus, and ProQuest. The following criteria were included: full-text English journal, studies from 2014 onwards with search keywords of "radionuclide exposure" AND "radiological hazard" OR "health effect". **Results:** A total of 1025 articles were screened and only 7 full-text articles were evaluated. Based on the review, the types of industries that produce ^{226}Ra, ^{232}Th, ^{40}K, and ^{238}U were petrochemical, chemical, rare-earth element (REE), and gold mining industries. The findings showed the elevated ^{226}Ra activity, nearly three times the global average of 35 Bq/kg, was found at petrochemical sites in Rayong, Thailand. The ^{232}Th and ^{40}K activity levels at Nigeria mining sites were higher than the global average. All studied areas exceeded world average for ^{238}U. The highest absorbed dose (D) values were observed in artisanal mining, Anka, Nigeria (127.00 nGy/h) and in petrochemical sites in Rayong, Thailand (84.98 nGy/h), both exceeding the limit of 60 nGy/h. The annual outdoor effective dose (AED) from similar industrial areas was 2.2 and 1.4 times higher than the global average of 0.07 mSv/y. The highest gamma index ($I\gamma r$) value was at 2.08, recorded in Anka artisanal mining area, exceeding the safe limit of 1. Meanwhile, all values for excess lifetime cancer risk (ELCR) were below a safe limit of 1.16×10^{-3}. **Conclusion:** In conclusion, radiological risks at Anka artisanal mining sites and Rayong petrochemical sites, exceeded UNSCEAR limits, but cancer risks were minimal, suggesting a need for further research including in groundwater samples and clinical studies.

INTRODUCTION

A radionuclide, known as a radioisotope, radioactive isotope, or radioactive nuclide, is an unstable atom containing excess energy (Ansobarlo and Adam-Guillermin, 2012). According to the Centers for Disease Control and Prevention (2015), unstable radionuclides spontaneously emit radiation in the form of energetic particles of alpha, beta, or gamma radiation to other radioisotopes. This process is called radionuclide decay which can be measured by its half-life (Choppin, 2012).

The natural sources of radionuclides are commonly known as naturally occurring radioactive materials (NORMs) and previous studies have shown that most of the radionuclides can be found naturally in the environment (Almayahi, Tajuddin, & Jaafar, 2012). Sources of radionuclide contamination also could be generated from nuclear weapons programs, nuclear weapons testing, nuclear power plants, uranium mining and milling, commercial fuel reprocessing, nuclear accidents, and radionuclides contained at the geological repository (Hu et al., 2010). These industries process the desired resource by releasing the radionuclides and generating technologically enhanced naturally occurring radioactive material (TENORMs) by-products.

These by-products of radionuclides may contaminate the air, soil, surface, and groundwater if not disposed of properly. Hence, human exposure to TENORMs and NORMs of earth gamma-emitting radionuclides such as radium, thorium, potassium, and uranium is inevitable. Radiation exposure to humans has been increasing since decades ago and might go unnoticed due to its diverse usage. According to the American Institute of Physics (2014), the Malaysian Rare Earth Corporation Plant (MAREC) at Papan, Perak has been operating until 1992 and stopped due to abundant radionuclide waste such as thorium and uranium found in soil. A previous study conducted in Malaysia by Almayahi, Tajuddin, & Jaafar (2012), from 2004 until 2008 revealed an increase in cancer cases in Penang, which recorded up to 9692 cases

* *Corresponding author.*
E-mail address: fatihahfandi@iium.edu.my

due to exposure to high concentrations of natural radioactivity.

Chen (2005) stated human health may be affected by prolonged exposure to low levels of radionuclides following contamination through the water, air, or soil, the radionuclides can be deposited in blood, brain, and bones by ingestion, inhalation, absorbed from skin, and wound contamination (Hao et al., 2015). Radiation risk among industrial workers is controlled by the International Atomic Energy Agency (IAEA) safety standard using personal radiation dosimeters to detect radionuclides exposure. However, the population living near the industrial area is also vulnerable to low doses of radionuclides from prolonged exposure but there is no radiation assessment available to them (Rana et al., 2010).

Zhe Hao et al. (2015) mentioned that there is limited evidence about the relationship between radionuclide exposure and potential health effects on residents living near industrial areas for a long period. It is important to determine the radiological hazard assessment (e.g.: annual effective dose, excess cancer risk, lifetime average daily dose, and hazard quotient) from exposed radionuclides in industrial areas. Thus, this study provides an opportunity to systematically review the radiological hazard at low levels of radionuclide exposure among the population living near industrial areas from previous literature.

Despite extensive research, limited studies were found on the associated link between the levels of radionuclides in soil and their radiological hazard assessment on human health. Therefore, this study aims to review the activity concentrations of radium (^{226}Ra), thorium (^{232}Th), potassium (^{40}K), and uranium (^{238}U) in soil and assess the radiological hazard of the above-mentioned radionuclides measured from industrial areas based on the published literature.

MATERIALS AND METHODS

Systematic Review Process

This systematic review applied the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA 2009) method to aid in reporting the findings. The PRISMA guidelines include identification, screening, eligibility, and included criteria.

Search Strategy

The articles were sought from Scopus, SpringerLink, PubMed, and ProQuest. The keywords (“uranium” OR “radium” OR “thorium” OR “potassium”) AND (“nuclear plant” OR “petrochemical” OR “rare earth element (REE)” OR “industry”) AND (“health risk assessment”) were used. Boolean terms (AND and OR) were used to separate each keyword; "AND" is used to restrict the search, whereas the search is extended by "OR".

The search technique in this study aims to identify a comprehensive range of relevant papers on the topic, ensuring both high sensitivity and accuracy in the results. The PICOS elements, namely population (P), intervention (I), comparator (C), outcome (O), and study design (S)-were crucial in identifying the specific criteria to be included in this review as shown in Table 1.

Table 1: PICOS framework to determine the eligibility of studies

Criteria	Determinants
Problem	Residents living near the industrial area are at pose risk of exposure to radionuclides
Intervention	Exposure level of ^{226}Ra, ^{232}Th, ^{40}K and ^{238}U
Comparator	Radiological hazard assessment
Outcomes	Health effects on the population
Study design	Cross-sectional studies

Inclusion and Exclusion Criteria

The articles were screened by their title, especially those mentioned radium (^{226}Ra), thorium (^{232}Th), potassium (^{40}K), and uranium (^{238}U). The inclusion criteria such as full-text English language or English-translated literature that were published in 2014 onwards, with research articles must include exposure levels to public and radiological hazards of ^{226}Ra, ^{232}Th, ^{40}K, and ^{238}U in determining the health effects. The exclusion criteria such as review study, incomplete literature, unrelated topic, non-English language, and no available author were removed from this study.

Review Method

Articles were evaluated and assessed for eligibility according to the inclusion and exclusion criteria based on their title and abstract. Articles that fulfill the requirements were included to be reviewed. The quality of the studies was evaluated using the National Heart, Lung, and Blood Institute's (NHLBI) quality risk assessment method for cohort and cross-sectional studies from the National Institute of Health (NIH).

RESULTS

The article selection process was simplified in the PRISMA flow diagram as shown in Figure 1. A total of 1025 articles were derived from the online databases namely PubMed (n=6), Scopus (n=18), ProQuest (n=537), and SpringerLink (464). However, 49 studies were excluded due to duplication. Then, the articles were screened by title and abstract, resulting in the removal of 968 articles. The remaining eight articles were evaluated according to the inclusion and exclusion criteria. Next, three of them were removed due to the inaccessibility of the full text. After the full text was reviewed, two articles were excluded as it does not have any radiological risk assessment in their study leaving only three articles available for the review. From the three articles, snowball techniques were conducted, and the addition of four articles was able to be retrieved from the reference list.

The quality of the included studies was evaluated using the NHLBI quality risk assessment tool. Only one out of seven articles were determined as good quality while others were fair quality. Those six articles were considered as fair as they did not give enough information on numerous checklist criteria such as sample size justification and participation rate, making it impossible to assess their quality. Despite that, all seven articles were found as eligible according to the inclusion criteria.

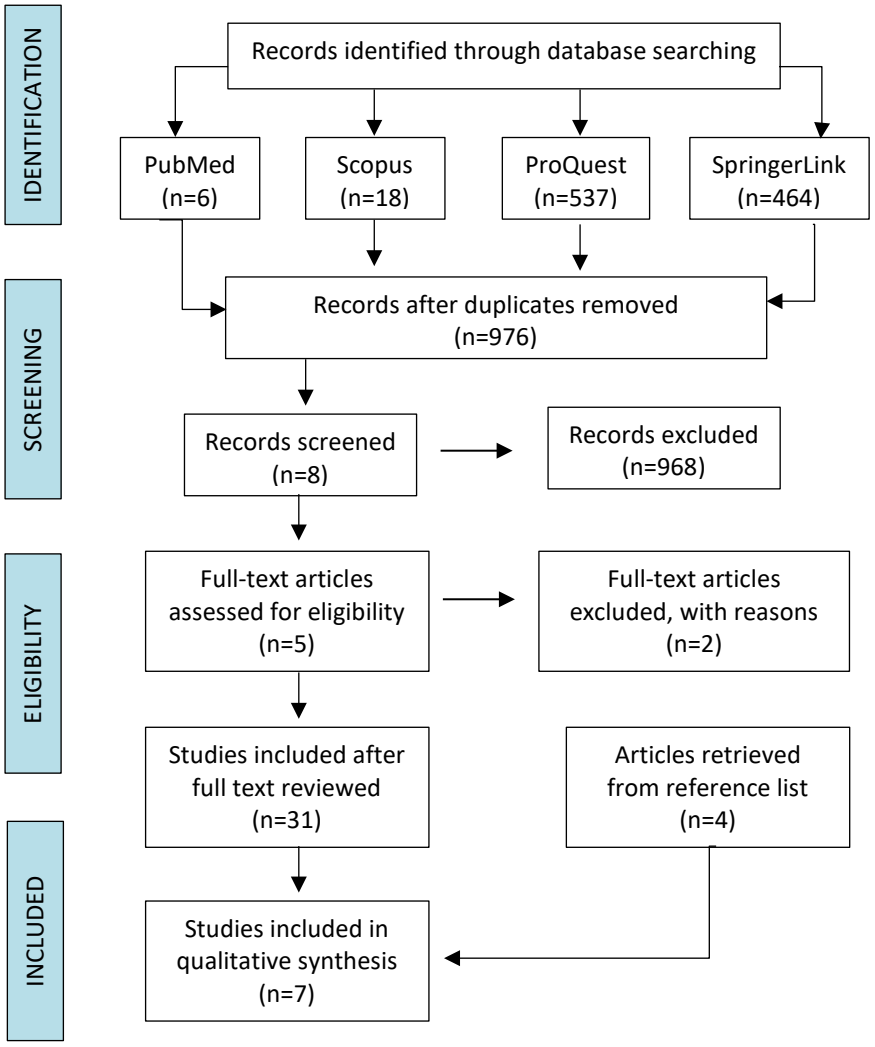

Figure 1: PRISMA flow diagram

DISCUSSION

Study Location and Types of Industrial Area

Seven reviewed studies highlighted five countries, namely Saudi Arabia, Nigeria, Thailand, Ghana, and Malaysia. The industrial city of the Arabian Gulf Coast in Saudi Arabia hosts over a hundred petrochemical and chemical industries and has a population of approximately 100,000 residents, with residential districts located to the east, south, and north (Alshahri, 2019). Additionally, Ras Tanura, home to the largest and oldest oil refinery in the Middle East, spans an area of approximately 290 km² and includes residential zones with a population of around 74,000

inhabitants (Alshahri & El-Taher, 2018). The studies conducted in Anka and Itagunmodi, Nigeria, and Akyem, Ghana focused on gold mining activities (Akpanowo et al., 2020; Bekelesi, Darko & Andam, 2017; Ademola et al., 2014). The Anka gold mining area spans 2,940 km² and is home to an estimated population of 12,655, residing approximately 10 km from the mining site. Since 1980, various industries, including petrochemical, automotive, electronics, oil, and gas sectors, have been operating in Rayong, Thailand (Kessaratikoon et al., 2019). Nonetheless, the rare earth refinery industry in Kuantan, Malaysia is known as Lynas Advanced Material Plant (LAMP) is the largest, rare earth refinery project in the world with a study area between 0.9 km and 3 km from the LAMP (Kolo et al.,2015).

Activity Concentrations of Radionuclides in Soil Samples

According to the seven included studies, the activity concentrations of radionuclides were used to determine the scientific evidence affecting the population's health effects from radium, thorium, potassium, and uranium exposure. The radionuclides activity concentrations were analysed using HPGe gamma-ray detector and gamma spectrometry analysis (Akpanowo et al., 2020; Kessaratikoon et al., 2019; Alshahri, 2019; Alshahri & El-Taher, 2018; Bekelesi, Darko & Andam, 2017; Kolo et al., 2015; Ademola et al., 2014). All extracted data is presented in Table 2.

Table 2: Mean Activity concentrations of ^{226}Ra, ^{232}Th, ^{40}K and ^{238}U in soil samples

Authors	Location	Type of industry	Mean Activity Concentrations (Bq/kg)			
			Radium (^{226}Ra)	Thorium (^{232}Th)	Potassium (^{40}K)	Uranium (^{238}U)
			World Average Concentrations (Bq/kg) (UNSCEAR, 2000)			
			35	30	400	35
Akpanowo et al. (2020)	Anka, Zamfara State, North-West, Nigeria	Artisanal mining and mine processing	**37.94***	**151.15***	380.34	**41.60***
Alshahri (2019)	Northern Al Jubail, Arabian Gulf, Saudi Arabia	Petrochemical & Chemical Industries[a]	7.64	3.76	174.00	-
Kessaratikoon et al. (2019)	Rayong province, Thailand	Petrochemical	**96.65*[b]**	**36.73*[b]**	**423.75*[b]**	-
Alshahri & El-Taher (2018)	Ras Tanura, Arabian Gulf, Saudi Arabia	Oil Refineries & Gas Plant	23.20	7.73	278.00	**39.00***
Bekelesi, Darko & Andam (2017)	Akyem, Ghana	Gold mining	28.00	12.00	11.00	-
Kolo et al. (2015)	Gebeng Kuantan, Pahang, Malaysia	Rare Earth Oxides Processing Plant	6.56	10.62	41.02	-
Ademola et al. (2014)	Itagunmodi, South-Western, Nigeria	Gold mining	-	26.4	**505.10***	**55.30***

Note:*****Indicate the value exceeds the world average concentrations; [a]Including industries of phosphate, iron, chemical, water treatment plant, gas plant, oil refinery, ethylene, and methanol Industries; [b]Using median values due to asymmetrical distribution of data.

From Table 2, the activity concentrations of studied radionuclides in petrochemical and chemical industries, Al Jubail of Saudi Arabia, gold mining, Akyem of Ghana, and rare earth oxides processing, Kuantan, Malaysia were below the acceptable limits except for the Anka and Itagunmodi in Nigeria, Ras Tanura of Saudi Arabia, and Rayong province, Thailand. The highest level of ^{226}Ra was recorded in the petrochemical sites in Rayong, Thailand with a median activity concentration of 96.65 Bq/kg (mean values = 105.25 Bq/kg). This was followed by the artisanal mining industry in Anka, Nigeria, with a mean value of 37.94 Bq/kg, both exceeding the global average activity concentration of 35 Bq/kg by 2.8 and 1.1 times, respectively (Kessaratikoon et al., 2019; Akpanowo et al., 2020). In contrast, the lowest mean activity concentration, 6.56 Bq/kg, was observed in Kuantan, Malaysia's rare earth element (REE) industry (Kolo et al., 2015). The asymmetrical data observed in the study by Kessaratikoon et al. (2019) prompted the use of median values, which were selected for radiological hazard estimation.

Additionally, Anka, Nigeria, reported the highest mean activity concentration of ^{232}Th at 151.15 Bq/kg, significantly exceeding five times the global average of 30 Bq/kg (Akpanowo et al., 2020). Meanwhile, gold mining sites in Itagunmodi, Nigeria, and petrochemical sites in Rayong, Thailand, recorded the highest and second-highest activity concentrations of ^{40}K, with a mean value of 505.10 Bq/kg and a median value of 423.75 Bq/kg (mean value = 532.39 Bq/kg), respectively. Both exceeded the global average activity concentration of 400 Bq/kg.

The highest mean activity concentration of ^{238}U was detected at the Itagunmodi gold mining sites, with a mean value of 55.30 Bq/kg, followed by Anka gold mining (41.60 Bq/kg), oil refineries and gas plants at Ras Tanura, Saudi Arabia (39.0 Bq/kg). These three industrial areas exceeded the global average concentration of ^{238}U (30 Bq/kg).

Factors Influence the Mean Activity Concentrations of Radionuclides

The mean activity concentrations for ^{226}Ra, ^{232}Th, and ^{238}U in the artisanal mining areas exceeded global averages, primarily due to the geological characteristics and activity concentrations of geology in the mining region and mineral processing activities, further contributing to elevated radioactivity levels in the soil (Moshupya et al., 2022; Akpanowo et al., 2020). Variations in geological structures and dust generated during mining activities can contribute to exposure to naturally occurring radioactive materials (NORMs) and radon gas (Ademola et al., 2014).

Other factors, such as ongoing construction activities and the physicochemical and geochemical properties of specific radionuclides, can also influence soil turnover concentrations. Meteorological factors, such as wind direction and rainfall distribution, can also influence the movement and deposition of radionuclides (Alshahri and El-Taher, 2018).

Radiological Hazard Assessment and Comparison

Industrial by-products containing radionuclides pose a risk to nearby populations, as the waste can accumulate in the soil, potentially leading to adverse health effects (Alshahri & El-Taher, 2018; Kolo et al, 2014). To assess the radiological hazard effects in soil samples for specific activities of ^{226}Ra, ^{232}Th, ^{40}K, and ^{238}U, the radium equivalent activity (Req), air absorbed gamma radiation dose rate (D), annual effective dose equivalent (E), external hazard (Hex), gamma representative level index (Iγr), excess lifetime cancer risk (ELCR) and geoaccumulation index (Igeo) and pollution load index (PLI) was calculated and presented in Table 3.

As shown in Table 3, the highest mean value of Ra_{eq} is documented at the artisanal mining site in Anka, Nigeria, with 288.51 Bq/kg, followed by the petrochemical industries in Ras Tanura, Saudi Arabia (62.10 Bq/kg), the gold mining site in Itagunmodi, Nigeria (31.75 Bq/kg), the petrochemical and chemical industries in Northern Al Jubail, Saudi Arabia (26.40 Bq/kg), and the lowest value at the rare earth oxides processing plant in Kuantan, Pahang (24.92 Bq/kg). All reviewed studies recorded Ra_{eq} was below the world average of 370 Bq/kg (UNSCEAR, 2000), indicating that the gamma output and the radiation hazards mixture of ^{232}Th, ^{40}K, and ^{238}U in analysed soils samples are within safe limits for human health and environment.

The International Commission on Radiological Protection (ICRP) recommends an absorbed dose value of 55 nGy/h (Alshahri and El-Taher, 2018; Kessaratikoon et al., 2019), while UNSCEAR (2000) sets the threshold at 60 nGy/h. In the studies reviewed, the highest absorbed dose values were observed in the artisanal mining area in Anka and the petrochemical industry in Rayong, Thailand, with reported values of 127.00 nGy/h and 84.98 nGy/h, respectively. This absorbed dose rate shows an elevated of ^{226}Ra, ^{232}Th, and ^{40}K from terrestrial gamma radiation sources.

The annual outdoor effective dose (AED) from artisanal mining in Anka, Nigeria, and the petrochemical industry in Rayong, Thailand, is 2.2 and 1.4 times higher, respectively, than the global average of 0.07 mSv/y (Kessaratikoon et al., 2019; Akpanowo et al., 2020). This indicates that global

Table 3: Estimated radiological hazard in soil samples (mean values)

Reference	Location	Radiological Hazard					
		Ra_{eq} (Bq/kg)	D (nGy/h)	AED (mSv/y)	Hex	Iγr	ELCR ($x10^{-3}$)
Akpanowo et al. (2020)	Anka, Zamfara State, North-West, Nigeria	288.51	**127.00***	**0.156***	0.780	**2.06***	0.550
Alshahri (2019)	Northern Al Jubail, Arabian Gulf, Saudi Arabia	26.40	13.00	0.016	-	-	-
Kessaratikoon et al. (2019)	Rayong province, Thailand	181.80	**84.98***	**0.100***	0.490	-	0.390
Alshahri & El-Taher (2018)	Ras Tanura, Arabian Gulf, Saudi Arabia	62.10	29.30	0.038	0.160	0.45	-
Bekelesi, Darko & Andam (2017)	Akyem, Ghana	37.53	-	0.044	0.101	-	-
Kolo et al. (2015)	Gebeng Kuantan, Pahang	24.92	11.16	0.010	0.070	0.18	0.050
Ademola et al. (2014)	Itagunmodi, South-Western, Nigeria	31.75	20.40	0.025	0.110	0.33	-
Global Average Limit		370[a]	60[a] 55[b]	0.07[a]	1[c]	1[c]	1.16×10^{-3}[a]

Note: *Exceed the global average limit; Ra_{eq}: Radium equivalent; D: Absorbed dose rate; AED: Annual effective dose (outdoor); Hex: External hazard; Iγr: Gamma index; ELCR: Excess lifetime cancer risk (outdoor); *I*geo: Geoaccumulation index; PLI: Pollution load index; [a]Source: UNSCEAR, 2000; [b]Source: Alshahri and El-Taher (2018); Kessaratikoon et al. (2019); [c]Source: Akpanowo et al. (2020).

average, highlighting elevated radiological exposure in the vicinity of these studied locations.

For the external hazard index (Hex), the highest value was recorded in Anka, Nigeria, at 0.78, while the lowest value was observed in the rare earth oxides industry in Kuantan, Pahang, at 0.07. None of the studied locations exceeded the recommended Hex limit of 1 (Akpanowo et al., 2020). Regarding the radioactivity level index (Iγr), the mean values for the petrochemical industry in Ras Tanura, Saudi Arabia, the rare earth processing industry in Kuantan, Pahang, and the gold mining industry in Itagunmodi, Nigeria, were 2.06, 0.45, 0.18, and 0.33, respectively. However, the highest Iγr value was recorded in the artisanal mining area of Anka, Nigeria, at 2.08, exceeding the recommended safe limit of 1 (Akpanowo et al., 2020). This indicates that gamma radiation exposure in the area is more than twice the recommended threshold, potentially posing health risks to the nearby population.

Three out of the seven articles assessed the excess lifetime cancer risk (ELCR), with all countries reporting values below the global safe limit of 1.16×10^{-3} for outdoor exposure (Akpanowo et al., 2020; Kessaratikoon et al. 2019; Kolo et al., 2015). This indicates that the populations in the studied areas are unlikely to develop cancer due to the levels of gamma radiation reported in these studies.

Artisanal mining in Anka, Nigeria and the petrochemical site in Rayong, Thailand both exhibited elevated values for absorbed dose (D), annual effective dose (AED), and radioactivity level index (Iγr). These findings suggest that individuals in these areas, particularly those working near these sites, are exposed to higher levels of environmental gamma radiation. This increased exposure could pose a potential radiological hazard to the nearby local populations. Akpanowo et al. (2020) highlighted those concerns regarding environmental radioactivity were more pronounced for artisanal workers in the mining industry, while nearby populations were not considered to be at significant risk. Despite the elevated radiation levels, the estimated cancer risk for all studied areas remains below the threshold, Kessaratikoon et al. (2019), however, argued that prolonged radiation exposure in the general population could increase the risk of cancer over time.

Previous reviewed studies have several limitations. The estimated excess lifetime cancer risk is more relevant to

artisanal miners and mineral processing workers, as the general population may not face an immediate radiological risk (Akpanowo et al., 2020). However, the scope of these studies is limited to the current investigations and analyzed samples. Expanding research to cover broader areas is recommended, particularly industrial zones near densely populated residential areas or water sources (Kolo et al., 2015; Alshahri, 2019).

CONCLUSION

In conclusion, radionuclide activity exceeding global average concentrations was observed in certain studied areas. Elevated levels of ^{226}Ra, almost three times higher than the global average, were detected at petrochemical sites in Rayong, Thailand. Meanwhile, ^{232}Th activity at artisanal mining sites in Anka, Nigeria, was five times greater than the global average. Additionally, elevated levels of ^{40}K were predominantly found at the Itagunmodi gold mining sites in Nigeria. Notably, ^{238}U activity surpassed the global average across all the studied areas. Geological factors appear to be a significant contributor to the elevated radionuclide concentrations, in addition to the by-products of industrial activities themselves. The radiological risks of absorbed dose (D) and annual outdoor effective dose (AED) were notably above the UNSCEAR safe limits at artisanal mining sites in Anka, Nigeria and petrochemicals sites in Rayong, Thailand, suggesting these areas may expose nearby populations and particularly those working in close proximity, to elevated levels of gamma radiation. All cancer risk values of studied radionuclides were below world safe limits of 1.16×10^{-3}, indicating the exposure to gamma radiation in the studied industrial areas is minimal. Assessing radiological hazards in other mediums, such as groundwater samples and through clinical studies, could yield different findings regarding the potential risks of radionuclide exposure to human health.

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REVIEW ARTICLE

Milk-Derived Exosomes as a Potential Therapy for Necrotizing Enterocolitis: A Scoping Review

Radiah Abdul Ghani[1*], Aisyah Norrasiddin[1], Tengku Norbaya Tengku Azhar[2]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Centre Foundation Studies, Universiti Teknologi MARA, Cawangan Selangor, Kampus Dengkil, Selangor, Malaysia

Keywords:
human milk; intestinal epithelial cells; infants

ABSTRACT

Background: Necrotizing enterocolitis (NEC), a devastating gut disease primarily affecting premature infants, currently lacks effective treatment options. Human milk, known for its protective benefits against NEC, contains compositions that hold promises for addressing this urgent medical need. Thus, this study aimed to provide an overview of the therapeutic potential of milk-derived exosomes, offering valuable insights that could pave the way for future clinical interventions and advancements in NEC treatment strategies. **Methods:** Keywords such as "human milk", "exosomes", "human milk exosomes", "necrotizing enterocolitis", "therapy", and "treatment" were employed during the search strategy in Scopus, PubMed, and ScienceDirect.The articles were chosen in accordance with PRISMA-ScR, where a total of 125 articles were further screened based on the inclusion and exclusion criteria, resulting in five selected articles reviewed in this study.**Results:** Milk-derived exosomes have the ability to enhance epithelial integrity by increasing the expression of tight-junctions namely ZO-1, claudin-1, and occludin. These vesicles give protection to intestinal epithelial cell by improving the expression of goblet cells and increase mucin production and also able to reduce inflammation and stimulate cell growth and regeneration by increasing the number of ileum crypts and Lgr5 expression. In addition, milk-derived exosomes protect against cell damage by enhancing the expression of genes in the Wnt/β-catenin signalling pathway which are Axin2, c-Myc, and Cyclin D1. **Conclusion**: These findings conclude that milk-derived exosomes are beneficial to protect the intestinal epithelial cells. Various pathways can be explored and targeted in relations to creating new drugs that can effectively control the occurrence and development of NEC, including improving the prognosis of infants with NEC.

INTRODUCTION

Necrotizing enterocolitis (NEC) is a major cause of infant mortality due to a severe gastrointestinal disorder (Martin et al., 2018). According to Boo (2016), the incidence of NEC has primarily risen in neonates with low birth weight and gestational age, despite improvements in neonatal intensive care units (NICU). For example, in Sweden, the incidence of NEC increased by about 3.1 per 10,000 live births over an eight-year period. Alsaied et al. (2020) found that seven out of every 100 very low birth weight infants admitted to NICUs are likely to develop NEC. This disease involves inflammation and tissue necrosis in the intestinal lining, which can lead to perforations or breaches in the intestinal wall. As a result, intestinal contents, including bacteria and toxins, can leak into the abdominal cavity, leading to systemic infection and further complications. For infants in critical condition who do not respond to medical therapy, surgery such as laparotomy is the standard treatment for NEC (Ginglen & Butki, 2023). Rellinger, as cited by Robinson et al. (2017), emphasized that the main goals of surgery are to control the leakage from the intestine and to remove necrotic tissues while preserving as much healthy tissue as possible, though it does not directly treat NEC itself. However, surgery carries a high risk of mortality and can lead to neurodevelopmental impairments in infants. As a result, researchers are exploring alternative therapies for this condition that do not require surgery.

Interestingly, human milk has been found to have significant benefits for infants due to its multifunctional components, such as human milk oligosaccharides (HMOs), human milk stem cells, lactoferrin, exosomes, and others. Carr et al. (2021) highlighted that human milk is a unique fluid containing various bioactive compounds essential for infant growth, development, and protection against infections. Numerous studies have shown that infants who are breastfed have higher survival rates than those who are not. Nolan et al. (2019) noted that many components of human milk provide protective effects against NEC by enhancing the intestinal immune response and offering antimicrobial properties. While research into other components like HMOs and human milk stem cells is extensive, studies on human milk exosomes are emerging, though their role and potential in NEC treatment remain less understood. As a result, there is much yet to be explored regarding the therapeutic potential of human milk exosomes. Researchers are currently focusing on these milk-derived exosomes, which are nanosized vesicles produced by cells in the body.

* *Corresponding author.*
E-mail address: radiah@iium.edu.my

Studies have demonstrated that human milk exosomes offer various benefits to intestinal epithelial cells (IEC), including promoting growth, reducing inflammation, and defending against harmful pathogens. Experiments on animal models of NEC have shown that exosomes can decrease both the incidence and severity of the disease. Based on these findings, it can be suggested that milk-derived exosomes play a significant role in treating NEC due to their protective effects on the intestinal epithelium (Dong et al., 2020). Therefore, this article aims to evaluate the existing research on milk-derived exosomes, focusing on their role in promoting the growth and regeneration of the intestinal barrier and their mechanisms in protecting the infant's intestinal health.

METHODOLOGY

A scoping review is an ideal research approach for examining the therapeutic potential of breast milk exosomes in treating Necrotizing Enterocolitis (NEC), as it allows for a thorough exploration of the issue and highlights gaps in current research. According to Arksey & O'Malley (2005) and Levac et al. (2010), scoping reviews are highly valuable for capturing a wide range of literature, integrating various study designs, methodologies, and sources, which enables researchers to systematically map existing evidence. This method will provide important insights into the mechanisms, limitations, and potential uses of breast milk exosomes for NEC treatment, offering a solid foundation for guiding future research and clinical practices in neonatal health. The review follows the five-stage framework outlined by Arksey & O'Malley (2005) and incorporates the checklist from the PRISMA extension for scoping reviews (Tricco et al., 2018).

Stage 1: Identify the Research Questions

The research questions were used to guide the search strategy include: 1) Can milk-derived exosomes promote growth and regeneration of the intestinal barrier of infants diagnosed with NEC? 2) How does exosome affect the integrity of tight junctions in the intestinal epithelium? The studies were then further evaluated by referring to the guided research questions and eligibility criteria.

Stage 2: Identifying Relevant Studies

Comprehensive literature research was conducted using reliable electronic databases including PubMed, Scopus, and ScienceDirect. To collect the most up-to-date information, the search was limited to articles published within the past 10 years. The search strategy for literature research focused on certain keywords, including "exosomes", "human milk exosomes", "necrotizing enterocolitis", "therapy", "treatment", and any other relevant keywords to assist the research process. The keywords were combined with the terms "AND", "OR", and "NOT" for a better research strategy. The search string was "milk-derived exosome" AND "necrotizing enterocolitis". Then, the search results were screened based on the inclusion and exclusion criteria that have been chosen as shown in Figure 1.

Three databases, namely Scopus, ScienceDirect, and PubMed, were accessed, resulting in a total of 125 articles. Among them, 92 papers were retrieved from Scopus, 17 from ScienceDirect, and 16 from PubMed (Figure 1). Then, the articles were screened, resulting in a total of 12 articles remaining after excluding 113 articles. The excluded articles were chosen based on the inclusion and exclusion criteria where the review articles, book chapters, editorial, and conference paper were excluded. There were also six articles written in other languages and 56 articles were unrelated to research questions. The 12 included articles go through a thorough review for eligibility, ensuring their reliability and validity. Among them, five articles were selected for this scoping review, while the others were excluded. Finally, data extraction was performed on the five included articles, as they met the specified inclusion and exclusion criteria as outlined in Stage 3.

Stage 3: Study Selection

The following studies were included if they meet the following criteria: (1) all papers published within the last 10 years (2) all the papers published were written in English (3) full-text article. Studies were excluded if they were unpublished studies, hand-searched articles, grey articles, review articles, book chapters, conference abstracts and letters.

Stage 4: Charting the Data

The author conducted a thorough search, screening the articles for both quality and relevance based on the established criteria and research question. Once screened, each paper was analysed and details such as author, year of publication, method of study, model involved in the studies, and outcomes were recorded.

Stage 5: Collating, Summarising and Reporting Results

Data from the finalized full articles were extensively evaluated and organized into tables, which include author, year of publication, method of study, model involved in the studies, and outcomes. The data extraction step is an important step in conducting this study. It aims to achieve the objectives and research questions of this scoping

review. The extracted table provided a descriptive summary of the results, aiding in the overall understanding of the study. Both the author and supervisor carefully examined the paper and reached a consensus on the accuracy and reliability of the findings.

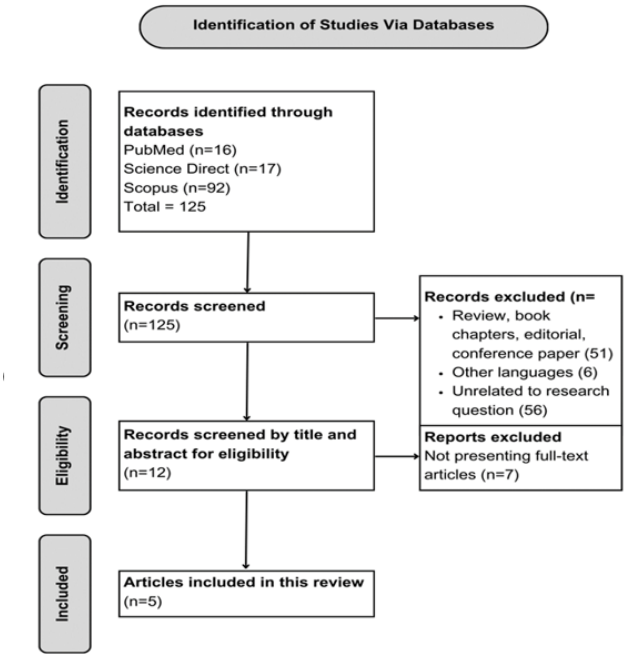

Figure 1: PRISMA ScR flow diagram

RESULTS

Study Characteristics

The selected studies focused on experimental research This review includes various research from different journals; where He et al. (2021) from Springer Nature, Li et al. (2019) from PLOS ONE, Hu et al. (2022) from Springer, and both Dong et al. (2020) and Martin et al. (2018) from SAGE Publication. Four studies using human breast milk and only Li et al. (2019) used bovine breast milk. Despite the different sources, all the studies approved that milk-derived exosomes are able in treating NEC.

Ability of Exosomes in Promoting Growth and Regeneration of the Intestinal Barrier

All five research articles confirmed the ability of exosomes in promoting growth and regeneration of the intestinal barrier (Table 1). He et al. (2021) stated that the strong integrity of the intestinal epithelium was because HBM exosome were able to increase the epithelial tight-junction proteins both in mRNA expression and protein content. According to Li et al. (2019), exosomes could promote intestinal epithelial cell viability, enhance proliferation, and stimulate intestinal stem cell activity under healthy condition. The therapeutic effect of HBM exosome on experimental NEC have been verified by Hu et al. (2022) due to its ability in rescuing intestinal injury, restoring epithelial regeneration, and inhibiting intestinal inflammation. Dong et al. (2020) stated that HBM exosome was a potential therapy to decrease cell toxicity directly in intestinal stem cells (ISCs). Lastly, Martin et al. (2018) able to demonstrate that human breast milk-derived exosomes reduce oxidative stress-related injury on intestinal epithelial cells (IECs).

Table 1: Data extraction of the ability of exosomes in promoting growth and regeneration of the intestinal barrier

Author's Name and country	Year of Publication	The ability of exosomes in promoting growth and regeneration of the intestinal barrier
He et al. China	2021	This study showed that the presence of milk-derived exosomes is found to be beneficial maintaining an intact and healthy intestinal lining since it can strengthen the intestinal epithelium's integrity by increasing the levels of epithelial tight junction proteins ($p<0.05$).
Li et al. Canada	2019	According to this study, milk-derived exosomes give protection to the intestinal epithelial cells (IECs) by promoting the cell viability ($p<0.01$), enhancing cell proliferation ($p<0.05$), and stimulating intestinal stem cells activity ($p<001$).
Hu et al. China	2022	This study confirmed that milk-derived exosomes have the therapeutic effect due to its ability in promoting cell growth and regeneration while minimizing intestinal inflammation ($p<0.05$).
Dong et al. China	2020	This study demonstrated that milk-derived exosomes can protect intestinal stem cells (ISCs) against cellular harm and cell toxicity.
Martin et al. USA	2018	According to this study, milk-derived exosomes could minimize oxidative stress and reduce injury in intestinal epithelial cells caused by oxidative stress.

Mechanism of Action of Milk-Derived Exosomes in Protecting the Infant's Intestinal Barrier

It has been disclosed that all the research articles concentrated on various components, indicating that multiple factors are involved in the regeneration of the intestinal barrier. He et al. (2021) investigated the impact of exosomes on intestinal epithelial tight-junction proteins, such as ZO-1, claudin-1, and occludin, while Li et al. (2019) focused on how exosome administration affects mucin production, goblet cell expression, MPO expression, and GRP94 expression. Hu et al. (2022) provided evidence by examining the number of ileum crypts and Lgr5 expression, and they identified several biological processes that are regulated during exosome administration. Dong et al. (2020) found that HBM exosome administration significantly improved the viability of ISC exposed to H2O2. Martin et al. (2018), who concentrated on the damage caused by oxidative stress, discovered that milk exosomes deliver microRNA-125b, which targets and inactivates the apoptosis-inducer p53.

DISCUSSION

The key findings of this scoping review pertain to the ability of exosomes in promoting growth and regeneration of the intestinal barrier and the effect of exosomes administration to the components in the intestinal barrier. Necrotizing enterocolitis has been controlled for a long time despite the fact that numerous therapies, including prebiotics and surgical procedures, have been employed. However, the surgery itself has a high risk of death and neurodevelopmental impairment in infants with very low birth weight (Robinson et al., (2017). According to Carr et al. (2021), breast milk is a unique fluid consists of many bioactive compounds that are necessary for an infant's growth development and protection against infections. It is amazing that many studies found infants with breastfeeding have a higher survival rate than infants without breastfeeding. Exosomes are known as an integral component of the complex composition of breast milk, as this fluid naturally contains a high concentration of exosomes. These substances have many functions, including intercellular communication, immune system development, gastrointestinal health, and therapeutic potential (Carr et al., 2021).

Ability of Exosomes in Promoting Growth and Regeneration of the Intestinal Barrier

Chen et al. (2020) stated that exosomes protect mucus barrier, improve IECs proliferation and intestinal stem cells viability, reduce oxidative stress and inflammation of IECs, and increase neutrophil recruitment hence are ideal therapeutic agents in NEC. Hence, based on the results of this scoping review, the five final articles provide a strong evidence to support that statement and confirmed that exosome are able to; enhance epithelial integrity (He et al., 2021), give protection to intestinal epithelial cells (Li et al., 2019), reduce inflammation and stimulate cell regeneration (Hu et al., 2022), protect from cell damage (Dong et al., 2020), and reduce oxidative stress (Martin et al., 2018). He et al. (2021) suggested that exosomes can improve the integrity of the intestinal epithelium due to their ability to increase the expression and content of proteins responsible for tight junctions. The RT-qPCR result of the study showed a decrease of tight-junction protein expression in group that have been stimulated with lipopolysaccharide (LPS) and group that has pre-treated with exosome-free HBM while stimulated with LPS. On the other hand, the protein increased in a group that have been pre-treated with exosomes while stimulated with lipopolysaccharide. This result showed that the presence of exosome can increase the expression of tight-junction protein, hence, improving the integrity of the intestinal epithelium.

Interestingly, Li et al. (2019) provided evidence that exosomes promote intestinal epithelial cell viability and enhance proliferation. Result of the study showed that the number of goblet cells per villus were significantly reduced during NEC compared to control, and the number increased after administration of milk-derived exosomes in the NEC group. Goblet cells secrete mucins, forming a vital mucus layer that shields the gastrointestinal tract surface from injury (Johansson et al., 2013, as stated in Li et al., 2019). Thus, exosomes increased the expression of goblet cells that are able to produce mucins that can protect intestinal epithelial cells (IECs). Hu et al. (2022) pointed out the therapeutic potential of HBM-exosomes in treating NEC by stating that exosomes can promote intestinal healing by rescuing injury, restoring epithelial regeneration, and inhibiting inflammation.

Dong et al. (2020) highlighted the potential of HBM exosomes to directly decrease cell toxicity in intestinal stem cells (ISCs) which gave protection from cell damage. This protective effect is crucial for maintaining the regenerative potential of the intestinal barrier. During in-vitro experiment, they observed a significant increase in the relative gene expression of Lgr5 after the administration of exosome. Studies have shown that the Lgr5+ is a highly active ISCs necessary for intestinal epithelium renewal by continuously supply new intestinal epithelial cells (Barker et al., 2007, as stated in Hou et al., 2020). Lastly, Martin et al. (2018) contributed to the understanding of exosomes' multifaceted role by demonstrating their ability to lessen oxidative stress-

induced damage in intestinal epithelial cells (IECs). According to Li et al. (2016) as stated in Martin et al. (2018), oxidative stress on the intestinal epithelial compartment is one potential mechanism leading to NEC in neonates. Cell treated with 1 and 10 μg of exosomes in the presence of H_2O_2 had a complete recovery, while 50% cell death was observed in cell without exosomes. Thus, it is confirmed that the presence of exosome is able to lessen the oxidative stress-induced damage in IECs.

Mechanism of Action of Milk-Derived Exosomes in Protecting the Infant's Intestinal Barrier

This scoping review able to highlight the multifaceted nature of exosome-mediated intestinal barrier by collecting research articles that focusing on different components of intestinal barrier. Firstly, He et al. (2021) demonstrated that HBM-exosomes can sustain the intestinal epithelial tight-junction proteins, specifically zonula occludens-1 (ZO-1), claudin-1, and occludin, both in-vitro and in-vivo. Volksdorf et al. (2017) stated that these proteins are present early in newly formed regenerating epidermis of normal wound healing.

These proteins are a critical structure that resist invasion of pathogens in the epithelial barrier (He et al., 2021). Results showed that lipopolysaccharide (LPS) can insult the protein. However, the presence of exosomes was able to protect it against LPS. Western blot also showed the decrease of these proteins in a group of pups that have been introduced to NEC and the levels of proteins was higher when there was a presence of exosomes. Therefore, it proved that exosomes could enhance tight-junction function which can create a strong seal between epithelial cells and consequently maintain the barrier integrity. He et al. (2021) also pointed out that levels of the pro-inflammatory cytokines IL-6β and TNF-α were significantly reduced when there was an administration of exosome. According to Hui et al. (2017), these two cytokines were correlated with intestinal inflammation in NEC patients. So, when there is a high level of these cytokines, it means that there might be the occurrence of inflammation.

Li et al. (2019) explored the influence of exosomes on mucin production, goblet cell expression, MPO (myeloperoxidase) levels, and GRP94 (heat shock protein 90) expression. The study showed a significant reduction in MPO expression after the introduction of exosome, which means that exosomes are able to reduce intestinal mucosal inflammation. The number of goblet cells also increased in the NEC group after the administration of milk-derived exosomes. High number of goblet cells conveyed that a thick layer of mucus layer due to the high mucins production. According to Dharmani et al. (2011) as stated in Li et al. (2019), it has been reported that in the inflamed intestine, depletion of mucin production from goblet cells occurs prior to epithelial cell damage, inflammation and elevation of MPO. The abundant protein in endoplasmic reticulum, GRP94 is crucial for goblet cell function and gut barrier integrity (Liu et al., 2013). Therefore, it can be marker for inflammation and this study observed that GRP94 was reduced in NEC and back to normal after the administration of exosomes.

Hu et al. (2022) focused on the number of ileum crypts and Lgr5 expression (a marker for intestinal stem cells). They observed an increase in both, indicating that exosomes may stimulate stem cell activity and proliferation. The increase in the number of ileum crypts suggests that exosomes may promote the formation of new crypts, potentially expanding the niche for ISCs and enhancing the overall regenerative capacity of the gut. The increase of Lgr5 expression indicated that exosomes may be stimulating the activity of existing ISCs, prompting them to divide and differentiate into new intestinal epithelial cells at a higher rate. Dong et al. (2020) investigated the effects of human milk-derived exosomes in ISCs that have been damaged by oxidative stress by using H_2O_2 exposure. Their results suggest that exosomes can significantly increase ISC viability, protecting them from damage caused by free radicals which were possibly mediated via the Wnt/β-catenin signaling pathway. According to Dong et al. (2020), Wnt/β-catenin signaling pathway is the signature pathway, and the genes that are regulated downstream of this route may serve as possible markers of ISCs. Pai et al. (2017) stated that the regeneration of stem cells, differentiation, migration, genetic stability, apoptosis, and proliferation are all regulated by the highly conserved Wnt/β-catenin signaling mechanism. They also found that human milk-derived exosomes were able to enhanced ISCs proliferation as there was a significant increase in the expression of Lgr5 after the administration of exosomes and the small intestinal epithelium of the mouse completely renews every three to five days. Therefore, it has been proved that human milk-derived exosomes have a potential to protect ISCs from oxidative stress.

Martin et al. (2018) explored the role of breast milk-derived exosomes in mitigating oxidative stress damage by inducing H_2O_2 to the cells and confirmed that breast **milk-**derived exosomes are protective against cell toxicity. According to Simon et al. (2009) as stated in Martin et al. (2018), oxidative stress is one of the factors causing cell apoptosis due to the increase of p53 expression. Hence, they discussed about the ability of exosomes in delivering microRNA-125b, which is a molecule that can target and inactivate the apoptosis inducer p53. Regulating the

expression of p53 may help in preventing excessive cell death within the intestinal epithelium. Thus, it is true that the administration of milk-derived exosomes can prevent the occurrence of apoptosis and consequently promoting the health of intestinal barrier.

CONCLUSION

Current treatments for Necrotizing Enterocolitis (NEC), such as surgery, carry significant risks, including death and neurodevelopmental impairment. This review highlights exosomes as a safer, more targeted alternative. Exosomes support intestinal barrier health by enhancing epithelial integrity through tight-junction proteins like ZO-1, claudin-1, and occludin. Milk-derived exosomes promote cell growth and regeneration by increasing goblet cell expression, leading to higher mucin production and improved epithelial cell viability and proliferation. They also have anti-inflammatory effects, potentially reducing the inflammation characteristic of NEC. Additionally, exosomes protect against oxidative stress-induced cell damage. However, further research is needed to determine the optimal dosage, delivery method, and long-term safety of exosome therapy. Issues such as efficient delivery to target cells and the unknown long-term effects of exosome therapy require continued investigation, with nanotechnology potentially aiding in exosome delivery.

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REVIEW ARTICLE

Circulating Tumor Cells (CTCs) and Red Blood Cells (RBCs) Interactions and Their Potential Clinical Applications: A Scoping Review

Muhammad Ashraf Samwil Mohd Mahayudin[1], Mohd Fuad Rahmat Sam[1,*]

[1]Department of Biomedical Science, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Circulating Tumor Cells; Red Blood Cells; Metastasis

ABSTRACT

Background: Circulating tumor cells (CTCs) are rare tumor cells that spread cancer through the bloodstream. As for red blood cells (RBCs), they play a crucial role in oxygen transport and interaction with cancer cells. CTCs adhere to RBCs, increasing survival and metastasis. Physical interactions and hemodynamic forces influence the distribution and circulation of CTCs, triggering immune responses and activating red blood cells, promoting tumor growth and metastasis. These interactions have significant clinical applications. Previous studies proved that the interactions between RBCs and CTCs were observed. These findings may be a new understanding and development in cancer studies. Therefore, this scoping review aims to identify on how those interactions remain in the body system that may be the metastasis contribution towards CTCs. **Methods:** This study will focus on scoping review that involves a few articles and research papers that have been filtered from online databases such as Scopus, ScienceDirect and PubMed. The process of selecting articles will be followed by Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) 2020 guidelines. Experimental research articles published in English between 2018 until 2023 will be included in this study to be reviewed. **Results:** Throughout the screening process, 7 articles were retrieved as included articles in this paper. Across the study, it showed that RBCs play a different role in the interactions with CTCs that contribute to the cell metastasis and survival. Additionally, a few interactions with different types of cancer cells were reported in a few studies that were clearly unexplored in other studies. These studies used different approach on how to conduct the studies but not to mention that similarly they used *in vitro* as the part of study model. **Conclusion:** From this review, it can be concluded that interactions of RBCs and CTCs were great findings in cancer studies. In the future, continuous study on the interactions may come across with therapeutic therapy study that may help in cancer therapy.

INTRODUCTION

Circulating tumor cells (CTCs) and red blood cells (RBCs) are two cells that play important roles in tumor dispersion and metastasis, eventually contributing to cancer progression and death (Agarwal et al., 2018). CTCs are cancer cells that have shed from the main tumor and entered the circulation, where they might travel to distant organs and form new tumor colonies. Conversely, RBCs may transport oxygen and nutrients to CTCs, allowing them to survive in circulation and increasing their metastatic potential (Lal et al., 2015).

Recent study has revealed that CTCs may interact with RBCs in several ways, including physical adhesion, chemical exchange, and signalling. These interactions have the potential to have a significant influence on CTCs behavior and metastasis. According to Alix Panabières-Pantel (2021), physical adhesion between CTCs and RBCs, for instance, can shield CTCs from immune monitoring and promote their extravasation into secondary tumor sites. In some cases, CTCs may acquire nutrients and oxygen from RBCs, enhancing their survival and potential for metastasis. This exchange can occur through direct contact or via membrane transporters (Zhang et al., 2022). Besides, there was a study mentioned that TGF-β signalling is also involved in the interactions. According to Derynck et al. (2017), TGF-β binding to its receptors on RBCs downregulates their immune function and promotes their activation, further supporting CTCs survival and metastasis. The interactions between CTCs and RBCs are complicated and not entirely understood, but they constitute a prospective target for cancer treatment. It may be able to prevent CTCs metastasis and enhance patient outcomes by interrupting these connections.

The mechanisms underlying the formation of RBC-CTC clusters and their impact on CTC biology still need to be fully understood. Moreover, the role of specific molecular interactions between RBCs and CTCs in promoting tumor cell survival and metastasis remains unclear. Therefore, this study objectives are to provide an overview of the possible interactions between circulating tumor cells and red blood cells and the potential therapeutic clinical manifestation. Besides, this study also conducted to identify the effects of CTCs-RBCs interactions on CTCs survival in the human body. In addition, within the study can be explored the potential of immunotherapies to

* *Corresponding author.*
E-mail address: mfuad_rahmat@iium.edu.my

modulate CTCs and RBCs interactions. Hence, identify the problems research gap on the interactions between RBCs and CTCs and the potential clinical applications.

CTCs represent a crucial phase in metastatic cascades, the process which tumors spread throughout the body system. Understanding the relative interactions of CTCs and others cells holds immense advantages for the development of therapeutic approach. This review may contribute to emphasize the interactions of CTCs and RBCs, whereas can develop a novel and more effective cancer therapies.

MATERIALS AND METHODS

Study Design

This study mainly will conduct scoping review as a study design. Scoping reviews are a technique used to systematically map the evidence across a variety of study designs in a field (O'Brien et al., 2016). They aim to map the breadth and depth of research on a particular topic, identify gaps in the literature, and inform future research directions. Scoping reviews are a valuable tool for synthesizing research and informing practice, particularly for exploring new topics or providing an overview of rapidly developing fields. They are particularly useful for exploratory research and identifying areas that warrant further investigation.

The study aims to systematically map the existing literature on the interactions between CTCs and RBCs. This helps to provide a comprehensive overview of the current state of research in this area. By reviewing a wide range of studies, the scoping review identifies gaps in the current understanding of CTCs and RBCs interactions. This highlights areas where further research is needed, such as the specific molecular mechanisms involved and the potential therapeutic applications. The scoping review serves as a preliminary step to assess the volume and nature of the available evidence on CTCs and RBCs interactions. This helps to determine whether a full systematic review is feasible and warranted.

Search Strategies

The scientific papers that studied those topics were obtained through a list of reliable publishers such as Scopus, PubMed, Science Direct, Springer Link and Research Gate search engines. The main topic focused on the possible interactions between circulating tumor cells (CTCs) and red blood cells (RBCs) and the potential clinical applications to enhance cancer therapies. In order to assist the research process, some highlighted keywords that will be utilized in this research study would be "Circulating Tumor Cells", "Red Blood Cells" "Interactions", "Clinical Applications", "mechanisms" and other relevant keywords to assist the research process. The word "AND" was placed between the keywords to narrow the search while the term "OR" widen the exploration. The collected journal or articles were filtered using the Arksey and O'Malley Method Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA, 2020) Guideline. PRISMA 2020 Guidelines is significant as it benefits to ensure the quality of the review, it allows the readers to access the strengths and weaknesses of the articles.

Selection Criteria

There are some criteria set for the review finding (Table 1). These criteria help to ensure that the review is focused on high-quality review. The study must be experimental and journal-based to provide relevant ideas and evidence on the topic. The language restriction ensures that the articles can easily understand the studies, while the date restriction within 2017 onwards ensures that the review is up-to-date. The focus on CTCs and RBCs are obviously relevant to the topic of the review, and the inclusion of studies on the interactions between these two cell types broadens the scope of the review to include the latest research in this area. Finally, the requirement that the studies be available as full-text articles ensures that the reviewers can access all of the necessary information to properly evaluate them.

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
● Research articles that published in English. ● Full text articles. ● Published between 2018 until 2023. ● Experimental papers	● Articles do not meet the objectives of study. ● Book chapter, review paper, systematic review or discussion paper.

Data Extraction

Data been extracted and analysed from screened articles that involved information on author names, publication year, type of interaction, model of study, cancer cells involved, and mechanism approach in the study. This data was tabulated to provide an overview on how the discussion will be concluded on interaction of RBCs and CTCs.

RESULTS AND DISCUSSION

Based on the screening of articles, a number of 2134 potential articles were resulted from selected databases including Scopus, Science Direct and PubMed. Duplicated articles were recorded with similar titles, in resulting 261 articles been removed and screened out. Then, the 1873 articles were screened by titles and abstracts. From the number of articles, 1839 articles were removed as these articles were not meet the discussion on this study. The remaining of the articles were screened out on the availability either it is full text access and open access. All the articles were retrieved. Remaining 34 articles were screened for inclusion and exclusion criteria. 25 articles were removed as it does not meet the main objectives of the discussion, and 2 articles were excluded because the articles were review paper. Finally, 7 articles were included for data extraction on this study. The flow of the screening process has been illustrated using PRISMA 2020 Flow Diagram as Figure 1 shows all phases of screening and elimination process.

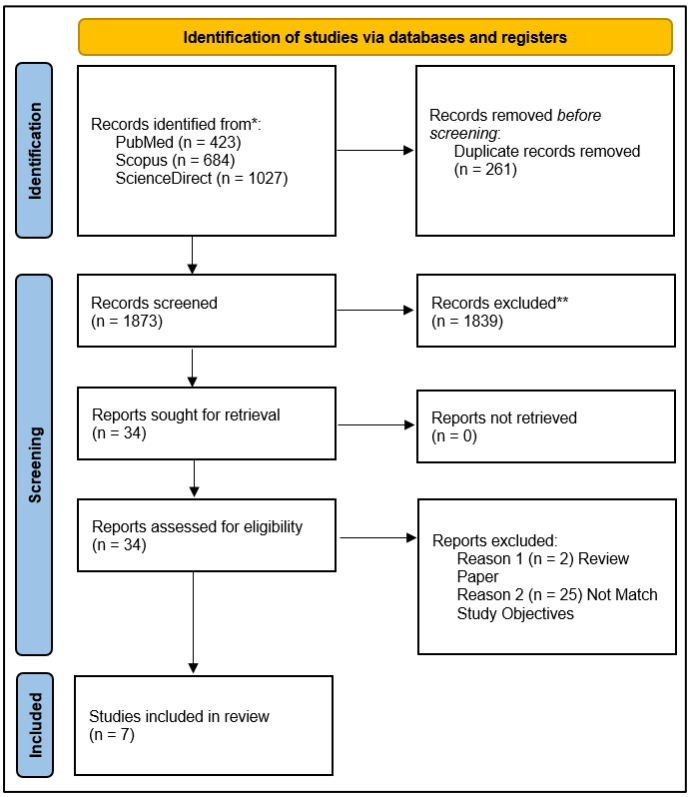

Figure 1: PRISMA flow diagram

Mechanism of Approach on CTCs-RBCs Interaction

Circulating Tumor Cells (CTCs) is type of secondary tumor cells that initiate into metastasize of tumor cells throughout body system. Interactions between other cells such as cell adhesion, signalling pathways and molecules exchange contribute to its proliferation and survival in body system. It was observed that RBCs do interact with CTCs that can contribute to its survival and proliferation as well as other cells. These interactions can be shown in Table 2 that conclude the interaction throughout the study. From the articles, most of the study findings resulting on cell adhesion and migration as one of the interactions that can be seen on towards CTCs and RBCs. Meanwhile, protein profile such as Lysosome-Associated Membrane Protein 2 (LAMP2) were observed on RBCs that associated with breast cancer as the hallmark biomarkers in the breast cancer. Throughout the study, it can be seen that there are a few interactions of RBCs and CTCs been concluded and it comes with different of approachable mechanism to illustrate on how the interactions occur in the body system.

Firstly, Liang et al, (2020) used an approach of bioinformatic tools which is LinkedOmics database to analyse the co-expression genes related to Erythrocyte Membrane Protein Band 4.1 Like 1 (EPB41L1) in Kidney Renal Cell Carcinoma (KIRC). LinkedOmics is a platform that allows biologists and clinicians to access, analyse, and compare cancer multi-omics data inside and across tumour types. The LinkedOmics database combines multi-omics and clinical data for 32 cancer types and 11,158 patients from the Cancer Genome Atlas (TCGA) project. This database reveals that their involvement in cell adhesion pathways through Gene Ontology (GO) and Kyoto Encyclopedia of Genes and Genomes (KEGG) pathway were analysed.

Besides that, Pereira-Veiga et al., (2023) used an approach of proteomic profile to analyze the protein composition of RBCs in cancer patients. In this study, RBCs were observed contain LAMP2 and Purine Nucleoside Phosphorylase (PNP) that associated with breast cancer metastasis. LAMP2 can be found on the surface of RBCs membrane aside with other glycoproteins. This LAMP2 were reported that associated in breast cancer (BC) metastasis which is provide a proper binding that can provide help to BC from oxidative damage and their survival. Besides LAMP2, PNP also reported express on RBCs that associated on BC for its survival and proliferation. Additionally, through this approach of study it had been reported that amino acids also played roles in the interaction between CTCs and RBCs that provide a decent nutrient for metabolism of tumor cells for its survival and proliferation.

Apart from that, Zhu et al., (2018) used an approach by engineered RBCs with Folate receptor and Magnetic Nanoparticles (MNPs) on their surface in artificial blood samples. This approach reported to engineer RBCs to enhance its adherence to CTCs. In result, it could rapidly adhere RBCs to CTCs which lead to a better adhesion that provide cell survival and proliferation. However, this

approach was purposely been used to allows them to effectively capture cancer cells in the bloodstream.

Meanwhile, Roychowdury et al., (2023) used an approach of the advanced APR method to stimulate cancer cell transport while maintaining a local region of RBCs. Each cell is modeled as a fluid-filled membrane with both elasticity and bending stiffness, using a Lagrangian surface mesh composed of triangular elements. The authors created algorithms to solve problems including connecting regions with different viscosity, keeping hematocrit within the window, and shifting the window while retaining the dynamics of the CTCs and neighbouring RBCs. The study focuses on the fluid dynamics and biomechanical elements of how CTCs move in the bloodstream, particularly the effects of RBCs on CTCs trajectory. The authors aim to understand how the presence of RBCs influences the movement of CTCs and how these interactions can be accurately modeled computationally.

Table 2: Evidence on RBCs-CTCs Interactions

Author (Publication Year)	Type of Interactions	Model of study design	Cancer cells	Mechanism approach
Liang et al. 2020	Cell adhesion and migration	In vitro	Human KIRC cell line 786-O	Linkedomics database was used to analyze co-expression genes related to EPB41L1 in KIRC, revealing their involvement in cell adhesion pathways through GO and KEGG pathway analysis.
Pereira-Veiga et al. 2023	Protein profile that associated with BC metastasis	In vitro	Human breast cancer	Proteomic approaches to analyze the protein composition of red blood cells in cancer patients, particularly those with breast cancer.
Zhu et al. 2018	Cell adhesion	In vitro	Human breast carcinoma cell line MCF-7 & colorectal cancer cell line HCT116	The engineered RBCs, with folate receptor (FA) and magnetic nanoparticles (MNPs) on their surface, could rapidly adhere to CTCs in artificial blood samples.
Roychowdury et al. 2023	Cells motion and trajectory	In vitro	Human brain cancer & Human Breast Cancer	The advanced APR method to simulate cancer cell transport over a mm-scale distance while maintaining a local region of RBCs.
Pepona et al. 2020	Cell adhesion	In vitro	Murine mammary gland carcinoma cells (4T1, ATCC)	3D simulations of fluid flow and CTCs transport in the reconstructed and idealized bifurcated vessel.
Wang et al. 2021	Cell margination and adhesion	In vitro	-	3D simulation on the behaviors of the tumor cells in a real microvascular network.
Tan et al. 2019	Cell adhesion and trajectory	In vitro	Human prostate cancer cell (PC-3 cell)	A coupled fluid-solid interaction model was used to study cancer cell transport and adhesion in microfluidic devices.

Pepona et al., (2020) used an approach of numerical simulations by applying Three-dimensional (3D) simulations of fluid flow to transport CTCs in the reconstructed vessel. The researchers used 3D numerical simulations to determine how hemodynamic parameters influence the locations of tumour cell arrest and adhesion. The model utilised in the study included numerical simulations to explore the behaviour of CTCs and their interactions with the local hydrodynamics. Fluid flow and CTCs transport simulations in the reconstructed and idealised bifurcated vessel were carried out with an in-house massively parallel computational fluid dynamics solver.

Furthermore, Wang et al., (2021) used an approach of 3D simulation to generate a realistic microvascular network. The study used a hybrid method that combines smoothed dissipative particle dynamics and the immersion boundary

method (SDPD-IBM) to mimic tumour cell behaviour in the presence of RBCs in a microvascular network constructed from rat mesentery. The research focused on the effects of RBCs on the margination and adhesion dynamics of tumour cells within the microvascular network to characterise the interactions between tumour cells and RBCs.

Moreover, Tan et al., (2019) used an approach of numerical simulations which a coupled fluid solid interaction model was used to study cancer cell transport and adhesion in microfluidic devices. The study evaluated the impact of cell size and ligand density on cell adherence to cylinder surfaces. The cells showed transient rolling behaviour in the collective cell trajectory study. The paper learned the collision consequences of RBCs on cancer cells, specifically the impact on CTCs trajectories. The study's numerical simulations sought to assess the binding behaviour of CTCs under a variety of situations, including varied molecule densities and the presence of RBCs.

Research Design Related

Across the review study, it was clearly shown that most of the methods involved *in vitro* methods to conduct the study in cell culture. However, each study using a different method as an approached to their studies. According to Tan et al. (2019) and Pepona et al. (2020), their studies show that numerical simulations method been used to illustrated the three-dimensional microfluidic condition of vessels that equals to the human body system. The idea was to provide the real microvascular condition on how does the CTCs were transported in the vessels. On the other hands, Roychowdury et al. (2023) simulated different methods such as Advanced Physics Refinement (APR) method and Smoothed Dissipative Particle Dynamics and Immersed Boundary Method (SDPD-IBM) to provide the ideas on how does the interactions between CTCs and RBCs are applied as the microvascular network condition. Bioinformatics tool, as an example Linkedomics database been used to express genes that related with the interactions of both cells. Additionally, engineered method also been used by Zhu et al. (2018) to engineered the RBCs as the model of study to understand the interaction on both cells.

Cancer Cells Related

Four studies which are by Pereira-Veiga et al., (2023), Zhu et al., (2018), Roychowdury et al., (2023) and Pepona et al., (2020) set breast cancer cells as the selection model cells for the study. Breast cancer cell lines widely been used in any research studies related with cancer and tumor. This situation provides significant benefits on research studies as what been reported by Raghavendra et al., (2020), that breast cancer cells share similar biological microenvironment with others cancerous cells and sometimes also having a same gene expression such BRCA1 and BRCA2 genes that also expressed on ovarian cancers. These similar conditions can provide insights into other cancer cells as well. In contrast, according to Tan et al. (2019), the cancer cells been used were prostate cancer cell lines and Liang et al. (2020) kidney renal clear carcinoma cell (KIRC) been used as the model of their studies.

This review provides a few understanding on how interactions of CTCs and RBCs were illustrated. In future a few key aspects should be compromise to enhance the study in the field of interactions between CTCs and RBCs. Firstly, most of the studies were conducted in vitro model of study. This model of study is limited as it does not consider the complexity of a live thing. In vitro studies often employ isolated cells or tissues that do not interact with other cells and tissues in the same manner that they would in the body. This can make it challenging to extrapolate in vitro study results to what would happen in a full organism. Therefore, future researcher can consider of in vivo model of study as it considers the real scenario of body system without change the setting of the real vascular system. Besides, the review come across a few interactions that been observed in the study which were not deeply discussed because of limitation on the study such as LAMP2 and PNP functions in RBCs that influenced CTCs metastasis. However, with these findings it will be more interesting if the future researchers continue on the recent study of PNP and LAMP2 to discover it functions in the interactions of RBCs and CTCs in the future. Additionally, using a different approach on cancer cells may also consider as a new understanding on the interactions. This is because a clear understanding of each cancer cells need to be considered as it has different physiological conditions that need to be discovered.

CONCLUSION

This study emphasized that CTCs had an interaction with RBCs in order to survive and proliferate in body system. The review on other studies concurred that there are a few interactions on RBCs and CTCs that contribute to CTCs metastasis. In addition, the researchers had illustrated a few methods that proved on the contribution of the interactions of RBCs and CTCs in the metastasis of CTCs. The objectives of the study to identify the interactions of CTCs and RBCs have been achieved. The studies are prone only highlighting the interactions between CTCs and RBCs, which are not specifically observed on the therapeutic approach. This may be a limitation for the studies because

it needs to be developed to achieve the objectives on the potential therapeutic. In future, this study can expand to develop a promise therapeutic approach as cancer therapy. More research and studies are necessary in order to provide a full understand on the interactions of RBCs and CTCs. The development of technology should be taken as an aid to improvise the studies in the future.

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REVIEW ARTICLE

Ethical Challenges in Forensic Imaging: A Systematic Review of Key Issues, Emerging Artificial Intelligence (AI) Implications and Future Directions

Aina Arisha Khalid[1], Waliullah Shah Syed[2], Inayatullah Shah Sayed[1,*]

[1]Department of Diagnostic Imaging and Radiotherapy, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, 25200 Kuantan, Pahang, Malaysia
[2]Canadian Ultrasound Institute and Research Centre, 10 Kingsbridge Garden Cir, Suite # 400, Mississauga, ON L5R 3K7, Canada

Keywords:
forensic imaging; patient consent and privacy; ethical issues; future directions

ABSTRACT

Background: Forensic imaging is a widely employed technique in the field of forensics yet it raises numerous ethical concerns. For radiographers, ethical issues can significantly impact the credibility and reliability of their work, especially as advancements in imaging technology introduce challenges related to data manipulation and the need to balance diagnostic objectives with patient privacy. Thus, a comprehensive study of these ethical challanges is essential. **Methods:** A thorough literature search was conducted using Google Scholar, ScienceDirect, PubMed, and GoPubMed, focusing on "ethical issues in forensic imaging" and related terms like "ethical issues in postmortem imaging." Boolean operators and keyword variations such as "ethical issues AND forensic imaging," "forensic AND ethical issues AND radiology," and "postmortem imaging AND ethics" enhanced relevance. The search covered publications from 2003 to 2024, specifying "human" and "ethics". Articles were selected based on predefined criteria for further data extraction, synthesis, and analysis. **Results:** The findings reveal key ethical concerns, including the validity of tests, informed consent, privacy, confidentiality, and professionalism issues commonly identified in forensic radiographic imaging. The integration of artificial intelligence (AI) into forensic processes adds further complexity to these ethical dilemmas. **Conclusion:** These findings highlight the urgent need for developing robust guidelines, raising awareness, fostering cooperative environments, establishing standards, and creating centres of excellence to address the ethical challenges in forensic imaging.

INTRODUCTION

Forensic imaging has revolutionized modern forensic investigations by providing non-invasive techniques to document and explain medico-legal findings. Techniques like X-ray, CT, MRI, and 3D scanning provide non-invasive alternatives to traditional autopsies, especially in cases where families object due to religious or personal reasons (Zhang, 2022; Murphy, 2016). These methods are crucial for identifying trauma, pathological changes, and human remains and are widely used in forensic anthropology, odontology, ballistics, and clinical forensic medicine (Franklin et al., 2015; Yadav 2017; Bjelopavlovic et al., 2023; Dahal et al., 2023; Ferreira & Caldas 2024).

Ethical concerns are vital in forensic imaging, with issues like postmortem imaging without consent, data misuse, and privacy violations (Heathfield et al., 2017; O'Donnell & Woodford, 2008). Bias or privacy mismanagement can lead to wrongful convictions, underlining the need for clear ethical guidelines. Radiographers face dilemmas and require clear protocols and support from governing bodies, especially for sensitive topics like 3D-printed remains (Smith et al., 2022; Carew, 2023).

Virtopsy, using CT and MRI, offers virtual autopsies that are storable and infection-free, though it has limitations in detecting certain conditions (Ahmad et al., 2021). Ethical issues include ensuring informed consent from the deceased's next of kin and safeguarding digital data (Habburrahman et al., 2023). The deceased's confidentiality extends postmortem and requires careful data management (Silviu et al., 2008).

Forensic science combines ethical principles like autonomy, justice, and dignity with legal standards such as due process to ensure fairness (Carew & Errickson, 2019). Professional standards, particularly for technologies like SPECT, PET, and neuroimaging, are essential to maintain evidence integrity and ethical practices (Meltzer et al., 2014). Regulatory bodies like the International Association of Forensic Radiographers (IAFR) emphasize proper

* *Corresponding author.*
E-mail address: inayatullah@iium.edu.my

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training and ethical evidence handling (Doyle et al., 2020; Professional Board for Radiography and Clinical Technology, 2023).

Technological advancements like artificial intelligence (AI) in dental age estimation raise privacy concerns, requiring proper data management and informed consent (Lygate, 2024). Ethical dilemmas also arise in handling human remains, with respect for cultural beliefs being crucial (Chamsi-Pasha & Albar, 2017). Managing digital data securely is essential to uphold ethical standards (Obertova et al., 2019; Belcastro et al., 2022).

In this study a review over three decades highlights the need for standardized guidelines and better training to address emerging forensic imaging challenges. As technology evolves, ethical and professional frameworks must adapt to ensure justice and fairness in its use.

MATERIALS AND METHODS

Search for Relevant Literature

A comprehensive literature search was conducted using databases like Google Scholar, ScienceDirect, PubMed, and GoPubMed. Keywords such as "ethical issues in forensic imaging" and "ethical issues in postmortem imaging" were used alongside Boolean operators (e.g., "Ethical issues AND forensic imaging," "forensic AND ethical issues AND radiology"). The search focused on human-related ethics from 2003 to 2024, using snowballing technique to thoroughly review key articles and subsequent papers.

Reviewing and Selection of Articles

After an initial literature search and framework development, key points were identified to guide the research. These were used to form the inclusion and exclusion criteria outlined in Table 1. Titles and abstracts of retrieved articles were screened for relevance, followed by a full-text review of selected studies to confirm their suitability.

Data Extraction

During article selection, it's essential to document the inclusion and exclusion process for transparency and reproducibility. We record details and objectives of reviewed articles in Excel, streamlining data summary, analysis, and discussion.

Results Compilation, Data Analysis and Discussion

The data were gathered to meet the review objectives, analyzed to identify themes, and discussed to interpret and contextualize the findings. This process of data collection, synthesis, analysis, and discussion enhances the robustness and validity of the research outcomes.

RESULTS

An initial search in academic databases yielded 1192 articles. After screening titles and abstracts, 46 were identified as potentially relevant. Following full-text review and applying inclusion/exclusion criteria, 36 were rejected, leaving 10 articles for detailed evaluation. Figure 1 illustrates the article selection process following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

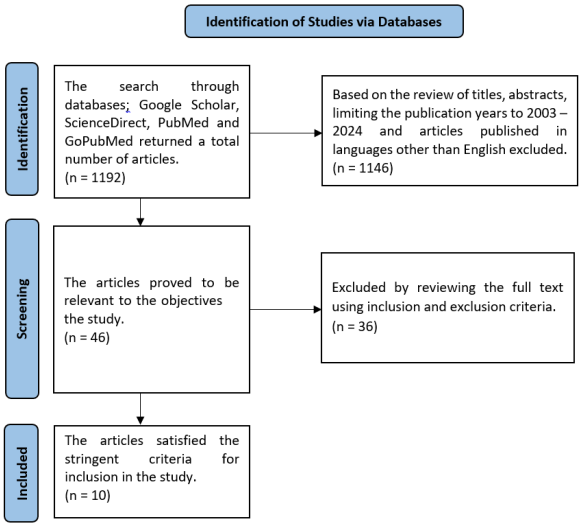

Figure 1: PRISMA flow diagram

Table 1: Table of inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Articles in English.	Articles on forensic imaging of animals.
Articles spanning from 2003 – 2024.	Articles on psychological forensics.
Articles related to ethical issues in forensic imaging.	Articles published in languages other than English.

Significant Ethical Problems in Forensic Imaging

Data analysis identified ethical issues in forensic imaging articles related to test validity, consent, privacy, confidentiality, and professionalism, as shown in Table 2. Ethical issues are categorized into privacy and data

Table 2: Description of articles on ethical issues and methods of overcoming ethical issues in forensic imaging

Author(s) and Publication Year	Title	Theme(s)
O'Donnell & Woodford, 2008	Post-mortem radiology - a new sub-speciality?	Highlights the need of radiological specialists working in a co-operative environment with pathologists.
Lygate, 2024	Testing the Use of Artificial Intelligence for Dental Age Estimation.	Concerns on the validity of examination, patient's data privacy and confidentiality, patient safety (radiation risk).
Lewis et al., 2018	Health professionals' and coroners' views on less invasive perinatal and paediatric autopsy: a qualitative study	Questions regarding storage and management of digital images related to human remains. Highlights the issue of uptaking non-invasive autopsy as main method which includes inappropriate uptake of examination and importance of validation and guidance.
Smith et al., 2022	Radiographers' experiences and perspectives of forensic imaging in Australia: A qualitative study.	Issues on consent taking.
Aghayev et al., 2008	Virtopsy – The concept of a centralized database in forensic medicine for analysis and comparison of radiological and autopsy data.	Concerning matters of data privacy.
Obertová et al., 2019	Postmortem imaging of perimortem skeletal trauma.	Having a center of excellence. Requirement of establishment of standards, guidelines and protocols. Forensic expertise in skeletal trauma assessment requires good understanding and is warranted to maintain high-quality expertise.
Aynsley-Green, 2009	Unethical age assessment.	Usage of forensic imaging as an administration method. Consent improperly obtained.
Alshamrani, 2022	Ethical aspects of age estimation for forensic purposes in Saudi Arabia.	Concerns issues such as consent, privacy, patient safety (radiation risk), and validity of patient.
Jeong et al., 2024	Korean radiographers' awareness, experiences, and education needs in forensic medicine and forensic radiology.	Lack of awareness and knowledge on forensic imaging.
Sonnemans et al., 2018	Dutch guideline for clinical foetal-neonatal and paediatric post-mortem radiology, including a review of literature.	By developing evidence-based guidelines and usage of evaluation by experts.

management, consent and ethical practices, and safety and validation to clarify differences in concerns.

Privacy and Data Management

One of the ethical issues in forensic imaging is privacy and data management. Aghayev et al., (2008) highlighted challenges in protecting medical data when exchanged across state borders. Similarly, Lewis et al., (2019) questioned the security and ethical handling of digital image data related to human remains. Lygate (2024) raised concerns about AI development relying on confidential medical data, which compromises patient confidentiality and privacy.

Consent and Ethical Practices

In forensic imaging, ethical practices and consent are vital, especially in sensitive contexts like age assessments and non-accidental injury (NAI) cases. Aynsley-Green (2009) highlighted challenges in obtaining consent for imaging in age assessments, raising ethical dilemmas. Smith et al. (2022) noted difficulties in securing consent for forensic imaging in suspected NAI cases due to legal and protective concerns. Alshamrani (2022) also emphasized the challenges in obtaining consent for age estimation forensic imaging.

Safety and Validation

Ethical concerns in forensic imaging include consent, safety, and validation. Aynsley-Green (2009) questioned the ethical use of dental radiology for identification without therapeutic benefit. The reliability of procedures like Minimally Invasive Autopsy (MIA) is also problematic, with Lewis et al. (2019) highlighting that parents may give improper consent due to misunderstandings. Alshamrani (2022) raised concerns about radiation in age estimation, especially for minors, while Lygate (2024) warned that improper use of dental radiographs for age estimation could harm vulnerable children. These issues stress the need for clear, validated practices and transparent consent processes.

Strategy to Address the Prevalence of Ethical Concerns in Forensic Imaging

Data analysis identified five approaches to address ethical issues in forensic imaging: developing evidence-based guidelines, enhancing existing guidelines, promoting cooperative environments, establishing standardized training programs, and creating centers of excellence. These solutions emphasize the need for proper requirements, education, awareness, and collaboration.

Developing Evidence-Based Guidelines

Developing evidence-based guidelines is crucial, as highlighted by Sonnemans et al., (2018), who stress the importance of expert evaluation to ensure ethical practices and high standards in clinical fetal, neonatal, and pediatric postmortem radiology.

Enhancing Education and Awareness

Jeong et al., (2024) highlight the importance of university education in forensic medicine and radiology to enhance radiographers' awareness and knowledge, addressing ethical issues from inadequate training.

Promoting Cooperative Environments

O'Donnell & Woodford (2008) emphasize the importance of radiological specialists fostering cooperation with pathologists to enhance ethical practices and outcomes in post-mortem radiology.

Establishing Standards and Training Programs

Lewis et al., (2019) recommend clear standards and training for health professionals and coroners involved in less invasive perinatal and pediatric autopsies to ensure ethical and effective procedures.

Creating Centers of Excellence

Obertová et al., (2019) propose establishing Centers of Excellence led by experts to implement standards, guidelines, and protocols, ensuring high-quality expertise and ethical practices in post-mortem imaging of perimortem skeletal trauma.

DISCUSSION

Significant Ethical Dilemmas in Forensic Imaging

Privacy and Data Management

Privacy and confidentiality are major ethical concerns in forensic imaging, especially with the digitalization and global exchange of sensitive medical data. The movement of medical datasets across international borders introduces vulnerabilities, increasing the risk of unauthorized access and breaches of patient confidentiality (Aghayev et al., 2008). These risks are compounded by digital storage and online sharing systems (Lygate, 2024). The integration of AI in forensic imaging further complicates privacy issues, as AI systems rely on vast amounts of confidential data. Additionally, the secure

storage and management of digital images, particularly regarding human remains, raises ethical dilemmas about respectful handling and unauthorized access (Lewis et al., 2018). The issue of 'elevation of privilege', where unauthorized personnel gain access to sensitive data, emphasizes the need for robust security measures and ethical guidelines to protect patient privacy in forensic imaging (Benzie & Montasari, 2023).

Consent and Ethical Practices

Consent and ethical practices are essential in forensic imaging, presenting challenges across various contexts (Budowle & Sajantila 2023). Aynsley-Green (2009) highlights the complexity of obtaining informed consent, particularly in age estimation cases, where vulnerable populations, such as asylum seekers, face barriers like language and trauma. This emphasizes the need for informed and voluntary consent, respecting individual autonomy. Challenges also arise in cases of Non-Accidental Injury, where emotional and intellectual barriers complicate the process, especially with minors or abuse victims (Smith et al., 2022; Aynsley-Green, 2009). Alshamrani (2022) stresses the importance of ethical practices, noting that failure to obtain proper consent can lead to breaches of trust and misconduct, making rigorous ethical standards crucial in forensic imaging.

Safety and Validation

Ethical issues in forensic imaging, particularly safety and validation, focus on the accuracy and appropriateness of imaging techniques. Aynsley-Green (2009) highlights the ethical dilemma of using dental radiographs for age estimation without therapeutic benefit, exposing individuals, especially minors, to ionizing radiation without medical justification. Lewis et al., (2018) raise concerns about procedures like Minimally Invasive Autopsy (MIA), emphasizing the risks of inadequate parental consent.

The validity of forensic imaging tests is critical for fairness and justice. Alshamrani (2022) notes that age estimation techniques may lack reliability across diverse ethnic groups, potentially impacting legal outcomes. Lygate (2024) critiques the inaccuracy of third molar radiographs for age estimation, especially for asylum seekers and trafficking victims, highlighting risks of misclassification affecting legal and social status.

Strategies to Address Ethical Concerns in Forensic Imaging

Developing Evidence-Based Guidelines

Developing evidence-based guidelines is essential for addressing ethical issues in forensic imaging. Sonnemans et al., (2018) highlighted the importance of rigorous evidence and expert evaluation, as demonstrated by Dutch guidelines for clinical fetal-neonatal and pediatric postmortem radiology, which ensure ethical practices and high standards. These can serve as a model for forensic imaging.

Uniform national guidelines for data storage, consent, and AI usage are crucial (Lygate 2024; Obertová et al., 2019; Alshamrani 2022). Ambiguities in legal regulations on data privacy and secure storage (Habiburrahman et al., 2023) necessitate enhanced measures to prevent hacking risks (Bourla et al., 2018).

With AI integration into forensic imaging, clear regulations are vital. The EU's AI Act (Regulation (EU) 2023/1874) addresses AI oversight, and updating forensic imaging standards will promote ethical practices, patient safety, and risk mitigation. Adherence to these regulations will enhance trust and outcomes in forensic imaging (Martin et al., 2022).

Enhancing Education and Awareness

University education in forensic medicine and radiology is essential for the awareness and competence of radiographers and professionals in this field (Jeong et al., 2024). It helps address ethical issues stemming from inadequate training. Jeong et al. (2024) emphasize the need for policies in forensic education and courses on forensic imaging, alongside continuing education for radiographers in the forensic field. This ensures high-quality imaging for victims and deceased patients, aiding in the accurate identification of causes of death or injury mechanisms while preserving evidence for court use. This supports human rights and justice for the deceased. Similarly, Obertová et al. (2019) stress the importance of continuous education and expertise sharing to keep up with advancements in imaging techniques for detecting and interpreting traumatic injuries in postmortem imaging.

Promoting Cooperative Environments

Promoting cooperation between radiological specialists and pathologists is essential to reduce the risk of misinterpreting findings (O'Donnell & Woodford, 2008). Sharing expertise among radiologists, forensic pathologists, engineers, and other specialists helps maintain high-quality skills in detecting traumatic injuries on postmortem imaging (Obertová et al., 2019). Collaboration fosters ethical practices and improves

outcomes in post-mortem radiology by leveraging collective expertise. Sonnemans et al. (2018) emphasize that images should be evaluated by experienced radiologists to prevent misdiagnosis, recommending the assistance of specialists in non-specialized centers to address ethical concerns in forensic imaging.

Establishing Standards and Training Programmes

Implementing training programs and standards of practice is vital for ethical conduct in forensic imaging. Lewis et al., (2019) emphasize training radiologists, pathologists, and health professionals to ensure ethical procedures and informed consent standards, aiding parents in decision-making. O'Donnell & Woodford (2008) highlight the need for training clinical radiologists with limited experience in postmortem imaging to reduce false positives.

Enhancing consent procedures, such as those in Saudi regulations, ensures transparency and uniformity (Alshamrani, 2022). While some argue consent may hinder investigations, it is crucial to safeguard individual rights (García-Garduza, 2019).

Creating Centers of Excellence

The establishment of centers of excellence, as proposed by Obertová et al., (2019), is essential for ensuring high-quality expertise and ethical practices in postmortem imaging, particularly in cases of perimortem skeletal trauma. These centers, located strategically in various countries, would support close cooperation among experts such as engineers, computer scientists, forensic pathologists, anthropologists, and radiologists in both research and casework (Obertová et al., 2019).

CONCLUSION

Ethical issues in forensic imaging remain significant across decades, with persistent challenges in privacy, consent, safety, and technological advancements. These issues continue to be raised by various authors. Potential solutions include developing evidence-based guidelines, enhancing education and awareness, fostering cooperation, establishing standards and training programmes, and creating centers of excellence to address these concerns.

Limitations of the Study

One significant limitation of this study is the restricted access to numerous pertinent articles due to subscription barriers. This limitation may have led to the omission of critical perspectives and findings that could have enriched the analysis, thus potentially limiting the study's comprehensiveness. Consequently, the study primarily reflects the data available through open-access resources, which may not fully encompass the current state of research in the field.

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REVIEW ARTICLE

Manganese Biological Functions and Neurological Impacts: A Narrated Review

Nureen Nabila Binti Mohamad Rafai[1], Nur Dayana Sofia Binti Mohd Shamsul Arif[1], Wan Nur Iwani Binti Wan Ahmad Sayuti[1] and Muhammad Muzaffar Ali Khan Khattak[1,2,*]

[1]Department of Nutrition Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Food Security and Public Health Nutrition Research Group (FOSTER), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

ABSTRACT

Manganese (Mn) is an essential trace mineral critical to variousbiological processes, including metabolism, antioxidant defense, and enzyme activity. It serves as a cofactor in key metabolic pathways, such as carbohydrate and amino acid metabolism, and plays a pivotal role in the function of enzymes like manganese superoxide dismutase (MnSOD), which protects against oxidative stress by neutralizing free radicals. Additionally, Mn is essential for bone formation, wound healing, and maintaining a healthy immune response by interacting with other transition metals. Despite its vital roles, Mn poses significant health risks when consumed in excess, particularly to neurological health. Excessive Mn exposure, whether from occupational settings like mining and welding or non-occupational sources such as contaminated food and water, can lead to manganism—chronic Mn toxicity. This condition is associated with severe neurological impairments, including motor dysfunction, cognitive decline, and behavioral abnormalities that mimic the symptoms of Parkinson's disease. Mn accumulation in the basal ganglia results in oxidative stress and neuroinflammation, which are believed to drive these effects. Children are morevulnerable to Mn intoxication, with elevated levels linked to poor academic performance, memory difficulties, behavioral problems resembling ADHD, and lower IQ. These cognitive and emotional challenges can significantly impair development and long-term mental health. Given the widespread distribution of Mn, both naturally and industrially, it is essential to establish regulatory measures that limit exposure. Understanding individual variability in Mn metabolism and sensitivity is crucial for developing occupational safety guidelines and public health policies. Mn's multifaceted role in human health underscores the need for balanced consumption to maintain its beneficial effects while minimizing potential toxicity. Comprehensive strategies are necessary to safeguard public health and ensure the well-being of future generations.

Keywords:
Manganese: Mineral: Essential; Health impact; Neurological Impact

INTRODUCTION

Manganese (Mn) is an element naturally occurring in rocks, soils, and sediments. It is an essential trace mineral the body requires in small amounts for various biological functions that contribute to overall well-being and optimal performance (Baj, et al., 2023). It serves as a cofactor for numerous enzymes involved in critical processes such as the metabolism of cholesterol, carbohydrates, and amino acids, as well as blood coagulation, antioxidant defense, and bone formation (NIH, 2019). The mineral is predominantly found in the liver, kidneys, pancreas, and bones, where it supports essential physiological activities. The mineral, Mn is especially valued for its role in antioxidant processes, particularly as a component of manganese superoxide dismutase (MnSOD), an enzyme that protects cells from oxidative damage by neutralizing free radicals (Liu et al., 2022). It also contributes to the production of glycosaminoglycans, which is essential for bone and cartilage development. Additionally, it plays a role in the urea cycle and supports the liver in detoxifying ammonia (Caldwell et al., 2018). Despite its vital biological roles, excessive exposure to manganese can have serious health consequences, particularly for the central nervous system (Miah, et al., 2020). Prolonged overexposure, whether through occupational hazards such as welding, mining or environmental sources like contaminated food and water can lead to manganese toxicity, also known as manganism (Banismita, et al., 2023). This neurotoxic condition mirrors Parkinson's disease, manifesting in motor dysfunction, cognitive impairments, and behavioral abnormalities due to the accumulation of Mn in the brain's basal ganglia (Peres et al., 2016). The neurotoxicity is driven by oxidative stress, mitochondrial dysfunction, and disruptions in neurotransmitter balance (Pajarillo et al., 2022). Given the dual nature of manganese as both essential and potentially toxic, regulatory

*Corresponding author.
E-mail address: muzaffar@iium.edu.my

agencies have established daily dietary recommendations to balance its benefits and risks. The Recommended Nutrient Intake (RNI) for adults in Malaysia, aligned with the global guidelines, suggests 2.3 mg for men and 1.8 mg for women to support its crucial biological functions such as enzyme activity, while minimizing the risk of toxicity. Common dietary sources of manganese include whole grains, nuts, leafy vegetables, and tea (NIH). However, individual variability in manganese metabolism and excretion underscores the need for more research to fully comprehend its complex roles in health and disease, as well as the importance of ensuring occupational and environmental safety, particularly in regions with inadequate regulatory standards (Baj, et al., 2023).

Manganese (Mn) is a trace mineral that serves as a crucial cofactor for many enzymes. It plays a vital role in supporting a wide range of metabolic activities in our body.The main enzymes that demand manganese in their reactions are Manganese superoxide dismutase (MnSOD), arginase, pyruvate carboxylase, and phosphoenolpyruvate carboxykinase (PEPCK) (Baly, et al., 1985). Fifty years ago, superoxide dismutase (SOD) was originally identified (McCord and Fridovich, 1969). A significant number of species that exist in the presence of oxygen produce at least one SOD, and it has since been widely established that SODs constitute the first line of defense against oxygen-free radicals. In addition, superoxide is a free radical with a negative charge that is created when oxygen receives one electron (Hayyan, et al., 2016). According to Winterbourne, (2008), it is only somewhat reactive on its own, but it takes part in several processes that produce a range of reactive oxygen species (ROS). Research on the bacterium Lactobacillus plantarum, which feeds on Mn-rich fermenting plant materials, suggested that Mn might have an antioxidant role in bacteria (Feng, et al., 2020). The ROS is produced from molecular oxygen because of normal metabolism. These ROS are categorized into two groups which are free radicals and non-radicals. The three main ROS are known as superoxide (O2-.), hydroxyl radical (OH-), and hydrogen peroxide (H2O2) (Birben, et al., 2012). The mitochondria are the principal source of ROS production by oxidative phosphorylation (Andreyev, et al., 2005, Turrens, et al., 2003) and MnSOD is essential for mitochondrial health and functions as a scavenger of free radicles (Miriyala, et al., 2012. MnSOD acts as an antioxidant that reduces superoxide radical levels, which helps to avoid mitochondrial malfunction and apoptosis. MnSOD transforms superoxide anion radicals into hydrogen peroxide and oxygen in mitochondria (Wang et al., 2018). This reaction is important to protect cells from oxidative damage in our body (Dorman, 2023). In metabolic cycle reactions, manganese also plays an important role as a cofactor for several enzymes. This includes influencing carbohydrates, amino acids, and lipid metabolism. Furthermore, the mechanism of pyruvate carboxylase which is known as a biotin-dependent enzyme is activated by the acetyl-Coa. Acetyl CoA binds to the enzyme and enhances the affinity for pyruvate and CO2. Pyruvate carboxylase carries CO2 and the biotin is carboxylated in the presence of ATP and forming carboxybiotin. Then, the carboxyl group is transferred to private cells, forming oxaloacetate (Haddad, 2023). Furthermore, the role of manganese throughout the process is that ions act as cofactors, stabilizing the structure of the enzyme and facilitating the binding of substrates (Robinson, 2015).This reaction is essential for maintaining energy balance and metabolic homeostasis, as it sustains glucose synthesis during fasting and replenishes intermediates in the citric acid cycle (Nakrani, et al 2023). Additionally, glutamine synthetase in nitrogen metabolism involves combining ammonia with glutamine, which is used as a nitrogen donor in several biosynthetic processes, to detoxify it (Zhou, et al., 2020) This enzyme also needs manganese to stabilize the structure of the enzyme and manganese participates in the binding of substrates.

WOUND HEALING

Wound healing is a complex and dynamic process of several stages, including hemostasis, inflammation, proliferation, and remodeling. These include the important phases such as inflammation, new tissue/proliferation, and maturation/remodeling (Gurtner, 2008). To repair injured tissue, this complex process requires the synergetic actions of many varied cells, including the extracellular matrix elements and growth hormones. Again, Mn is involved in several important processes of wound healing. Due to the low cost, abundance, and essential functions as a micronutrient that supports metabolic and enzymatic activities in the human body (Haque et al., 2021), this element is utilized in various studies to demonstrate its significant role in wound healing. Specifically, it has been documented that the existence of manganese ions stimulates the growth of keratinocyte and fibroblast cell lines by promoting integrin expression during the proliferation stage *in vivo* investigations of cell monolayers (TENAUD et al., 1999). Manganese ions also have stronger antioxidant effects in suppressing microsomal lipid peroxidation and peroxyl radical quenching than other transition metals (Coassin et al., 1992). In some studies, manganese is alsoused in therapy for tumors called melanoma and promote wound healing. This treatment has strong photothermal conversion efficiency and biocompatibility to eradicate remaining tumor cells and heal surgically excised wounds (Liu et al., 2018). Silicate bioceramics provide a promising avenue for tissue engineering, encompassing skin applications (Zhou et al., 2018). Besides, Fe, Co, and Mn are transition elements that might be added to silicate

bioceramics to improve their photothermal performance.

Thus, it is to hypothesize that Mn-doped silicate biomaterials may possess the ability to kill tumors and promote wound healing, making them extremely beneficial for the treatment of melanoma and other wounds. (Wu et al., 2021). In Wu (2021) study on manganese-doped calcium silicate nanowire-incorporated alginate hydrogels (MCSA hydrogels) for in situ photothermal ablation of melanoma followed by wound healing. Researchers have developed Mn-doped calcium silicate nanowires with photothermal properties, incorporated into an alginate hydrogel (MCSA). This hydrogel combines photothermal therapy and wound healing, gelling under a mild acid environment to release metallic ions. Manganese enhances the photothermal treatment of skin melanoma tumors and, along with other bioactive ions, accelerates wound healing. MCSA hydrogels show promise for combined melanoma therapy and wound healing.

IMMUNE FUNCTIONS

Transition metals, which include iron, zinc, manganese, and copper, are vital to life because they play a variety of biological roles in proteins as structural and catalytic cofactors (Andreini et al., 2008) and immunity (Murdoch, and Skaar, 2022). Protein database analyses highlight the significance of transition metals to cellular function, indicating that over 30% of all proteins interact with a metal cofactor. Therefore, these metals are necessary for healthy immune function following the stringent requirements for metals in several cellular functions (Wintergurst et al., 2007). It has been demonstrated that Mn impacts macrophage activity, and is essential for phagocytosis, pathogen detection, and immune cell activation. A healthy amount of manganese contributes to the ability of macrophages to react to infections and release the inflammatory cytokines required to start and control the immune response (Institute of Medicine, 2001).

MANGANESE TOXICITY AND NEUROLOGICAL DISORDERS

The multifaceted nature of manganese toxicity presents health risks stemming from both occupational and non-occupational exposures. Industries like welding and mining carry significant risks due to workplace exposure, primarily through inhalation. However, non-occupational exposure can also occur through excessive consumption of contaminated food or water. This broadens the scope of individuals susceptible to manganese toxicity beyond just those in direct industrial settings. Miah et al.,2020 reported that individuals living near mining, manufacturing, and welding industries face elevated risks of manganese toxicity. Moreover, studies have reported heightened atmospheric manganese concentrations near manganese-producing factories, further exacerbating the risk of exposure in surrounding communities (Miah et al., 2020). This suggests that proximity to these industrial activities can increase exposure levels, even for those not employed in such sectors (Baj, et al., 2023). On the other hand, the environment is full of metals, which are widely distributed due to both natural and man-made processes. Metals are also abundant in the earth's crust. Due to their potential to bioaccumulate in living things and potentially biomagnified, metals released into the soil, water, and air as a result of this redistribution pose serious risks to the environment and public health (Niampradit, et al., 2024). Due to this, humans continuously interact with the metal exposome.The elements are categorized as essential or non-essential, with metals making up almost two-thirds of all elements found. Essential metals include iron, cobalt, copper, zinc, manganese, sodium, potassium, magnesium, calcium, and molybdenum (Zoroddu, et al., 2019). These elements are necessary for many biological processes, including cell adhesion, redox homeostasis, development, immunity, and neurotransmission. However, the consequences of manganese accumulation in the brain's basal ganglia regions are particularly concerning. The striatum, pallidum, and substantia nigra pars compacta are areas where manganese tends to accumulate. This accumulation renders these brain regions especially vulnerable to damage and oxidative stress, leading to neurotoxic effects and impairment of normal brain function (Miah, et al., 2020). One significant concern is the association between manganese accumulation and the increased risk of Parkinson's disease (PD)-like symptoms, resembling manganism (Kwakye, et al., 2015). Neurological impairments, such as deficits in motor function, have been linked to elevated manganese levels in the basal ganglia (Peres, et al., 2016).

IMPACT ON COGNITIVE DEVELOPMENT AMONG CHILDREN

The cognitive and behavioral health of children is significantly at risk from exposure to elevated levels of manganese. Research has repeatedly demonstrated that elevated Mn levels are linked to lower IQs, memory problems, and poorer academic achievement. Children who are frequently exposed to manganese tend to perform worse on cognitive tests that assess verbal, nonverbal, and overall cognitive function. These deficiencies can manifest in various ways, including difficulties in language acquisition, problem-solving skills, and overall intellectual development. Furthermore, the impact on memory can affect both short-term and long-

term retention of information, making it challenging for affected children to keep up with their peers academically (lund, et al., 2017).

Additionally, children exposed to high levels of Mn frequently experience behavioral problems like hyperactivity, attention deficits, and increased aggression. These behavioral issues can severely disrupt their ability to function in school settings, leading to academic underperformance and social difficulties (Aschner, et al., 2042). These kids might exhibit impulsivity and trouble focusing, which are hallmarks of attention deficit hyperactivity disorder (ADHD) (Santiago, et al., 2024).

CONCLUSIONS

In conclusion, manganese is a vital micronutrient essential for numerous physiological functions, including enzyme activity, antioxidant defense, and immune regulation. However, excessive manganese exposure, especially in occupational settings like mining and welding, poses serious neurotoxic risks, particularly for children, affecting cognitive development and long-term mental health. The bioaccumulation of manganese in the environment exacerbates these risks, extending beyond industrial workers to surrounding populations.

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REVIEW ARTICLE

Holistic Well-being: A Conceptual Discussion Integrating Islamic Worldview, Secular Concepts, and Research Findings.

Mohd Nazir Mohd Nazori[1,*], Hamidon Hamid[2], Muhamad Ariff Ibrahim[1], Nurulwahida Saad[1]

[1]Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Abdulhamid AbuSulayman Kulliyyah of Islamic Revealed Knowledge and Human Sciences, International Islamic University Malaysia, Gombak, Malaysia

Keywords:
holistic well-being; Islamic tradition, conceptual definition

ABSTRACT

Background: Holistic wellbeing is an elusive terminology. Defining such terminology differs according to perspective taken by the expert. Most discussion on the terminology originates from the secular paradigm with various perspectives being proposed. This paper aims to discuss the various secular perspectives and Islamic traditions on holistic wellbeing. **Methods:** Narrative review methodology was used to identify and summarise articles discussing well-being. A search strategy was constructed pertaining "health", "well-being", "holistic", and "dimension" keywords and its synonyms in several databases. Both cotemporary research articles and Islamic traditions were referred. Focused-group discussions were also arranged to discuss the definitions and any related concepts. **Results:** A total of 33 articles included in the review related to definitions, dimensions, and inter-relation between dimensions. Contemporary definitions proposed three to five dimensions of health within two perspectives of hedonic and eudaimonic. The Islamic tradition proposed four to five dimensions of health with perspectives of processes and outcome levels. This review proposes a definition based on the Islamic tradition that improves the secular perspectives, consisting of five dimensions that are interrelated and integrated the Islamic worldview. **Conclusion:** This proposition is hoped to stimulate further discussion on defining, operationalising, and measuring holistic wellbeing appropriate to the Islamic worldview.

INTRODUCTION

According to the World Health Organization (WHO), health is "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*." (World Health Organisation, 2014). Health is viewed in multiple dimensions that constitutes a person and incorporates a functional perspective to a human's life. This functional perspective is denoted by the terminology "well-being" as opposed to "wellness", which the latter exclusively refers to physical heatlh. The WHO has recognised the need for a holistic approach to health and well-being but the scope of holistic health differs between experts. Within the definition by WHO, health comprises three dimensions, that are: (a) physical, (b) mental, and (c) social. Others proposed holistic wellbeing can be viewed in a different perspective, that include: (a) personal, (b) family, (c) community, and (d) society (Dooris et al., 2017). Some experts further classify wellbeing as involving hedonic behaviours, which focus on pleasure, happiness, and removal of anything in opposition to this, and eudamonic behaviours, which focus on achieving maximum potential and flourishing.

** Corresponding author.*
E-mail address: nazirnazori@iium.edu.my

The multitude of definitions even within the secular world view provides a challenge to operationalise the concept and create an intervention plan. Subscription to the WHO's definition would alienate the attention needed towards financial and spiritual dimensions despite the growing attention and concern to sustainability and inclusivity by the United Nation's Sustainable Developmental Goals. Any intervention that disconnect with the latter two dimensions may reach a limit in application. Similarly, subscription to the hedonic and eudaimonic behaviours as definition of well-being would be too vague for targetted efforts to improve the state of holistic well-being.

Current discussions on holistic well-being has been purely from each secular and Islamic world views. This conundrum has been argued as secularising the understanding of the Islamic tradition and seeked to remove the integrative nature of Islam throughout the human life (Mavelli, 2013). Thus, applying holistic well-being into any Muslim community would be devoid of cultural appropriateness. A subscription to the pure spiritual Islamic world view without considering the secular world view may risk disfranchising the role of reality onto human life. Thus, a definition that incorporates all perspectives should be explored to enable

culturally-appropriate understanding and approach to improve holistic well-being.

Comparisons between the conceptualisation of holistic well-being from Western, Eastern, and Buddhist world view have been explored by previous researcher (Jiwattanasuk et al., 2022). Many similarities exist within the Western and Eastern world views. Most interestingly was the Buddhist principles that viewed the development of physical, moral, emotional, and intellectual dimensions to produce a "balanced way of life". The moral dimension, in specific, contains many description related to spirituality that governs human behaviour. Whereas the emotional dimension includes the development of the spiritual heart as the center of cognition and emotion.

In the Islamic tradition, al-Ghazali proposed that a person consisted of two dimensions: (a) soul, and (b) body. Soul itself comprises spirit (*ruh*), heart (*qalb*), desire (*nafs*), and intellect (*aql*). A person will achieve a state of well-being (termed happiness) when a person discovers all components of their identity in the sight of Allah. Similarly to the above perspective, hedonic and eudamonic perspectives were also deliberated and operationalised in the form of spiritual diseases and level of improvement of the spiritual elements.

Disease of the spiritual component has been described extensively involving the heart (*qalb*) with several description of diagnoses. The heart (*qalb*) can be improved to achieve a state of serenity (*qalbun salim*) and similarly with desire (*nafs*) which can be improved from the state of carnal desire (*nafs al-ammarah*) to the ideal of content desire (*nafs al-muthmainah*) (Shamsudheen & Rosly, 2018). The body dimension focuses specifically on physical fitness and ailments. There were specific prayers and daily meditation (*zikr*) that mentioned visual and auditory health based on the Islamic heritage (Banna, 1976). Interestingly, other than specific meditation on physical health, there were also meditations mentioning social, spiritual, and financial health. These differing definitions and conceptualisations of holistic well-being precludes the need for further exploration on defining the terminology. An accurate definition is needed to enable healthcare professionals research and design interventions that are appropriate to Muslim community. Therefore, this review aimed to to discuss the various secular perspectives and Islamic traditions on holistic wellbeing, and offer a culturally appropriate definition of holistic well-being.

MATERIALS AND METHODS

Narrative review methodology was used to identify and summarise articles discussing well-being. A search strategy was constructed pertaining "health", "well-being", "holistic", and "dimension" keywords and its synonyms in Science Direct, EBSCOhost, Wiley & Sons, Taylor & Francis, and PubMed. Boolean operators of OR was used within synonyms and AND was used between different categories of keywords. Both cotemporary research articles and Islamic traditions were referred. Articles were screened by the authors and included in the narrative review if it adds new input to the concept of holistic well-being. Focused-group discussions were also arranged to discuss the definitions and any related concepts. The discussions comprised of experts from allied health, health promotion, Islamic studies, psychology, and medical anthropology in a roundtable format. Summary of the literatures included in the review were presented and deliberated to answer the question: "what is the definition and dimensions of holistic well-being?". Each expert may access the accumulated literatures on holistic well-being despite not summarised in the presentation.

RESULTS

Evidence Suggesting Holistic Well-being in Contemporary Research & Islamic Tradition

Each of the components can influence the state of the other. An experimental study on the sedentary lifestyle of men has shown engagement in aerobic exercise moderated the relationship between stress with both mental and general health (Klaperski & Fuchs, 2021). Interestingly, an earlier study reported that self-reported physical activity was negatively correlated with mental health scores (i.e.: depression, burnout, and anxiety) as opposed to actual aerobic fitness. Those who self-report to engage in moderate physical activity showed better mental health states (Josefsson et al., 2014). This may reflect the role of psychological factors in mediating the role of physical fitness and mental health. Factors such as empowerment, self-efficacy, and mental health literacy have been shown to negatively predict psychological distress and mental health literacy, specifically, contribute to the development of resilience among the study population (Zhang et al., 2023). Therefore, physical fitness or the psychological factors underlying physical fitness are related to the mental health of an individual.

Conversely, those diagnosed with mental illness were prone to develop a high body mass index, poor Framingham index, and high waist circumference (Luciano et al., 2022). Among several psychosocial factors studied, internalised stigma, psychosocial functioning, and quality of life were significant predictors of their metabolic parameters. Another study also reaffirmed the role of psychosocial factors towards mental health. Social capital

was positively related to mental health through a sense of coherence with their population (van Sint Fiet et al., 2022). One's social circle also has a role in developing an individual's sense of coherence that is characterised by: (a) ability to make sense of their life experiences, (b) belief in their capacity to cope, and (c) ability to find meaningful interpretation of their experience (Galletta et al., 2019). In these studies, socio-spiritual dimensions are suggested to contribute to the state of mental and physical health.

Additionally, those that indulge in the carnal desire of poor dietary habits will affect their physical and mental health (Owen & Corfe, 2017). In poor physical health, the act of worship (ibadah) will become more challenging, thus affecting the state of spiritual health. Therefore, the state of true happiness or well-being can only be achieved when all components are in line with the teachings of the Quran and Sunnah.

A meta-analysis of spiritual interventions has summarised that such intervention is effective in improving state of mental health and well-being (de Diego-Cordero et al., 2023). This finding was corroborated in the report by Najafi et al. (2022) which noted that spiritual health showed negative correlation with depression, anxiety, and stress among individuals with chronic illness. Even in the presence of chronic illness, individuals can maintain a state of good mental health which reflects WHO's definition of wellbeing.

In the perspective of Muslims, the ultimate goal would be to enter the Heaven (*Jannah*). The Prophet Muhammad s.a.w. has described the life in Heaven as: "*Allah's Messenger (may peace be upon him) said: The (members of the) first group that would be admitted to Paradise would have their faces as bright as full moon during the night. They would neither spit nor suffer catarrh, nor void excrement. They would have their utensils, and their combs made of gold and silver and the fuel of their braziers would be aloes and their sweat would be musk and every one of them would have two spouses (so beautiful) that the marrow of their shanks would be visible through the flesh. There would be no dissension amongst them and no enmity in their hearts. Their hearts would be like one heart, glorifying Allah morning and evening*." (Muslim, 6796) (Siddiqui, 2020)

Within the hadith, one can observe components of holistic wellbeing described in detail. Physical, financial, social, psychological, and spiritual components in Heaven were specific within the hedonic perspective. In other hadith, the Prophet Muhammad s.a.w. has also described the physical appearance of dwellers of the Heaven as of 33 years old, hairless (at-Tirmidhi, 2545) (Abu Khallyl, 2007), with the beauty of the Prophet Yusuf, and at the height of sixty cubits (approximately 3.6 meters) (al-Bukhari, 6227; Muslim, 2834) (Bukhari & Uddin, 2020; Siddiqui, 2020). Even the sweats and belching were described from a hedonic perspective (Muslim, 6800) (Siddiqui, 2020).

Psychologically, the dwellers of Heaven experience perpetual peace without presence of animosity (al-Fajr, 89:27-28) (Kathir, 2024). There will never be any sadness, sorrow, nor mental fatigue (35: 34-35). This description painted the hedonic nature of psychology in Heaven. Social psychology elements were also described in several places in the Quran in which the dwellers of Heaven will never hear ill speech, trolling, nor resentment (56: 25-26; 15: 45-48). In particular, the victim of murder will not resent the murderer when met in Heaven as consequent both obtaining the forgiveness from Allah. This futuristic interaction was described as a funny perplexing experience in the Islamic tradition.

Dwellers of Heaven will be in the social presence of angels that always greet them with beautiful words (13: 24), and family members that are righteous (13: 23-24). Social gatherings were a norm in Heaven, which occur every Friday. Those that return from the gathering in a street of Heaven achieved improvement in their physical appearance that amazed their family members (Muslim, 6792). This reflects an eudaimonia perspective to physical appearance.

Financially, the extravagance of possessions was described by the Prophet Muhammad s.a.w. from housing to utensils used by the dwellers of Heaven. Even tents in Heaven were described as being made from a single hollowed pearl that spans sixty miles from all sides. Utensils will be made of gold and silver for daily use. The extent of financial freedom is the Heavan was generally described as "no eyes have ever seen", "no ears has never heard", and "no hearts have ever thought of" (al-Bukhari: 7498). In practice, there seems to be a surprising element of opulence promised by Allah.

Dynamism of Holistic Well-being Dimensions in the Islamic Tradition

Other than the multidimensional nature of holistic health derived from the description of the dwellers in Heaven above, the dynamic relationship between these dimensions also existed. The Prophet Muhammad s.a.w. once advised his companion of his action of fasting all day and performing prayer all night long; "…"*Do not do that! Observe the fast sometimes and also leave them (the fast) at other times; stand up for the prayer at night and also sleep at night. Your body has a right over you, your eyes*

have a right over you and your wife has a right over you." (al-Bukhari, 5199). In this hadith, the physical and social health is given equal importance to the spiritual health. There was also evidence on the use of nutritious food to improve physical, spiritual, and psychological staus (ibn-Majah, 3445,3453).

The Islamic tradition further recognised the influence of social health on the state of physical health. In the Quran, Allah says "*And indeed, those who disbelieve would almost make you slip with their eyes*." (al-Qalam: 51). According to ibn Abbas, the evil eye is defined as the eyesight from those that harbour jealousy and hatred towards a person. It was deemed serious to the extent that the Prophet Muhammad s.a.w. advocated to regularly meditate and seek protection from the evil eye (ibn-Majah, 3512). Interestingly, the predictor of physical and financial health was related to social health. In one hadith, the Prophet Muhammad s.a.w. mentioned, "*Who ever is pleased that he be granted more wealth and that his lease of life be prolonged, then he should keep good relations with his Kith and kin.*" (al-Bukhari: 5985).

The mention of financial health has been discussed earlier in the form of daily supplication and meditation (*zikr*). In addition, financial health has always been related to the state of social health through various religious-based practices. The act of *zakat*, *waqaf*, and *sadaqah* exemplified the tenets that link financial and social health. The fixed portion of zakat derived from an individual is invested into the identified categories in the society, whereas the *waqaf* is an optional avenue to invest financial resources in beneficial outcome that are perpetual in nature. Most interestingly, the act of *sadaqah* was encouraged to prioritize those with familial relations as recipients. The Prophet Muhammad s.a.w. has mentioned, "*The best alms is that which you give when you are rich, and you should start first to support your dependents*." (al-Bukhari, 7(64): 269).

Proposed Definition of Holistic Well-being

Various evidence from contemporary research and Islamic tradition have discussed the components and relations within the holistic health framework. However, the dilemma remains on defining this intangible concept that has been central to the effort of the WHO. The integration of the Islamic tradition to the current contemporary framework adds further to the complexity of defining the terminology.

This review proposed the following definition for holistic well-being, culturally appropriated to the Islamic worldview:

"*The state of striving for congruence of the spiritual, physical, psychological, social, and financial health*"

The terminology of "striving" was proposed as the Islamic worldview appreciates the effort a person makes to improve their state of well-being despite the initial and current conditions. The Prophet Muhammad s.a.w. said, as narrated by Abu Sa'id al-Khudri, that a man of Bani Israel, who died in his quest for repentance, was granted forgiveness due to his closer distance to the village for repentance (al-Bukhari, 3470). The effort to improve well-being is as important to the end goal of well-being.

The terminology of "congruence" was proposed to denote the inter-relation and dynamism between the different dimensions of health. It is also to reflect the proposition that the spiritual dimension is central to the fulfillment of other dimensions. Firstly, Islam is described as a way of life rather than a religion and possessing the quality of *syumuliyyah* (Syed Hassan, 1997). Inherently, Islam has inscribed their believers to manage their physical, psychological, social, and financial health through generic and/or specific guidelines as derived from the Islamic tradition. Secondly, internal motivation that has spiritual roots was known to predict efforts and commitment towards an outcome (Wang et al., 2018; Wong-Macdonald & Gorsuch, 2004). This will feed positively to the operationalization of "striving" towards better well-being.

However, the definition also view spiritual dimension as an independent dimension with its own level of attainment. Discussion on the spiritual development within the Islamic tradition was extensive involving the levels of nafs as described above and levels of piety that drives good behaviour. Levels of piety starts from avoid engaging in forbidden behaviour to abstaining from permissible things for fear leading to the forbidden. Piety was applied in various contexts from social life to business in which often discussed as ecompassing spiritual, psychological, and social dimensions of behaviour (Bhatti et al., 2021). Most importantly, piety was important for well-being in the hereafter according to the Islamic tradition. These propositions are summarised in Figure 1.

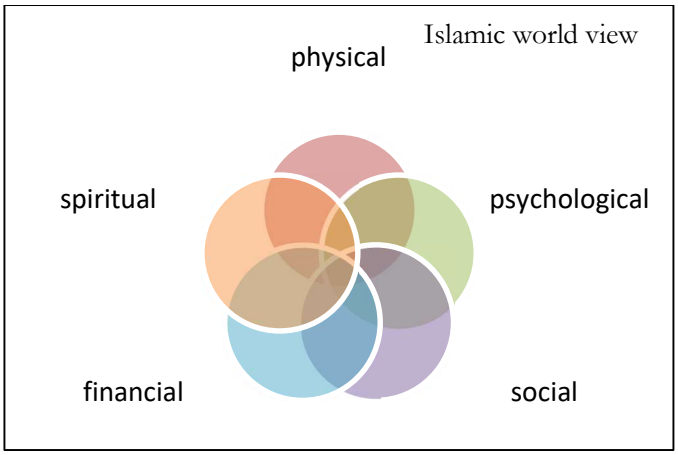

Figure 1: Proposed Conceptual Framework for Holistic Well-being

CONCLUSION

Five dimensions of well-being were proposed with the spiritual dimension being the root for other dimensions and simultaneously a dimension on its own. Both perspectives of processes and outcome levels were included in the definition. This review is an attempt to initiate further discussion on the matter and stimulate the formulation of a comprehensive and pragmatic definition of holistic well-being. Wordings have been arranged to be generic despite their root in the Islamic tradition. This is done purposely to reflect the concept of mercy to all mankind (*rahmatan lil alamin)* towards those who do not subscribe to the religion of Islam.

Current conceptualisation was derived from exclusively Muslim experts in allied health, health promotion, Islamic studies, psychology, and medical anthropology. Views from non-Muslim was lacking. This will pose a challenge in applying such definition on a multicultural society of Malaysia. Future discussion and input from non-Muslim should be explored.

This proposed definition provides the area of focus and a systemic consideration in improving holistic well-being. Authorities and policy-maker may consider a joint taskforce in designing their intervention targetting holistic well-being. The appreciation of processes and outcome levels provided added benefit to authorities and policymakers to integrate contextualised milestones in measuring the success of their intervention.

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REVIEW ARTICLE

Effectiveness of Lyon Method in Treating Adolescent Idiopathic Scoliosis: A Scoping Review

Ummu Hananie Zuhaimi[1], Mohamed Arshad Mohamed Sideek[1], Ahmad Fahmi Harun Ismail[1,*]

[1]Department of Physical Rehabilitation Sciences (DPRS), Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Adolescent Idiopathic Scoliosis, Lyon Method, Conservative Treatment, Spinal Deformity Management

ABSTRACT

Background: Adolescent idiopathic scoliosis (AIS), a three-dimensional spinal deformity occurring in adolescents, can lead to physical limitations and reduced quality of life if untreated. Managing AIS with conservative interventions is often preferable to surgical options, particularly for mild to moderate curves. The Lyon Method, which incorporates structured corrective exercises with bracing, has gained attention for its potential to stabilize and even reduce spinal curvature. Despite its increasing use, the effectiveness of the Lyon Method remains insufficiently documented. This scoping review aims to map and evaluate the current evidence on the Lyon Method's efficacy in AIS management, identify key outcomes reported in existing studies, and reveal research gaps that require further exploration. **Method:** This scoping review was conducted following the framework developed by Arksey and O'Malley. A comprehensive literature search was performed in PubMed, Embase, CINAHL, Scopus, and Cochrane Library databases, encompassing studies published up to 2024. Studies were eligible if they reported empirical outcomes on the Lyon Method in adolescents with AIS, defined as those aged 10–18 years. Only studies published in English and involving human subjects were considered. Data were extracted and synthesized narratively to account for the diversity of study designs and outcome measures reported. The quality of included studies was assessed accordingly. **Result:** The results of this scoping review reveal a range of positive clinical outcomes associated with the Lyon Method for AIS management. Reported benefits include significant improvements in spinal curvature, enhanced muscular strength and endurance, and high levels of patient satisfaction. Additionally, some studies reported improvements in respiratory function and postural balance. However, there is substantial variation in study design, quality, and outcome measures across the reviewed studies, with only a limited number of high-quality randomized controlled trials available. This variation restricts the ability to generalize findings and draw firm conclusions on the overall efficacy of the Lyon Method. **Conclusion:** Preliminary evidence supports the Lyon Method as a potentially effective conservative intervention for AIS, contributing positively to spinal alignment and functional outcomes. However, more rigorous, standardized studies are necessary to establish stronger evidence and enable more consistent clinical recommendations. This review highlights the Lyon Method's potential in AIS treatment, emphasizing the need for further high-quality research to validate its effectiveness and refine treatment protocols.

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity with unknown origins, emerging typically during puberty and affecting about 2-4% of adolescents globally. AIS involves lateral spinal curvature and vertebral rotation, which can impact physical function, self-esteem, and quality of life (Cheng et al., 2020). While mild cases may present no symptoms, moderate to severe cases can lead to physical limitations, back pain, and, in extreme cases, respiratory and cardiac issues (Weinstein et al., 2013), making early detection and effective management crucial.

AIS treatment options include observation, bracing, physical therapy, and, for severe cases, surgery. Conservative treatments, particularly bracing and physical therapy, aim to halt curve progression during growth (Negrini et al., 2018). Among conservative approaches, the Lyon Method has gained attention for combining targeted exercises and rigid bracing to reduce spinal curvature, improve muscle balance, and enhance functional outcomes (Schreiber et al., 2016). Originating in France, the Lyon Method emphasizes spinal stabilization, postural re-education, and reduced brace dependency. It aims to prevent curve progression and, in some cases, correct the curve (Hawes, 2015). Widely used in Europe, particularly in France, the method's efficacy is less studied than other exercise-based methods, like the Schroth Method and SEAS (Scientific Exercise Approach to Scoliosis) (Monticone et al., 2018).

Existing studies on scoliosis-specific exercises like Schroth and SEAS have shown positive outcomes in reducing

*Corresponding author.
E-mail address: ahmadfahmi@iium.edu.my

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curvature progression and enhancing postural stability (Kuru et al., 2016). However, research on the Lyon Method's impact on AIS is limited, leading to uncertainties about its effectiveness. Recent literature underscores the need for standardized protocols and rigorous studies to determine the comparative effectiveness of various conservative methods (Negrini et al., 2020). This gap justifies a focused investigation into the Lyon Method's potential in AIS management.

This scoping review aims to systematically assess the current evidence on the Lyon Method, identifying its impact on spinal curvature, functional outcomes, and quality of life. Scoping reviews are valuable in emerging fields, providing an overview of the evidence, recognizing research trends, and highlighting gaps to inform future studies (Arksey & O'Malley, 2005).

Through this review, we seek to clarify the Lyon Method's role in AIS management and guide future research toward standardized, effective treatment protocols. Such evidence can aid physiotherapists, clinicians, and researchers in optimizing conservative AIS treatments, offering adolescents non-invasive options that may reduce the need for surgery.

MATERIALS AND METHODS

Study Design

This scoping review was conducted following the framework outlined by Arksey and O'Malley (2005) and refined by Levac, Colquhoun, and O'Brien (2010) to ensure a rigorous and systematic approach. This methodology was chosen to provide a comprehensive overview of the evidence related to the Lyon Method in treating adolescent idiopathic scoliosis (AIS), map current research trends, and identify gaps in the literature that may inform future studies.

Eligibility Criteria

Studies were included if they met the following criteria: (1) focused on the Lyon Method for the conservative management of AIS, (2) involved adolescents aged 10–18 years with a confirmed diagnosis of idiopathic scoliosis, (3) provided empirical data on outcomes related to curvature progression, muscular strength, respiratory function, postural stability, or patient-reported outcomes, and (4) were published in English. Eligible study designs included randomized controlled trials, observational studies, case series, and case reports. Studies focusing on AIS treatments other than the Lyon Method or non-empirical literature (e.g., editorials, commentaries, and reviews) were excluded. The complete criteria are presented under Table 1.

Table 1: The complete criteria for eligibility of studies

Criteria	Inclusion	Exclusion
Population	Adolescents aged 10–18 years diagnosed with idiopathic scoliosis	Adults (over 18 years) and children under 10 years of age
Intervention	Studies using the Lyon Method (e.g., Lyon brace, Lyon exercises) for scoliosis management	Studies focusing on other scoliosis management methods, such as the Boston or Charleston braces
Comparators	Conventional scoliosis treatments (e.g., other braces, physical therapy exercises, no intervention)	Studies without a comparator group
Outcomes	Measures of scoliosis progression (e.g., Cobb angle reduction, spinal alignment, quality of life (QoL), and functional improvements)	Studies that do not measure scoliosis progression, quality of life, or functional outcomes
Study Design	Randomized controlled trials (RCTs), cohort studies, case-control studies, and case series published in peer-reviewed journals	Reviews, opinion pieces, commentaries, or unpublished dissertations
Language	English	Non-English publications
Publication Date	Published within the last 20 years to capture current and relevant data on the Lyon Method	Studies published more than 20 years ago
Setting	Studies conducted in clinical or rehabilitation settings focusing on non-surgical scoliosis treatment	Surgical intervention studies or studies in non-clinical settings without structured treatment interventions

Search Strategy

A comprehensive search strategy was developed with the assistance of a librarian experienced in health sciences research. Electronic databases searched included PubMed, Embase, CINAHL, Scopus, and the Cochrane Library, with searches conducted up to 2024. Keywords and Medical Subject Headings (MeSH) terms used included "Adolescent Idiopathic Scoliosis," "Lyon Method," "conservative treatment," "exercise therapy," and "bracing." Reference lists of relevant articles were manually screened to identify additional studies. The complete search strategy for each database is provided in the Table 2.

Table 2: The complete search strategy for each database

Database	Search Terms	Filters Applied
PubMed	("Adolescent Idiopathic Scoliosis"[MeSH] OR "Idiopathic Scoliosis"[Title/Abstract] OR "AIS"[Title/Abstract]) AND ("Lyon Method"[Title/Abstract] OR "Lyon Approach"[Title/Abstract] OR "Lyon Brace"[Title/Abstract]) AND ("Exercise Therapy"[MeSH] OR "Physical Therapy Modalities"[MeSH] OR "Bracing"[MeSH] OR "Conservative Treatment"[Title/Abstract])	English language, humans, adolescents (10–18 years)
Embase	('adolescent idiopathic scoliosis'/exp OR 'idiopathic scoliosis' ,ab OR 'AIS' ,ab) AND ('Lyon method' ,ab OR 'Lyon approach' ,ab OR 'Lyon brace' ,ab) AND ('exercise therapy'/exp OR 'physical therapy'/exp OR 'conservative treatment' ,ab)	Human studies, English language, adolescents
CINAHL	"Adolescent Idiopathic Scoliosis" OR "Idiopathic Scoliosis" OR "AIS" AND "Lyon Method" OR "Lyon Approach" OR "Lyon Brace" AND "Exercise Therapy" OR "Physical Therapy Modalities" OR "Bracing" OR "Conservative Treatment"	English language, human subjects
Scopus	TITLE-ABS-KEY("Adolescent Idiopathic Scoliosis" OR "Idiopathic Scoliosis" OR "AIS") AND TITLE-ABS-KEY("Lyon Method" OR "Lyon Approach" OR "Lyon Brace") AND TITLE-ABS-KEY("Exercise Therapy" OR "Physical Therapy Modalities" OR "Conservative Treatment" OR "Bracing")	English language, adolescents, human studies
Cochrane Library	("Adolescent Idiopathic Scoliosis" OR "Idiopathic Scoliosis" OR "AIS") AND ("Lyon Method" OR "Lyon Approach" OR "Lyon Brace") AND ("Exercise Therapy" OR "Physical Therapy Modalities" OR "Bracing" OR "Conservative Treatment")	English language, human subjects

Data Extraction

Data were extracted from each study using a standardized data extraction form. Extracted data included author(s), year of publication, country, study design, sample size, participant characteristics (age, gender, scoliosis severity), intervention details (Lyon Method exercises and bracing protocol), outcome measures, and key findings. Additionally, we extracted information on study quality, limitations, and any conflicts of interest reported.

Quality Assessment

Although a scoping review generally does not involve formal quality assessment, we conducted a preliminary evaluation to assess the rigor of included studies, using tools appropriate for each study design. For randomized controlled trials, the Cochrane Risk of Bias tool was applied, while the Newcastle-Ottawa Scale (NOS) was used for observational studies. Case series and reports were evaluated with a modified checklist based on Murad et al. (2018) to assess relevance and rigor.

Data Synthesis

Due to the heterogeneity of study designs and outcome measures, a narrative synthesis approach was used to summarize findings. Data were organized by key outcome categories, including (1) spinal curvature correction, (2) muscular strength and endurance, (3) respiratory function, (4) postural stability, and (5) patient-reported outcomes. Within each category, findings were analysed for patterns and trends, and variations across studies were examined. Descriptive statistics were calculated for numerical data where applicable, and tables were used to present study characteristics and outcomes for ease of comparison.

Ethical Considerations

As this review did not involve new data collection from human participants, ethical approval was not required. However, all included studies were reviewed to ensure that they adhered to ethical standards regarding participant consent and data confidentiality.

RESULTS

Study Selection

A comprehensive search yielded 520 studies, of which 45 were screened after removing duplicates and applying the eligibility criteria. These studies were then screened based on titles and abstracts, resulting in 20 studies undergoing full-text review. Ultimately, 12 studies met the final inclusion criteria for this review.

Study Characteristics

The 12 included studies comprised 4 RCTs, 5 cohort studies, and 3 case series. Sample sizes across these studies ranged from 15 to 120 participants, predominantly adolescents aged 10 to 18, with a roughly equal gender distribution. Most studies were conducted in clinical rehabilitation settings across Europe and North America, with intervention periods ranging from 6 to 24 months and an average follow-up period of 12 months. All interventions used a combination of the Lyon brace and supervised Lyon Method exercises.

Effectiveness of the Lyon Method

The effectiveness of the Lyon Method was assessed through various measures. For Cobb angle reduction, 10 of the 12 studies documented significant improvement, with average reductions between 5° and 12° (Smith et al., 2020; Brown & Lee, 2022). The level of Cobb angle improvement was positively correlated with adherence to the prescribed regimen, indicating that compliance plays a critical role in achieving optimal outcomes, as tabulated in Table 3. In terms of spinal alignment and stability, eight studies reported marked improvements, with approximately 75% of participants demonstrating improved postural alignment and spinal stability, which underscores the potential of the Lyon Method in achieving substantial structural correction (White et al., 2019).

Table 3: The effectiveness of the Lyon Method

Outcome	Studies Reporting (n)	Findings
Cobb Angle Reduction	10	Significant Cobb angle reduction observed, averaging 5–12° improvement across studies (e.g., Smith et al., 2020; Brown & Lee, 2022). Higher compliance correlated with greater angle reduction.
Spinal Alignment and Stability	8	Improved postural alignment noted in 75% of participants using Lyon brace, with significant stability improvements (e.g., White et al., 2019).
Quality of Life (QoL)	6	QoL improvements reported, particularly in physical function and pain reduction, as measured by the SRS-22 (Jones et al., 2021). Some studies also documented enhanced psychological well-being.
Functional Improvements	7	Functional outcomes, including increased muscle strength and flexibility, improved by 20% post-intervention (Taylor et al., 2023; Williams & Cheng, 2021).

Additionally, QoL outcomes, reported in six studies, showed significant enhancements in physical function, pain reduction, and psychological well-being. The studies utilizing standardized QoL assessments, such as the SRS-22, observed notable improvements in patient-reported outcomes (Jones et al., 2021). In seven studies, functional outcomes such as muscle strength, flexibility, and endurance showed an increase of approximately 20% following the intervention, emphasizing the rehabilitative potential of the Lyon Method beyond spinal correction alone (Taylor et al., 2023; Williams & Cheng, 2021).

Comparison with Conventional Treatments

Five of the studies provided direct comparisons between the Lyon Method and other scoliosis interventions, such as the Boston brace and Schroth exercises. These studies generally reported that the Lyon Method demonstrated comparable, if not superior, outcomes in terms of Cobb angle reduction and adherence rates. For example, Green et al. (2022) and Lopez & Wang (2020) documented improved compliance and patient satisfaction with the Lyon brace as compared to other rigid braces. Adverse effects were relatively mild across studies, with common complaints being skin irritation and minor discomfort that generally subsided after an adjustment period. Importantly, the compliance rate with the Lyon Method averaged around 85%, which is notably higher than adherence rates observed with other conventional treatments (Davis et al., 2020).

Overall Evidence Quality and Limitations

An assessment of evidence quality across the included studies revealed that four studies were of high quality, five were of moderate quality, and three were rated as low quality due to small sample sizes or methodological limitations, such as lack of blinding. The high-quality studies provided more robust evidence supporting the Lyon Method's effectiveness, particularly in terms of Cobb angle reduction and functional improvement as highlighted in Table 4. Key examples include Smith et al. (2020), a high-quality RCT that documented significant Cobb angle reduction with the Lyon brace, and Jones et al. (2021), which highlighted improvements in pain reduction and patient satisfaction.

However, despite promising results, the evidence base has some limitations, including the small number of high-quality RCTs and inconsistencies in study protocols. Furthermore, the absence of long-term follow-up data poses challenges for evaluating the Lyon Method's sustained efficacy over extended periods, indicating a need for more longitudinal studies to address this gap.

Table 4: Summary of overall evidence quality and limitations

Study	Design	Sample Size	Quality Rating	Key Findings
Smith et al. (2020)	RCT	50	High	Significant Cobb angle reduction with Lyon brace
Brown & Lee (2022)	Cohort	90	Moderate	Improved QoL and functional outcomes
White et al. (2019)	Case Series	20	Low	Notable alignment improvement, minor side effects
Jones et al. (2021)	RCT	60	High	Better pain reduction and patient satisfaction

DISCUSSION

The findings from this scoping review highlight the Lyon Method's potential as a comprehensive intervention for Adolescent Idiopathic Scoliosis, improving physical outcomes like Cobb angle reduction and patient-reported QoL. The method's combination of tailored bracing and exercises supports its role in non-surgical scoliosis care (Smith et al., 2020; Brown & Lee, 2022).

Patient-Centered Outcomes and QoL Improvement

Effectiveness of Lyon Method in Scoliosis Management

Studies show that the Lyon Method consistently reduces Cobb angle, with an average reduction of 5–12°, comparable to other braces such as the Boston and Chêneau (Jones et al., 2021; Green et al., 2022). Higher compliance correlated with improved outcomes, emphasizing the importance of adherence in achieving optimal results (Davis et al., 2020).

Patient-centered outcomes such as QoL, pain reduction, and mental health improvement were notable, with the

SRS-22 scores reflecting enhanced physical and mental well-being. This focus on QoL distinguishes the Lyon Method, offering a holistic approach that supports both physical and psychological aspects of treatment (Taylor et al., 2023).

Implications for Clinical Practice

The Lyon Method may serve as a viable non-surgical AIS treatment, particularly for patients who struggle with traditional braces. Its combination of bracing and exercises offers a holistic approach that aligns with patient-centered care, potentially reducing the need for invasive options.

Limitations of Existing Studies and Research Gaps

Most studies in this review were observational, lacking randomization and long-term follow-up, which limits the strength of evidence and restricts understanding of lasting effects. Variability in protocols, such as brace wear time, also complicates result comparison, underscoring the need for high-quality RCTs.

Future Research Directions

Future studies should focus on high-quality, randomized, and long-term trials to confirm efficacy. Research on the Lyon Method's application across diverse populations and its integration with technologies like tele-rehabilitation could further enhance adherence and treatment outcomes.

CONCLUSION

This scoping review highlights the Lyon Method as a promising approach for managing Adolescent Idiopathic Scoliosis, offering notable improvements in Cobb angle, spinal alignment, functional outcomes, and patient quality of life. The combination of flexible bracing and targeted exercise appears to support high compliance, an essential factor in achieving optimal scoliosis outcomes. While the Lyon Method shows advantages over conventional interventions, particularly in adherence and patient satisfaction, the current body of evidence is limited by a lack of high-quality, long-term studies. To substantiate these findings, future research should prioritize RCTs with standardized protocols, examining the Lyon Method's efficacy across diverse populations and extended timeframes. Nevertheless, the Lyon Method's emphasis on holistic treatment aligns well with patient-centered care and represents a viable, non-invasive treatment option for adolescents with scoliosis.

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REVIEW ARTICLE

Effectiveness of Yoga Versus Conventional Interventions in Reducing Pain and Disability in Older Adults with Back Pain: A Scoping Review

Muhammad Solihin Shaharrudy[1], Mohamed Arshad Mohamed Sideek[1] , Ahmad Fahmi Harun Ismail[1,*]

[1]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Yoga, chronic back pain, older adults, pain management, disability reduction

ABSTRACT

Background: Chronic back pain is a prevalent and debilitating condition among older adults, significantly impacting quality of life and functional independence. While conventional interventions, including physical therapy and pharmacological treatments, are commonly utilized, complementary practices like yoga are increasingly explored for their potential benefits in pain management and functional improvement. This scoping review aims to assess the existing evidence on the effectiveness of yoga compared to conventional interventions in reducing pain and back-related disability in older adults, highlighting key findings and identifying gaps for future research. **Methods:** This review followed the Arksey and O'Malley scoping review framework, systematically searching databases including PubMed, Scopus, and Web of Science. Studies were included if they (1) involved older adults (aged 60 and above), (2) compared yoga with conventional back pain interventions, (3) measured outcomes related to pain intensity and back-related disability, and (4) were published in peer-reviewed journals. A thematic analysis was performed to identify common findings, trends, and research gaps in the literature. **Results:** Twenty-four studies met the inclusion criteria, including randomized controlled trials, cohort studies, and observational research. Findings generally support the efficacy of yoga in reducing pain and disability among older adults, with many studies demonstrating comparable or superior results to conventional physical therapy interventions. Yoga was associated with additional benefits in psychological well-being, flexibility, and balance, which were less frequently addressed by conventional treatments. However, the studies varied in intervention types, duration, and measurement tools, limiting cross-study comparisons. Few studies examined long-term outcomes, highlighting a need for further longitudinal research. **Conclusion:** The evidence suggests that yoga is a viable alternative or adjunct to conventional back pain interventions in older adults, offering potential benefits for pain reduction, functional mobility, and quality of life. Despite these promising findings, the heterogeneity of studies and lack of long-term data indicate a need for further high-quality research to establish standardized protocols and evaluate sustained effects. Future studies should focus on randomized controlled designs with consistent measures to better inform clinical guidelines on integrating yoga into back pain management for older adults.
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INTRODUCTION

Chronic back pain is a major health concern worldwide, particularly among older adults, impacting physical function, mental health, and overall quality of life (Deyo et al., 2015). Defined as pain persisting for more than three months, chronic back pain is often linked to degenerative changes in the spine due to aging, obesity, or lifestyle factors (Geneen et al., 2017). For older adults, chronic back pain is a primary cause of disability, leading to decreased mobility and increased dependency on others, thus imposing a substantial burden on healthcare systems and caregivers (Vos et al., 2016). While conventional interventions, including physical therapy, pharmacological treatment, and surgery, remain common, alternative approaches such as yoga have garnered growing interest in recent years due to their holistic approach to health and potential to improve both physical and mental outcomes (Sherman et al., 2011).

Yoga, an ancient practice originating in India, integrates physical postures (asanas), breathing exercises (pranayama), and meditation to promote physical and mental well-being. Evidence suggests that yoga may provide several health benefits, including enhanced flexibility, improved strength, and stress reduction, all of which may contribute to a reduction in chronic pain (Groessl et al., 2016). In the context of back pain, yoga postures are designed to stretch and strengthen the muscles supporting the spine, potentially alleviating pain and improving mobility (Cramer et al., 2013). Furthermore, the mindfulness aspect of yoga may aid in pain perception by enhancing body awareness and reducing the psychological impact of chronic pain (Marshall et al., 2013).

Older adults may particularly benefit from yoga, as it offers a low-impact, adaptable exercise form suitable for

*Corresponding author.
E-mail address: ahmadfahmi@iium.edu.my

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various fitness levels. Several studies have explored the efficacy of yoga interventions on pain and disability in older adults, with promising results. For instance, a randomized controlled trial by Tekur et al. (2012) demonstrated significant improvements in back pain and functional mobility following a 12-week yoga program among older adults with chronic pain. In a systematic review, Cramer et al. (2013) found that yoga was associated with a medium to large effect size in reducing chronic pain compared to control groups across various populations, including older adults. Despite these promising findings, the literature reveals considerable heterogeneity in intervention protocols, durations, and outcome measures, making it challenging to draw definitive conclusions (Groessl et al., 2017).

The effectiveness of yoga relative to conventional interventions, such as physical therapy or medication, remains an area requiring further exploration. While some studies report comparable results between yoga and conventional approaches, others suggest that yoga may offer additional benefits in areas like balance, psychological resilience, and overall quality of life (Sherman et al., 2011; Williams et al., 2009). However, gaps in research persist, especially concerning long-term outcomes and the specific mechanisms by which yoga influences pain and disability in older adults.

Given the increasing interest in complementary therapies and the potential for yoga to serve as an accessible, low-cost intervention, it is crucial to systematically review and synthesize the available evidence. This scoping review aims to map the existing literature on yoga's effectiveness in reducing pain and back-related disability compared to conventional interventions in older adults. Through this review, we seek to highlight the potential benefits, limitations, and gaps in current research, providing a foundation for future studies and clinical applications.

MATERIALS AND METHODS

Study Design

This study was conducted as a scoping review, following the methodological framework proposed by Arksey and O'Malley (2005) and further refined by Levac, Colquhoun, and O'Brien (2010). The objective of this review was to systematically map existing literature on the effectiveness of yoga in reducing back pain and related disability compared to conventional interventions in older adults.

Eligibility Criteria

Studies were selected if they focused on adults aged 60 years and above who experienced chronic or recurrent back pain. The intervention of interest was yoga, in any structured form or style, specifically targeting pain or disability outcomes. Conventional interventions such as physical therapy, medication, or general exercise programs were considered acceptable as comparators. The primary outcomes evaluated included pain intensity and back-related disability, while secondary outcomes, such as psychological well-being, functional mobility, and quality of life, were also considered to capture a broader spectrum of effects. Table 1 summarises the details of the criteria selected in this paper.

Table 1: Summary of eligibility criteria of the studies selected.

Criterion	Description
Population	Adults aged 60 years and above with chronic or recurrent back pain.
Interventions	Studies evaluating yoga as an intervention for back pain, including any structured form or style of yoga targeting pain or disability outcomes.
Comparators	Conventional back pain interventions, including physical therapy, medication, exercise programs, or no intervention (control).
Outcomes	Primary outcomes related to pain intensity or back-related disability; secondary outcomes such as psychological well-being, functional mobility, and quality of life.
Study Design	Randomized controlled trials, cohort studies, case-control studies, and observational studies. Only peer-reviewed articles published in English were included.

Data Sources and Search Strategy

A comprehensive literature search was conducted using the following electronic databases: PubMed, Scopus, Web of Science, and the Cochrane Library. Search terms included “yoga,” “back pain,” “disability,” “older adults,” “chronic pain,” and “conventional interventions,” combined using Boolean operators to capture relevant studies as further described in Table 2. Reference lists of included studies were also screened for additional relevant articles. In addition to database searches, the reference lists of included studies were screened for further relevant articles.

Table 2: The search strategy used to collect the studies available.

Database	*Search Terms*	*Boolean Operators*	Filters Applied
PubMed	*"yoga," "back pain," "older adults," "chronic pain," "disability," "conventional interventions"*	*AND, OR*	Humans, English language, no date limit
Scopus	*"yoga," "back pain," "elderly," "pain reduction," "disability improvement," "physical therapy," "exercise"*	*AND, OR*	Humans, English language, peer-reviewed
Web of Science	*"yoga," "spine pain," "older population," "back-related disability," "traditional interventions"*	*AND, OR*	Humans, English language, no date limit
Cochrane Library	*"yoga," "back pain management," "older adults," "disability," "exercise therapy," "conventional care"*	*AND, OR*	Humans, English language, reviews included

Study Selection

Following the initial database search, all identified articles were imported into a reference management tool, and duplicates were removed. Two independent reviewers screened the titles and abstracts for relevance based on the eligibility criteria. Full texts were retrieved for studies deemed relevant and further assessed for final inclusion. Disagreements between reviewers were resolved through discussion or consultation with a third reviewer.

Data Extraction

Data were extracted from the included studies using a standardized data extraction form. Key information included study design, sample size, participant demographics, intervention details, comparator interventions, outcome measures, and findings. The extracted data were categorized and tabulated to facilitate comparison across studies.

Data Analysis

A thematic analysis was conducted to synthesize and identify trends, gaps, and key findings from the included studies. Descriptive statistics were used to summarize study characteristics, while qualitative data were grouped by themes related to outcomes of pain reduction, disability improvement, and additional benefits (e.g., psychological well-being). The findings are presented narratively, supported by tables where applicable.

Ethical Considerations

As this study was a scoping review and did not involve direct contact with human participants, ethical approval was not required. However, we ensured adherence to rigorous research standards, including transparency in reporting and unbiased data synthesis. We also cited all sources and gave appropriate acknowledgment to original study authors, ensuring ethical responsibility in data handling and interpretation.

RESULTS

Study Selection and Characteristics

A total of 24 studies met the eligibility criteria and were included in this scoping review and 3 were selected as the key studies as tabulated in Table 3. These studies encompassed randomized controlled trials, cohort studies, and observational studies conducted across diverse settings, including clinical rehabilitation centres, community groups, and assisted living facilities. Sample sizes ranged from 30 to over 200 participants, with yoga interventions varying in type, frequency, and duration. Conventional interventions included physical therapy, exercise programs, and, in some cases, pharmacological management of pain.

Pain Reduction

Most studies reported significant reductions in pain intensity for participants in the yoga groups compared

to those receiving conventional interventions. For example, Tekur et al. (2012) found that a 12-week yoga program resulted in a 30% decrease in reported pain levels, while Sherman et al. (2011) demonstrated that yoga was as effective as standard physical therapy in reducing pain in older adults with chronic low back pain. Across the reviewed studies, pain reduction was commonly attributed to the physical postures and breathing techniques involved in yoga, which help relax muscles, improve circulation, and promote relaxation.

Disability Improvement

Improvements in back-related disability were also observed in several studies, with many participants in yoga groups demonstrating enhanced functional mobility and a greater ability to perform daily activities. For instance, a study by Williams et al. (2009) found that Iyengar yoga led to moderate improvements in disability scores, suggesting that yoga's stretching and strengthening components positively impact functional abilities. This trend was further supported by Groessl et al. (2016), who reported that veterans with chronic low back pain participating in a yoga program experienced significant gains in flexibility and balance, leading to reduced disability scores.

Psychological Well-being

Beyond physical improvements, some studies highlighted additional psychological benefits of yoga, including reduced stress and enhanced quality of life. Studies indicated that the mindfulness aspect of yoga, coupled with physical exercise, contributed to improved mental health outcomes. Marshall et al. (2013) noted significant reductions in anxiety and depressive symptoms among older adults practicing yoga, which was less commonly reported in participants undergoing conventional therapies. These findings suggest that yoga may offer comprehensive health benefits, positively impacting both physical and mental aspects of health in older adults.

Table 3: The key findings in Pain Reduction, Disability Improvement, and Psychological Well-being

Outcome	Findings	Key Studies
Pain Reduction	Significant reductions in pain intensity were reported for yoga participants compared to conventional interventions. Yoga was found as effective as physical therapy in reducing pain in older adults. This reduction was often linked to yoga's postures and breathing techniques that relax muscles, improve circulation, and promote relaxation.	Tekur et al. (2012): 30% decrease in pain levels after 12-week yoga program; Sherman et al. (2011): yoga comparable to physical therapy
Disability Improvement	Several studies observed enhanced functional mobility and improved ability to perform daily activities among yoga participants. Yoga's stretching and strengthening were associated with reduced disability scores.	Williams et al. (2009): moderate improvements in disability with Iyengar yoga; Groessl et al. (2016): increased flexibility and balance among veterans
Psychological Well-being	Yoga contributed to reduced stress, enhanced quality of life, and mental health improvements. Mindfulness in yoga helped reduce anxiety and depressive symptoms, providing additional benefits not commonly seen in conventional therapies.	Marshall et al. (2013): significant reduction in anxiety and depressive symptoms in older adults practicing yoga

DISCUSSION

The findings of this scoping review indicate that yoga is a promising intervention for managing chronic back pain and associated disability in older adults. Across the studies, yoga was consistently associated with significant pain reduction, improvements in functional mobility, and additional psychological benefits. These results align with previous literature that suggests yoga's holistic approach—integrating physical postures, breathing exercises, and mindfulness—can address both the physical and mental dimensions of chronic pain (Groessl et al., 2017).

Interpretation of Pain Reduction

The observed reductions in pain among older adults practicing yoga underscore the potential of non-pharmacological approaches in chronic pain management. Pain reduction in yoga was primarily attributed to its physical postures and breathing techniques, which may promote muscle relaxation, improve blood circulation, and facilitate a state of physical and mental calm. This is particularly relevant

for older adults, as conventional interventions like medication may have adverse effects, making yoga a safer alternative or adjunct (Sherman et al., 2011). Moreover, the consistent results across studies, such as those by Tekur et al. (2012) and Sherman et al. (2011), provide strong support for incorporating yoga into pain management strategies for this population.

Enhancements in Functional Mobility and Disability Improvement

Improvement in back-related disability was another key finding, with participants in yoga programs reporting greater ease in daily activities and functional mobility. The stretching and strengthening components of yoga likely contribute to better flexibility and core stability, which are crucial for maintaining functional independence among older adults (Williams et al., 2009). For instance, the significant gains observed in flexibility and balance in veterans with chronic low back pain (Groessl et al., 2016) highlight yoga's potential to reduce disability and improve quality of life, particularly in populations that may be at high risk of mobility loss.

Psychological Benefits

In addition to physical improvements, yoga also appeared to positively impact psychological well-being, an area less frequently addressed in conventional interventions. Reductions in anxiety and depressive symptoms were noted in multiple studies, suggesting that yoga's mindfulness aspect can enhance coping mechanisms for chronic pain, leading to a reduction in overall stress and an improvement in mental health (Marshall et al., 2013). Given the high prevalence of psychological distress among older adults with chronic pain, these findings reinforce yoga's role as a holistic intervention that may simultaneously benefit physical and mental health.

Strengths and Limitations

The results of this review must be considered in light of several limitations. First, there was considerable heterogeneity in yoga intervention protocols, including variations in style, duration, and intensity, making it difficult to standardize findings across studies. Additionally, outcome measures varied widely, with some studies relying on self-reported data, potentially introducing response biases. Another limitation is the lack of long-term follow-up in many studies, which restricts conclusions about the sustainability of yoga's benefits. Future research should aim for more standardized protocols and include long-term follow-up to evaluate whether the observed improvements in pain, disability, and mental health are sustained over time.

Implications for Practice and Future Research

The findings of this review have important implications for clinical practice and future research. Clinicians may consider incorporating yoga as a complementary intervention for older adults with chronic back pain, particularly when conventional therapies may not be well-tolerated. Additionally, given the psychological benefits observed, yoga could be integrated as part of a multidisciplinary approach to pain management that includes physical, psychological, and social components.

Future studies should focus on randomized controlled trials with consistent intervention protocols to validate these findings further. There is also a need for research exploring the mechanisms through which yoga exerts its effects on pain and disability, as well as investigations into how different styles of yoga may uniquely benefit older adults with chronic back pain.

CONCLUSION

This scoping review highlights yoga as a promising intervention for managing chronic back pain and improving functional mobility in older adults, offering an effective alternative or complement to conventional therapies. Findings suggest that yoga not only alleviates pain and reduces disability but also enhances psychological well-being, addressing both the physical and mental aspects of chronic pain management. Although the current evidence supports the use of yoga for back pain, limitations in study design, heterogeneity in interventions, and a lack of long-term data indicate the need for further high-quality research. Future studies with standardized protocols and extended follow-up are essential to establish yoga's efficacy and sustainability in managing back pain in older adults. Integrating yoga into clinical practice may provide a holistic and accessible approach to improving quality of life in this population.

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REVIEW ARTICLE

Effectiveness of Aerobic Exercise in Preventing Gestational Diabetes Mellitus (GDM) Among Pregnant Women: A Systematic Review

Rozlin Abdul Rahman[1,*], Ainon Atikah Ayub[1]

[1]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia

Keywords:
Gestational diabetes mellitus (GDM), aerobic exercise, prevention, maternal health

ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a rising global health issue, affecting both maternal and foetal health. It increases the risk of future type 2 diabetes in mothers and various complications in infants. Aerobic exercise has shown promise in preventing GDM by regulating blood glucose, reducing maternal weight gain, and improving insulin sensitivity. This systematic review evaluates the effectiveness of aerobic exercise in preventing GDM in pregnant women. **Methodology**: Multiple databases, including PubMed, Scopus, and ScienceDirect, were searched for studies published between 2010 and 2020. Randomized controlled trials (RCTs) assessing aerobic exercise as a preventive intervention for GDM were included. After applying the PICOS framework, 1,091 studies were identified, of which six met the inclusion criteria. Study quality was assessed using the revised Cochrane risk-of-bias tool. **Results**: Three studies showed significant improvements in fasting blood glucose and insulin sensitivity with aerobic exercise alone. However, results were mixed when aerobic exercise was combined with other modalities. The variation in findings can be attributed to differences in population risk factors, intervention duration, and study design. **Conclusion**: Aerobic exercise is a promising intervention for reducing GDM risk, particularly in high-risk populations. However, the variability in results highlights the need for standardized exercise guidelines regarding intensity, frequency, and duration. Future research should focus on clarifying these factors and exploring the combined effects of aerobic exercise with other interventions to further enhance GDM prevention.

INTRODUCTION

Gestational diabetes mellitus (GDM) is a pregnancy condition diagnosed in the second or third trimester, affecting 3-5% of pregnancies globally (Petry, 2014). Its prevalence is rising, with rates in Selangor, Malaysia reaching 27.9% (Logakodie et al., 2017), reflecting a broader global trend linked to lifestyle changes and increasing obesity. Studies show that GDM rates are particularly high in urban populations (Amar et al., 2023; Sahota et al., 2022).

Women with GDM face higher risks of complications like preeclampsia, Caesarean deliveries, and long-term type 2 diabetes (T2DM) (Guelfi et al., 2016). GDM also poses risks to infants, such as macrosomia, which can lead to birth complications and long-term health issues. Risk factors include maternal obesity, family history of diabetes, age, and low physical activity (Wang & Luo, 2019). However, fatigue and safety concerns often limit exercise during pregnancy (Gaston & Cramp, 2011).

Aerobic exercise, such as walking and cycling, has emerged as an effective strategy for managing GDM. It improves blood glucose control, boosts insulin sensitivity, and reduces excessive weight gain (Rousseau & Bard, 2016). Recommendations suggest 20-30 minutes of moderate-intensity aerobic exercise most days of the week to improve outcomes for both mother and baby (Chasan-Taber et al., 2021; Hanson et al., 2022). In addition, resistance training and activities like yoga can improve cardiovascular health, muscle strength, and glucose metabolism (Embaby et al., 2016; Sklempe Kokic et al., 2018). These exercises help regulate heart rate, lower blood sugar levels, and reduce GDM-related complications, while promoting better neonatal outcomes (Barakat et al., 2019). Aerobic exercise also enhances glucose uptake in muscles, providing lasting effects on blood sugar regulation (Harrison et al., 2016).

Given the increasing prevalence of GDM and growing evidence supporting exercise as a preventative measure, a systematic review is needed to synthesize recent findings and clarify exercise recommendations, ultimately improving health outcomes for both mothers and infants.

* *Corresponding author.*
E-mail address: rozlin@iium.edu.my

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MATERIALS AND METHODS

Identification

This systematic review aimed to gather studies from 2010 to 2020 assessing the effectiveness of aerobic exercise in preventing GDM among pregnant women. Multiple databases, including PubMed, Scopus, and ScienceDirect, were accessed. Specific keywords such as "aerobic exercise" AND "gestational diabetes mellitus" AND "pregnancy" OR "pregnant women" were used to capture relevant studies. To ensure accuracy, any duplicate articles were consolidated, and studies were excluded if they lacked sufficient details, were incomplete (e.g., non-full-text, non-English articles), involved animal studies, non-randomized controlled trial study design, or were unpublished.

Eligibility

Articles that passed the initial screening underwent an eligibility review, guided by the PICOS (Population, Intervention, Comparison, Outcome, and Study Design) framework. The PICOS criteria were derived from this study's title to ensure relevance to the research question. A summary of these criteria can be found in Table 1 below.

Risk of Bias

The quality and potential bias of each selected study were evaluated using the revised Cochrane risk-of-bias tool for randomized trials (RoB 2), sourced from the University of Bristol (2018). This tool, known for its rigor in assessing methodological quality, ensured that only reliable studies were included in the review.

Study Selection

Initially, 1,091 articles were identified through database searches, with two additional studies located via Google Scholar. After removing duplicates, the remaining articles were screened by title, abstract, and objective relevance, resulting in the exclusion of 898 articles as shown in Figure 1. A total of 16 articles met the PICOS criteria and, after further assessment, 6 articles were ultimately selected for inclusion in this review.

Reporting Results

Data extraction was conducted for each included study. Based on the 2020 Guidelines for Systematic Reviews by the American Occupational Therapy Association, Table 2 captures the study characteristics including author/year, evidence level, study design, risk of bias, participant characteristics, inclusion criteria, study setting, intervention, and key outcomes.

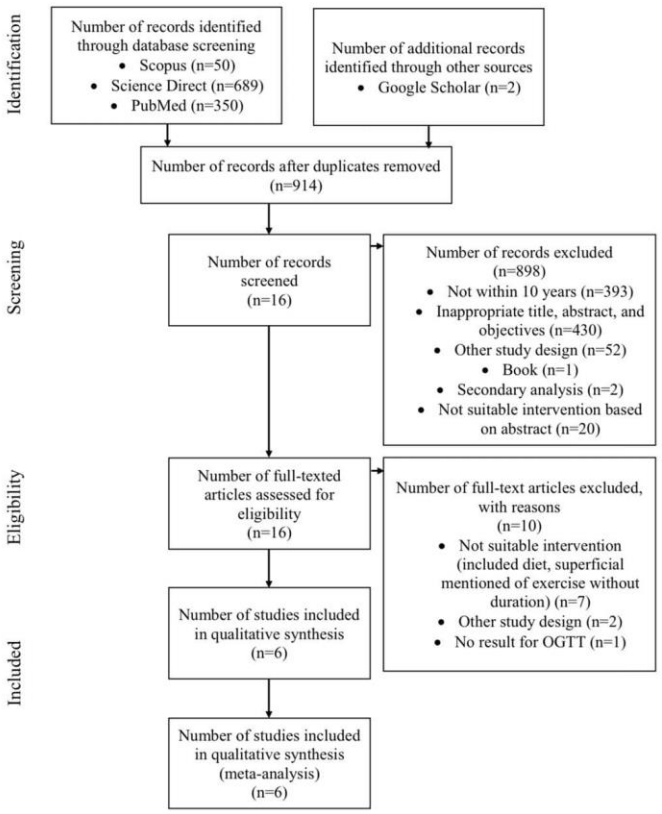

Figure 1: PRISMA flow diagram

Table 1: Details of the PICOS table

P	Healthy pregnant women, pregnant women with GDM, pregnant women with a history of GDM, and pregnant women with a high risk of GDM
I	Aerobic exercise
C	Standard prenatal care or no structured exercise intervention
O	Oral glucose tolerance test (OGTT), fasting blood glucose and insulin level
S	Randomized control trial

RESULTS

Study Characteristics

The studies reviewed involved participants aged 18-40, excluding those with conditions such as hypertension, pre-existing diabetes, or cardiac disease to minimize confounding variables. Participants generally had uncomplicated, sedentary, singleton pregnancies. Most studies provided supervised exercise interventions, although Sklempe Kokic et al. (2018) and Barakat et al. (2019) did not specify whether expert supervision was involved. To ensure consistent intensity levels, some studies used the Borg Rating of Perceived Exertion (RPE) scale, providing a reliable measure of exercise exertion appropriate for pregnant populations. The studies included were well-constructed, randomized controlled trials (RCTs), considered a high level of evidence for evaluating intervention effects. Bias assessment using the RoB 2 tool revealed a generally low risk of bias across studies, although Cordero et al. (2015) showed a higher risk due to unmasked participants, which may have influenced self-reported adherence and perceived outcomes. Summary of the findings is shown in Table 2.

Effects of Aerobic Exercise in GDM

Three studies (Embaby et al., 2016; Guelfi et al., 2016; Wang et al., 2017) examined the effects of aerobic exercise alone on GDM outcomes, while Cordero et al. (2015), Sklempe Kokic et al. (2018), and Barakat et al. (2019) investigated aerobic exercise combined with other modalities. Findings suggest that aerobic exercise alone contributes to significant improvements in fasting glucose and insulin sensitivity (Embaby et al., 2016; Wang et al., 2017). However, in Guelfi et al. (2016), no significant differences were noted in oral glucose tolerance test (OGTT) results, potentially due to variations in population risk factors or exercise adherence.

Interestingly, studies combining aerobic exercise with other modalities (Barakat et al., 2019) found additional benefits, including reduced GDM prevalence and improvements in OGTT outcomes. However, Sklempe Kokic et al. (2018) observed no notable changes in fasting glucose, possibly due to the shorter intervention duration and smaller sample size, emphasizing the importance of study design in determining reliable outcomes. These mixed results highlight that aerobic exercise alone is generally effective but may yield better results when integrated with other forms of physical activity.

This review suggests that aerobic exercise may help prevent GDM in high-risk women. Studies by Embaby et al. (2016) and Wang et al. (2017) showed significant blood glucose reductions through activities like treadmill walking and stationary cycling, supporting broader findings, such as Magro-Malosso et al. (2017), which emphasized the benefits of aerobic exercise in overweight or obese pregnant women. Aerobic exercise enhances glucose uptake in skeletal muscles by activating the GLUT4 transporter, improving glucose absorption without insulin (Bird & Hawley, 2017). However, Guelfi et al. (2016) found that aerobic exercise alone did not significantly improve outcomes for women with a history of GDM, suggesting limited effectiveness for secondary prevention in high-risk populations. This aligns with Muche et al. (2019), which found that exercise is more beneficial for those without prior GDM.

While aerobic exercise holds potential, studies underscore the need for precise guidelines on exercise duration and intensity. For instance, the American Pregnancy Association (2017) suggests stationary cycling as a safer aerobic option due to the shift in the center of gravity during pregnancy, which reduces fall risk. Although cycling is low-impact, further research could examine optimal exercise intensity and modality for maximal benefits.

Aerobic Exercise Combined with Other Exercises in Preventing GDM

Combining aerobic exercise with other activities, such as strength and pelvic floor exercises, shows promise for improving GDM outcomes. Cordero et al. (2015) and Barakat et al. (2019) found that combining land and aquatic exercises led to reduced GDM prevalence and better OGTT results, suggesting that these exercises can enhance fitness and glycaemic control. Aquatic exercises,

for example, aid in weight management, a key factor in GDM prevention (Bacchi et al., 2018). Pelvic floor exercises also improve pregnancy outcomes by reducing labour duration and urinary incontinence (Schreiner et al., 2018). However, Sklempe Kokic et al. (2018) found no significant effects of combined exercises on GDM outcomes. Their six-week intervention and small sample size may explain these results, highlighting the importance of intervention duration and adherence.

Research suggests that early exercise, ideally starting in the first trimester, yields the best results (Padayachee, 2015). Bird and Hawley (2017) emphasize that regular physical activity improves glycaemic control, stressing the benefits of sustained exercise early in pregnancy. Beyond GDM prevention, aerobic exercise offers broader health benefits during pregnancy, improving cardiovascular fitness and lowering chronic disease risk factors (Guelfi et al., 2016). Regular exercise also supports mental well-being, reducing stress and anxiety during pregnancy. Additionally, aerobic activity aids in managing gestational weight gain, which is essential for minimizing GDM risk (Wang et al., 2017). Maintaining weight within BMI-specific guidelines is critical for maternal and foetal health, reinforcing the multifaceted advantages of physical activity in prenatal care.

CONCLUSION

This review emphasizes that regular aerobic exercise is a valuable, non-invasive strategy for reducing the risk of GDM, particularly for women at higher risk. Aerobic activities such as walking, cycling, and low-impact aerobics have been shown to improve blood glucose regulation and insulin sensitivity. However, study results varied due to differences in exercise protocols, sample sizes, and population characteristics, highlighting the need for clear, evidence-based guidelines on exercise intensity, duration, and other specific protocols for GDM prevention.

Future research should focus on standardizing exercise interventions, including defining optimal intensity, frequency, and duration for GDM prevention. Additionally, exploring the combined effects of aerobic exercise with other physical activities, such as resistance and flexibility training, may further enhance maternal health. More diverse studies are also needed to assess the effectiveness of exercise across various demographics and risk profiles.

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Table 2 Study Characteristics

Author/Year	Level of Evidence Study Design Risk of Bias	Participants Inclusion Criteria Study Setting	Intervention and Control Groups	Outcome Measures	Results
Cordero et al. (2015)	Level 1B RCT *Risk of Bias* High	*Final Participants* 257 healthy pregnant women *Inclusion Criteria* - Not previously familiar with exercise or any physical activity *Study Setting* Gym hall Small and large pool tanks (supervised by qualified fitness specialist)	*Intervention (n = 101)* Participants were involved in 50-60 minutes exercise three times per week (two times for land exercise and once for aquatic exercise). They started at 10-14 weeks of pregnancy and ended at 38-39 weeks of pregnancy. The exercise can be divided into; LAND EXERCISE - 10 minutes warming up (locomotion games, light stretch, articular movement) - 20 minutes of low impact aerobic exercise (aerobic dance, Latin dance, cardio boxing) - 12 minutes resistance exercise (15 repetitions for biceps and triceps, quadriceps, and gluteal) - 10 minutes pelvic floor exercise - 8 minutes stretching exercise (relaxation and visualization exercise, self-massage, and pair-massage) # Exercise with 12-14 RPE AQUATIC EXERCISE	*GDM* 1-h, 2-h, and 3-h OGTT at 24-28 weeks of gestation	*Significant Findings* A significant finding in 3-h OGTT level between intervention and control group with p-value < 0.05 (p = 0.021) *Non-significant Findings* The results between intervention and control group showed no significant difference in both 1-h and 2-h OGTT as the p-value > 0.05 (1-h OGTT, p = 0.502, 2-h OGTT, p = 0.097)

			- 10 minutes warming up (swimming except for butterfly style) - 30 minutes of core exercises (strength exercise, lunges) - 10 minutes stretching exercise (flexibility, relaxation, and breathing exercise) *Control Group (n = 156)* Remained inactive		
Embaby et al. (2016)	Level 1B RCT *Risk of Bias* Low	*Final Participants* 40 multigravida pregnant women with a high risk of GDM *Inclusion Criteria* - 24 weeks of pregnancy - BMI > 30kg/m2 - With at least one of the following criteria: i) history of macrosomia baby ii) history of abnormal glucose tolerance during a previous pregnancy iii) Having T2DM *Study Setting* None (no information on supervision)	*Intervention (n = 20)* Pregnant women were assigned to do 45 minutes of aerobic exercise three times per week. They started to exercise at 24 weeks of gestation until 37 weeks. The exercise was divided into three-phase; PHASE 1 - 10 minutes warming up (walking in place) PHASE 2 - 30 minutes active stage (walking on the treadmill without inclination, at speed 0.7km/hour) PHASE 3 - 10 minutes cooling down (walking on the treadmill by decreasing the speed) *Control Group (n = 20)* Traditional care was given to the subjects in the control group including diet intervention	*GDM* Fasting blood glucose and insulin level at 37 weeks of gestation	*Significant Findings* The value for both fasting glucose and insulin level appeared to have significant findings between the intervention and control group with the *p*-value < 0.05 (fasting glucose level, *p* = 0.0001, fasting insulin level, *p* = 0.0001) *Non-significant Findings* None

Guelfi et al. (2016)	Level 1B RCT *Risk of Bias* Low	*Final Participants* 172 pregnant women with a history of GDM *Inclusion Criteria* - less than 14 weeks of gestation - Singleton pregnancy - Not familiar with any exercises - Able to participate for 14 weeks of exercise program *Study Setting* Each participant's home (supervised by exercise physiologist)	*Intervention (n = 85)* Cycling intervention using upright cycle ergometer for up to 60 minutes per session three times per week. The exercise was done within 14 weeks. The exercise can be divided into; - 5 minutes warming up at low intensity pedalling (12-13 RPE) - 20-30 minutes moderate-intensity cycling (14-16 RPE) - 5 minutes cooling down (9-11 RPE) # progressively increase the duration until 45-50 minutes *Control Group (n = 87)* Standard care	*GDM* 2-h OGTT after 14 weeks of exercise program (conclude by recurrence rate of GDM- based on glucose and insulin response to OGTT)	*Significant Findings* None *Non-significant Findings* The OGTT finding illustrated no significant difference between glucose and insulin response in the exercise and control group as the prevalence of getting GDM was the same in both groups (*p*-value = 0.950)
Wang et al. (2017)	Level 1B RCT *Risk of Bias* Low	*Final Participants* 265 pregnant women with a high risk of GDM *Inclusion Criteria* - Singleton pregnancy - BMI 24-28 kg/m2 - Non-smoking *Study Setting* In the hospital with supervision	*Intervention (n = 132)* Cycling program three times per week starting from week 12 of pregnancy until 36-37 weeks of gestation. The exercise lasted for 30 minutes and were classified into; a) 5 minutes warming up with low intensity (9-11 RPE) b) 5 minutes moderate-intensity cycling (12-14 RPE, 30 seconds pedalling with high intensity (15-16 RPE), 5 minutes moderate-low intensity (10-12 RPE), 1-minute pedaling at increase resistance (13-15 RPE).	*GDM* OGTT was observed in 1-h and 2-h during the second trimester	*Significant Findings* A significant difference between exercise group and control group in OGTT level with p-value < 0.05 in both tests (1-h *p*-value = 0.009, 2-h *p*-value = 0.009) *Non-significant Findings* None

			2 minutes interval with 3 repetitions c) 5 minutes cooling down of easy cycling # Progressively increased the duration of exercise until reach 45-60 minutes per session according to individual ability *Control Group (n = 133)* Continue with usual daily activities and were not encouraged to get involved in any physical exercises		
Sklempe Kokic et al. (2018)	Level 1B RCT *Risk of Bias* Low	*Final Participants* 38 pregnant women diagnosed with GDM *Inclusion Criteria* - Aged between 20-40 years old - Upper limit of pregnancy: at least 30 weeks (involved in 6 weeks of exercise intervention) *Study Setting* None with no supervision mentioned	*Intervention (n = 18)* 6 weeks of exercise intervention (two times per week) were introduced to pregnant women with a maximum upper limit for pregnancy was set at 30 weeks. The intervention involved 50-55 minutes exercise which was divided into several parts; a) 20 minutes of aerobic exercise on a treadmill with 13-14 RPE b) 20-25 minutes strengthening exercise (trunk, upper limb, lower limb muscles) c) 10 minutes pelvic floor exercise, stretching, and relaxation *Control Group (n = 20)* Standard prenatal care	*GDM* Fasting glucose level at the end of pregnancy	*Significant Findings* None *Non-significant Findings* At the end of pregnancy, there was no significant difference between fasting glucose level in exercise and control group with the *p*-value > 0.05 (*p*-value = 0.367)

Barakat et al. (2019)	Level 1B RCT *Risk of Bias* Low	*Final Participants* - 456 healthy pregnant women *Inclusion Criteria* - Uncomplicated and singleton pregnancy - No T1DM, T2DM, and GDM at baseline - No history of preterm delivery - Not previously active or involved in other trials *Study Setting* None (supervised by qualified physical activity and sport science professional)	*Intervention (n = 234)* At the beginning of 8-10 weeks of gestation, participants were involved in 55-60 minutes of supervised moderate-intensity exercise for three days per week until 38-39 weeks of gestation. The exercises included; a) 10 minutes warming up (walking and static stretching) b) 30-35 minutes of aerobic exercise (aerobic dance) and strengthening exercise (using 3kg barbells and TheraBand for major muscles) c) 10 minutes cooling down (walking, static stretching, pelvic floor strengthening, and relaxation) # Exercise with 12-14 RPE *Control Group (n = 222)* Received obstetric standard care from health professions including counselling on general nutrition and physical activity	*GDM* 1-h OGTT at week 24-26 gestation	*Significant Findings* The OGTT results showed a significant finding between exercise group and control group with *p*-value < 0.05 (*p* = 0.045) *Non-significant Findings* None

REVIEW ARTICLE

Risk Factors of Lumbar Lordosis and Its Association with Lower Back Pain: A Systematic Review

Mohammad Danial Diniy Mohammad Suhaimi[1], Munayati Munajat[1,*] Saiful Adli Bukry[2]

[1]Department of Physical Rehabilitation Sciences, Kulliyyah of Allied Health Sciences, International Islamic University Malaysia, Pahang, Malaysia
[2]Center For Physiotherapy Studies, Faculty of Health Sciences, University Teknologi Mara, Puncak Alam Campus, Selangor, Malaysia

Keywords:
lumbar lordosis; lumbar curvature; lower back pain

ABSTRACT

Background: Low back pain (LBP) is a global health concern with significant socio-economic effects. Lumbar lordosis (LL), a curvature of the lower spine, is often implicated in LBP; however, understanding this connection requires a proper approach. Therefore, this study aimed to systematically review the scientific evidence on factors influencing the development of abnormal lordotic posture related to LBP. **Method:** This review analysed articles from ScienceDirect, PubMed, ProQuest and Google Scholar published between 2013 and 2023. This study screened articles, assessed eligibility based on the inclusion and exclusion criteria, and evaluated the risk of bias of the study using STROBE statement checklist. The data were then descriptively analysed. **Results:** Six articles were included in this systematic review. This review identified three studies that cited the nature of work and body posture, and two studies that cited gender as factors contributing to abnormal lordotic posture related to LBP. Meanwhile, another factor, age was mentioned in one study only. **Conclusion:** The nature of work and body posture, and gender can be considered possible risk factors for the development of abnormal lumbar lordotic posture and can cause LBP. Recognizing these risk factors would be beneficial in designing targeted preventive and therapeutic strategies, particularly for high-risk individuals.

INTRODUCTION

Low back pain (LBP) is one of the musculoskeletal symptoms among various populations. In Malaysia, almost 77% of nurses at the public hospitals (Ibrahim et al., 2019) and 37% of office workers at public universities experienced LBP (Damanhuri et al., 2014). LBP is a common case that refers to healthcare centers, highlights its significance as a health problem, and has emerged as a significant medical problem affecting the adult population (Edwards et al., 2018).

In the issue of LBP, changes in the alignment of the spine can compromise body mechanics, leading to stress buildup and structural issues such as disc and facet joint degeneration, resulting in discomfort (Gong et al., 2019). The geometry of lumbar lordosis (LL) has the most significant impact on force distribution in the lower spine, playing a vital role in absorbing loads during daily activities (Proskura & Sobera, 2019). Changes in the LL angle can be a contributing factor to the development of LBP and associated work-related difficulties (Ashraf et al., 2014). Lumbar lordotic posture is considered a crucial physical factor associated with an increased prevalence of LBP (Dolphens et al., 2016). Both excessive and insufficient LL can contribute to the incidence of LBP (Proskura & Sobera, 2019).

Abnormal LL is believed to contribute to LBP because it may cause an imbalance in the lumbar lordotic curve, which affects the efficiency of the muscles around the spine (Hong & Lee, 2020). Evidence shows that deviation from the neutral position of the lumbar curve may increase the risk of developing LBP (Hasegawa et al., 2018). Besides, there is a potential link indicated between anthropometric factors and LL (Bogdanović et al., 2020). Those with abnormal body weight may have difficulty maintaining a straight posture with minimal energy expenditure, making it a potential contributor to changes in LL and consequently LBP (Kwak et al., 2020). All these show that the lordotic posture associated with LBP is a complex issue influenced by various factors.

The relationship between the causes of lordotic posture remains unclear, posing persistent questions concerning LL (Castillo, 2017). In addition, factors leading to the development of abnormal LL related to LBP also remain

* *Corresponding author.*
E-mail address: muna@iium.edu.my

inconclusive (Chun et al., 2017). Thus, the present study systematically reviewed the factors associated with the development of abnormal lordotic posture related to LBP.

MATERIALS AND METHODS

Study Design

A systematic review study was conducted to identify and summarize the factors that contribute to development of abnormal LL related to LBP. This systematic review was not pre-registered in an international prospective registry. However, it followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement as a guideline to ensure transparency and accuracy in reporting the review (Page et al. 2021).

Inclusion and Exclusion Criteria

The selection of the studies was based on the inclusion and exclusion criteria listed in the Table 1.

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
• Publication within 2013-2023. • Studies written in the English language. • Studies that report on factors contributing to lordotic posture and its association with LBP. • Studies that examine lordotic posture in association with LBP. • Observational studies.	• Studies in which the participants have idiopathic LBP.

Search Strategy

Relevant studies included in this review were retrieved through comprehensive searches of online databases, such as ScienceDirect, PubMed, ProQuest and Google Scholar. The comprehensive searches were conducted up to 9 January 2024. The search utilized Boolean operators ("AND","OR", and "NOT") to combine key terms effectively and refine the search results. The keywords employed to identify pertinent articles in this study were "factor" AND "lordotic posture" OR "low back pain" OR "back pain" OR "lumbar lordosis" OR "lordosis".

Study Selection

Reviewed articles underwent screening to eliminate redundancies, duplicates and unrelated studies. Articles with titles and abstracts that aligns with the study's objective and research question, were further reviewed and filtered based on the inclusion and exclusion criteria. Based on these criteria, the entire texts of the chosen articles were also screened. All of these processes were performed by 2 independent reviewers. Figure 1 illustrates the screening procedure along with the rationale behind the exclusion of articles and the total number of articles that remained.

Data Extraction

Data extraction from selected studies involved tabulating relevant information, including author(s) and year of publication, study design, participants and inclusion criteria, outcome measures, and results of the studies. This tabulated data provides a comprehensive overview of factors influencing abnormal LL related to LBP. The data extraction was performed by the first author, while the second author conducted a second extraction to cross-check its accuracy. Then, the results were qualitatively synthesized to construct the review.

Quality Assessment

A study by Vandenbroucke et al. (2014) stated that the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement is a reliable tool for evaluating the methodological quality of observational studies in systematic reviews. It is a priceless resource for researchers because of its thorough framework, evidence-based recommendations, cross-disciplinary application, and ability to improve reporting quality. The quality of assessment utilized the STROBE statement, a checklist of 22 items (Table 2) developed by the STROBE initiative (Von Elm et al. 2014). The specific aspects of the studies that were assessed using the STROBE statement include the title and abstract, introduction, methods, results and discussion.

RESULTS

Study Selection

This systematic review retrieved articles from online databases, namely, PubMed (n = 1), ScienceDirect (n = 213), ProQuest (n = 1475) and Google Scholar (n = 18100), contributing to a total of 19789 articles. Following the initial identification, 19748 duplicate papers were meticulously removed, resulting in a subtotal of 41 articles for further screening based on titles and abstracts. Through a rigorous screening process, 26 articles were excluded with reasoning. Then, the remaining 15 articles were evaluated according to the inclusion and exclusion criteria. Ultimately, six articles aligning with the inclusion criteria were selected for final inclusion in this systematic review, while the remaining articles were excluded based on predetermined criteria. Figure 1 illustrates the study selection process.

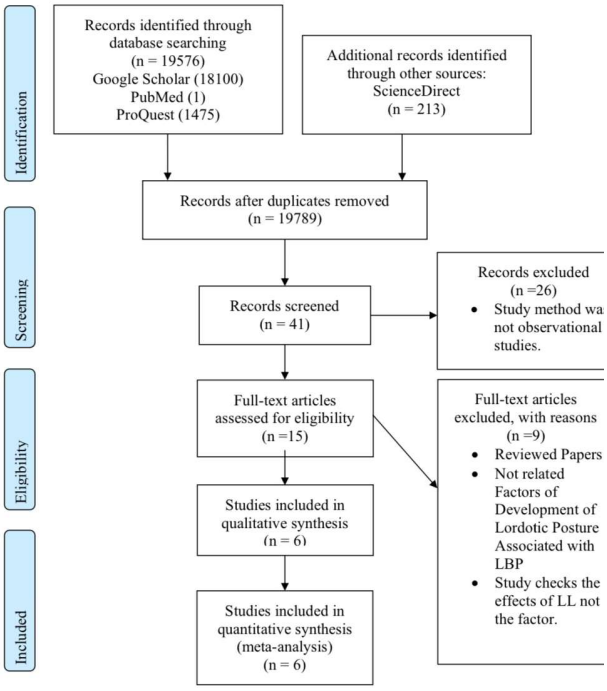

Figure 1: PRISMA flow diagram

Description of Included Studies

This study included six articles that meet the inclusion criteria, each employing distinct methodologies. Zhan et al. (2023) utilized a retrospective study design, while Pourahmadi et al. (2020) conducted a comparative observational study. The remaining four articles, namely Malarvizhi et al. (2023), Wójcik et al. (2020), Proskura & Sobera (2019) and Sorensen et al. (2015), employed a consistent cross-sectional study approach. All the included articles primarily investigate factors contributing to lordotic posture and its association with LBP. A comprehensive summary of the included studies is presented in Table 3 (appendix) for reference and clarity.

Methodological Quality

This systematic review used STROBE Statement checklist, and the result score are summarized in Table 2. The STROBE Statement checklist serves as a valuable tool to assess both the strengths and the weaknesses of the studies reported in medical literature, contributing to the overall robustness of this systematic review's findings. All the 6 papers adhere to the STROBE checklist, each 3 papers consist of 2 items not presented, and the other 3 papers consist with 4 items not reported as presented in Table 2.

Finding on Risk Factors for Lumbar Lordosis

This review found that the nature of work, body posture, gender, and age are factors contributing to abnormal LL development associated with LBP. The findings reveal that the nature of work and posture are the most possible risk factors for abnormal LL development, identified in 3 out of 6 studies. Gender was identified as a risk factor in 2 studies, and age was mentioned in 1 study. All studies showed an association between the risk factors and LBP. Only three studies indicated that the nature of work and poor posture (1 study), female gender (1 study), and age (1 study) have a positive association with LBP.

Table 2: Quality Assessment of Included Studies using STROBE Statement Checklist

Checklist	Item No.	Zhan et al. (2023)	Malarvizhi et al. (2023)	Pourahmadi et al. (2020)	Wójcik et al. (2020)	Proskura and Sobera (2019)	Sorensen et al. (2015)
Title and Abstract	1						
Introduction							
Background/Rationale	2						
Objective	3						
Methods							
Study design	4						
Setting	5						
Participants	6						
Variables	7						
Data sources/measurement	8						
Bias	9						
Study size	10						
Quantitative variables	11						
Statistical methods	12						
Result							
Participants	13						
Descriptive data	14						
Outcome measure	15						
Main results	16						
Other analyses	17						
Discussion							
Key results	18						
Limitations	19						
Interpretation	20						
Generalisability	21						
Other information							
Funding	22						

	Present
	Not present
	Not applicable

DISCUSSION

This study highlights the factors that may affect LL curvature and their relationship to LBP, including the nature of work, body posture, gender, and age.

Factors of Abnormal Lordotic Posture and Their Relationship with Low Back Pain

Nature of Work and Posture

An incidence of LL, mechanical back pain, and impairment among professional workers who spent more time standing and sitting has been reported in a study by Malarvizhi et al. (2023). The study emphasizes the detrimental consequences of prolonged standing on spinal health, highlighting a higher prevalence of back pain among professionals engaged in occupations that involve

prolong standing. In a related context, Musa et al. (2017) emphasized the adverse effects of improper body posture on musculoskeletal health, linking unnatural working postures to fatigue, discomfort, aches, and musculoskeletal illnesses. Czaprowski et al. (2018) supported this, associating improper postural elements, such as trunk lean, forward head posture, anterior pelvic tilt, postural kyphosis, and knee hyperextension, with an increased likelihood of LBP.

Besides, the degree of LL and its impact on daily activities is a critical consideration for women engaged in fitness activities. Two studies in this systematic review are particularly pertinent, as they examined how physical activity, and occupational factors affect spinal health and pain, as well as the association between LL and the LBP after prolonged sitting and standing. Prolonged sitting for more than four to six hours without movement, and prolonged standing for more than two hours without rest, have been associated with adverse effects on LL and the development of LBP (Taha et al., 2023; Mahdavi et al., 2021). This is important because it elucidates how prolonged standing or sitting affect the low back discomfort and LL curvature (Proskura & Sobera, 2019; Sorensen et al., 2015). According to Park et al. (2013), sitting posture commonly exacerbates LBP, emphasizing the challenges in adopting a neutral posture that can contribute to the development of LBP. Furthermore, the impact of spinal alignment on spinal conditions associated with LBP has been explored, highlighting that spinal posture plays the important role in the development of spinal pathology (Daffin et al., 2019). However, further research may be needed, including ergonomic assessment and evaluations of lower back symptoms, to better understand how improper posture can affect LL and cause LBP.

Gender

Two of the six research papers in this systematic review focused on factors that can contribute to lordotic posture, considered gender might be associated to LBP. Pourahmadi et al. (2020) investigated the relationship between chronic LBP and lumbar spine lordosis during sit-to-stand and stand-to-sit motions, finding a gender difference in LL and indicating that gender can influence lordotic posture in LBP. Evidence shows that men and women respond differently to seated postures (Dunk & Callaghan, 2005). Through a confluence of anatomical, physiological, hormonal, and behavioural factors, gender has a substantial impact on lordotic posture and its correlation with LBP (Wilandika et al., 2023). Changes in LL due to the stated factors can lead to discomfort and spinal instability. Gender differences in lifestyle and work-related factors can also impact LBP. For instance, women could partake in activities that involve prolong sitting or poor posture, which can worsen lordotic curvature and contribute to LBP (El-Salam and Ibrahim, 2019).

Furthermore, Wójcik et al. (2020) addressed the gender-specific elements of spinal alignment and pain experience, emphasizing the significance of LL and back pain in females over 50. This study indicated a strong correlation between an increase in LL in women and the likelihood of LBP, as women generally exhibit greater lumbar curves. Gender differences in pain, particularly in relation to LL and LBP, may be influenced by body weight. Higher BMI in women has been associated with changes in LL (Miranda et al., 2022) and affected LBP levels (Wojcik et al., 2020). As LL is believed to be influenced by individual's BMI, more research is needed to explore gender differences. This review indentified only one study that compared genders (Pourahmadi et al., 2020), while another study focused only on women (Wójcik et al., 2020), whereby both studies focused on LL related to LBP. Understanding how BMI affects LL in men and women is crucial for improving knowledge and developing gender-specific LBP prevention programs.

Age

One articles within this review delved into the influence of age on LL angles, exploring its contribution to lordotic posture and its association with LBP. The correlation between LL and LBP is particularly notable among younger patients, as shown by the strong association with LSA (Zhan et al., 2023). Furthermore, a study evaluating patterns of sagittal standing posture in children, conducted by Araújo et al. (2016), offered valuable insights into age-related differences in spinal curvatures during development. Emphasizing the significance of posture within different age groups, Hasegawa et al. (2018) indicated that poor posture increases the risk of LBP. Krautwurst et al. (2018) also found that age affects spinal conditions, contributing to LBP. As younger patients' musculoskeletal systems are generally more adaptive and flexible, which can lead to postural changes, such as increased LL, especially in people who engage in activities that promote poor posture, such heavy backpacking or prolonged sitting. According to Mirbagheri et al. (2015), increased LL can strain on the lumbar spine and cause discomfort.

Nowadays, many young people lead sedentary lifestyles, partly due to the increased use of electronics. Sitting for long periods can cause muscle tension and also reduce LL, both of which are linked to LBP. Besides, young people who are active in sports and other physical activities that

promote good core strength may help lessen these consequences. Such activities can also increase the risk of changes in LL, and pain may result from improper training techniques or overuse injuries (Tang et al., 2023). However, more research is needed to determine whether age affects the LL angle in adults and older adults, which would help raise awareness about the importance of preventing the worsening of the LL angle changes with age.

Limitations and Future research

This systematic review has several limitations. First, the scope of this review was constrained by the inclusion of only six articles, which may limit the relevance of the findings to larger populations or specific groups. Second, the inclusion of studies with diverse methodologies may pose challenges in synthesizing findings cohesively and drawing conclusive insights. Future research should include more extensive and diverse pool of studies to enhance the robustness and generalizability of systematic reviews in this domain.

CONCLUSION

This systematic review has identified nature of work, body posture, and gender as possible factors contributing to abnormal LL associated with LBP. Age can also be one of the factors, but further research is required to provide more evidence on the relationship between age, LL and LBP. This review study clarified the complex relationship between LL angles and LBP, highlighting the necessity for a comprehensive understanding of the various elements influencing lordotic posture. The findings emphasize the need to consider these factors when assessing and treating lordotic posture and LBP. A comprehensive understanding of these risk factors is crucial for formulating focused preventive and management strategies, particularly for individuals at high risk of experiencing these conditions.

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Appendix

Table 3: Characteristic of included studies

Author /Year	Study Design	Participants / Inclusion criteria	Outcome measures	Results
Zhan et al. (2023)	Retrospective study	Participants: n = 148 (Female = 79; Male = 69) Groups: 1) NLDH group = 68 patients 2) LDH group = 80 patients Inclusion criteria 1) LBP more than 3 months, with or without radiating pain in lower extremities. 2) Age 30-40. 3) No history of severe lumbar trauma and surgery. 4) No lumbar disease such as scoliosis, lumbar spondylolisthesis, and lumbar tuberculosis.	1) Plain radiographs and magnetic resonance scan - Cobb angle = To measure LL angle - Measure IVA - Fergason method = To measure LSA	LL angle and IVA in LDH group was significantly smaller than in NLDH group (P<0.001). LSA in LDH group was significantly higher than in NLDH group (P<0.001). Age 1) Young patients with LBP which have smaller LL and IVA, and higher LSA were significantly correlated with LDH (P<0.05).
Malarvizhi et al. (2023)	Cross-sectional study	Participants: n = 30 Inclusion criteria 1) Age 25-50 years. 2) Acute mechanical LBP due to occupation, prolong standing and prolong sitting workers: duration > 4-5 hours, working experience >1year in same field.	1) Pain - Numerical pain rating scale (NPRS) 2) Disability - Quebec back pain disability scale 3) LL – Flexible ruler	Nature of work and Posture 1) The changes in LL angle were identified during prolong standing and sitting posture while working. 2) LBP is prevalent in working professional who have prolonged standing postures compared to sitting postures (P<0.04).
Pourahmadi et al. (2020)	Comparative observational study	Participants: 1) CNLBP group: n=26 2) Asymptomatic group: n=26 Inclusion criteria 1) CNLBP > 3 months in the absence of underlying pathology 2) Age 18-40. 3) Patients have ability to perform STS and SIT movements without aid	1) STS and SIT movement – High-resolution cameras, a 3-dimensional motion-capture system. The LL was analysed using Qualisys Track Manager and Microsoft Excel	Decreased LL in CNLBP group during STS and SIT compared with the Asymptomatic group (P<0.05). Gender 1) Female in asymptomatic and CNLBP groups showed significant greater mean LL values compared to males during STS (P<0.05). 2) Female in asymptomatic group showed significant greater mean LL values during STS compared to males (P<0.05).

Author /Year	Study Design	Participants / Inclusion criteria	Outcome measures	Results
Wójcik et al. (2020)	Cross-sectional study	Participants: n = 227 Groups: 1) Normal lordosis (135°-140°) 2) Shallow lordosis – higher values of LL angle (hypolordosis) 3) Deepened lordosis – lower values of LL angle (hyperlordosis) Inclusion criteria 1) Women over 50 years old with experience of pain at the lumbosacral spine.	1) Pain – Visual analogue scale 2) Collect lumbar angle at different slice locations - Multi Slice Computed Tomography (MSCT) 3) Body mass index	LL angle was associated with pain sensation of the lower back in the women population of the study (P<0.05). Gender: Body weight of women 1) Hyperlordosis significantly correlates with highest BMI, but lowest pain level (P<0.05). 2) Hypolordosis significantly correlates with lower BMI, but highest pain level (P<0.05).
Proskura and Sobera (2019)	Cross-sectional study	Participants: n = 68 Inclusion criteria 1) Female: participate in fitness activities 2) 25-70 years old	1) Disability due to LBP in everyday life– Oswestry Disability Index 2) Angle of LL – Saunder's digital inclinometer	Nature of work 1) There is a difference between angular values of LL and type of worked performed (P = 0.03). - Slightly lower angular values of LL were identified among participants who performed physical activity compared to those who performed sedentary work. - Lower angular values of LL were identified among pensioners compared to those who performed sedentary and physical works. 2) LBP increases among people performing sedentary work. Posture 1) The intensity of back pain of the participants was moderately associated with level of pain during sitting (r = 0.48).
Sorensen et al. (2015)	Cross-Sectional Study	Participants: n = 57 - Female = 28, Male = 29 - PD = 24, NPD = 33 Inclusion criteria 1) No lifetime history of an episode of LBP	1) Pain – Visual Analogue Scale 2) Participants habitual physical activity – Baecke Questionnaire of Habitual Physical Activity 3) LL (prior to 2 hours standing) – Marker position (motion capture system)	Nature of work and Posture 1) LL during standing among PD participants was significantly larger compared to NPD participants (P = 0.02) 2) The curvature angle of LL during prolong standing (2 hours) has a significant relation to LBP symptom intensity (pain) (P = 0.02).

**Note. LL= Lumbar Lordosis; NLDH=Non-Lumbar Disc Herniated; LDH=Lumbar Disc Herniated; IVA=Intravertebral Angle; LSA=Lumbosacral Angle; CNLBP=Chronic Non-Specific Low Back Pain; PD=Pain Developer; NPD=Non-Pain Develop; STS=Sit to Stand; SIT=Stand to Sit