Consenso brasileiro de medicamentos potencialmente inapropriados (CBMPI) associados a idade avançada, polifarmacia e multimorbidade circulatória

Brazilian consensus on potentially inappropriate medications (BCPIM) associated with advanced age, polypharmacy and cardiovascular multimorbidities

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RESUMO
Objetivo. Essa pesquisa se propôs a investigar a associação entre variáveis demográficas, clínicas e o uso de Medicamentos Potencialmente Inapropriados (MPI) em idosos em assistência ambulatorial medica de especialidades. **Métodos.** Estudo observacional, quantitativo e de base populacional conduzido com indivíduos com idade igual ou superior a 60 anos de um serviço público de nível secundário à saúde, município de Carapicuíba, SP, Brasil. Para análise, utilizaram-se informações referentes às consultas médicas consolidadas em prontuários eletrônicos e, posteriormente, empregou-se o Consenso Brasileiro de MPI (CBMPI) para idosos. Para estatística, utilizou-se analise descritiva simples e de regressão logística. **Resultados.** Totalizaram-se 1.548

medicamentos em uso contínuo por um grupo de 233 idosos assistidos por médicos clínicos. Verificou-se que, ¾ da amostra estava em uso de MPI, de acordo com CBMPI. A utilização do inibidor irreversível não seletivo da COX (7,69%) e dos inibidores de bomba de prótons (4,90%) foram os mais prevalentes. A presença de idade avançada (OR=3.39; IC95%=1.05-10.9; p=0.04), multimorbidades (OR=7.39; IC95%=2.95-18.4; p<0.001), desordens do sistema cardiovascular (OR=3.00; IC95%=1.28-6.99; p<0.001) e a polifarmácia (OR=3.88; IC95%=1.26-11.9; p<0.001) foram as principais variáveis fortemente associadas ao aumento do risco com o uso de MPI em idosos. **Conclusão.** Variáveis demográfica e clínicas de caráter crônico estiveram fortemente relacionadas ao uso de MPI em idosos assistidos por médicos em nível ambulatorial. Acredita-se que, essa pesquisa corrobora para consolidação dos principais fatores modificáveis e não modificáveis para prevenção de eventos iatrogênicos indesejáveis neste grupo etário.

Palavras-chave: Assistência a idoso, Uso indevido de medicamentos, Polimedicação, Lista de medicamentos potencialmente inadequados, Iatrogenia, Multimorbidade.

ABSTRACT

Objective. This research aimed to analyze the association between demographic, clinical variables and the use of Potentially Inappropriate Medications (PIM) in elderly patients from a medical specialties clinic. **Methods.** An observational, quantitative and population-based study was conducted with individuals of 60 years old and over from a public service of secondary health level located at Carapicuíba, Sao Paulo, Brazil. Information related to medical consultations filled in electronic charts were used to analyze possible iatrogenic causes with posterior application of the Brazilian Consensus on Potentially Inappropriate Medications (BCPIM). For statistics, simple descriptive analysis and logistic regression were used. **Results.** There were a total of 1,548 medications in continuous use by a group of 233 elderly patients assisted by clinicians. It was found that ¾ of the sample was using PIM, according to BCPIM. The use of the non-selective irreversible COX inhibitor (7.69%) and proton pump inhibitors (4.90%) were the most prevalent. The presence of advanced age (OR = 3.39; 95% CI = 1.05-10.9; p = 0.04), multimorbidity (OR = 7.39; 95% CI = 2.95-18.4; p <0.001), disorders of the cardiovascular system (OR = 3.00; CI95 % = 1.28-6.99; p <0.001) and polypharmacy (OR = 3.88; 95% CI = 1.26-11.9; p <0.001) were the main variables strongly associated with increased risk within the use of PIM in the elderly. **Conclusion.** Demographic and clinical variables of a chronic nature were fully related to the use of PIM in elderly assisted by doctors. It is believed that this research supports the consolidation of the main modifiable and non-modifiable risk factors for the prevention of undesirable iatrogenic outcomes in this age group.

Key words: Old Age Assistance, Prescription Drug Misuse, Prescription Drug Overuse, Potentially Inappropriate Medication List, Iatrogenic, Multimorbidity.

1 INTRODUCTION

Medicalization involves risks to the health security of the elderly, because, if the risk is greater than the clinical benefits provided, when safer and more effective alternatives are available, it is considered to be potentially inappropriate for the individual.[1,2] Medicalization involves risks to the overall health of the elderly. This is based on the fact that if the risk is greater than the clinical benefits provided by the medication or when safer and more effective alternatives are available, that medication is considered to be potentially inappropriate for the individual. Based on this concept, in order to minimize the risks related to medicated therapy, researchers have developed straightforward criteria for preventing inappropriate prescription to the elderly.[3,4]

For a long time researchers sought to adapt different lists of PIM that were developed and applied to other groups of different conditions than the ones in Brazil. This had led to the lack of a list that meets the particularities of commercializing, prescribing and dispensing medications in public health services throughout the national territory. In addition, this also reflects on the underestimation consistent on Brazilian research data. In consequence, the first Brazilian Consensus on Potentially Inappropriate Medications (CBMPI) for Elderly was launched in 2016. [4,5]

The need to develop this research arose from the social and clinical relevance of the aforementioned theme. The purpose was to investigate the possible associations between demographic and clinical variables and the continuous and regular use of PIM based on the BCPIM, within the elderly patients from a medical specialties clinic of a hospital.

2 MATERIALS AND METHODS

2.1 STUDY DESIGN AND ETHICAL CONSIDERATIONS

This observational, quantitative and retrospective study cutout was conducted in 2017 with 233 elderly from a public service at secondary level care. The institutional review board (IRB), called Research Ethics Committee of Centro Universitário São Camilo (CUSC-SP), reviewed and approved this study (protocol number 2.450.912).

2.3 SAMPLE SIZE

The sample size estimation was performed considering the sampling error of 5%, with 95% confidence level and a total population of 544 elderly receiving medical care

in a specialized outpatient service. A sample size of at least 226 elderly people in therapeutic regimen with medical assistance was considered to carry out this research.

2.4 LOCATION, PARTICIPANTS AND ELIGIBILITY CRITERIA

The health service employed on the development of this research provides assistance related to short, medium and long-term health issues in the municipality of Carapicuíba, São Paulo, Brazil. It is a public service for cases of medium and high complexity.

The Hospital has 241 beds, including the following medical specialties: general, vascular, plastic, paediatrics and thoracic surgery; orthopaedics and traumatology, gynaecology and obstetrics, ophthalmology, paediatrics, internal medicine, respirology, geriatrics, palliative care, cardiology, nephrology, hematology, dermatology and neurology. In addition to providing assistance in referred emergency/urgency cases with the need for hospitalization and hemodialysis, this service also provides health care for a continuous period via the outpatient medical specialties department.

The eligibility criteria of the research participants were: individuals with (i) age equal to or above 60 years old, based on the definition of the World Health Organization (WHO);[6] (ii) within outpatient follow-up at the service previously mentioned, and (iii) who were in a therapeutic drug regimen. The lack of information in electronic medical records during the data collection process was adopted as an exclusion criteria.

2.5 DATA COLLECTION AND ANALYSIS VARIABLES

A structured survey was used to systematically search for relevant variables in electronic medical records, considering the eligibility criteria for inclusion in this research. The researchers completed the surveys and, subsequently, this information was consolidated into a database exclusive to the research.

All data were subjected to review and categorization and, when conflicting or inconsistent information was evidenced, correction was carried out by consulting the original electronic medical chart. Using demographic specifics, morbidity, drug therapy and health service utilization survey created by the researchers, it was possible to characterize the research population group.

The independent variables were: sex; age; presence of morbidity, categorized according to the International Classification of Diseases (ICD-10);[7] consultation motive;

medications in continuous use; polypharmacy, considered as continuous and regular consumption of five or more medications;[3] specialists seen and service follow-up time.

It should be noted that the dependent variable was the use of at least one PIM. To characterize the use of PIM, the BCPIM for Elderly was applied, regardless of the clinical condition.[5]

The BCMPI was based on content of the American Society of Geriatrics - AGS Beers Criteria 2012 [8] and STOPP (Screening Tool of the Older Person's potentially inappropriate Prescriptions) 2006 [9] to obtain its final consensus, creating two lists of PIM dependent on and independent of clinical conditions. The content used to create the Brazilian Consensus consists of lists that have been widely tested and applied in geriatric clinics, hospitals and educational centers, previous studies, and even as indicators of the quality of public health services. This consensus emerged from the need for a list adjusted to the reality of commercialization and local prescription of drugs for the geriatric population. The goal was to improve quality and safety while prescribing to individuals most vulnerable to complications related to medication. [5]

2.6 STATISTICAL ANALYSIS

The analysis of the data used the descriptive statistics. To investigate the association between the use of PIM and the independent variables, the logistic regression (Stepwise Forward Method) was employed. For this model, the independent variables that obtained a p-value <0.20 were included in the final multivariate model, through adjustment.

The data were analyzed using the software Stata version 15.1 (Stata Corporation, College Station, United States - USA) and a level of statistical significance was considered when the variables maintained a p-value <0.05.

3 RESULTS

There was a predominance of elderly males (50.2%), whose average age was equal to 75 (SD ± 9) years old. It is noteworthy that, in this group, no significant association was found between the variables age and sex (p> 0.05). Regarding the assistance provided, there was a higher demand for general practitioners (70%), followed by pulmonologists (41.6%) and cardiologists (22.7%), reaching framing an average of elderly people being monitored by 2.5 (SD ± 1.2) doctors for a period of 3 (SD ± 2) years

in this service. As for the reasons for consultation, the main one was follow up on previous treatments (41.2%).

The **Table 01** shows that disorders of the cardiovascular and endocrine systems were the main ones present in the analyzed group, such as Systemic Arterial Hypertension and Diabetes Mellitus respectively. However, the predominance of Stroke and Chronic Obstructive Pulmonary Disease (COPD) should also be highlighted. In the total analysis of 1,138 morbidities, an average of 5 (SD ± 2.8) multimorbidity per elderly was found.

Table 01. Main chronic degenerative morbidities categorized, according to the International Classification of Diseases 10 (ICD-10) in the elderly with clinical assistance in an outpatient clinic of medical specialties.

Systems	Morbidities		n (%)
	Diagnosis	ICD-10*	
Cardiovascular (421; 3%)	Systemic Arterial Hypertension	I10	185 (16.2)
	Dyslipidemia	E78	56 (4.9)
	Heart Failure	I50	55 (4.8)
	Acute Myocardial Infarction	I21.9	46 (4.0)
	Arrhythmias	I49.9	39 (3.4)
Metabolic and Hormonal (210; 18.4%)	Diabetes *Mellitus*	E14	77 (6.7)
	Hypothyreoidism	E03.9	28 (2.4)
	Gastroesophageal Reflux Disease	K21.0	23 (2.0)
	Obesity	E.66.9	13 (1.1)
Neurological (164; 14.4%)	Brain Stroke	I64	76 (6.6)
	Insanity	F03	38 (3.3)
	Depression	F32	13 (1.1)
	Parkinson's Disease	G20	6 (0.5)
Respiratory (129; 11.3%)	Chonic Obstructive Pulmonary Disease	J44.9	68 (5.9)
	Rhinitis		
	Asthma	J30.4	20 (1.7)
	Pulmonary Thromboembolism	J45.9	13 (1.1)
		I26	6 (0.5)
Musculoskeletal and Osteoarticular (73; 6.4%)	Osteoarthritis	M19.9	18 (1.5)
	Osteoporosis	M81	13 (1.1)
	Femoral Fracture	S72	6 (0.5)
	Gouty Arthritis	M10.9	6 (0.5)
Genitourinary (67; 5.8%)	Chronic Kidney Disease	N18	30 (2.6)
	Benign Prostatic Hyperplasia	N40	14 (1.2)
	Urinary Incontinence	R32	6 (0.5)
	Nephrolithiasis	N20	4 (0.3)

Sense Organs (22; 1.9%)	Cataract	H25	7 (0.6)
	Glaucoma	H40	3 (0.2)
	Amaurosis	H54	3 (0.2)
	Vertigo	R42	2 (0.1)
Dermatological (19; 1.6%)	Skin Neoplasm	D485	6 (0.5)
	Dermatitis	L30.9	3 (0.2)
	Ulcer	L98.4	3 (0.2)
	Psoriasis	L40	2 (0.1)
Infectious (16; 1.4%)	Chagas	B57	10 (0.8)
	HIV	B20	2 (0.1)
	Herpes Zoster	B02	1 (0.08)
	Erysipelas	A46	1 (0.08)
Hematopoietic (12; 1.0%)	Anemia	D64.9	4 (0.3)
	Polyglobulia	D45	4 (0.3)
	Idiopathic Thrombocytopenic Purpura	D69.3	2 (0.1)
Others (5; 0.4%)	Immobility Syndrome	M62.3	3 (0.2)
	Breast Neoplasm	C50.9	2 (0.1)
	Fragility Syndrome	R54	1 (0.08)
	Caregiver Syndrome	Z74	1 (0.08)
	Sjogren's Syndrome	M35.0	1 (0.08)

*ICD-19: International Classification of Diseases, 10° review in 2014.[7]

Within the treatment of these morbidities, an average of 6.6 (SD ±3.1) elderly people using polypharmacy and 2 (SD ±1.3) in use of PIM was found, according to BCPIM. Among the 476 PIM identified, there was a predominance of irreversible non-selective COX inhibitors (7.6%) and proton pump inhibitors (4.9%). Applied to logistic regression, it was noted that the presence of advanced age (OR=3.39; 95% CI=1.05-10.9; p=0.04), multimorbidity (OR=7.39; 95% CI=2.95-18.4; p<0.001), disorders the cardiovascular system (OR=3.00; 95% CI=1.28-6.99; p<0.001) and polypharmacy (OR=3.88; 95% CI=1.26-11.9; p<0.001) were the main variables associated with increased risk of use of PIM in the elderly (Table 2).

Table 02. Logistic regression to identify variables associated with increased risk of using Potentially Inappropriate Medicines (PIM), according to the Brazilian Consensus of Potentially Inappropriate Medicines (BCMPI).

Variables	Univariate Analysis		Multivariate Analysis	
	OR (95% CI)*	p	*OR* (95% CI)*	p
Sex				
Male	1.32 (0.57-3.05)		1.23 (0.45-3.34)	
Female	1.00	0.512	1.00	0.681
Age				
60-69	1.00		1.00	
70-79	1.44 (0.56--3.71)	0.447	1.09 (0.35-3.41)	0.878
≥80	**3.39 (1.05-10.9)**	**0.04**	3.33 (0.90-12.3)	0.071
Multimorbidity				
<3	1.00		-	
≥3	**7.39 (2.96-18.4)**	**<0.001**	-	-
Cardiovascular multimorbidity				
No	1.00		-	
Yes	**3.00 (1.28-6.99)**	**<0.001**	-	-
Polypharmacy				
No	1.00		1.00	
Yes	**11.47 (4.32-30.4)**	**<0.001**	**3.88 (1.26-11.9)**	**<0.001**
Period in health care	1.19 (0.97-1.45)	0.903	-	-

*OR: Odds Ratio (estimated by Stepwise Forward logistic regression); 95 CI%: 95% Confidence Interval.

4 DISCUSSION

This research identified a prevalence of 30.7% of the elderly using PIM in outpatient medical care and an increased risk of using PIM was also noted in individuals with advanced age, using polypharmacy and patients with multimorbidity, especially of the circulatory system. It should be noted that the prescription and use of PIM in clinical practice is not contraindicated, however, it must be executed with caution, in with routine monitoring and attention to the development of new symptoms. [4,5,8]

It is interesting to note that, despite the frequency of PIM use found in this research, this group is in the midway of the prevalence seen in previous studies that used the same screening tool (26.6% to 58.4%).[3,10] However, it is noteworthy that those studies were conducted with groups of elderly of an exclusive gender, related to the Brazilian private health sector and with hospitalized patients, in contrast to the group included in this research. [3,10]

On the other hand, it is relevant to consider the common factors into taking this action in clinical practice in Brazil. The target population of this research is of a city marked by poverty, with a population growth rate of 0.5% per year, considered the second most populous city among the adjacent ones in the region. [11] Therefore, it is believed that the presence of low socioeconomic conditions that restrain from the purchase of safer medications combined with lower educational levels are directly related to the use of medications that are less safe but more accessible to this group.[12]

The high prevalence of PIM identified as non-selective irreversible COX inhibitors and proton pump inhibitors are consistent with the national literature [2,3,13] and justified for this group. Those medications are free and easily dispensed in Brazilian pharmacies under the restriction of medical prescriptions. [14] Even though they represent group of drugs that imply imminent health risks for the elderly. In addition to promoting sodium and water retention, the non-selective COX inhibitors reduce the inhibition of chloride absorption and the action of antidiuretic hormone, increasing the propensity to hyperkalemia, edema and blood pressure levels decompensation, specially in hypertensive individuals. Furthermore, this medication carries the risk of causing dyspepsia, heartburn, gastric and duodenal ulceration, increasing bleeding time due to platelet dysfunction, acute renal injury in consequence of renal hypo flux and decreased glomerular filtration rate. [5,8,13]

As for the proton pump inhibitors, the use for more the eight weeks can lead to changes in the gastric pH facilitating secondary infections by Clostridium difficile, hypomagnesemia, hypokalemia, B12 and iron deficiency as a result of gastric atrophy and malabsorption. Other additional risks related to the prolonged use of this therapeutic group are: osteoporosis and fractures in consequence of reduced bone mineral density, dementia, kidney injury, pneumonia, and development of gastric neoplasia in Helicobacter pylori infected patients or with previous successful eradication. [3,14]

The longevity revolution, the process of aging within the general population, has become a phenomenon in the national territory. Previous research has pointed it out as an

associated factor for different outcomes, and this one was no different. [15,16,17] The presence of advanced age was related to the increase of the risk for PIM use, as well as the presence of multimorbidity, specially of the circulatory system, and the use of polypharmacy. These data, already published, [10,18,19,20,21] support the need for the implementation of measures of health promotion within the elderly.

Older elderly, in many cases, have multiple and chronic disorders, outlining the condition of multimorbidity, being those of the circulatory system the main one identified in this group. In this scenario, the prescription of medications with different mechanisms for controlling morbidities and preventing associated complications becomes necessary and commonplace, as evidenced in several studies. However, it should be noted that it is a cascade and/or way of management which increase the risk for unwanted and potentially inappropriate outcomes to the health and therapeutic safety of the elderly. [10,18,19,20,21]

4.1 LIMITATIONS

The lack of screening for socioeconomic variables, determination of the period in use, dose of medications and evaluation of the use of PIM depending on the clinical condition were some of the limitations of this research and which may have mimicked predictors of the explored group. The unlikelihood of generalizing the findings of this study is also considered.

5 CONCLUSION

The use of PIM, according to the BCPIM, was of high prevalence within the elderly seen in outpatient medical care of medical specialties. Distinguished factors such as advanced age, use of polypharmacy and multimorbidity, specially related to the circulatory system, endorsed the increased risk for unwanted therapeutic outcomes in this age group. It is believed that these data validate the consolidation of the main modifiable and non-modifiable factors associated with the risk of common iatrogenic events in the treatment of the elderly.

AUTHOR'S CONTRIBUTION

All authors contributed to the creation, development and writing of the manuscript, in addition, all of them read and approved the final version of the manuscript.

DECLARATION OF CONFLICTING INTERESTS

The authors declare that there are no conflicts of interests exist.

ETHICAL CONSIDERATION

This research used data and information in the public domain and, thefore, this research strictly followes all the recommended ethical precepts.

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