Assessment of Potentially Inappropriate Prescribed Medications in Older Patients Using STOPP/START Criteria at Soba University Hospital: A Descriptive Retrospective Study

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A R T I C L E   I N F O

A B S T R A C T

Background: Potentially inappropriate prescriptions (PIPs) have significant clinical, humanistic, and economic impacts. Identifying PIPs may reduce their burden of adverse drug events. "Screening Tool of Older Person's potentially inappropriate Prescriptions (STOPP) and Screening Tool of Alert doctors to the Right Treatment (START) criteria" are promising tools that formulated to identify potentially inappropriate medications (PIMs) and potential prescribing omissions (PPOs) in geriatrics. To determine the PIMs and PPOs using STOPP/START criteria and to determine the most frequent PIPs.

Methods: The study was a descriptive cross-sectional hospital-based retrospective study. Medical files of elderly (≥65 years) patients admitted to the internal medicine unit at Soba university hospital from January to July 2020 were used. Data were collected using a checklist of STOPP/START criteria (version 2) to determine PIPs. Statistical package for social sciences was used for data analysis.

Results: A total of 100 patients were included, around 59% were aged between 65-70 years, and 58% were males. The mean number of medications was 5.3 ± 1.9 drugs/patient. The results showed that the prevalence of PIPs was 68%. The STOPP criteria detected 209 PIMs in 42 patients, whereas the START criteria detected 155 PPOs in 45 patients. Furthermore, the drugs that used beyond the indication period was the most common PIMs, whereas the most detected PPOs were observed in the cardiovascular system medications.

Conclusion: : The study revealed a high prevalence of PIPs among elderly patients. This necessitates a further evaluation of its impact on clinical outcomes and implements interventions to improve prescribing practice.

J Pharm Care 2022; 10(1): 3-10.

Introduction

Potentially inappropriate prescriptions (PIPs) are defined as "the prescriptions that introduce a significant risk of an adverse drug related event when there is evidence for an equally or more effective alternative medication" (1). PIPs have been linked to increased risk of iatrogenic morbidity and mortality and higher healthcare expenses (2). Inappropriate prescribing happens when the hazards of prescribing a drug outweigh the treatment's potential benefit in a specific patient (3). Inappropriate prescribing

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has different forms, which include; I. Drug used without clear indication, II. Using of higher doses of prescribed drugs, III. Longer duration, IV. Combination of drugs from the same drug class, V. Drug-drug or drug-illness interactions, VI. Prescribing to a patient who is susceptible to certain adverse effects (4).

Management of geriatric patients is always challenging, as they are mostly suffering from multiple diseases that may result in problematic prescriptions and high potential of PIPs due to poly-pharmacy (5). Changes in the pharmacodynamics and pharmacokinetics paramaters in elderly patients are highly contributed in the negative consequences of poly-pharmacy and PIPs (6). Main consequences are due to drug-drug interactions and ADEs that may lead to increase hospitalization and death rates (7). The prevalence of ADE is linked to more frequent visits to the emergency department, unexpected hospitalizations, increase in healthcare costs, high morbidity, and mortality in geriatrics (8). Thus in order to reduce PIPs and its consequences, when treating multimorbid geriatric patients, the prescriber must find a balance between optimizing chronic illness control and avoiding PIPs and poly-pharmacy hazards.

In order to reduce and prevent PIPs in geriatric patients, several criteria-based strategies have been published to address and reduce the risk of PIPs. Explicit criteria are statements that are explicitly stated and indicate PIPs in specific clinical situations. This set of criteria is based on data from trials, expert opinion, and consensus procedures (9). In this strategy, alerting the prescriber to the potential PIP is the main goal rather than clinical intervention (4, 10). Other intervention tools used to minimize PIPs and enhance prescribing appropriateness are FORTA (Fit fOR The Aged) list, Beer's criteria, and the Screening Tool of Older Persons potentially inappropriate Prescriptions (STOPP) and the Screening Tool to Alert doctors to the Right Treatment (START) (11-13). In recent randomized controlled trials, only the FORTA list and the STOPP/START criteria have been shown to have high significant positive patient-related outcomes (14). The STOPP/START has been globally applied in Asian, American, European, and African countries to test and treat inappropriate medication use (15-20).

Early detection of PIPs can help reduce ADEs and their consequences and improve geriatric care. In addition, measuring the PIPs prevalence is frequently used to measure prescription quality and can improve the quality of life of geriatric patients (7, 21). In Sudan, the number of geriatric populations increases as in the whole world, this lead to making the drug prescribing quality and safety for the elderly patient a major health issue. Hence, till date no available report about PIPs for Sudanese elderly patients. Thus, in an attempt to document the PIPs in hospitalized older patients, we conducted the first study to identify the potentially inappropriate medications (PIMs) and Potential prescription omissions (PPOs) using the STOPP/START

criteria in Sudanese elderly patients.

Methods
This study was a descriptive cross-sectional hospital-based retrospective study. It was carried out in the internal medicine unit at Soba University Hospital, Khartoum state, Sudan. The ethical clearance (FPEC-13-2020) was obtained from the Ethical Committee of the Faculty of Pharmacy, University of Khartoum. Before the beginning of data collection, another permission was taken from Soba University Hospital. To maintain anonymity throughout the study, all data was encoded, and all personally identifiable information was removed.

The study population was all geriatric patients (≥65 years of age) who were admitted to the internal medicine unit at Soba University Hospital from January to July 2020.

Medical files of geriatric patients admitted to the internal medicine unit at Soba university hospital from January to July 2020. A total coverage sampling was applied based on the inclusion criteria and exclusion criteria. All admitted geriatric patients with at least one medication were included, whereas medical files with missing information were excluded from this study.

STOPP and START criteria (version 2) were used in this study to assess PIPs (22). The STOPP includes 65 indicators for potentially inappropriate medications (PIMs), which include "drug prescribed without an evidence-based clinical indication; drug prescribed beyond the recommended duration, where treatment duration is well defined; and duplicate therapy", and raised the risk of cognitive decline and falls in the elderly. START is a set of 22 drug indicators that should be examined for various diseases, assuming there are no contraindications to prescription and potential prescription omissions (PPOs). The STOPP/START criteria are divided into categories based on physiological systems, as well as analgesic use, anticholinergic load, and medicines that enhance the risk of falling.

Clinical pharmacist assessed the PIMs and PPOs from the included medical files after performing the medication review. Collected data included patient's demographic profiles (age, gender, health insurance), clinical data (comorbid diseases), and medication-related data.

The primary outcome of interest in this study was to estimate the prevalence of PIMs and PPOs in older patients using the STOPP and START criteria (version 2). The secondary outcome was identifying the patients and treatment characterisitics (gender, age, and the number of medications) that affected the distribution of PIMs and PPOs in geriatric patients.

Collected data were analyzed using by the Statistical Package for Social Sciences (SPSS), Version 22.0 software (Armonk, NY: IBM Corp). Descriptive statistics were demonstrated in frequency tables, and expressed as the number and frequency %. Chi-square test was used to test the statistical differences in demographics and number of medications between older patients with and without PIMs

or PPOs. P-value ≤ 0.05 was considered to indicate the statistical significance.

Results

In this study, the highest population (41%) were aged 66-70 years, and the oldest group aged ≥ 85 years was about 12% (Table 1). The majority of the patients were males with (58%) while the females were (42%). Regarding health insurance, only 23% of the patients had health insurance. The highest frequency regarding the number of medications was (35%) for 5-6 medications/patient, then (29%) for 3-4 medications/patient, whereas 5% of the patients were considered as excessive poly-pharmacy as they had 9-10 medications/patients (Table 1). The mean number of medications was 5.3 ± 1.9 drugs/patient.

Table 1. Distribution of socio-demographic and number of medications among the study sample (n=100).

Characteristics	Number (Frequency %)
Gender	
Males	58 (58)
Females	42 (42)
Age (years)	
65	18 (18)
66-70	41 (41)
71-75	18 (18)
76-80	11 (11)
> 80	12 (12)
Health Insurance	
Yes	22 (22)
No	78 (78)
Number of medications	
1-2	8 (8)
3-4	29 (29)
5-6	35 (35)
7-8	23 (23)
9-10	5 (5)

To systematically apply the STOPP/START criteria, the clinical pharmacist needed around 15 minutes for each patient on average. Overall inappropriate prescribing was found in 68% of the participants (n = 68), i.e., those who had at least one STOPP's PIM or at least one START's PPO. According to the STOPP criteria, 209 instances of PIMs were detected in 42% (n = 42) of the study population, with the highest proportion of inappropriateness in using the antiplatelet/anticoagulant drugs (Table 2). Moreover, when we applied the START criteria, a total of 155 instances of PPO were detected in 45% (n = 45) of the included patients, with the highest frequency (76.8%) for the cardiovascular system drugs (Table 2).

The STOPP criteria detected PIPs, following PIPs for the antiplatelet/anticoagulant drugs, the drugs that used beyond the indication and drugs used for gastrointestinal system diseases showed the high percentages (19.6%) of PIPs with, whereas PIPs detected in the cardiovascular system, renal system, and with endocrine system represented 11.5%, 5.3%, and 2.9%, respectively for the and the least percentage (1.91%) for the analgesics (Table 2). The most frequent criterion for the PIPs were "NSAID and vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in combination" and "Drugs likely to cause constipation in patients with chronic constipation where non-constipating alternatives are available" and "Long-term aspirin at doses greater than 160 mg per day" with 21, 15, and 14 instances, respectively (Table 3).

Table 2. Total number and distribution of detected instances according to the STOPP/SART criteria.

Variable	Number (Frequency %)
Prevalence of detected of PIMs and PPO according to STOPP/ SART criteria	
PIMs according to STOPP criteria	42 (42)
PPOs according to START criteria	45 (45)
STOPP Criteria (n= 209)	
Drug beyond the indication period	41 (19.6)
Cardiovascular system	24 (11.5)
Gastrointestinal system	41 (19.6)
Endocrine system	6 (2.9)
Renal system	11 (5.3)
Antiplatelet/Anticoagulant Drugs	82 (39.2)
Analgesic	4 (1.9)
START Criteria (n= 155)	
Cardiovascular system	119 (76.8)
Gastrointestinal system	15 (9.7)
Endocrine system	18 (11.6)
Analgesic	3 (1.9)

STOPP= Screening Tool of Older Person's potentially inappropriate Prescriptions, START= Screening Tool of Alert doctors to the Right Treatment, PIMs= Potentially inappropriate medications, PPOs= Potential prescription omissions

Table 3. Number of potentially inappropriate medications identified according to STOPP criteria.

STOPP Criteria	Instances
Indication of medication	
Any drug prescribed beyond the recommended duration, where treatment duration is well defined.	41
Cardiovascular System	
Beta-blocker in combination with verapamil or diltiazem (risk of heart block).	4
Loop diuretic as first-line treatment for hypertension (safer, more effective alternatives available).	5
Loop diuretic for dependent ankle edema without clinical, biochemical evidence or radiological evidence of heart failure, liver failure, nephrotic	1
Loop diuretic for treatment of hypertension with concurrent urinary incontinence (may exacerbate incontinence).	7
Centrally-acting antihypertensives (e.g. methyldopa, clonidine, moxonidine, rilmenidine, guanfacine), unless clear intolerance of, or lack of efficacy with, other classes of antihypertensives (centrally-active antihypertensives are generally less well tolerated by older people than younger people)	3
Aldosterone antagonists (e.g. spironolactone, eplerenone) with concurrent potassium-conserving drugs (e.g. ACEIs, ARBs, amiloride, triamterene) without monitoring of serum potassium (risk of dangerous hyperkaliemia i.e. > 6.0 mmol/l – serum K should be monitored regularly, i.e. at least every 6 months).	4
Gastrointestinal System	
Prochlorperazine or metoclopramide with Parkinsonism (risk of exacerbating Parkinsonian symptoms).	5
PPI for uncomplicated peptic ulcer disease or erosive peptic esophagitis at full therapeutic dosage for > 8 weeks (dose reduction or earlier discontinuation indicated).	10
Drugs likely to cause constipation (e.g. antimuscarinic/anticholinergic drugs, oral iron, opioids, verapamil, aluminum antacids) in patients with chronic constipation where non-constipating alternatives are available (risk of exacerbation of constipation).	16
Oral elemental iron doses greater than 200 mg daily (e.g. ferrous fumarate> 600 mg/day, ferrous sulphate > 600 mg/day, ferrous gluconate> 1800 mg/day; no evidence of enhanced iron absorption above these doses).	10
Endocrine System	
Sulphonylureas with a long duration of action (e.g. glibenclamide, chlorpropamide, glimepiride) with type 2 diabetes mellitus (risk of prolonged hypoglycaemia).	2
Beta-blockers in diabetes mellitus with frequent hypoglycemic episodes (risk of suppressing hypoglycemic symptoms).	4
Renal System	
The patients took NSAIDs if eGFR < 50 ml/min/1.73m^2 (risk of deterioration in renal function).	8
The patients Metformin if eGFR < 30 ml/min/1.73m^2 (risk of lactic acidosis)	3
Antiplatelet/Anticoagulant Drugs	
Long-term aspirin at doses greater than 160 mg per day (increased risk of bleeding, no evidence for increased efficacy).	15
Aspirin with a past history of peptic ulcer disease without concomitant PPI (risk of recurrent peptic ulcer).	11
Aspirin, clopidogrel, dipyridamole, vitamin K antagonists, direct thrombin inhibitors or factor Xa inhibitors with concurrent significant bleeding risk, i.e. uncontrolled severe hypertension, bleeding diathesis, recent non-trivial spontaneous bleeding) (high risk of bleeding).	7
Aspirin plus clopidogrel as secondary stroke prevention, unless the patient has a coronary stent(s) inserted in the previous 12 months or concurrent acute coronary syndrome or has a high grade symptomatic carotid arterial stenosis (no evidence of added benefit over clopidogrel monotherapy)	2
Aspirin in combination with vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in patients with chronic atrial fibrillation (no added benefit from aspirin)	6
Antiplatelet agents with vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in patients with stable coronary, cerebrovascular or peripheral arterial disease (No added benefit from dual therapy).	5
Vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors for first deep venous thrombosis without continuing provoking risk factors (e.g. thrombophilia) for > 6 months, (no proven added benefit).	1
Vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors for first pulmonary embolus without continuing provoking risk factors (e.g. thrombophilia) for > 12 months (no proven added benefit).	1
NSAID and vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in combination (risk of major gastrointestinal bleeding).	21
NSAID with concurrent antiplatelet agent(s) without PPI prophylaxis (increased risk of peptic ulcer disease)	13
Analgesic Drugs	
Use of regular (as distinct from PRN) opioids without concomitant laxative (risk of severe constipation).	4
TOTAL instances of according to STOPP Criteria	209

STOPP= Screening Tool of Older Person's potentially inappropriate Prescriptions,ACEIs= Angiotensin-converting-enzyme inhibitors, ARBs= Angiotensin-receptor blockers ,NSAIDs= Non-steroidal anti-inflammatory drugs,PPIs= Proton Pump Inhibitors,eGFR= estimated glomerular filtration rate, PRN= pro re nata

Regarding the PPOs identified by The START criteria, following the cardiovascular system (11.6%) for the endocrine system, (9.7%) for the gastrointestinal system, and the least percentage of PPOs was for the analgesics with (1.9%) (Table 2). As demonstrated in Table 4, the most common PPOs was "Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease, unless the patient's status is end-of-life or age is > 85 years" and "Antihypertensive therapy where systolic blood pressure consistently > 160 mmHg and/or diastolic blood pressure consistently >90 mmHg; if systolic blood pressure > 140 mmHg and /or diastolic blood pressure > 90 mmHg, if diabetic" with 34 instances for each of them. Followed by "Antiplatelet therapy with a documented

history of coronary, cerebral or peripheral vascular disease" and "ACE inhibitor or Angiotensin Receptor Blocker (if intolerant of ACE inhibitor) in diabetes with evidence of renal disease i.e. dipstick proteinuria or microalbuminuria (>30mg/24 hours) with or without serum biochemical renal impairment" that represented 22 and 18 instances, respectively (Table 4).

When the Chi-square test was performed to check the statistical difference between independent variables and distribution of PIMs or PPOs, as demonstrated in Table 5, there were no significant associations between the presence of PIMs or PPOs and socio-demographics (gender and age), and the number of used medications.

Table 4. Number of potential prescription omissions identified according to START criteria.

START Criteria	Instances
Cardiovascular System	
Vitamin K antagonists or direct thrombin inhibitors or factor Xa inhibitors in the presence of chronic atrial fibrillation.	2
Aspirin (75 mg – 160 mg once daily) in the presence of chronic atrial fibrillation, where Vitamin K antagonists or direct thrombin inhibitors or factor Xa inhibitors are contraindicated.	2
Antiplatelet therapy (aspirin or clopidogrel or prasugrel or ticagrelor) with a documented history of coronary, cerebral or peripheral vascular disease.	22
Antihypertensive therapy where systolic blood pressure consistently > 160 mmHg and/or diastolic blood pressure consistently >90 mmHg; if systolic blood pressure > 140 mmHg and /or diastolic blood pressure > 90 mmHg, if diabetic.	34
Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease, unless the patient's status is end-of-life or age is > 85 years.	34
ACEIs with systolic heart failure and/or documented coronary artery disease.	10
Beta-blocker with ischemic heart disease.	7
Appropriate beta-blocker (bisoprolol, nebivolol, metoprolol or carvedilol) with stable systolic heart failure.	8
Gastrointestinal System	
PPIs with severe gastro-esophageal reflux disease or peptic stricture requiring dilatation.	9
Fiber supplements (e.g. bran, ispaghula, methylcellulose, sterculia) for diverticulosis with a history of constipation.	6
Endocrine System	
ACEIs or ARBs (if intolerant of ACE inhibitor) in diabetes with evidence of renal disease i.e. dipstick proteinuria or microalbuminuria (>30mg/24 hours) with or without serum biochemical renal impairment.	18
Analgesics	
High-potency opioids in moderate-severe pain, where paracetamol, NSAIDs or low-potency opioids are not appropriate to the pain severity or have been ineffective.	1
Laxatives in patients receiving opioids regularly	2
TOTAL instances of according to START criteria	155

START= Screening Tool of Alert doctors to the Right Treatment ,mmHg= millimetre of mercury, ACEIs= Angiotensin-converting-enzyme inhibitors, ARBs= Angiotensin-receptor blockers ,NSAIDs= Non-steroidal anti-inflammatory drugs, PPIs= Proton Pump Inhibitors

Table 5. Association between presence and absence of PIMs and PPOs with demographics characteristics and number of medications distribution among older patients (n=100)

Characteristics	PIMs, n(%)		P value	PPOs, n(%)		P value
	Yes	No		Yes	No	
Gender						
Male	21 (21)	37 (37)	0.168	29 (29)	29 (29)	0.238
Female	21 (21)	13 (21)		16 (16)	26 (26)	
Age (years)						
65	5 (5)	13 (13)		11 (11)	7 (7)	
66-70	17 (17)	24 (24)		18 (18)	23 (23)	
71-75	9 (9)	9 (9)	0.673	9 (9)	9 (9)	0.2
76-80	5 (5)	6 (6)		5 (5)	6 (6)	
> 80	6 (6)	6 (6)		2 (2)	10 (10)	
Number of medications						
1-2	2 (2)	6 (6)		5 (5)	3 (3)	
3-4	11 (11)	18 (18)		15 (15)	14 (14)	
5-6	15 (15)	20 (20)	0.71	16 (16)	19 (19)	0.47
7-8	12 (12)	11 (11)		7 (7)	16 (16)	
9-10	2 (2)	3 (3)		2 (2)	3 (3)	

PIMs= Potentially inappropriate medications, PPOs= Potential prescription omissions, n(%)= Number (Frequency %)

Discussion

The current research highlights the suitability of using STOPP/START criteria by clinical pharmacists at internal medicine unit for admitted geriatric patients. Utilization of such criteria will help detect potential inappropriate prescriptions early, which reduces the adverse events and improves geriatric care. Our study indicated that the overall inappropriate prescribing prevalence was 78%, which is high and in agreement with previous studies using STOPP-START criteria that showed a prevalence of approximately 80% in Spain (23) and higher than other studies conducted in Malaysia (58.5%), Ireland (35%) and England (40%) (15, 24, 25).

Poly-pharmacy is one of the main risk factors linked with inappropriate prescribing in geriatrics, associated with potential drug-disease and drug-drug interactions (26). In this study, reviewing the medical files showed that the mean number of medications was almost five (5.3±1.9) medications per patient, and 63% of elderly patients used five or more drugs, indicating a significant prevalence of poly medication in the studied sample. The same findings were shared by Malaysian and Japanese studies (15, 17). In contrast, a South Korean study showed a lower sample with poly medication (16).

The STOPP criteria demonstrated the specific prevalence of inappropriate prescriptions was 42%, which is higher than other studies conducted in Malaysia (34.9%) and Ireland

(35%) (15, 24), and less than that reported from geriatric patients admitted to six European hospitals (51.3%) (27). The most frequent PIMs were the medications prescribed beyond the recommended duration of therapy that represented 41% of total PPI insults.

Non-steroidal anti-inflammatory drugs (NSAIDs) and vitamin K antagonists, direct thrombin inhibitors, or factor Xa inhibitors in combination were the most commonly found possible inappropriate drugs, which enhance the risk of significant gastrointestinal bleeding (28). This reveals a lack of knowledge about their mechanism of action and side effects and a proper diagnosis for their usage. Also, using NSAIDs with concurrent antiplatelet agents and without PPI prophylaxis was detected, increasing the risk of peptic ulcer disease (29). The use of this combination remains insecure, as the prescription is not required for its acquisition. Self-medication with NSAIDs is always harmful as it's linked to a higher risk of cardiovascular and thromboembolic events in chronic medication users. Acute renal damage can also be caused by NSAIDs (AKI). In addition, it can rarely cause bronchospasm (in people sensitive to aspirin) and pulmonary infiltration with eosinophilia (30).

Applying the START criteria demonstrated the prevalence of identified PPO was (45.08%), which was higher than the findings of the Malaysian study, in which there was (34.9%) omitted medications were detected (15), and lower than that found in another study in Ireland, in which 57.9% of hospitalized geriatric patients had at least one appropriate

medication was omitted from their regular prescription (31). Moreover, most detected PPOs were observed in the cardiovascular system medications, similar to those reported in other studies that assessed the PPOs in geriatric patients (15, 32).

The most frequent PPO (61%) was an omission in the prescription of antihypertensive medications. As the incidence of hypertension increases with age, lifestyle changes are recommended as a method for its control, but when these changes are insufficient, additional pharmacological therapy must be added. Other common omissions in patients' prescriptions were related to ACEIs, statins, and antiplatelet therapy for diabetic patients and patients with cardiovascular diseases, in those the prevention of thrombus formation and possible ischemia, are very important. The START criteria support ACEIs because they reduce blood pressure, which prevents the onset of common disorders like heart failure and delays the advancement of retinopathy and diabetic nephropathy (31). This demonstrates the necessity to examine the prescriptions of older people who rely on them for their survival.

The current study has some limitations. Firstly, it was a single-institution study, so the result cannot be generalized to other hospitals. Second, the study's cross-section retrospective design did not allow to establish a link between inappropriate prescriptions and the development of clinical consequences such as adverse reactions. Thirdly, the drug data were only collected from medical files, leading to missing information about over-the-counter medications and PIPs. Fourthly, the study focused on the drug groups that caused PIPs, and we didn't assess the common individual medications that led to PIPs. Despite these limitations, this is the first research to assess PIPs using STOPP/START criteria in Sudanese geriatric patients. Further multicenter studies with a larger population are required, in which the complete list of medications will be collected, and the relationship between inappropriate prescribing and the occurrence of a clinical consequence will be demonstrated in elderly patients.

In conclusion, the present study reported the prevalence of PIMs and PPOs prescribed for Sudanese geriatric patients in Soba University hospital-based on STOPP/START criteria version 2. Our study showed a high prevalence of inappropriate prescribing among the studied sample. Furthermore, this study revealed the importance of clinical pharmacists in addressing the inappropriate prescribing that may lead to ensuring the appropriateness of prescribing medication to elderly patients. This necessitates a further evaluation of its impact on clinical outcomes and permits interventions to improve prescribing practice in these settings.

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