Use of potentially inappropriate medications by the elderly at home

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Abstract *The goal of this study was to assess how often potentially inappropriate medicines are used by the elderly at home, and analyze its clinical significance. This is a retrospective cross-sectional study, a segment of a study on the use of medication conducted at a public hospital. Inappropriate medication was classified according to the three criteria in the 2012 Beers List. 190 elderly were included in this study; the prevalence of the use of inappropriate medicines was 44.2%. The therapeutic classes of most often used inappropriate medicines were non-steroid anti-inflammatories, cardiovascular agents, benzodiazepines and antidepressants. We found a positive association between the use of inappropriate medicines and polypharmacy, polypathology and hypertension. The 2013 Rename identified 35 inappropriate drugs (34.3%). The study showed a high prevalence of using inappropriate medicines by the elderly. The clinical consequences of using inappropriate medicines are important for public health due to the risk of adverse events and a negative impact on elderly functionality. When it comes to caring for the elderly, it is important to develop measures to foster the rational use of medication.*
Key words *Beers criteria, Pharmacoepidemiology, Elderly, Use of medication*

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Introduction

In recent decades, the world's population has undergone a period of demographic transition, resulting in a significant increase in the number of people over 60 years of age. Among the determinants of this transition are improved living and health conditions, which have contributed to lower mortality[1,2]. Many of these elderly present multiple chronic diseases or some form of functional limitation requiring constant care, increased use of healthcare services and continued use medication[3]. Treating the different pathologies of the elderly requires a wide array of pharmacological alternatives, which results in the concomitant use of different medicines by a single patient[4-6].

Certain medicines are classified as inappropriate for use by the elderly, as in this population group the risks outweigh the benefits[7,8]. Therefore, due to the increased risk of adverse reactions, avoiding the use of inappropriate medicines by the elderly is an effective strategy to ensure safe drug therapy in this age group.

The Beers criteria are a set of explicit criteria that identify medicines considered potentially inappropriate for the elderly, describing the associated risks. For 20 years the Beers list was the most widely used criterion to assess drug prescriptions for the elderly[7-10]. The Beers criteria were reviewed in 2012 by experts of the American Geriatrics Society, grouping inappropriate medicines into three different categories: Potentially Inappropriate Medications In The Older Adults (PIM), potentially inappropriate medications and classes to avoid in older adults with certain diseases and syndromes that the drugs listed can exacerbate, and medications to be used with caution in the elderly[7].

The use of medication by the elderly is the topic of research in Brazil and the world, looking at it both from the perspective of care as well as collective health[11-29]. The product of these scientific endeavors is important to create guidelines for programs of care and lines of care for the elderly. To date, no studies looking at all three categories of the 2012 de Beers category have been performed in Brazil.

The rational use of medication by the elderly population is essential to avoid adverse events that can compromise the health and quality of life of this population group[6,14]. Public health policies should also consider the specificities of the elderly and, within the scope of pharmaceutical assistance, provide medicines that are appropriate for this age group[11,12]. The use of inappropriate medicines by this population is a public health problem, thus the importance of investigating the frequency of use of these medicines by the elderly using the three categories of the most recent Beers Criteria.

Objectives

The present study aims to determine the frequency of using potentially inappropriate medications by the elderly at home, and analyzing its clinical significance.

Methods

A cross-sectional, retrospective study. A segment of a study on medication use conducted at a public general teaching hospital in Belo Horizonte, Minas Gerais. This is a university hospital engaged in teaching, research and care. It is a reference institution for the city and state healthcare systems, providing care for patients with medium to high complexity pathologies.

This segment will approach inappropriate medicines used at home by elderly patients in the hospital where the study was performed. Medication inappropriate for the elderly were investigated according to the 2012 de Beers criteria[7]. This study was authorized by the institution and approved by the Federal University of Minas Gerais Research Ethics Committee.

The study population was made up of patients hospitalized between January and December 2010. The patients selected for the study came from a unit with a preponderance of internal medicine beds serving the following specialties: endocrinology, geriatrics, hematology, nephrology and oncology. The sample was not probabilistic but included all patients meeting the inclusion criteria: aged over 60, information on home use of medicines recorded in the medical chart, availability of the medical chart in the Statistical Medical Files Service. The absence of information on home use of drugs in the medical chart was an exclusion criterion. The list of hospitalized patients was taken from a report issued by the hospital's computerized bed management system.

Clinical and demographic data, and information regarding home use of medicines was collected from admission notes, clinical progress notes and prescriptions found in patient files.

The data was recorded using a tool developed specifically for this study.

The clinical description of the patients is based on the diagnostic on admission and co-morbidities mentioned in the medical chart. The diagnostic on admission and comorbidities were identified and classified according to the tenth edition of the International Code of Diseases (ICD 10)[30]. The Charlson Comorbidity Index was also calculated. This is a score used to assess patient prognosis based on age and comorbidities, and to analyze the effect of comorbidities on health outcomes. This index has been validated for use in hospitals and the community[31].

The PIM used by the elderly at home were classified according to the 2012 Beers criteria as follows: potentially inappropriate, inappropriate considering the syndromes /disease, inappropriate to be used with caution in the elderly[7].

The 2012 Beers list was prepared by the American Geriatrics Society based on medicines available in the US. We checked the availability of these PIMs in Brazil, and if they were included as treatment options in the Brazilian Unified Healthcare System, looking at the 2013 Brazilian National List of Essential Medicines – Rename[32,33]. This analysis considered only the drug, regardless of the or presentation available in the 2013 Rename, and drugs mentioned in one of the three 2012 de Beers criteria (inappropriate, inappropriate for the diagnostic/disease, inappropriate, to be used with caution in the elderly). Where the 2012 de Beers criteria listed only therapeutic class, without specifying the drugs, we were of course unable to define the drug and check whether or not it is listed in the 2013 Rename.

Polypharmacy, the categorical variable, was defined in this study as the concomitant use of five or more medicines, and polypathology as the presence of five or more diseases.

The database was created using EpiData, version 3.1. A descriptive analysis of the data was performed, determining the frequency and percentages for the categorical variables, measurements of central trend (mean and median), and dispersion measurements (standard deviation and inter-quartile range - IQR) for the quantitative variables. The unit of analysis for the study variables was the number of elderly patients.

Categorical variables were the use of PIM, polypharmacy, comorbidity and gender. Quantitative variables were age, number of medicines used in the home, Charlson Comorbidity Index and number of pathologies. The study response variable was use of a PIM, considering the use of at least one PIM in one of the three 2012 de Beers criteria. The explanatory categorical variables were compared to the response variable using contingency tables, using chi-squared to calculate the odds ratio. SPSS 17.0 was used for statistical analyses.

Results

Of the 190 elderly included in the study, 99 (52.5%) were female. Participants ranged in age from 60 to 100, with 50% of the elderly in the study between the ages of 60 and 69. A detailed description of the study population is available in Table 1.

The Charlson Comorbidity Index had a median of 5.0 and IQR of 3.0. The median number of medicines used by the elderly on admission was 4.0 with an IQR of 3.0. The number of pathologies in the population had a median of 3.0 and IQR of 2.0.

Table 1. Demographic and clinical characteristics of 190 elderly subjects, Belo Horizonte, Minas Gerais, 2010.

Demographic and clinical characteristics	
Female Gender - n (%):	99 (52.1)
Median Age (IQR)	69,5 (12.0)
Age group - n (%)	
60-69	95 (50.0)
70-79	59 (31.0)
80-89	33 (17.4)
≥ 90	3 (1.6)
Charlson Comorbidity Index - Median (IQR)	5.0 (3.0)
Number of pathologies - median (IQR)	3.0 (2.0)
Comorbidities - n (%)	
Systemic Hypertension	125 (65.8)
Heart Failure	67 (35.3)
Chronic Renal Disease	50 (26.3)
Diabetes Mellitus	49 (25.8)
Acute Myocardial Infraction	41 (21.6)
Chronic Obstructive Pulmonary Disease/ Asthma	37 (19.5)
Atrial Fibrillation	31 (16.3)
Cerebrovascular Disease	31 (16.3)
Dementia	18 (9.5)
Pharmacotherapy	
Number of medicines - median (IQR)	4.0 (3.0)
Polypharmacy - n (%)	91 (47.9)

Of the 190 elderly in the study, 164 (86.4%) had up to four pathologies, with a median of 3.0. Systemic hypertension was the most prevalent, present in 125 (65.8%) of the elderly, followed by congestive heart failure (35.3%), chronic renal disease (26.3%) and diabetes mellitus (25.8%). The breakdown of the main comorbidities in the 190 elderlies can be seen in Table 1.

The use of five or more medicines, the traditional concept of polypharmacy, was found in 91 (47.9%) patients. However, if we adopt the concept of Jyrkaa et al.[34], which is 6 to 9 medicines, polypharmacy prevalence dropped to 51 (26.8%), and excessive polypharmacy ($\geq$ 10 medicines) to 7 (3.7%).

The frequency of elderly people using PIMs according to the three 2012 de Beers categories in the study group was 44.2% (84 patients). Analyzing the frequency using the 2012 de Beers criteria, we found that the frequency of elderly patients using PIM was 35.6% (67 patients), regardless of the diagnosis. 38 (20.0%) used a PIM that should be prescribed with caution in the elderly, and 13 (6.8%) used a PIM considering diseases and syndromes.

Of the 67 (35.7%) elderly patients using PIM regardless of diagnosis, we found that 53 (27.9%) used one PIM, 14 (3%) used two and one (0.5%) used three. Of the 38 (20.0%) using a PIM that should be used with caution in the elderly , one patient was using four medicines, but the majority (25 or 13.2%) were using only one PIM. Among the 13 elderlies using PIM considering diseases and syndromes, only one was using two such medicines.

If we analyze the use of PIMs regardless of diagnostic but according to therapeutic class, non-steroid anti-inflammatories, central alpha agonists, class III anti-arrhythmics and sulfonylureas emerged as the most prevalent (Table 2). The 15 PIMs used by the elderly considering diseases and syndromes are listed on Table 2, PIMs used by the elderly with heart failure were the most frequent.

Of the 51 medicines that should be used with caution in the elderly, the most prevalent class in this study were the vasodilators, used by 13 (25.5%) patients, followed by tricyclic antidepressants (11 or 21.5%) and selective serotonin reuptake inhibitors (9 or 17.6%) (Table 3).

An analysis of the association between the use of PIMs and the demographic and clinical variables showed the following statistically significant associations with PIM use, with the following odds ratio and confidence intervals:

polymorbidity (2.7; 1.1-6.5), hypertension (2.1; 1.1-3.9) and polypharmacy (5.4; 2.9-10.2).

An analysis of the medicines in the 2012 de Beers list found 175 medicines classified as PIM. 104 of these (59.4%) are available in Brazil. Among the 104 PIMs available in Brazil, 35 (33.6%) are on the Rename list.

Discussion

Awareness of the pharmacoepidemiology of PIMs among the elderly people of a community is an important piece of information to promote the rational use of medicines within a healthcare system. This study found a high frequency of use of PIMs among the elderly on the order of 45%. In Brazil, the publication of pharmacoepidemiological studies on the use of inappropriate medicines by the elderly is only incipient. Studies published to date have different designs, most of them using the 2003 de Beers criteria, and analyze the use of PIMs without taking into consideration the diagnosis[11-29]. Those that did use the 2012 de Beers criteria did not include PIMs that should be used with caution in the elderly, nor did they take into account the diseases and syndromes, of these patients[20,22,25,26]. The scenarios of these studies included community elderly, hospitalized patients and others in long-term care institutions[11-28]. Studies on the use of PIM by community elderly mostly used the 2003 de Beers criteria to classify the medicines[15-18,20-25]. Thus, the frequency of using PIM by the elderly in the community, using the three components of the 2012 de Beers criteria, and the methodological approach we used has not been the subject of any study to date in Brazil.

The prevalence of using PIMs calculated in Brazilian studies using the 2003 de Beers criteria ranges from 20.6 to 48.0%[15,16,21,23,25,26]. A study of the population base in the city of São Paulo found the prevalence of the use of PIM of 16, 2% in the 60-75 age bracket[21].

Prevalence also varied in Brazilian studies using the 2012 Beers criteria[25,26]. A cross-sectional study in Ribeirão Preto, São Paulo, analyzed the prevalence and clinical and demographic factors associated with the use of PIM in patients in a teaching hospital, using the 2003 and 2012 de Beers criteria. This study found a prevalence of 59.2% when using the latest de Beers criteria. The authors included not only prescription PIMs, but also over the counters(OTCs) used in the last 30 days[25]. On the other hand, the geriatric clinic of

Table 2. Distribution of Potentially Inappropriate Medication in older adults used by the 190 study participants at home, Belo Horizonte MG 2010.

	Frequency	
	Absolute	Relative
Potentially Inappropriate Medication in the older adults regardless of diagnosis		
Non-selective cyclooxygenase non-steroidal anti-inflammatories: diclophenac, ketoprofen, ibuprofen, naproxen	13	15.7
Central Alpha Agonist: methyldopa, clonidine	10	12.1
Class III Anti-arrhythmics: amiodarone	9	10.8
Sulfonylureas: glibenclamide	8	9.6
Tricyclic Antidepressants: amitriptyline, imipramine, clomipramine	7	8.4
Benzodiazepines: diazepam clonazepam	7	8.4
Aldosterone Antagonist: spironolactone > 25 mg daily	6	7.2
Digitalic: digoxine > 0.125 mg daily	5	6
Conventional antipsychotic: haloperidol	4	4.9
Alpha Blocker: doxazosine	4	4.9
Atypical Antipsychotic: risperidone	3	3.6
Platelet Aggregation Inhibitor: ticlopidine	2	2.4
Acetic acid derived NSAIDs: ketorolac	1	1.2
First-generation Antihystamines: dexchlorpheniramine	1	1.2
Antibacterial: nitrofurantoin	1	1.2
Barbiturates: Phenobarbital	1	1.2
Muscle Relaxants: carisoprodol	1	1.2
Total	83[*]	100
Medication Inappropriate according to the diseases and syndromes		
Heart failure: ketorolac, nimesulide, diltiazem, verapamil	8	53.5
Delirium: clonazepam, dexamethasone	3	20
History of falling: amitriptyline, sertraline, nortriptyline	3	20
Chronic Syndromes and Epilepsy: thioridazine	1	6.6
Total	15[**]	100

[*] The same individual may be using more than one medicine, thus the total adds up to more than 67. [**] The same individual may be using more than one medicine, thus the total adds up to more than 13.

Table 3. Distribution of Potentially Inappropriate Medication to be used with caution in older adults, used by the 190 study participants at home, Belo Horizonte MG 2010.

	Frequency	
	Absolute	Relative
Potentially Inappropriate Medicine to be used to be used with caution in older adults		
Vasodilators: isosorbide mononitrate, isosorbide dinitrate	13	25.5
Tertiary Tricyclic Antidepressants: amitriptyline, imipramine, cloimipramine, nortiptyline	11	21.5
Selective serotonin reuptake inhibitors: fluoxetine, paroxetine citalopram, sertraline	9	17.6
Acetylsalicylic acid (Aspirin) for primary prevention of cardiovascular events	8	15.7
Antipsychotics: thioridazine, haloperidol, risperidone	7	13.7
Antiepileptics: carbamazepine	1	1.9
Selective serotonin reuptake inhibitors/noradrenaline: venlaxafine	1	1.9
Mirtazapine	1	1.9
Total	51[*]	100

[*] The same individual may be using more than one medicine, thus the total adds up to more than 38.

Teaching Hospital in Pará found that 25% of the elderly in their study were using at least one PIM, according to the 2012 version[26].

Studies in other countries using the 2012 Beers criteria relate broad use of inappropriate medicines by the elderly population in the community. A cohort study in New Zealand found the prevalence of use of PIM by the elderly to be 42.7%[22]. In Taiwan, the population of elderly people using home care was the object of a cross-sectional study using three different tools to classify PIMs, finding a prevalence of 82.6% using the 2012 Beers list[24].

The variation in the prevalence of using PIMs in Brazilian and international studies can be attributed to the design of each study, the sociodemographic and clinical profile of the elderly, the medicines available and the de Beers list used. The prevalence found in the cases investigated agrees with what we found described in the literature. However, this comparison must be made with some reservation due to the small number of Brazilian publications using the 2012 Beers criteria to classify PIMs used by the elderly in the community.

Just as it is important to know the prevalence of the use of PIMs, it is also important to analyze the pharmacotherapeutic profile of the PIMs used. An analysis of PIMs by therapeutic class shows that the most prevalent were non-cyclooxygenase selective non-steroidal anti-inflammatories. These drugs are classified as potentially inappropriate for use in the elderly regardless of the diagnosis, as they are known to increase the risk of gastrointestinal bleeding and peptic ulcer[7,8]. This therapeutic class is also considered inappropriate for use in patients with a diagnosis of systolic heart failure as it can lead to fluid retention and exacerbate heart failure[7]. Many elderly present not only with heart failure, but also other cardiovascular diseases that require the use of platelet anti-aggregants and anticoagulants. The concomitant use of these therapeutic classes and Non-Steroidal Anti-Inflammatories-NSAIDs increases the risk of gastrointestinal bleeding[35-38]. Studies in France and Croatia described the relationship between the prior use of acetylsalicylic acid and hospitalization of elderly patients due to bleeding[20,39]. Low doses of acetylsalicylic acid as primary prevention of cardiovascular events should be used with cautions in people 80 years of age or more, as there is limited evidence of the risks and benefits for patients in this age group[7].

The elderly may self-medicate with NSAIDs and muscle relaxants. Most muscle relaxants are not well tolerated in this age group due to their anticholinergic and sedative effects[7]. A survey in Brazil of elderly outpatients in a teaching institution found that the muscle relaxant carisoprodol, in a fixed dose association with dipyrone and paracetamol, was the most frequently used PIM[15]. The cross-sectional study conducted at a teaching health institution in Ribeirão Preto found that 30.0% of the elderly self-medicated, and that orphenadrine was the most often used self-medication, along with other pain medication[25]. In the cases investigated, we found only one elderly person using carisoprodol, possibly because the data collection did not assess self-medication. However, in Brazil a number of medicines are available without a prescription, so it is important to warn patients of the risks associated with self-medication for pain, which includes the use of muscle-relaxants, NSAIDs and other analgesics. This is concerning, as a large number of specialty pharmaceuticals are available in Brazil, many containing fixed dose muscle relaxants and other drugs, including NSAIDs, most of which are classified as PIMs. The absence of warnings on package leaflets and the sale of these drugs without a prescription makes the problem worse, and fosters exposure of elderly patients to these PIMs.

Central alpha agonists are the second most use category of PIMs, represented by methyldopa and clonidine. In an analysis of PIMs in the SABE Study (Health, Well-Being and Aging), the authors found that methyldopa was the third most used PIM among the elderly in the community[21]. This drug is not considered the first choice to treat hypertension in the elderly due to its CNS effects, ability to induce bradycardia and orthostatic hypotension[7,40]. It is important to point out that therapeutic options suitable for the elderly are available on the Rename list.

Among the elderly with heart failure, use of digoxin in doses larger than 0.125 mg does not provide any benefit and can increase the risk of toxicity due to reduced renal clearance and the narrow therapeutic index of digoxin[7]. Non-dihydropyridinic calcium channel blockers, diltiazem and verapamil are also inappropriate in the presence of heart failure due to fluid retention and exacerbation of the symptoms of heart failure[7,40].

The use of Class III antiarrhythmics is not recommended as first line treatment atrial fibrillation in the elderly. Amiodarone is associated with multiple toxicities, such as thyroid disorders, QT interval prolongation and pulmonary disorders[7]. Amiodarone was the third most used PIM among the elderly of a European hospi-

tal, and is one of the main PIMs that act on the cardiovascular system identified by the SABE study[20,21]. For the treatment of arrhythmias in the elderly, it is important to assess the risks and benefits of amiodarone, and when it is indicated, closely monitor the patient to enable prevention or early detection of adverse events.

Vasodilators are another class of cardiovascular drugs considered PIMs. They should be used with caution in the elderly as they can cause syncope in patients with a prior history[41,42]. A review published in 2011 shows an association between vasodilators and increased risk of falling[42]. This study found that, among PIMS to be used with caution, vasodilators where the pharmacological class used most often.

Like cardiovascular diseases, diabetes is frequent among the elderly and often demands treatment with medication. Oral hypoglycemic agent glibenclamide, a long-acting sulfonylurea, should be avoided by the elderly due to the risk of severe hypoglycemic events[7]. This study found this PIM, but although described abroad, it is not mentioned in any of the studies done in Brazil[20,21,25,26,43]. According to the de Beers criteria, glyburide, is another name for glibenclamide, a name not used in Brazil, which may explain the fact that this drug is not mentioned in Brazilian studies. The use of glibenclamide by elderly patients using the SUS system should be analyzed regarding the awareness of managers and prescribers of this PIM. The Rename list does include gliclazide, a sulfonylurea more suited for treating the elderly, but sometimes not prescribed as prescribers are not aware of it or because the managers of pharmaceutical assistance do not provide it in the cities for which they are responsible.

Antidepressants and benzodiazepines are among the main Central Nervous System -CNS PIM used by the elderly. Tricyclic antidepressants can cause clinically relevant adverse events due to their anticholinergic activity and ability to induce orthostatic hypotension and stimulate the CNS[7]. Selective serotonin reuptake inhibitors and tricyclic antidepressants should be used with caution, due to their ability to exacerbate or cause inappropriate secretion of antidiuretic hormone or hyponatremia[7]. Another justification for avoiding their use in the elderly is that they may induce sedation, which affects psychomotor function and increases the risk of falls and fractures[44,45].

Benzodiazepines are included in international therapeutic guidelines for the management of anxiety and insomnia; however, duration of treatment should be short - no longer than three months. The high prevalence of chronic use of benzodiazepines by the elderly, together with increased dementia in developed nations are important public health issues, in particular in light of a control study showing a higher risk of Alzheimer's Disease among chronic users of benzodiazepines[46].

The finding of an association between the use of PIM and polypharmacy and polymorbidity are widely described in the literature, and reflect the use of multiple drugs by the elderly due changes related to senility and senescence[21-23,27-29]. The association with hypertension is explained by the high prevalence of this disease in the study sample due to the widespread use of medicines for the cardiovascular system by the elderly[47].

The Beers list is developed based on the drugs available in the US pharmaceutical market, only about 60% of which are marketed in Brazil. We must take the difference in availability into account when comparing the results of different studies published in the literature. From the perspective of the Unified Healthcare System, it is important to mention that about one-third of the PIMs available in the country are in the 2013 Rename list. While Rename does not have options for long-acting benzodiazepines and antidepressants, it does have options for oral hypoglycemics, short-acting nifedipine and methyoldopa. Therefore, when selecting drugs to be included in the SUS list, it is essential to expand the therapeutic options that cover the needs of the elderly.

Given that a significant number of PIM are distributed by the SUS, most of which require a prescription, awareness and disclosure of information about PIMs to healthcare professionals is an important tool to support an improvement in the quality of care provided to elderly patients. The existence of risks associated with the use of PIMs must be analyzed in the different scenarios in which the elderly receive healthcare. To avoid the adverse events resulting from the use of PIMs, and make sure the elderly receive safe and effective drug therapy, multidisciplinary efforts should be encouraged when planning and analyzing lines of care and including pharmaceuticals, providing these teams with pharmacists trained in geriatrics[48]. Pharmaceutical assistance activities, in particular those related to primary care, should consider the demands of the elderly population, with measures to provide access to drugs, define protocols and train prescribers. The

role of sanitary vigilance is to expand the information provided in package leaflets about inappropriate use by the elderly, especially in over-the-counter medicines.

This study expands knowledge of PIMs in Brazil and analyzes their use in a clinical and healthcare system scenario. However, it has some limitations that bear mentioning. The first is that data was collected retrospectively, making it subject to the variability resulting from the systems used by prescribers to record information on the home use of medicines, and may create a bias in the frequency of use of PIMs. The absence of information about medication for acute use and self-medication should also be considered, as these may not be reported and recorded in medical chart. This was a convenient sample of only 190 elderly patients, and thus there are limitations on generalizing the results.

Conclusion

The study showed a high prevalence of using inappropriate medicines by the elderly at home, according to the 2012 de Beers list. The use of inappropriate medicines showed a positive association with polypharmacy, polypathology and hypertension. The clinical consequences of using inappropriate medicines are important for public health due to the risk of adverse events and a negative impact on elderly functionality.

When it comes to caring for the elderly, it is important to develop measures to foster the rational use of medication. It is also important to implement strategies to ensure access to drugs that are safe and suited to the specificities or pharmacotherapy of the elderly.

Collaborations

LM Lopes, TP Figueiredo and AMM Reis helped design the study, interpret the data, draft and review the article, and were involved in the final approval of the version for publication. SC Costa helped design the study, review the article and with the final approval of the version for publication.

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