Article

Identification of inappropriate prescribing in a Brazilian nursing home using STOPP/START screening tools and the Beers' Criteria

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The objective of this study was to determine the prevalence of Potentially Inappropriate Medication (PIM) use and associated factors, as well as the prevalence of Prescribing Omissions (PO). A cross-sectional study was conducted in a philanthropic Brazilian nursing home involving 46 individuals aged 60 years or older. The following information was collected from medical records and drug prescriptions: gender, age, health conditions and drugs used in the past thirty days. PIM and PO were identified according to the Beers' Criteria and the STOPP/START screening tools. Over one third (37%) of the population used at least one PIM according to the Beers' Criteria (n=17) and 60.9% according to the STOPP tool. A significant association was found between polypharmacy (use of five or more drugs) and use of PIM according to the Beers' Criteria, but not according to the STOPP. Eight residents (17.4%) were exposed to eight PO. This study allowed the diagnosis of a concerning drug utilization profile with use of a high number of PIMs. Thus, there is an evident need to implement strategies for improving geriatric prescription.

Uniterms: Pharmacoepidemiology. Pharmaceutical care. Elderly/inappropriate use of medicines. Medicines/inappropriate prescribing. Medicines/inappropriate use. Beers' Criteria.

O objetivo deste estudo foi determinar a prevalência de uso de medicamentos potencialmente inadequados (MPI) e fatores associados, bem como a prevalência de omissões farmacoterapêuticas (OF). Trata-se de um estudo transversal realizado em uma instituição filantrópica brasileira de longa permanência com 46 indivíduos com 60 anos ou mais. As seguintes informações foram coletadas a partir de prontuários e prescrições: sexo, idade, condições de saúde e medicamentos utilizados nos últimos trinta dias. MPI e OF foram identificados pelo Critério de Beers e as ferramentas de triagem STOPP/START. Mais de um terço (37%) da população utilizou pelo menos, um MPI de acordo com os critérios de Beers (n=17) e 60.9% de acordo com a ferramenta STOPP. Associação estatisticamente significante foi detectada entre a polifarmácia (consumo de cinco ou mais medicamentos) e uso de MPI de acordo com os critérios de Beers, mas não de acordo com o STOPP. Oito residentes (17,4%) foram expostos a oito OF. Este estudo permitiu o diagnóstico de um perfil de utilização de medicamentos preocupante com número elevado de utilização de MPI. Isso indica a necessidade de implementar estratégias para melhorar a qualidade da prescrição geriátrica.

Unitermos: Farmacoepidemiologia. Atenção farmacêutica. Idoso/uso inapropriado de medicamentos. Medicamentos/prescrição inadequada. Medicamentos/uso inapropriado. Critério de Beers.

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INTRODUCTION

The aging process in developing countries has occurred at a fast pace, particularly in Brazil, where the number of elderly has increased from 3 to 20.5 million in the last 50 years (1960 to 2010) (IBGE, 2010).

Demographic changes in the Brazilian population have been accompanied by an epidemiological transition, which is characterized by a reduction in the incidence of infectious and parasitic diseases and a progressive increase in the occurrence of chronic diseases predominantly affecting the elderly population (Schramm *et al.*, 2004). This health profile weakens and reduces the independence of the elderly population, generating a continuous and growing demand for multidisciplinary health care teams, hospitalizations, use of medications and even institutionalization (Berenstein, Wajnman, 2008).

In this scenario, the use of multiple medications encompasses risks and benefits. For this reason, the appropriateness of drugs prescription and use are important indicators for assessing the quality of health for the elderly.

The process of selecting drugs for the elderly should be made with caution, since the use of some active ingredients may present more risks than benefits in this age group (Hamilton, Gallagher, O'Mahony, 2009). Such medications are called Potentially Inappropriate Medications (PIM). The Beers' Criteria and the STOPP (Screening Tool of Older Persons' Potentially Inappropriate Prescriptions) are important references that list drug classes, specific medications and prescribing patterns that fit this category (Fick *et al.*, 2003; O'Mahony *et al.*, 2010). Moreover, the nonprescription of needed drugs, or Prescribing Omissions (PO), also represents an important problem that can be detected by the START (Screening Tool to Alert to Right Treatment): a list of prescription patterns that should be implemented when a specific diagnosis is detected (O'Mahony *et al.*, 2010).

International studies show that the use of PIM and the occurrence of PO are associated with an increased risk of falls, fractures, postoperative confusion, gastrointestinal bleeding, constipation, worsening of congestive heart failure, depression and renal failure (Hamilton, Gallagher, O'Mahony, 2009). Consequently, the prescription of PIM has also been associated with increased mortality and hospitalization among the elderly (Hamilton, Gallagher, O'Mahony, 2009; Ruggiero *et al.*, 2010).

However, many prescribers are unaware of these tools, and the identification of PIM use among the elderly has been internationally documented in nursing homes (NH) (Ruggiero *et al.*, 2010; Gutiérrez-Rodríguez, López-Gaona, 2010; García-Gollarte *et al.*, 2012) in hospitals (Gallagher, O'Mahony, 2008; Nagendra Vishwas *et al.*, 2012), emergency services (Dalleur *et al.*, 2012) and the community (Cahir *et al.*, 2010).

The use of PIM and the occurrence of PO are even more worrying when taking into consideration NH residents, since this population tends to have more debilitated health and functional status and uses more drugs (Braunseis *et al.*, 2011). However, there are few studies investigating drug utilization in Brazilian NHs, and there are no studies applying the STOPP/START tool to assess geriatric prescription quality in Brazil.

The overall aim of this study was therefore to determine the health conditions and drug utilization patterns in the studied population, the prevalence of PIM use and associated factors, as well as the prevalence of PO.

METHODS

A cross-sectional observational study was conducted in a philanthropic NH located in the city of Divinopolis, Minas Gerais State, Brazil.

The eligible study population comprised all individuals aged 60 years or older (criteria for defining elderly subjects in developing countries), residing in the NH in September 2010.

The following information was collected from medical records and drug prescriptions: gender, age, health conditions and drugs used in the last thirty days.

Drugs prescribed were coded using the first and second level of the Anatomical Therapeutic Chemical (ATC) classification system (WHO, 2012). Polypharmacy was defined as the use of five or more drugs. PIM were identified according to the Beers' Criteria (independent / considering diagnosis or conditions) (Fick *et al.*, 2003) and the Screening Tool for Older Persons' Prescriptions (STOPP) (O'Mahony *et al.*, 2010). Identification of PIM according to the STOPP also took into consideration the data from previous prescriptions in order to define the period of utilization. POs were detected using the Screening Tool to Alert to Right Treatment (START) (O'Mahony *et al.*, 2010).

The present study was conducted in compliance with the standards required by the Helsinki Declaration and its ethical approval was granted by the Research Ethics Committee of the Educational Foundation of Divinopolis (FUNEDI) of the State University of Minas Gerais (UEMG) in May 2010, under ethical statement no. 27/2010.

Statistical analysis

A database to store the information gathered was

created on EpiInfo 3.5.3. Data were primarily analyzed through descriptive statistics: frequency distribution, measures of central tendency (mean and median) and dispersion (range and standard deviation).

The association between sex, age groups (60-79 and >79 years) and polypharmacy and PIM prescription was assessed using bivariate analyses. Pearson's Chi-square test was performed for the comparison of proportions or Fisher's exact test when pertinent. The selected association measure was the odds ratio with 95% confidence interval, estimated by logistic regression. For median comparison, the Mann-Whitney test was used. A 5% significance level was defined for all comparisons.

RESULTS

Study sample demographics and health conditions

All the elderly residents were included in the study (n=46). The detected mean±SD age was 80.5±8.5 years and 61% of the elderly were female.

A total of 49 diagnoses were identified on the medical charts (mean=1,1, ranging from 0 to 2) and the most frequent were: Hypertension (17.4%), Diabetes (15.2%), Senile Dementia (9.8%), Parkinson's Disease (9.8%) and Bipolar Affective Disorder (9.8%).

In total, 95.7% of the population under study used at least one drug (n=44) and a total of 196 drugs was prescribed (mean±SD of 4.3 ± 2.7). Polypharmacy was prescribed to 38.6% of the residents (n=17).

The most frequently prescribed medications belonged to the "Nervous System" anatomical group (34.7%), followed by the "Cardiovascular System" (29.7%) and "Alimentary Tract and Metabolism" (17,9%). Taking into considerations the therapeutic classification, the "Psycholeptics" (14.8%) and "Diuretics" (9.7%) were the most prescribed group of drugs.

Prevalence of PIM use

Over one third (37%) of the population used at least one PIM according to Beers' Criteria (n=17). Twenty (10.2%) out of the 196 prescribed drugs were classified as a PIM according to the Beers' Criteria – independent of diagnosis or conditions (Table I), and only one of these (diazepam prescribed to an elder with urinary incontinence) was simultaneously classified as a PIM considering diagnosis or conditions. Diazepam was also the most prescribed PIM among the residents (prescribed to nine of the residents) followed by immediate release nifedipine (three residents) and amitriptyline (two residents).

Taking the STOPP tool into consideration, the prevalence rate of PIM use among residents was 60.9%. Among the medications consumed, 47 PIM were detected (24% of the drugs prescribed). Omeprazole (prescribed to 28.3% of the elderly; n=13), Diazepam (19.7%; n=9) and Haloperidol (10.9%; n=5) were the most frequently prescribed PIM (Table II). A statistically significant difference was found between the medians of number of PIM detected with the STOPP tool and the Beers' Criteria (0.0 vs. 1.0 drug, respectively; p=0.006).

TABLE I - Frequency of potentially inappropriate medication prescription according to the Beers' criteria

Potentially Inappropriate Medication	Absolute Frequency (n)	Relative Frequency (%)
Diazepam – Prolonged sedation and increased risk of falls and fractures	9	45.0
Nifedipine – Potential for hypotension and constipation	3	15.0
Amitriptyline – Presents strong anticholinergic and sedation properties	2	10.0
Alprazolam (dose>2 mg) – Because of increased sensitivity to benzoadiazepines in elderly patients, smaller doses may be effective as well as safer	1	5.0
Amiodarone - Associated with QT interval problems and risk of provoking torsades de pointes. Lack of efficacy in older adults.	1	5.0
Digoxin (dose > 0.125 mg) - Decreased renal clearance may lead to increased risk of toxic effects	1	5.0
Doxazosin - Potential for hypotension, dry mouth, and urinary problems	1	5.0
Flurazepam - Prolonged sedation and increased risk of falls and fractures	1	5.0
Promethazine – Presents potent anticholinergic properties.	1	5.0
TOTAL	**20**	**100**

Factors associated with PIM use

There was no association between age groups or sex and use of PIM according to the Beers' Criteria (p=0.220 and 0.828 respectively) or the STOPP (p=0.828 and 0.979). Polypharmacy was found to be associated with PIM identification according to the Beers' Criteria (p<0.05), but not according to the STOPP tool (p=0.125) (Table III).

Prevalence of PO

With the application of the START tool, eight residents (17.4%) were found to be exposed to eight PO (Table IV).

TABLE II - Frequency of Potentially Inappropriate Medication prescription according to the STOPP

Potentially Inappropriate Medication	Absolute Frequency (n)	Relative Frequency (%)
Omeprazole – Proton pump inhibitor for peptic ulcer disease at full therapeutic dosage for > 8 weeks	13	27.7
Diazepam – Long-term (i.e.>1 month) long-acting benzodiazepines	9	19.1
Haloperidol – Long-term (i.e.>1 month) neuroleptics as long-term hypnotics	5	10.6
Biperiden – Anticholinergics to treat extrapyramidal side-effects of neuroleptic medications	2	4.3
Chlorpromazine – Long-term (i.e.>1 month) neuroleptics as long-term hypnotics	2	4.3
Furosemide – Loop diuretic as first-line monotherapy for hypertension	2	4.3
Loperamide – Loperamide for treatment of diarrhoea of unknown cause	2	4.3
Alprazolam – Drug that adversely affect those prone to falls (≥1 fall in past 3 months)	1	2.1
Bromazepam - Drug that adversely affect those prone to falls (≥1 fall in past 3 months)	1	2.1
Carvedilol – Betablocker in combination with verapamil	1	2.1
Digoxin – Digoxin at a long-term dose > 125 µg/day with impaired renal function	1	2.1
Etodolac – Non-steroidal anti-inflammatory drug with moderate-severe hypertension	1	2.1
Flurazepam – Long-term (i.e.>1 month), long-acting benzodiazepines	1	2.1
Glibenclamide – Glibenclamide with type 2 diabetes mellitus (risk of prolonged hypoglycaemia)	1	2.1
Levomepromazine – Long-term (i.e.>1 month) neuroleptics as long-term hypnotics	1	2.1
Nifedipine – Calcium channel blockers with chronic constipation	1	2.1
Prednisone – Long-term corticosteroid as monotherapy for rheumatoid arthritis	1	2.1
Promethazine – Prolonged use of first generation antihistamines (risk of sedation and anticholinergic side effects)	1	2.1
Warfarin – Warfarin for first, uncomplicated deep venous thrombosis for longer than 6 months duration	1	2.1
TOTAL	**47**	**100**

TABLE III - Association with PIM use analysis

Variables	Use of PIM – Beers' Criteria p value / OR (95% CI)	Use of PIM – STOPP p value / OR (95% CI)
Age groups (60-79 and >79 years)	0.220 / 2.13 (0.63-7.25)	0.729 / 0.81 (0.24-2.68)
Sex	0.828 / 0.87 (0.26-2.97)	0.979 / 0.98 (0.29-3.31)
Polypharmacy	0.019 / 4.49 (1.24-16.26)	0.125 / 3.03 (0.80-11.54)

TABLE IV - Frequency of prescribing omissions

Prescribing Omission	Absolute Frequency (n)	Relative Frequency (%)
Aspirin or clopidogrel with a documented history of atherosclerotic coronary, cerebral or peripheral disease in patients with sinus rhythm	3	37.5
Angiotensin-converting-enzyme inhibitor with chronic heart failure	2	25.0
Levodopa in idiopathic Parkinson's disease with definitive functional impairment and resultant disability	1	12.5
Bisphosphonates in patients taking maintenance oral corticosteroid therapy	1	12.5
Antiplatelet therapy in diabetes mellitus IF one or more co-existing major cardiovascular risk factors present	1	12.5

DISCUSSION

Like in the present NH under study, hypertension was one of the most frequent diagnoses identified in other Brazilian NHs, and likewise in Italy, Spain and Norway (Correr *et al*., 2007; Danilow *et al*., 2007; Aguiar *et al*., 2008; Araújo *et al*., 2008; Gonçalves *et al*., 2008; Gutiérrez-Rodriguez, López Gaona, 2010; Halvorsen *et al*., 2010). This portrays the escalating prevalence and mortality of cardiovascular diseases detected in Brazil and worldwide (IBGE, 2010).

The average number of drugs used (4.3 ± 2.7) detected in the present study was similar to the average number of drugs detected by Araújo *et al*. (2008) in another Brazilian NH (average = 4.8 drugs/elderly). The average proved higher however, than those detected by Aguiar *et al*. (2008) and Correr *et al*. (2007) in two other Brazilian NHs (2.7 and 3.0 respectively), but lower than those detected in a Belgian NH by Azermai *et al*. (2011) (average = 7), and by Gutierrez-Rodríguez & López-Gaona (2010) and García-Gollarte *et al*. (2012) in Spanish NHs (averages of 6.3 and 6.5, respectively). Nonetheless, the higher the number of drugs used by the elderly, the higher the level of therapeutic complexity.

Mirroring other studies, the most prescribed drugs were those used to treat diseases of the nervous system and cardiovascular system (Castellar *et al*., 2007; Correr *et al*., 2007; Aguiar *et al*., 2008; Gutiérrez-Rodriguez, López Gaona, 2010). However, in most cases, the anatomical group "Cardiovascular System" tends to rank first, but this was not the case in the present study (Castellar *et al*., 2007; Correr *et al*., 2007; Danilow *et al*., 2007; Aguiar *et al*., 2008; Gutiérrez-Rodriguez, López Gaona, 2010). This may indicate excessive and irrational prescription of Nervous System acting drugs or inadequate diagnosis, since drugs classified as psycholeptics were the most prescribed. This group of drugs can reduce functionality and predispose the elderly to falls.

In the present study, the percentage of elderly using at least one PIM according to the Beers' Criteria (38.6% of medication users) was high, indicating a possible lack of knowledge regarding the Beers' Criteria among prescribers, representing a higher rate than that detected by Aguiar *et al*. (2008) (32.9%) and Varallo *et al*. (2012) (29,2%) in Brazil.

The prevalence of PIM according to the Beers' Criteria among the prescribed drugs (10.2%) was similar to the rate detected by Correr *et al*. (2007) in Apucarana - Brazil (13.5%). In both these Brazilian studies, short acting nifedipine and amitriptyline were among the three most prescribed PIM, and in a study by Aguiar *et al*. (2008), amitriptyline was the most prescribed PIM. Diazepam, the most prescribed PIM in the present study, however, ranked only fourth in the studies by Correr *et al*. (2007) and Aguiar *et al*. (2008).

It is noteworthy that the three most prescribed PIM in the present study (diazepam, short acting nifedipine and amitriptyline) predispose the elderly to falls and fractures due to its pronounced sedation effect or increased risk of hypotension (Fick *et al*., 2003).

As for the identification of only one PIM considering diagnosis or conditions according to the Beers' Criteria, this is believed to be an underestimated indicator, due to the low quality of the patient charts in the studied institution.

Using the STOPP, however, the number of PIM detected was higher (n=47, 24% of the prescribed drugs) and prescribed to a higher number of individuals (n=28, 63.6% of the medications users), despite the fact that STOPP contains less criteria for potentially inappropriate prescribing than the Beers' Criteria. No Brazilian studies with the use of the STOPP have been published, but international studies in NHs in Spain conducted by

García-Gollarte *et al.* (2012) in Valencia and Gutierrez-Rodríguez and López-Gaona (2010) in Asturia both detected greater prevalences than that detected in the present study (79% and 71.4%, respectively) (Gutiérrez-Rodríguez, López-Gaona., 2010; García-Gollarte *et al.*, 2012).

The three most prescribed PIMs according to the STOPP were: omeprazole, diazepam (also identified as the most prescribed PIM according to the Beers' Criteria in the present institution) and haloperidol. In the study conducted by García-Gollarte *et al.* (2012), the most prescribed PIM were also proton-pump inhibitors, benzodiazepines and antipsychotic drugs. Once again, the fact that the latter two drug groups predispose the elderly to falls and/or fractures draws attention (Fick *et al.*, 2003).

As established by international studies, the present study also detected a statistically significant difference between the number of PIM identified by the Beers' Criteria and the STOPP, indicating that the latter tool has a higher potential for detecting unsafe prescription that can lead to drug-related adverse events (Hamilton, Gallagher, O'Mahony, 2009). However, no association between sex, age and use of PIM was encountered.

The prevalence of polypharmacy among the residents was high (37%) and greater than the prevalence detected in other national studies (Castellar *et al.*, 2007; Correr *et al.*, 2007; Danilow *et al.*, 2007; Aguiar *et al.*, 2008; Gonçalves *et al.*, 2008). Polypharmacy exposes the elderly to a higher risk of developing adverse events and, for this reason, should only be employed when the use of multiple drugs is indispensable (McLean, Le Couteur, 2004; Kostoff, Delafuente, 2006; Viktil *et al.*, 2007; Hajjar, Cafiero, Hanlon, 2007). The association between polypharmacy and the use of PIM according to the Beers' Criteria detected in the present study corroborates with this fact. However, no association between polypharmacy and the use of PIM was identified according to the STOPP, unlike other studies conducted in hospitals (Gallagher *et al.*, 2011).

The use of the START enabled the detection of PO for a substantial proportion of the studied population (17.4% of the elderly), however, it is believed that this value was underestimated due to problems concerning the documentation of health problems in the medical records/charts and insufficient medical assistance.

To date, there are no studies in Brazil that show the use of the START, but the few international studies published show a higher frequency of PO among the elderly (52.4% detected in Asturias and 74% in Valencia) (Gutiérrez-Rodríguez, López-Gaona, 2010; García-Gollarte *et al.*, 2012).

The non-prescription of agents in a bid to reduce cardiovascular risk was the most common inappropriateness identified with the START (among six elderly). However, it is important to point out that the two patients with no angiotensin converting enzyme inhibitor (ACEI) in their prescriptions who had chronic heart failure used losartan (an angiotensin II antagonist that can substitute ACEI in cases where the patient develops adverse drug reactions to the latter).

Another PO detected was the need for prescription of antithrombotic agents to patients with diabetes and high cardiovascular risk (n=1). Nevertheless, in the light of recent knowledge, this practice has been questioned, since there are no studies showing that the use of aspirin reduces the risk of cardiovascular events in diabetic patients (Berger *et al.*, 2011). Besides, the use of aspirin in low doses has been increasingly associated with the development of gastrointestinal bleeding, an adverse drug reaction especially dangerous in patients with diabetes mellitus, since this group tends to have an increased risk of presenting such events (up to 55%) (Berger *et al.*, 2011).

In contrast with the present study, in Valencia, Spain, the most commonly detected PO in NH were nonprescription of vitamin D, statins and aspirin (García-Gollarte *et al.*, 2012).

CONCLUSIONS

Despite the small number of subjects, the present study allowed the diagnosis of a concerning drug utilization profile. Although the clinical outcomes of the drug therapy were not analyzed, the high number of inadequacies indicates a low level therapeutic decision process in the studied institution.

Thus, there is an evident need to implement strategies for improving geriatric prescription and clinical documentation. Pharmacists assuming the role of being co-responsible for geriatric drug therapy, as well as propagators of global knowledge in this area, represents a plausible alternative that could generate positive results, as described in the literature (Romano-Lieber *et al.*, 2002).

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