ORIGINAL ARTICLE

A Cross-Sectional Study on Solid Oral Dosage Form Modifications among Older Patients Admitted to A Malaysian Teaching Hospital

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ABSTRACT

INTRODUCTION: Older adults often require multiple medications, increasing their risk of polypharmacy and drug-related problems (DRPs). Solid oral dosage forms (SODFs) are the most common medication formulation used by patients. However, administering SODFs to older adults can be challenging, especially for those with swallowing difficulties, leading to practices such as crushing, splitting tablets, or opening capsules. These modifications can affect medication efficacy and safety. This study aims to examine the prevalence of SODF modification among hospitalized older adults, the methods used, the reasons for modification, and the appropriateness of these practices. **MATERIALS AND METHOD:** This cross-sectional study included patients aged 60 years and above admitted to the general medical ward of a tertiary teaching hospital. Eligible participants were identified through the hospital's electronic registration system. Sociodemographic and clinical data were collected using a standardized form. Participants were interviewed about their SODF modification practices, and swallowing difficulties were assessed using the PILL-5 questionnaire. **RESULTS:** Of 122 participants, 54.1% were aged 60–69, and 9.8% reported dysphagia. SODF modification was practiced by 55.7%. Swallowing problems and pill dysphagia are significantly associated with SODF modification. Among those modifying SODFs, 47.1% incorrectly believed all medications could be safely altered. Splitting tablets was the most common practice (92.6%). **CONCLUSION:** Both dysphagia and pill dysphagia are significantly associated with SODF modification practices among older patients. Healthcare providers should be vigilant about these practices in older patients with swallowing difficulties. Proper education and assistance in medication handling are essential for this population.

Keywords
Solid oral dosage form, modification, older people

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INTRODUCTION

Global advancements in healthcare, early diagnosis, and effective treatments have increased life expectancy, leading to a growing population of older adults.[1] This aging population is associated with a higher prevalence of multi-morbidity, [2] which often necessitates the use of multiple medications.[3,4] Solid oral dosage forms (SODFs), such as tablets and capsules, constitute approximately 65% to 70% of the available dosage forms in the market,[5,6] and are commonly used by older patients.[7,8]

However, administering SODFs to older people presents challenges that sometimes necessitates modifications, such as crushing or splitting tablets and opening capsules.[9] These medication modification practices are often adopted by older adults to overcome difficulties associated with administration, which are influenced by various factors. These factors include the physical characteristics of the medication, such as size and shape, as well as medical conditions like stroke or age-related swallowing difficulties[10] Research indicates that a significant proportion of older people modified medications, highlighting the need to address this issue.[10-13]

SODF modifications can lead to several potential issues, including drug instability, unpalatable taste, and improper administration of doses, potentially resulting in underdosing or overdosing.[11,14] Alarmingly, fatal outcomes from SODF modifications have been reported.[15] Additionally, modifying SODFs adds extra steps for older adults before administering drugs, thus can increase the complexity of their medication regimen, and potentially decreasing medication adherence.[16]

Certain medications in modified-release formulations must be ingested intact to ensure proper drug absorption. Modifying these SODFs can significantly impact their efficacy.[17,18] Furthermore, improper handling of modified SODFs, especially those containing allergenic, teratogenic, or carcinogenic substances, can pose serious health risks.[11] Additionally, off-label use of modified SODFs not explicitly indicated in product labelling can result in legal complications and adverse drug events.[19]

Despite these risks, SODF modification practices remain prevalent among older adults, particularly in care settings where medications administration often relies on caregivers. Studies conducted in Australia and Norway have explored these practices in nursing homes for the elderly. For instance, 18% of SODF modifications were reported in Australian residential aged care facilities, while 20.5% were conducted by nurses in Norwegian nursing homes. Notably, the prevalence of inappropriate SODF modifications was reported to be 32% in the Australian study and 10.7% in the Norwegian study.[7,8] Furthermore, Forough et al. (2020) highlighted that 12.5% of SODF modifications in Australian aged care facilities were classified as inappropriate, with 88.5% of these cases occurring despite the availability of suitable alternative formulations.[20]

Hospitals play a pivotal role in the care of older adults with complex medical conditions and polypharmacy. Unlike nursing homes, where medication management is primarily overseen by caregivers, many hospitalized older adults manage their own medications prior to admission and after discharge. The hospital setting also differs significantly in terms of the acuity of medical conditions and the complexity of care. This population may face unique challenges in medication management, including difficulties in administering SODFs due to acute illnesses, polypharmacy, or dysphagia, which require immediate intervention. A thorough understanding of SODF modification practices in the hospital setting is crucial to improving medication safety for older patients.

Despite the clinical relevance of this issue, no published studies have yet explored the prevalence or practices of SODF modifications among older adults in Malaysia. The objectives of this research are to investigate the prevalence of SODF modifications among a group of inpatient older adults, determine the practices of SODF modification within the group, identify the reasons for the modifications, and assess the appropriateness of the modifications.

MATERIALS AND METHODS

Study design

This cross-sectional study was conducted at Al-Sultan Abdullah Hospital (HASA), a 400-bed teaching hospital affiliated with *Universiti Teknologi* MARA (UiTM) and located in Puncak Alam, Selangor, Malaysia. The study was carried out over a six-week period from June to July 2023. Ethics approval was granted by the Research Ethics Committee of UiTM (600-FF[RES.5/4]), and permission to conduct the research at HASA was obtained from the hospital research committee (500-PJI [18/4/50]). Written informed consent was obtained from all study participants prior to their inclusion in the study.

Study participants

The Inclusion criteria for the study encompassed older patients aged 60 and above who were admitted to the general medical ward at HASA, were currently using at least one long-term SODF medication (defined as medications used for one month or longer), were proficient in either Malay or English, and willing to participate in the study. Exclusion criteria included patients with cognitive impairment or those with inaccessible chronic medication records. The number of participants recruited was determined using the Raosoft sample size calculator, with a 95% confidence level and a 5% margin of error, based on an estimated 170 older

patients in the medical ward over six weeks. The minimum number of participants required for the study was calculated to be 119.

Study tool

The study employed a specially developed data collection form that incorporated a validated questionnaire to assess pill dysphagia. The form was structured into four main sections. Section 1 gathered sociodemographic information, including age, gender, race, and other relevant details. Section 2 covered medical and medication history. Section 3 featured the PILL-5 assessment tool, a validated questionnaire designed to evaluate pill-swallowing difficulty and quantify the severity of pill (capsule and tablet) dysphagia.[21] Finally, Section 4 investigated patients' practices regarding the modification of solid oral dosage forms (SODFs).

The data collection form underwent a review process involving six pharmacists with over five years of clinical experience, ensuring its content relevance and appropriateness. A pilot test was conducted in April 2023 on ten older patients to assess the form's usability and practicality. Both the pharmacist review and the pilot test confirmed the suitability and practicality of the data collection form for the study.

Study procedure

Participants were recruited using a convenience sampling method. Initially, potential participants were identified using an electronic patient registration system. They were then approached face-to-face in the medical ward, where they were screened against the inclusion and exclusion criteria. If eligible, they were asked to provide consent to participate. The primary researcher collected sociodemographic information and clinical details using a standardized data collection form. Various methods were employed to gather this information, including the Hospital Information System (UniMeds), which contains electronic medical records and medication charts, as well as patient interviews.

Comorbidities were assessed using the Age-adjusted Charlson Comorbidity Index (ACCI). This index assigns scores based on comorbid conditions as defined by the Charlson Comorbidity Index (CCI),[22] with additional points assigned based on age above 40 years.[23] Participants were categorized into three ACCI groups: low (0–1), intermediate (2–3), and high (≥ 4).

The Anticholinergic Cognitive Burden (ACB) score for each regular medication was determined using a validated calculator.[24] Medications were scored from 0 (no anticholinergic effects) to 3 (severe anticholinergic effects). The total ACB score for each participant was calculated by summing the scores of all regular medications.

Additionally, the participants completed the PILL-5 questionnaire to assess pill dysphagia using the interviewer-administered questionnaire. The questionnaire comprises five items scored on a scale of 0 to 4. A total score of less than 6 indicates normal pill swallowing, while a score of 6 or higher indicates abnormal swallowing. The internal consistency reliability of the tool was acceptable with a Cronbach's alpha value of 0.895.

Patients were also interviewed about their practices regarding the modification of SODFs. Those who had modified their SODFs were further questioned about specific medications, methods, devices used, administration practices, challenges encountered, and reasons for modification. For each modified SODF, the primary researcher assessed the appropriateness of the modification by reviewing the product inserts and existing guidelines.[25,26]

Statistical analysis

Statistical analysis was performed using IBM SPSS version 28 (IBM, Armonk, NY, USA). Categorical data were presented as frequency and percentage. The chi-square or Fisher's exact tests were used to compare categorical variables. Statistical significance was determined at a *p*-value <0.05.

RESULTS

A total of 156 older patients were hospitalized in the general medical ward during the 6-week data collection period, and all of them were screened for inclusion and exclusion criteria. Twenty-six patients did not meet the inclusion criteria and were excluded from the study. Additionally, of the 130 eligible patients, 8 refused to participate, giving a final total sample of 122 older patients.

Sociodemographic characteristics

The majority of the participants are in the 60–69 age group (66/122, 54.1%) and females (63/122, 51.6%) (Table 1). Most patients show an ACCI score of ≥4 (93/122, 76.2%). Additionally, the presence of dysphagia is noted in 9.8% (12/122) of participants.

Of the 122 participants, 68 (55.7%) practiced SODF modifications, while 54 (44.3%) did not. The analysis of participants' sociodemographic characteristics revealed no significant association with the practice of modifying SODFs. Similarly, no significant association is observed between the clinical characteristics, including ACCI categories and the number of medications, with the practice of modifying SODFs, except for the presence of dysphagia, which is significantly associated with SODF modification.

Table 1. Sociodemographic characteristics of study participants and their association with SODF modification practices (n=122)

Characteristics		All (n=122)	Practice SODF modification, n (%)		*p*-value [a]
			Yes (n=68)	No (n= 54)	
Age Group	60 – 69	66 (54.1)	32 (47)	34 (63)	0.154
	70 – 79	41 (33.6)	25 (36.8)	16 (29.6)	
	≥80	15 (12.3)	11 (16.2)	4 (7.4)	
Gender	Male	59 (48.4)	30 (44.1)	29 (53.7)	0.293
	Female	63 (51.6)	38 (55.9)	25 (46.3)	
Race	Malay	106 (86.9)	58 (85.3)	48 (88.9)	0.559
	Non-Malay	16 (13.1)	10 (14.7)	6 (11.1)	
Marital Status	Single	1 (0.8)	0 (0)	1 (1.8)	0.152 [b]
	Married	88 (72.1)	46 (67.6)	42 (77.8)	
	Widowed/ divorced	33 (27)	22 (32.4)	11 (20.4)	
Living arrangement	Living alone	4 (3.3)	1 (1.5)	3 (5.6)	0.472 [b]
	Living with a non-family caretaker(s)	6 (4.9)	4 (5.9)	2 (3.7)	
	Living with a family member (s)	112 (91.8)	63 (92.6)	49 (90.7)	
Highest education	Primary school	17 (13.9)	10 (14.7)	7 (13)	0.938
	Secondary school	53 (43.4)	30 (44.1)	23 (42.6)	
	Tertiary education	35 (28.7)	18 (26.5)	17 (31.5)	
	No education	17 (13.9)	10 (14.7)	7 (13)	
Employment	Employed	6 (4.9)	3 (4.4)	3 (5.6)	1.000 [b]
	Unemployed / Retired	116 (95.1)	65 (95.6)	51 (94.4)	
Age-adjusted Charlson comorbidity index	Low (0–1)	2 (1.6)	2 (2.9)	0 (0)	0.219 [b]
	Intermediate (2–3)	27 (22.1)	12 (17.6)	15 (27.8)	
	High (≥4)	93 (76.2)	54 (79.4)	39 (72.2)	
Presence of dysphagia[c]	Yes	12 (9.8)	11 (16.1)	1 (1.9)	***0.013*** [b]
	No	110 (90.2)	57 (83.8)	53 (98.1)	
Number of medications taken	<5	31 (25.4)	14 (20.6)	17 (31.5)	0.170
	≥5	91 (74.6)	54 (79.4)	37 (68.5)	
Anticho linergic burden (ACB) risk [d]	Low risk (<3)	113 (92.6)	62 (91.2)	51 (94.4)	0.493
	High risk (≥3)	9 (7.4)	6 (8.8)	3 (5.6)	

[a] Chi-square test used unless specified otherwise.
[b] Fisher's exact test used.
[c] Based on diagnosis documented in patient medical records.
[d] Based on total ACB score of all regular medications taken by patients.

Pill dysphagia and its association with SODF modifications

Table 2 presents patients' responses to the PILL-5 questionnaire items. Overall, 19.1% (13/68) of those practicing SODF modification reported experiencing pills sticking in their throat "almost always" and "always" compared to none among those not practicing SODF modification (*p*-value = 0.002).

Additionally, 10.3% (7/68) of those modifying SODF experienced interference with medication intake due to swallowing problems "almost always" and "always" in contrast to none among those not modifying SODF (*p*-value <0.001). Similarly, the need to crush pills or use other forms of assistance is notably higher among those modifying SODF. Specifically, 11.8% (8/68) of those modifying SODF required assistance "almost always" and "always" compared to none among those not modifying SODF (*p*-value <0.001).

Regarding the PILL-5 score classification, 86.9% (106/122) of participants exhibit a normal pill swallowing score (<6). However, a significantly higher percentage (23.5%) of individuals who practiced SODF modification exhibited dysphagia, as indicated by an abnormal score (≥6), compared to none among those who did not modify SODF (*p*-value <0.001).

Table 2. Pill dysphagia and its association with SODF modifications (n=122)

PILL-5 item	All (n=122)	Practice SODF modification, n (%)		*p*-value [a]
		Yes (n =68)	No (n=54)	
Pills stick in my throat				
Never or almost never	76 (62.3)	36 (52.9)	40 (74.1)	***0.002***
Sometimes	33 (27)	19 (27.9)	14 (25.9)	
Almost always and always	13 (10.7)	13 (19.1)	0 (0)	
Pills stick in my chest				
Never or almost never	115 (94.3)	62 (91.2)	53 (98.1)	0.327 [b]
Sometimes	5 (4.1)	4 (5.9)	1 (1.9)	
Almost always and always	2 (1.6)	2 (2.9)	0 (0)	
I have fear swallowing pills				
Never or almost never	112 (91.8)	59 (86.8)	53 (98.1)	0.059 [b]
Sometimes	8 (6.6)	7 (10.3)	1 (1.9)	
Almost always and always	2 (1.6)	2 (2.9)	0 (0)	
My problem swallowing pills interferes with my ability to take my medicine				
Never or almost never	108 (88.5)	54 (79.4)	54 (100)	***<0.001*** [b]
Sometimes	7 (5.7)	7 (10.3)	0 (0)	
Almost always and always	7 (5.7)	7 (10.3)	0 (0)	
I can't take my pills without crushing, coating, or using other forms of assistance				
Never or almost never	105 (86.1)	51 (75)	54 (100)	***<0.001*** [b]
Sometimes	9 (7.4)	9 (13.2)	0 (0)	
Almost always and always	8 (6.6)	8 (11.8)	0 (0)	
PILL-5 score classification				
• Pill swallowing is normal (score <6)	106 (86.9)	52 (76.5)	54 (100)	***<0.001***
• Pill swallowing is abnormal (score ≥6)	16 (13.1)	16 (23.5)	0 (0)	

[a] Chi-squared test used unless specified otherwise.
[b] Fisher's exact test used.

Medication modification practice among participants

Table 3 presents an overview of the medication modification practices among participants who were engaged in SODF modifications. A considerable portion of participants (32/68, 47.1%) believe that all medications could be safely modified, while 26.5% (18/68) are unsure, and another 26.5% (18/68) consider that not all medications are suitable for modification. Sources of information on SODF modifications vary, with 23.5% (16/68) relying on pharmacists, 22.1% (15/68) on doctors, and only 2.9% (2/68) referring to product leaflets. Overall, the 68 participants who practiced SODF modifications modified a total of 102 medications, averaging 1.5 modified SODFs per person. Among these participants, 63 split medications (92.6%), 5 crushed medications (7.4%), and 2 opened the capsules of medications (2.9%). One participant admitted to splitting and crushing the medications, while another participant practiced opening capsules and crushing the medications.

Table 3. Medication modification practice and experience among participants (n=68)

Medication modification practice and experience		n (%)
Perceived that all medications are safe to be modified	Yes	32 (47.1)
	No	18 (26.5)
	Not Sure	18 (26.5)
Source of information about SODF modification	Pharmacists	16 (23.5)
	Doctors	15 (22.1)
	Product leaflets	2 (2.9)
	Not specified	35 (51.5)
Method of SODF modification [a]	Splitting	63 (92.4)
	Crushing	5 (7.4)
	Opening (capsules)	2 (2.9)
	Splitting and crushing	1 (1.5)
	Opening (capsules) and crushing [b]	1 (1.5)

[a] Participants can provide more than one response and therefore responses do not add up to 100%.
[b] Capsules were opened and the pellets contained inside were crushed.

Specific methods, reasons, administration methods, and types of medications for SODF modifications

Table 4 specifically reports the methods of SODF modification, reasons for modification, administration methods after modification, and the types of medications that were modified before administration. For splitting (n=63), the main methods used are using hands (29/63, 46%), tablet splitters (27%), cutting with a knife (10/63, 15.9%), using scissors (8/63, 12.7%), using teeth (4/63, 6.3%), and using a paper cutter (1/63, 1.6%). The primary reasons for splitting are following the doctor's instructions (74.6%) besides having swallowing difficulty (9/63, 14.3%). Most participants (61/63, 96.8%) swallowed the split medication whole. The most common medications that were split include simvastatin tablet (10/63, 15.9%), atorvastatin tablet (9/63, 14.3%), and bisoprolol tablet (8/63, 12.7%).

In the case of crushing (n=5), the methods used include tablet crushers (2/5, 40%), mortar and pestle (2/5, 40%), and the back of a spoon (1/5, 20%). The main reason for crushing is due to swallowing difficulty (4/5, 80%). After crushing, the medications are either dissolved in water (3/5, 60%) or other liquids (2/5, 40%). The medications usually crushed include metformin (3/5, 60%), amlodipine (2/5, 40%) and atorvastatin (2/5, 40%) tablets.

Meanwhile, the reason for opening capsules (n=2) is primarily due to swallowing difficulty (2/2, 100%). The content of the capsules is either dissolved in water (1/2, 50%) or other liquids (1/2, 50%). The medication capsules commonly opened before administration are omeprazole.

Table 4. Specific methods, reasons, administration methods, and types of medications for SODF modifications

SODF Modification		n (%)
Splitting (n = 63)		
Splitting method used[a]	Using hands	29 (46)
	Using tablet splitter	17 (27)
	Cutting with knife	10 (15.9)
	Using scissors	8 (12.7)
	Using teeth	4 (6.3)
	Using paper cutter	1 (1.6)
Reason for splitting[a]	Follow doctor's instruction	47 (74.6)
	Having swallowing difficulty	9 (14.3)
	Tablet size too big	9 (14.3)
	To save cost	1 (1.6)
Administration method after splitting	Swallow whole	61 (96.8)
	Incorporate in food	2 (3.2)
Medications that were split before administration[b]	Simvastatin tablet	10 (15.9)
	Atorvastatin tablet	9 (14.3)
	Bisoprolol tablet	8 (12.7)
	Metformin tablet	7 (11.1)
	Perindopril tablet	5 (7.9)
	Sitagliptin and metformin film coated tablet	4 (6.3)
	Spironolactone tablet	4 (6.3)
	Atenolol tablet	3 (4.7)
	Empagliflozin tablet	3 (4.7)
	Frusemide tablet	3 (4.7)
	Metoprolol tablet	3 (4.7)
	Prazosin tablet	3 (4.7)
	Levothyroxine tablet	2 (3.2)
	Telmisartan tablet	2 (3.2)
	Valsartan tablet	2 (3.2)
Crushing (n = 5)		
Crushing method used	Using tablet crusher	2 (40)
	Using mortar and pestle	2 (40)
	Using the back of spoon	1 (20)
Reason for crushing	Having swallowing difficulty	4 (80)
	Not specified	1 (20)
Administration method after crushing	Dissolve in water	3 (60)
	Dissolve in other liquid	2 (40)
Medications that were crushed before administration	Metformin tablet	3 (60)
	Amlodipine tablet	2 (40)
	Atorvastatin tablet	2 (40)
	Simvastatin tablet	1 (20)
	Aspirin/glycine tablet	1 (20)
	Clopidogrel tablet	1 (20)
	Ezetimibe tablet	1 (20)
	Ferrous fumarate tablet	1 (20)
	Levetiracetam tablet	1 (20)
	Memantine tablet	1 (20)
	Vitamin B_1, B_6 and B_{12} tablet	1 (20)
	Omeprazole capsule [c]	1 (20)
	Sodium valproate tablet	1 (20)
Opening of capsule (n=2)		
Reason for opening of capsule	Having swallowing difficulty	2 (100)
Administration method after opening of capsule	Dissolve in water	1 (50)
	Dissolve in other liquid	1 (50)
Medication capsule that was opened before administration	Omeprazole capsule	2 (100)

[a] Participants can provide more than one response and therefore responses do not add up to 100%.
[b] Only the top 15 medications are presented.
[c] Capsules were opened and the pellets contained inside were crushed.

Difficulties and problems faced with SODF modification

Among those who practiced SODF modification, the most frequently reported difficulty was the tablet's high hardness (15/68, 22.1%), followed by small tablet size (10/68, 14.7%). Other difficulties included time-consuming modification (2/68, 2.9%), absence of a scoreline on the tablet (2/68, 2.9%), tablet coating starting to dissolve in humid conditions leading to a sticky or slippery surface (2/68, 2.9%), trembling hands (2/68, 2.9%), and the tedious nature of SODF modification (2/68, 2.9%). One participant (1/68, 1.5%) reported requiring assistance from others to modify the SODF. In terms of problems encountered during SODF modification, the most common issue was unequal splitting (30/68, 44.1%), followed by medication spilling out or the tablet cracking into pieces (12/68, 17.6%), and unpalatable taste (7/68, 10.3%).

Inappropriate SODF modifications among study participants

Of all patients who modified SODFs, 13 (19%) practiced modifications deemed inappropriate based on the product leaflet or existing guidelines. The most common inappropriate modifications involve splitting sitagliptin/ metformin film-coated tablets (n=4). Inappropriate splitting was also observed in one case each for erythromycin 250 mg enteric-coated tablets, metformin hydrochloride 500 mg extended-release tablets, perampanel film-coated tablets, sacubitril/ valsartan 50 mg tablets, sodium valproate 200 mg enteric-coated tablets, tenofovir disoproxil fumarate 300 mg tablets, and propranolol hydrochloride 10 mg tablets. Additionally, one case involved opening an omeprazole 20 mg enteric-coated capsule and crushing its pellets. Another case involved crushing a sodium valproate 200 mg enteric-coated tablet, while one patient crushed an aspirin 100 mg and glycine 45 mg combination tablet.

DISCUSSION

This study is the first in Malaysia to investigate SODF modifications among older patients. Our results show that over half of the participants engaged in such

modifications. Nearly 50% of those who modified SODFs believed that all medications were safe to be modified. Many used inappropriate methods, such as using their hands or teeth, and 19% of all patients who modified SODFs practiced inappropriate SODF modifications. These findings underscore the need for healthcare providers to monitor SODF modifications closely and offer appropriate guidance to ensure safe medication use.[29]

In this study, 9.8% of the participants were diagnosed with dysphagia, a prevalence notably lower than the 31% to 64% reported in previous research.[30,31] The discrepancy in prevalence rates is likely due to variations in assessment methods. Previous studies employed tools such as the 10-item Eating Assessment Tool (M-EAT-10), the multiple consistency test, and the water swallow test,[32] whereas this study relied on the physician's notes for a dysphagia diagnosis. Despite the lower observed prevalence, the findings of this study indicate that individuals who modified SODFs are significantly more likely to have a dysphagia diagnosis than those who did not engage in SODF modifications.

Research suggests that healthcare providers are often less proactive in addressing swallowing difficulties,[33] resulting in inadequate attention to issues related to dysphagia. As a result, patients with dysphagia may resort to unsupervised modifications of SODFs, which could be inappropriate. In this study, a significantly higher proportion of older patients who modified their SODFs had abnormal pill swallowing difficulties (PILL-5 scores of ≥6) compared to those who did not engage in such modifications. This finding proposes that the PILL-5 questionnaire holds potential as a tool for screening pill dysphagia and could aid in identifying patients who may require additional interventions in medication administration.[21]

In this study, inappropriate modifications were observed in 19% of participants who modify SODFs. This prevalence is consistent with previous studies, which report rates of inappropriate SODF modifications ranging from 10.7% to 32%.[7,8,13,20] Identified inappropriate modifications include splitting extended-release or film-coated formulations and crushing enteric-coated tablets. These modifications can disrupt the delivery systems of the formulations, increasing risks of toxicity, and causing poor taste and potential skin irritation.[25,34] Additionally, crushing enteric-coated tablets compromises their protective coatings, leading to reduced efficacy and potential gastric irritation.[18]

These inappropriate modifications may arise from a lack of awareness that certain SODFs cannot be safely modified. This is supported by the prevalent belief among study participants that all medications are safe to modify, reflecting a misunderstanding of the safety of SODF modifications.[35,36] Furthermore, only a small proportion of patients received information on SODF modifications from pharmacists or physicians, suggesting that many patients undertake these modifications without adequate professional oversight.

The lack of adequate guidance is further highlighted by the observation that, although most patients who split medications do so according to their physician's instructions, many used inappropriate methods, such as splitting tablets with their hands or teeth. Additionally, although most modified medications were not deemed inappropriate according to product leaflets or existing guidelines, many patients who split or crushed their medications reported issues such as uneven splits and medications spilling or cracking. These findings suggest that while medication modifications may be safe for many patients, the process can lead to suboptimal dosing, potentially impacting clinical outcomes.[36-38] Notably, patients who split, crush, or open capsules often mix them with food or non-water liquids, risking food-drug interactions that could compromise medication efficacy and safety.[39]

Our study highlights the need for healthcare providers to be more proactive in offering guidance on SODF modifications and emphasizes the critical role of vigilant patient care for older patients, especially those with dysphagia or pill dysphagia. Educating patients and caregivers about the risks of inappropriate SODF modifications is essential for ensuring optimal medication management and patient safety.

LIMITATION

Despite the valuable insights gained from this study, several limitations must be acknowledged. The study was conducted in a single center and involved only the general medical wards, which limits the generalizability of the findings to other healthcare settings and wards. Furthermore, the skewness in the distribution of participants based on sociodemographic characteristics, such as ethnicity, limited the representativeness of the general older population in Malaysia. Additionally, the study was conducted over a short data collection period of six weeks, resulting in a small sample size. The reliance on self-reported data may introduce recall bias, and potential social desirability bias might have affected participants' responses, leading to an overestimation or underestimation of their practices. The study also did not measure the impact of SODF modifications on clinical outcomes.

Future studies could replicate this research with a larger sample across multiple centers to provide a broader perspective on SODF modification practices. Longitudinal studies could further enhance our understanding by offering evidence of the long-term impact of SODF modifications on patient outcomes. Additionally, developing strategies to support patients in safely modifying their medications when necessary is warranted.

CONCLUSION

This study examines the prevalence and practices of SODF modifications among older patients at a Malaysian teaching hospital. Over half of the participants engaged in SODF modification practices, primarily through pill splitting. There was a significant association between dysphagia and pill dysphagia, with SODF modifications. Some modifications were found to be inappropriate, potentially compromising patient safety and therapeutic effectiveness. Future longitudinal and multi-center research is needed to further explore SODF modification practices among older patients. Additionally, developing standardized guidelines and training for healthcare providers is essential to ensure safe SODF modifications. The study underscores the importance of addressing inappropriate SODF modifications to improve medication management and safety for older patients, highlighting the need for proper education and support for both patients and caregivers in medication administration.

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