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Knowledge, practices and regulatory challenges associated with portable handheld dental x-ray devices utilization among Indonesian dentists: A cross-sectional study

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Abstract

Objective: This study aimed to assess the knowledge of Indonesian dentists regarding the usage, safety practices, and regulatory frameworks for portable handheld dental X-ray devices.

Material and Method: A descriptive, cross-sectional study was conducted among dentists in Surabaya, Indonesia, between June and October 2024. A total of 1,770 dentists were invited to participate via an online questionnaire, with 184 completing the survey (10.4% response rate). The validated questionnaire assessed knowledge across 12 fields, each with subpoints. A Likert index percentage formula was used to quantify knowledge, and logistic regression analysis explored correlations between knowledge levels and professional characteristics.

Results: Dentists' overall knowledge was moderately low (44.9%). Ownership of handheld devices was associated with lower knowledge of licensing requirements (OR=0.089, p=0.002), radiation protective equipment (OR=0.122, p=0.016), and acrylic shielding plates (OR=0.214, p=0.041). Years of practice positively correlated with interest in purchasing devices (OR=2.230, p=0.020).

Conclusion: Despite their benefits, portable handheld dental X-ray devices pose risks without proper training and adherence to regulations. Targeted education, standardized training, and regulatory clarity are essential to ensure safe and compliant use in clinical practice.

Keywords: Dental radiography, Diagnostic, health services, radiation safety, safety regulations, x-rays
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Introduction

Radiographs are vital in daily clinical dentistry, offering diagnostic insights beyond standard examinations.[1] They support diagnosis, treatment planning, and outcome evaluation. Recent advancements have introduced portable handheld dental X-ray devices, which are compact and designed for ease of use.[2] As noted by Indonesia's Nuclear Energy Regulatory Agency (BAPETEN), these suitcase-equipped devices are portable and user-friendly.[3] Unlike conventional units, clinicians operate them by hand during exposure.[4] Though they emit lower radiation doses, strict safety protocols are crucial to protect operators and patients.[5]

The availability of portable X-ray devices has expanded globally, with growing sales through online marketplaces. In Indonesia, both certified and uncertified devices are increasingly marketed by dental distributors, prompting regulatory concerns.[6,7] Their advantages include portability, affordability, and usefulness in specific situations, such as treating sedated or remote patients.[8,9] However, their growing use underscores the need for strict safety guidelines.

Globally, the use of portable handheld dental X-ray devices has increased significantly.[7,10,11] Both the UK and South Korea lack specific national regulations exclusively addressing the routine use of handheld dental X-ray devices.[12,13] In the UK, their use is guided by general radiation safety principles under the Ionising Radiations Regulations 2017 (IRR17), which require dental practices to register with the Health and Safety Executive (HSE).[13] In the United States, these devices are permitted in some states but must comply with stringent safety and performance standards set by the FDA, with non-compliant devices flagged as unsafe due to issues such as inadequate shielding and excessive radiation doses.[14] In Indonesia, BAPETEN regulations prohibit routine use, allowing these devices only in specific scenarios, such as remote areas, disaster relief, conflict zones, and mass screenings.[3] Similarly, the Ireland Environmental Protection Agency and the Heads of the European Radiological Protection Competent Authorities (HERCA) further discourage the routine use of handheld devices, recommending their application only in exceptional scenarios, such as nursing homes, residential care facilities, forensic investigations or remote operations.[15,16]

Although portable handheld devices offer convenience, they also pose risks, particularly for operators. Proximity to the X-ray tube during exposure increases radiation exposure risks.[17,18] Leakage and scattered radiation can expose operators to ionizing radiation, but studies show that protective measures—such as backscatter shields, lead aprons, and maintaining distance—can effectively minimize these risks.[18,19] Radiation leakage is generally minimal

Table 1. Characteristic of respondents.

Characteristic	N	%
Age		
21-30	86	46.7
31-40	58	31.5
41-50	23	12.5
51-60	13	7.1
61-70	4	2.2
Gender		
Male	57	30.9
Female	127	69.1
Professional **Background**		
General Dentist	136	73.9
Specialist Dentist	48	26.1
Years of Practice		
<5 years	76	41.3
>5 years	108	58.7
Own a Portable Handheld Dental X-ray		
Yes	26	14.1
No	158	85.9

Table 2. Distribution of respondents' answers of knowledge in each section.

Field(s) of Knowledge	Final Likert Scoring Scale	n (%)
(1) Knowledge of portable handheld dental x-ray devices	Very knowledgeable about	26 (14.1%)
	Knowledgeable about	132 (71.7%)
	Uncertain	10 (5.4%)
	Unknowledgeable about	16 (8.7%)
	Very unknowledgeable about	0
(2) Knowledge of regulatory agency that regulates the safety and licensing of portable handheld dental x-ray devices	Very knowledgeable about	17 (9.2%)
	Knowledgeable about	81 (44%)
	Uncertain	26 (14.1%)
	Unknowledgeable about	42 (22.8%)
	Very unknowledgeable about	18 (9.8%)
(3) Know and understand the basic law of safety radiation protection in the use of portable handheld dental x-ray devices	Very knowledgeable about	4 (2.2%)
	Knowledgeable about	33 (17.9%)
	Uncertain	45 (24.5%)
	Unknowledgeable about	65 (35.3%)
	Very unknowledgeable about	37 (20.1%)
(4) Knowledge that the device must get a license to be used	Very knowledgeable about	18 (9.8%)
	Knowledgeable about	100 (54.3%)
	Uncertain	16 (8.7%)
	Unknowledgeable about	34 (18.5%)
	Very unknowledgeable about	16 (8.7%)
(5) Knowledge of licensing processes that must be submitted to the official regulator agency (BAPETEN)	Very knowledgeable about	4 (2.2%)
	Knowledgeable about	32 (17.4%)
	Uncertain	37 (20.1%)
	Unknowledgeable about	74 (40.2%)
	Very unknowledgeable about	37 (20.1%)
(6) Knowledge of obligation to use radiation protective equipment by operators during exposure	Very knowledgeable about	53 (28.8%)
	Knowledgeable about	113 (61.4%)
	Uncertain	10 (5.4%)
	Unknowledgeable about	8 (4.3%)
	Very unknowledgeable about	0
(7) Know that the device can emit the radiation effect as any other x-ray machine	Very knowledgeable about	37 (20%)
	Knowledgeable about	103 (56%)
	Uncertain	37 (20%)
	Unknowledgeable about	7 (4%)
	Very unknowledgeable about	0
(8) Know that the device can emit radiation effects that harmful to the operator and patient	Very knowledgeable about	37 (20%)
	Knowledgeable about	116 (63.2%)
	Uncertain	19 (19%)
	Unknowledgeable about	10 (10%)
	Very unknowledgeable about	1 (1%)
(9) Knowledge of obligation to maintenance the device	Very knowledgeable about	37 (20%)
	Knowledgeable about	107 (58.4%)
	Uncertain	13 (7.2%)
	Unknowledgeable about	24 (12.8%)
	Very unknowledgeable about	3 (1.6%)
(10) Knowledge of operator's obligation of being in the right position and angle according to existing procedures	Very knowledgeable about	32 (17.6%)
	Knowledgeable about	107 (58.4%)
	Uncertain	29 (16%)
	Unknowledgeable about	15 (8%)
	Very unknowledgeable about	0
(11) Knowledge that personnel except operator and patient have to maintain a certain distance from the device	Very knowledgeable about	34 (18.4%)
	Knowledgeable about	119 (64.8%)
	Uncertain	16 (8.8%)
	Unknowledgeable about	13 (7.2%)
	Very unknowledgeable about	1 (0.8%)
(12) Knowledge of acrylic plate that must be fixed to the device as a back-scatter shield	Very knowledgeable about	10 (5.6%)
	Knowledgeable about	66 (36%)
	Uncertain	34 (18.4%)
	Unknowledgeable about	40 (21.6%)
	Very unknowledgeable about	34 (18.4%)

compared to scatter, and exposure levels typically remain below occupational dose limits of 50 mSv/year when safety protocols are followed.[17,20] However, inconsistent compliance with radiation safety norms in many settings poses ongoing risks.

Advancements in device design, such as longer cylinders and rectangular collimators, have improved safety by reducing scattered radiation.[8] Additionally, maintaining a 2-meter distance from the X-ray source for other staff and ensuring operators use extended arm positions during exposure further reduce risks.[21] Stricter enforcement of regulations is critical for ensuring the consistent application of protective measures, including mandatory operator training and monitoring cumulative radiation doses.[3] Stochastic radiation effects, such as cancer and genetic damage, highlight the need for ALARA-based practices.[22–24] While these devices emit lower radiation doses, frequent use can lead to cumulative exposure.[7] Therefore, regulatory adherence and safety practices are essential. This study aimed to assess Indonesian dentists' knowledge of handheld dental X-ray device usage, safety, and regulations.

Material and Methods

This study adhered to the principles outlined in the Helsinki Declaration of 1975, as revised in 2000, and the research protocol was reviewed and approved by the Universitas Airlangga Faculty of Dental Medicine Health Research Ethical Clearance Commission (Approval No. 517/HRECC.FODM/VIII/2022). Written informed consent was obtained from all participants prior to their involvement in the survey. Furthermore, participants' confidentiality was strictly maintained by ensuring that no names or any private data were mentioned or recorded in the data collection and analysis process.

This research was a descriptive study employing a cross-sectional approach, with the population and sample comprising a group of dentists practicing in the city of Surabaya, Indonesia. The study was conducted from June to October 2024, using a random sampling method to recruit participants. A total sample of 1,770 dentists domiciled in Surabaya based on the official database of the Indonesian Dentist Association (PDGI) were invited to participate via an online questionnaire distributed through Google Forms. The questionnaire was shared on social media platforms and broadcasted as a message using the official account of PDGI to the members. The recruitment process involved contacting potential respondents, explaining the purpose of the study, and outlining the inclusion and exclusion criteria. Inclusion criteria required participants to be general or specialist dentists registered within PDGI's database, domiciled in Surabaya, and actively practicing in private clinics or hospitals. Respondents who did not fully complete the questionnaire were excluded from the study.

This study aimed to evaluate dentists' under-

Table 3. Identified significant relationships based on the logistic regression analysis.

Variable of characteristics	Field(s)	Estimate (B)	Odds Ratio (OR)	95% CI for OR	p-value
Years of practice	Interest in purchasing	-2.112	0.121	[0.025, 0.596]	0.005
Ownership	Knowledge the basic law of safety radiation	-.2418	0.089	[0.019, 0.406]	0.002
	Licensing process to national regulator	-2.107	0.122	[0.022, 0.675]	0.016
	Obligation to use protective equipment	-1.543	0.214	[0.047, 0.965]	0.041
	Knowledge of acrylic shielding plate	0.802	2.230	[1.129, 4.406]	0.020

standing using a validated questionnaire assessed knowledge across 12 fields, each containing subpoints addressing specific aspects of safety and usage. After describing the distribution of respondents' answers regarding the knowledge variable, the answers were categorized to determine the level of knowledge about radiation protection safety in the use of portable handheld dental X-ray devices. To quantify the knowledge level, a percentage index formula was calculated, converting respondents' answers into Likert scale scoring numbers. The resulting percentages were calculated using the provided index and matched against the interpretation table to classify the overall respondents' knowledge sentiment level accurately.

The instruments utilized in this study included an informed consent form, an online questionnaire via Google Forms, Microsoft Excel 2019 (Microsoft Corp., Redmond, WA, USA) for data organization, and IBM SPSS statistics software (version 26.0; IBM Corp., Armonk, NY, USA) for analysis. Statistical tests were conducted to evaluate the validity and reliability of the questionnaire items. Descriptive statistics were calculated to summarize the demographic and baseline characteristics of the participants. Subsequently, logistic regression analysis was conducted to examine the individual relationships between specific fields of knowledge and distinct professional backgrounds, years of practice and ownership characteristics. A priori power analysis was conducted using G*Power (version 3.1.9.7; Germany) to determine the minimum sample size required for logistic regression analysis. Assuming a medium effect size (odds ratio = 1.5), an alpha level of 0.05, statistical power of 0.80, and inclusion of up to 10 predictors, the minimum required sample size was calculated to be approximately 308 participants.

Results

The results confirmed that all questions used in this study were both valid and reliable, ensuring the robustness of the data collected. The validity of the instrument, as assessed during a pilot test, was confirmed with a significance level of $p<0.001$ (two-tailed), indicating strong construct validity. Reliability was assessed using Cronbach's alpha, which yielded a value of 0.752, demonstrating an acceptable level of internal consistency for the items included in the questionnaire. These results confirm that the instrument was both valid and reliable for assessing dentists' knowledge regarding portable handheld dental X-ray devices.

Out of the total population, only 184 respondents met the inclusion criteria and completed the questionnaire, resulting in a final response rate of 10.4%. Since a minimum sample size of 308 is required to achieve a statistical power of 80% with a 5% significance level, this study's sample size of 184 respondents falls short of the recommended threshold, which may limit the ability to detect smaller effects. All data provided by respondents is complete and can be analyzed. The demographic and professional characteristics of the respondents are presented in table 1, while the distribution of their responses concerning knowledge of portable handheld dental X-ray devices is detailed in table 2. Using the Likert index percentage formula, calculated by dividing the total score by the total number of respondents and multiplying by 100, the analysis revealed that respondents' overall knowledge of radiation protection and safety in the use of portable handheld dental X-ray devices was categorized as moderately low, with a score of 44,9%.

In the logistic regression analysis, most fields of knowledge showed no significant relationships with dentists' professional background, years of practice, or ownership characteristics ($p>0.05$), underscoring the limited influence of these factors across the majority of knowledge areas. However, significant associations were identified in specific cases. Years of practice was positively correlated with interest in purchasing portable X-ray devices (OR=2.230, 95% CI:1.129–4.406, p=0.020). Ownership of portable X-ray devices also demonstrated significant associations with several knowledge areas. It was positively associated with knowledge of the basic law of safety radiation protection (OR=0.121, 95% CI: 0.025-0.596, p=0.005) and licensing processes (OR=0.089, 95% CI: 0.019-0.406, p=0.002). Conversely, ownership was negatively associated with knowledge of radiation protective equipment (OR=0.122, 95% CI: 0.022–0.675, p=0.016) and the use of acrylic shielding plates (OR=0.214, 95% CI: 0.047–0.965, p=0.041). These results are summarized in table 3.

Discussion

This study assessed dentists' knowledge of the utilization and safety practices associated with portable handheld dental X-ray devices using a validated questionnaire comprising 12 main items. Overall, the participants in this study demonstrated a moder-

ately low level of knowledge in general, with a final calculated score of 44.9%. Several areas of concern were identified, revealing gaps in understanding that warrant further investigation and targeted educational efforts.

The majority of dentists demonstrated strong knowledge about portable handheld dental X-ray devices, with 14.1% being "very knowledgeable" and 71.7% "knowledgeable". This high awareness can be attributed to the rapid development of technology and the demand for dentists to stay updated with advancements in dental science and technology. Most respondents admitted that they became familiar with the devices through their regular suppliers, exhibitions at seminars and dental conferences, as well as social media, with a small portion discovering them through online marketplaces. Furthermore, the widespread accessibility of these devices through various channels and media without significant limitations has further enhanced exposure and familiarity.[7,14]

Dentists' knowledge of regulatory agencies overseeing safety and licensing, such as BAPETEN, was moderate, with 9.2% classified as "very knowledgeable" and 44% as "knowledgeable". This reflects the importance of radiographic devices in dentistry and the necessity of complying with safety regulations. However, knowledge about the basic laws of radiation protection was notably lower, with 35.3% of respondents categorized as "unknowledgeable" and 20.1% as "very unknowledgeable". Similarly, awareness of the licensing process and requirements for these devices was limited, with 40.2% "unknowledgeable" and 20.1% "very unknowledgeable". These findings point to the need for increased regulatory outreach and comprehensive educational efforts tailored to the Indonesian context. Furthermore, comparative insights from regions with stringent handheld X-ray regulations, such as the United States and Europe, could guide policy adaptations in Indonesia. Adopting standards like FDI guidelines or CE certification as a baseline requirement could ensure that these devices meet strict safety and performance criteria before being sold or used. These devices must undergo rigorous testing to validate their safety, effectiveness, and reliability, thereby minimizing radiation exposure to operators, patients, and the public.

Dentists generally demonstrated a strong understanding of key radiation safety measures, including the use of protective equipment, maintaining proper positioning and angles, and ensuring safe distances for non-operators and patients. The majority of respondents identified themselves as "knowledgeable" or "very knowledgeable" in these areas. However, the positioning and angles required for portable handheld dental X-ray devices differ significantly from those for conventional units, as the operator directly holds the device during operation.[1,25] Overangulating these handheld devices can increase radiation exposure,[25] and estimated annual operator exposures are expected to be higher compared to wall-mounted or portable devices activated from a protected area, such as at a distance or behind shielding.[2] This underscores the need for specific and distinct safety measures to mitigate these risks. Consequently, handheld devices should only be used in scenarios where patient accessibility makes their use necessary, and when a portable device on a stand or a wall-mounted unit is not reasonably feasible. Although most respondents claim to have a solid grasp of radiation safety, it is uncertain whether they fully understand the additional precautions required for handheld devices. These measures are fundamental to radiation protection and are reinforced by regulatory requirements. Future research should assess adherence to these safety protocols in clinical settings to identify gaps in implementation and address any deficiencies in understanding.

Most dentists recognized that portable handheld X-ray devices emit radiation similar to other X-ray machines, with 56% "knowledgeable" and 20% "very knowledgeable". Respondents were also aware of the harmful effects of radiation on operators and patients, as well as the need for maintenance to optimize radiation safety. This reflects a foundational understanding of the potential risks associated with these devices and their proper maintenance.

A significant gap was identified in dentists' knowledge regarding the requirement for an acrylic protective shielding plate to be fixed to the device. Many respondents were "uncertain" (18.4%), "unknowledgeable" (21.6%), or "very unknowledgeable" (18.4%). Notably, 17 out of 26 respondents who currently use such devices also expressed uncertainty regarding this requirement. Acrylic plates serve as an additional protective barrier against back-scattered radiation exposure, and their use is mandated in most international guidelines and studies.[7,10,12] However, the absence of specific national regulations addressing acrylic plates likely contributes to the low awareness. Given this gap, collaborative initiatives between regulatory bodies and professional associations could be pivotal in improving awareness and compliance. Practical demonstrations and guidelines on the use of acrylic plates might further support their adoption in clinical settings.

The respondents' sentiment toward

purchasing portable handheld dental X-ray devices demonstrated a diverse distribution. A significant proportion (41.6%) expressed a willingness to buy the devices, reflecting notable interest in adopting this technology. Meanwhile, 24.8% of respondents reported uncertainty about making a purchase, suggesting hesitance or a need for additional information and assurance. While the rest of 32% expressed no intention to purchase the devices, indicating a lack of interest or perceived necessity. Various factors influence these decisions, including perceived utility, cost considerations, familiarity with the technology, and concerns about radiation safety.

The Likert percentage value indicates that dentists' knowledge of portable handheld dental X-ray devices is moderately low (44.9%), falling below the neutral threshold of 50%. Based on the logistic regression results, this study highlights that dentists who own portable handheld dental X-ray devices are significantly less likely to report higher levels of knowledge about licensing processes. This finding suggests that despite owning the devices, participants may lack sufficient understanding of licensing requirements. Similarly, device owners were less likely to demonstrate higher knowledge about the obligation to use radiation protective equipment and the use of acrylic shielding plates. Regrettably, a small number of owners in this study reported regularly using portable X-ray devices in their clinical practice, raising concerns about their practical implementation amid unclear licensing and regulatory frameworks in the country. Additionally, dentists with more years of practice, and thus greater experience, were significantly more likely to express a higher interest in acquiring portable X-ray devices, possibly reflecting increased exposure to practical applications or higher patient demand driving this interest. These findings underscore the importance of targeted educational initiatives, particularly for non-owners, alongside strategies to promote adherence to current best practices among senior dentists. Establishing standardized and comprehensive training programs is essential to ensure uniform understanding and compliance with radiation safety protocols across the profession.

This study has several limitations. The reliance on self-reported questionnaire responses introduces potential bias, as participant honesty could not be verified. Additionally, the use of a Likert scale with a neutral response option limited the ability to determine definitive trends in responses. Furthermore, while the study assessed knowledge, it did not evaluate the practical application of this knowledge, leaving uncertainty about whether dentists' understanding translates into adherence to safety protocols. Moreover, the large sample size enhances the reliability of the descriptive findings, ensuring that the results are representative of the surveyed population. Future investigations should prioritize assessing the practical application of dentists' knowledge of radiation safety measures to ensure alignment with clinical practices. Targeted educational initiatives should address critical knowledge gaps, particularly in areas such as regulatory compliance and the use of protective equipment like acrylic shielding plates. Any regulatory bodies, including BAPETEN, must intensify efforts to establish and disseminate clear, comprehensive guidelines for portable handheld X-ray devices. Furthermore, interagency collaboration and the integration of international best practices in radiation safety can expedite the development of robust regulatory frameworks. Regular training programs focusing on technical proficiency and regulatory compliance are essential to enhance diagnostic accuracy and mitigate radiation-related risks.

Notably, the routine use of portable handheld X-ray devices by many dentists currently violates existing regulations, which explicitly prohibit their daily application. Such unauthorized use undermines regulatory authority and increases radiation risks for patients, operators, and the public due to inadequate safety measures. While these devices are valuable for specific applications, such as in remote or emergency scenarios, their use in routine clinical practice requires stringent operational guidelines and mandatory safety protocols. Multiple studies have shown that handheld X-ray devices can provide diagnostic image quality comparable to wall-mounted units;[17,26,27] however, they are more prone to critical errors, such as cone-cutting and horizontal angulation issues.[26] These devices should be operated by trained personnel with strict adherence to protective measures, ideally using equipment equipped with protective discs and elongated cones, and are best suited for specific settings.[28] This highlights the need for proper operator training to achieve optimal results and minimize radiation exposure risks. Furthermore, this study emphasizes the importance of continuous education, regulatory reinforcement, and rigorous oversight to empower dentists in adopting safe and compliant practices when using portable handheld dental X-ray devices.

Conclusion

This study reveals significant gaps in dentists' knowledge of portable handheld dental X-ray devices, with a Likert index of 44.9% indicating moderately low awareness. Ownership was associated with lower knowledge of licensing requirements, protective equipment, and acrylic shielding plates, highlighting insufficient training and regulatory oversight. While experienced dentists showed greater interest in adopting these devices, inconsistent safety practices pose risks to operators, patients, and the public. These findings emphasize the need for targeted education, standardized training, and clearer regulations to ensure safe and compliant device use. Collaborative efforts are crucial to bridging knowledge gaps and enhancing radiation safety in clinical settings.

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Conflict of Interest

The authors report no conflict of interest.

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