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Use of STOPP/ START Criteria to Perform Active Pharmacovigilance in the Elderly

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Abstract

Background: Inappropriate prescription of drugs is common in the elderly and contributes to an increased risk of adverse drug reactions. Several tools have been developed to detect potentially inappropriate prescription but the STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment) criteria resulted better than others to identify medicines that lead to negative outcomes. The purpose of this work was to study the prevalence of Potentially Inappropriate Medicines and Potential Prescribing Omissions in Uruguayan hospitalized elderly patients using these criteria.

Methods: A cross-sectional study was carried out in different Services of the University Hospital. STOPP and START criteria were applied to identify inappropriate medicines or omissions.

Results: Potentially Inappropriate medicines identified by STOPP represent 21.2% of the total prescriptions (862) and Potential Prescribing Omissions identified by START account for the 5.7%.

Conclusions: Using STOPP-START criteria could be a useful tool to improve prescription in the elderly and can contribute to the rational use of medicines in this age group.

Keywords: Elderly patients; STOPP-START criteria; Potentially inappropriate medicines; Potential prescribing omissions

Introduction

Population ageing is a worldwide phenomenon, in Uruguay elderly population (65 years of age and above) has doubled in the last forty years rising from 7% in 1960 to 14% in 2011 [1]. As stated by many authors [2,3] elderly patients are particularly vulnerable to inappropriate prescribing (IP) because of non-adherence to prescribing guidelines specifically designed for this population and the insufficient number of geriatric physicians to follow-up treatments. In addition to this, the elderly are a heterogeneous group of patients with multiple comorbidities and as polymedication is the common rule, there is an increased risk of adverse drug reactions (ADRs) and consequently higher rates of morbidity and mortality. This risk is compounded by age-related changes in physiology (e.g., decreased renal function, reduced muscle mass) that directly impact in drug pharmacokinetics and pharmacodynamics. Some authors [4] reported that thirty percent of hospital admissions in elderly patients may be linked to drug related problems or toxic effects. Adverse drug events in older patients have been linked to preventable problems such as depression, constipation, falls, confusion, and hip fractures among others [4,5].

Several lists of medications have been created to guide clinicians to avoid certain medications in the elderly such as the Beers list [6] or the Canadian criteria [7]. The Screening Tool for Older Person's Prescription (STOPP) and Screening Tool to Alert doctors to Right Treatment (START) are also guidelines designed with this purpose and widely used in international settings not only to detect Potentially Inappropriate Medicines (PIMs) but also to detect the omission of some medications that are necessary (Potential Prescribing Omissions, PPO) [8].

STOPP criteria, based on physiological systems, contains a list of 65 explicit rules for avoidance of certain drugs/drug classes, and START criteria, also physiological-system based, lists 22 common instances of PPO in patients with particular medical conditions. Pharmacists and physicians possess poor knowledge of these tools and as a consequence these guidelines are rarely used to review older adults' prescriptions.

Elderly patients in hospitals are generally sicker than ambulatory patients. Performing active pharmacovigilance in hospitalized patients gives the opportunity to health care professionals to detect drug related problems in a setting where they can be detected soon after the misprescription, whose consequences can be followed thoroughly and therefore are more easily to correct.

The purpose of this work was to study the prevalence of PIMs and PPOs in hospitalized elderly patients of the Uruguayan University Hospital, with the aim of setting a starting point of active pharmacovigilance in the older adults.

Methods

A cross-sectional study was carried out in the University Hospital of Uruguay during 2013. This Hospital is a tertiary referral center with 320 beds available. The study was carried out in nine medicine services of the hospital. The services included: general medicine, neurology, urology, otorhinolaryngology, cardiology and general surgery. Data

collection was in charge of researcher pharmacists and took place over a 1-month period. Data was obtained from clinical charts and a form was designed for patient data collection which included age, reason for hospitalization, medical history, medication, and relevant laboratory results. Prescribed drugs were then analyzed using STOPP-START criteria. Drugs prescribed among the study population were compared with the drugs included in the STOPP/START criteria and were deemed inappropriate if the prescribed drug was included in the listed criteria.

Permissions

No ethical approval was needed.

Results

A total of 181 patients were hospitalized in the aforementioned services and 78 (43%) were 65 years old or above. The mean age (range) of the patients was 74 (65-91) years old, 62% were male. Sixty-one patients (78%) presented at least one cardiovascular disease (hypertension was present in 51 patients) and 18 (23%) had diabetes mellitus. All the patients were polymedicated and the total number of medicines prescribed was 862 with a mean of 11 and a range of 4-21 medicines per patient. Thirty-five per cent of the patients received more than 12 drugs during the study.

Among the drugs prescribed, 248 were for cardiovascular disorders (calcium channel blockers, diuretics, beta blockers, antiplatelet drugs among others), 89 were for pain control (NSAIDs, opioids and acetaminophen), 87 were for gastrointestinal disorders (omeprazole, ranitidine), 70 were drugs for neurological disorders, 68 were antibiotics, 37 were for respiratory problems and 23 were for diabetes mellitus (insulins, sulphonylureas and metformin).

Using STOPP criteria a total of 183 PIMs were identified in 68 patients (87.2%). In comparison with women, men exhibited more PIMs (60.3%). Eighteen patients (26.5%) had one PIM and fifty patients (73.5%) had more than one PIM. Thirty-one (47.7%) of the 65 STOPP criteria were used to identify potential IP.

Drugs related to falls (H criteria) had the highest prevalence of Potential IP (29.5% - 54 PIMs), followed by drugs affecting Musculoskeletal System (E) (in particular NSAIDs with moderate-to-severe hypertension) and Cardiovascular System (A) with 26.8% and 15.8% respectively. Prescribing of duplicate drug-class (J) accounted for 11.5% of PIMs and Central Nervous System and psychotropic drugs (B) accounted for 8.7% of PIMs (in particular benzodiazepines with long-acting metabolites) (Table 1).

A total of 49 PPOs were identified using START criteria in 33 patients (22 men and 11 women). Twenty-four patients (72.7%) had one PPO and 9 patients (27.3%) had more than one PPO.

Fifteen (68.2%) of the 22 START criteria identified the PPOs in this study. As it can be observed in Table 2, the Endocrine System (F) accounted for most of the PPOs identified (44.9%). Metformin and antiplatelet medication were the commonest PPO identified in this system.

Omissions of antihypertensive therapy, warfarin and beta-blocker were the commonest PPO for the cardiovascular system. Corticoids were the commonest Respiratory System PPO identified. There were no PPOs identified under the Central Nervous System or Gastrointestinal system criteria.

	Stopp Criteria	N
A1	Digoxin at a long-term dose >125g per day with impaired renal function	1
A2	Loop diuretic for dependent ankle edema only, i.e., no clinical signs of heart failure	4
A3	Loop diuretic as first line therapy in hypertension	1
A4	Thiazide diuretic with a history of gout	1
A5	Non selective β-blocker in patients with COPD	1
A7	Use of diltiazem or verapamil with NYHA class III or IV heart failure.	3
A8	Calcium channel blockers with chronic constipation.	3
A12	Aspirin at dose >150 mg	13
A13	Aspirin with no history of coronary, cerebral or peripheral vascular symptoms or occlusive event.	1
A17	Aspirin, clopidogrel, dipyridamole or warfarin with concurrent bleeding disorder.	1
B7	Long term, long acting benzodiazepines and benzodiazepines with long acting metabolites.	14
B12	Serotonin selective re-uptake inhibitors with history of clinically significant hyponatremia.	1
B13	Prolonged use (> week) of first generation antihistamine.	1
C3	Metoclopramide with parkinsomism.	1
D2	Systemic corticosteroids with COPD.	4
E2	NSAID with moderate-to-severe hypertension.	33
E3	NSAID with heart failure.	2
E5	Warfarin and NSAID together.	4
E6	NSAID with chronic renal failure.	8
E7	Long-term corticosteroids (>3 months) as monotherapy for rheumatoid arthritis or osterarthritis.	2
F3	Antimuscarinic drugs with chronic constipation.	1
F4	Antimuscarinic drugs with chronic prostatism.	1
G1	Glibenclamide or chlorpropamide with type 2 diabetes mellitus.	4
G2	B-blockers in those with diabetes mellitus and frequent hypoglycemic episodes	2
H1	Benzodiazepines.	14
H2	Neuroleptic drugs.	2
H3	First-generation antihistamines.	2
H4	Vasodilator drugs with persistent postural hypotension.	16
H5	Long-term opiates in those with recurrent falls.	20
I2	Regular opiates for more than two weeks in those with chronic constipation without concurrent use of laxatives.	1
J	Any duplicate drug class prescription.	21

Table 1: Absolute frequency of IP as determined by STOPP Criteria.

	Start Criteria	N
A1	Warfarin in the presence of chronic atrial fibrillation.	3
A3	Aspirin or clopidogrel with a documented history of atherosclerotic coronary, cerebral or peripheral vascular disease in patients with sinus rhythm.	1
A4	Antihypertensive therapy with systolic blood pressure consistently > 160 mmHg.	4
A5	Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease where the patient´s functional status remains independent for activities of daily living and life expectancy is greater than 5 years.	2
A6	Angiotensin converting enzyme (ACE) inhibitor with chronic heart failure.	2
A7	ACE inhibitor following acute myocardial infarction.	1
A8	B-blocker with chronic stable angina.	3
B1	Regular inhaled β2-agonist or anticholinergic agent for mild-to-moderate asthma or COPD.	1
B2	Regular inhaled corticosteroid for moderate/severe asthma or COPD, where predicted FEV_1< 50%.	6
E1	Disease-modifying antirheumatic drug with active/severe rheumatoid disease lasting >12 weeks.	2
E2	Bisphosphonates in patients taking maintenance corticosteroid therapy.	2
F1	Metformin with type 2 diabetes ± metabolic syndrome (in the absence of renal impairment).	7
F2	ACE inhibitor or angiotensin receptor blocker in diabetes with nephropathy.	3
F3	Antiplatelet therapy in diabetes mellitus with coexisting major cardiovascular risk factor.	7
F4	Statin therapy in diabetes mellitus if coexisting major cardiovascular risk factors are present.	5

Table 2: Absolute frequency of IP as determined by START Criteria. (COPD – Chronic Obstructive Pulmonary Disease; FEV_1 - Forced Expiratory Volume in 1 second)

Discussion

This study shows that the rate of potential IP in the Uruguayan University Hospital is not negligible. PIMs identified by STOPP represent 21.2% of the total prescriptions (862) and PPOs identified by START account for the 5.7%. This is the first study using STOPP-START criteria in our setting and therefore there are no other studies with which to compare the current data.

A high percentage (87%) of patients received one or more PIM. It has been stated that prescribing of inappropriate drugs is associated with significant increase in ADEs and iatrogenic morbidity. This should be an important message for the Uruguayan prescribers who should adopt this or other criteria in order to diminish inappropriate prescribing in the elderly.

Long acting benzodiazepines, i.e. diazepam, continue to be prescribed in elderly patients in our hospital for insomnia even though their long-term prescription has been discouraged due to the link with falls and fracture risk [9,10]. In the population studied, tramadol had the highest number of prescriptions. Tramadol is an opiate highly metabolized to active and inactive metabolites, all of which are then excreted in urine. Elderly patients have a physiological decrease in renal function which in turn could impair tramadol and its metabolites elimination. Taking this into consideration, tramadol dosage should not exceed 200 mg/day to avoid adverse drug events in this population. Proton Pump Inhibitors (PPIs) are commonly prescribed in our hospital, even when patients have no clear reason for the prescription. This class of drug was not included in the study because of the impossibility of determining the beginning of the therapy. Although it is believed that long-term PPI treatment in older people is harmless, hypomagnesemia caused by PPIs (especially omeprazole) [11] is an adverse effect many prescribers are no aware of and may cause cardiovascular and central nervous system problems.

There are some limitations to the current research. One limitation of the study is the lack of information in the clinical charts of oseo densitometric determination for the female population. Therefore, regarding START criteria, it was impossible to verify the presence of ostheoporosis or osteopenia in most of the female patients, so the applicability of the criteria: "supplementation of calcium and vitamin D in patients with osteoporosis" could be biased. It could be stated that patients over 65 years of age are all prone to osteoporosis, if all women were included in this category, the total PPO would raise to 78, reaching a rate of 9.0%, similar to the one reported in international literature [12]. Another limitation was that the duration of PPIs therapy, as it was discussed before, was not stated in the clinical chart, so the STOPP criteria "use of PPIs for peptic ulcer at full therapeutic dosage for more than 8 weeks" was not taken into account.

Conclusions

This is the first study performed in our setting using the STOPP-START criteria; therefore there are no previous results from public hospitals and/or private institutions with which to compare. The results obtained accompany the ones stated in international literature, finding a significant proportion of potential errors of prescribing commission and omission in the areas studied.

In our opinion, pharmacists should incorporate the STOPP-START tools into their everyday practice helping prescribers to take more accurate decisions, preventing the patients from longer hospitalizations and saving the system from unnecessary costs. Performing active pharmacovigilance is a challenge our group has started to embrace, and applying STOPP-START criteria has proved to be a useful tool.

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