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Prevalence of Anticholinergic Burden Related to Medication used by the Elderly: A Cross-sectional Retrospective Analysis

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ABSTRACT

Introduction: According to IBGE (2022), the total number of people over 60 years old reached 15.6%, making Brazil the world's fourth-largest pharmaceutical consumer market. In this context of polypharmacy, one of the concerns is the anticholinergic burden, which refers to the accumulation of intrinsic anticholinergic activity in various drugs. The analysis of the prevalence and frequency of anticholinergic burden provides relevant data, as several adverse effects are attributed to the accumulation of these substances in the body. **Objective:** To identify the prevalence of use and the anticholinergic burden of medications used by the elderly. **Method:** A retrospective cross-sectional observational study with an analysis of electronic medical records from a geriatric outpatient clinic, aiming to determine the prevalence of anticholinergic drug use in the elderly, as well as to calculate the anticholinergic burden using the Anticholinergic Risk Scale (ARS) and the Brazilian Anticholinergic Scale (BAS). **Results:** EBA identified 69% of patients as users of medications with an anticholinergic burden, whereas the ARS scale indicated only 38%. The high anticholinergic risk was also higher according to BAS's assessment: 28%, compared to 7.6% according to ARS. **Conclusion:** A high frequency of anticholinergic medication use among the elderly was confirmed, especially considering BAS. This finding is alarming, as anticholinergic burden has central and peripheral effects and is associated with unfavorable clinical outcomes, including cognitive and functional impairment, falls, hospitalization, and death. Implementing preventive strategies at primary healthcare levels is essential to mitigate the risks of iatrogenesis, including the investigation of specific data and the validation of tools to calculate the anticholinergic burden of medications used in Brazil.

Keywords: Cholinergic Antagonists, Elderly, Adverse Effects, Drug Toxicity, Deprescription.

INTRODUCTION

Population aging is a global trend. In Brazil, according to the 2022 Demographic Census, the total number of people aged 60 or older reached 15.6% of the population[1]. As a result, the consumption and demand for medications have also increased, establishing Brazil as the fourth-largest pharmaceutical consumer market worldwide[2]. After all, longevity is commonly associated with the prevalence of chronic diseases and comorbidities among the elderly[3]. In this context, the clinical management of elderly individuals with multiple comorbidities presents a challenge, as the concurrent use of various medications and the physiological changes associated with aging make these patients more susceptible to drug toxicity and adverse effects[4].

The anticholinergic burden, for example, is one of the warning signs of polypharmacy in the elderly. This effect corresponds to the accumulation of intrinsic anticholinergic activity in various drugs, even if they are not necessarily categorized as antimuscarinic agents[5,6]. Anticholinergic drugs are widely used to treat several conditions common in the elderly, such as depression, gastrointestinal disorders, Parkinson's disease, urinary incontinence, and epilepsy. These drugs block acetylcholine in the nervous system in various actions, including cognitive ones, and for this reason, they are considered potentially inappropriate or should be avoided in the elderly, especially the frail ones, according to the STOPP/START criteria and Beers' Criteria. This influence is so significant that there are various guiding scales for classifying medications with anticholinergic effects based on the degree of accumulation[6,7,8,9].

The analysis of the prevalence and frequency of anticholinergic burden is therefore highly relevant, as several adverse effects have already been attributed to the accumulation of these substances, both at the peripheral level (constipation, tachycardia, dysphagia, and dry mouth) and the central level (worsening of motor coordination, delirium, and cognitive dysfunction)[5]. A significant association between the use of anticholinergic drugs and an increased risk of cognitive impairment was demonstrated in 23 of the 25 analyzed review studies[10]. Other publications also reinforce this finding, indicating that the risk of adverse effects is dose and time-dependent, appearing to be worse with continuous use, and reversible after discontinuation[4].

From this perspective, a collective effort has been made to investigate the impact of anticholinergic burden on health outcomes and to contribute to clinical decision-making by guiding safer prescribing practices[6,10]. After all, accumulated anticholinergic burden not only reduces patients' quality of life but also increases the incidence of severe adverse outcomes, including falls, hospitalization, institutionalization, and higher mortality rates[5,6]. These negative consequences for the elderly are particularly concerning, especially given their financial implications for public health.

In 2015, in the United States, for example, costs related to fatal and non-fatal falls among the elderly reached approximately US$50.0 billion, with 99% of this amount allocated to managing non-fatal falls[11]. In Brazil, considering only Hospitalization Authorizations (in Portuguese AIH, Autorizações de Internação Hospitalar) through the Brazilian unified health system, called SUS, 1,746,097 AIHs related to falls among older adults were recorded between 2000 and 2020, corresponding to a cost of R$2.3 billion for the Brazilian healthcare system[12]. Regarding cognitive decline and the increasing prevalence of dementia, the global economic burden of Alzheimer's disease and other related dementias in 2019 was estimated at $2.8 trillion. It is expected that this value will rise to approximately $4.7 trillion by 2030, $8.5 trillion by 2040, and $16.9 trillion by 2050[13]. Data from the study "Global Burden of Disease", published in The Lancet, estimates that

dementia cases in Brazil could increase by 206%, rising from 1.8 million in 2019 to 5.6 million by 2050[14].

In this context, it is essential to implement preventive measures aimed at elderly healthcare. Therefore, this study seeks to investigate the prevalence of anticholinergic burden associated with medications used by a sample of older adults at the Geriatrics Outpatient Clinic of the faculty Faculdade Ciências Médicas de Minas Gerais (FCMMG), in Belo Horizonte city. This assessment is of great importance, as it addresses a public health issue that impacts both the well-being of the elderly population and healthcare management.

METHODS

Study design

This is a retrospective cross-sectional observational study conducted through a review of electronic medical records from the Geriatrics Department at the Outpatient Clinic of FCMMG in Belo Horizonte. Data collection was carried out between June 2023 and December 2023. The study was approved by the Ethics Committee in Research of FCMMG (CEPCM-MG), identified by the protocol number (CAAE) 65534222.0.0000.5134. The research was exempted from the requirement for informed consent (TCLE) by the respective committee.

Sample:

Based on a total of 451 consultations between October 2020 and October 2022 at the Geriatrics Outpatient Clinic of FCMMG, a sample size calculation was performed for this study, considering a 5% significance level, a 5% maximum error, and a conservative approach for $\hat{p}$ (assumed to be 50%). The ideal sample size was calculated to be at least 208 participants for this study [15].

The following inclusion criteria were applied to the analyzed medical records: patients over 60 years of age, with records of educational level and score on the Mini-Mental State Examination (MMSE)[16]. Inactive records or those that did not meet both criteria were excluded, resulting in a final sample of 209 medical records.

Instruments Used:

A bibliographic search was conducted in PUBMED and SCIELO using the descriptors "Anticholinergic Antagonists," "Elderly," "Adverse Effects," and "Drug Toxicity." From this search, it became apparent that there is a scarcity of validated scales in Brazil for calculating anticholinergic burden. Therefore, two different scales, described in national studies, were chosen considering the context of the population and the Brazilian pharmacopoeia: the Anticholinergic Risk Scale (ARS) and the Brazilian Anticholinergic Scale (EBA).

The Anticholinergic Risk Scale (ARS) is a validated tool developed by Rudolph et al. in 2008. It is based on publications regarding medications and the pharmacology of aging, considering the 500 most prescribed medications in the "Veteran Affairs Boston Healthcare System." These medications were evaluated by a physician and two pharmacists to identify those with potential anticholinergic effects. Ophthalmic, otologic, and inhalant preparations were excluded [17]. The medications were categorized into four groups, with scores ranging from 0 to 3, where the risk was proportional to the sum of the points for the various medications used by the patient. The ARS categories are: 1) Moderate Risk (1 point per medication); 2) Strong Risk (2 points per medication); and 3) Very Strong Risk (3 points per medication). A final score of 3 or higher is considered indicative of severe risk[17]. When the ARS score was calculated as severe, at least 70% of the elderly patients reported two or more anticholinergic adverse effects. These adverse effects were categorized as central (falls, dizziness, and confusion) and peripheral (xerostomia, xerophthalmia, and constipation)[17].

Brazilian researchers developed the Brazilian Anticholinergic Scale (BAS) through a review and compilation of data from various scales, aiming to include and grade the anticholinergic activity of drugs [6].

The list was initially based on medications categorized under level 4 of the Anatomical Therapeutic Chemical (ATC) classification system, and later expanded to include medications with a strong anticholinergic burden according to the 2015 Beers' Criteria[8]. Subsequently, drugs mentioned in at least two of the eleven anticholinergic scales identified in a bibliographic search in PubMed/Medline were added. The result was a list of 125 medications with anticholinergic burden, excluding drugs not commercialized in Brazil and those administered via the ophthalmic route. The classification of the anticholinergic burden assigned to each medication was systematized, considering the evidence of serum anticholinergic potential and the anticholinergic effects reported by experts. The intensity of the burden was graded using scores of 1, 2, and 36. These respective scores were identified as: 1) Evidence of potential serum anticholinergic activity or anticholinergic effect reported by an expert; 2) Medication with anticholinergic activity related to the dose, as reported by an expert; 3) Medication with strong anticholinergic activity, as known and reported by an expert. Medications not included in the BAS were classified with a score of 0. The proposed instrument is an attempt to measure the anticholinergic burden of the most commonly marketed medications in Brazil, although the scale is not validated yet[6].

Procedures

The following information was collected from the selected medical records: age, sex, education, comorbidities, lifestyle habits, functionality, medications in use, and the results of the Mini-Mental State Examination (MMSE)[16]. The data were organized in Microsoft Excel spreadsheets, excluding any personal identifying information such as name, address, contact details, or other data that could directly identify the patient. For the calculation of anticholinergic burden, only the medications listed in the patient's record from the same consultation in which the other data were collected were considered.

After selecting the medical records, all medications used by each patient were identified. Then, the anticholinergic burden for each drug was calculated based on the scores from the two scales, BAS and ARS. The total burden for each scale was obtained by adding the scores for each medication. The dose and duration of medication use were not taken into account in this assessment, as these factors are not used by the scales to determine anticholinergic burden. Additionally, since this was a cross-sectional study, these data were not always available in the reviewed medical records.

Statistical Analysis

Descriptive statistics were performed, with qualitative variables characterized by simple frequencies and percentage frequencies.

RESULTS

Among the 209 patients studied, the majority were female (70%) and had low levels of education (88% with a maximum of 8 years of schooling, 29% of whom were illiterate). The median age was 80 years, with a significant number of smokers or former smokers (49%) and alcohol users or former users (28%). The most common comorbidities were systemic arterial hypertension (79%), cognitive decline or dementia (54%), depressive disorder (37%), and diabetes (29%). Regarding sensory impairments in the sample, 28% had reduced visual acuity and 13% had hearing impairment. The remaining variables are detailed in Table 1.

Table 1. Characterization of the Sample

Characteristics	N = 209[1]
Gender	
Feminine	146 (70%)
Masculine	63 (30%)
Age	
60-79 years	104 (49,8%)
≥ 80 years	105 (50,2%)
Education Level	
Illiterate	61 (29%)
1-8 years of study	124 (59%)
≥ 9 years of study	24 (11%)
Life Habits	
Smoker/former smoker	
NO	91 (51%)
YES	88 (49%)
Unknown	30
Alcohol user/former alcohol user	
NO	129 (72%)
YES	50 (28%)
Unknown	30
Comorbidities	
Systemic arterial hypertension	
NO	44 (21%)
YES	165 (79%)
Diabetes	
NO	148 (71%)
YES	61 (29%)
Depression	
NO	131 (63%)
YES	78 (37%)
Alzheimer's disease	
NO	158 (76%)
YES	51 (24%)
Dementias	
NO	169 (81%)
YES	40 (19%)
Cognitive disorder	
NO	187 (89%)
YES	22 (11%)
Parkinson's disease	
NO	176 (84%)
YES	33 (16%)
Hypoacusis	
NO	182 (87%)
YES	27 (13%)
Hypercholesterolemia and/or dyslipidemia	
NO	155 (74%)
YES	54 (26%)
Visual impairment	
NO	151 (72%)
YES	58 (28%)
Mood disturbance	
NO	206 (99%)
YES	3 (1.4%)
Coronary artery disease	
NO	195 (93%)
YES	14 (6.7%)
Congestive heart failure	
NO	191 (91%)
YES	18 (8.6%)

1Median (AIQ); n (%)

[1]Median (AIQ); n (%)

Regarding the use of anticholinergic medications in the total sample, only 31% of patients were classified as risk 0 according to BAS, and 62% were classified as grade 0 according to the ARS. Therefore, BAS identified 69% of the patients as users of anticholinergic drugs, while ARS identified use in only 38% of the sample. The frequency of elderly individuals at high anticholinergic risk was defined as a score of 3 or higher, which was also higher according to BAS's assessment: 28% versus 7.6% according to ARS. The prevalence of anticholinergic burden is detailed in the table below (Table 2).

Table 2 - Prevalence of anticholinergic burden by scales

Characteristics	N = 209[1]
Classification according to the anticholinergic burden scales	
ARS2 Score	
Grade 0	130 (62%)
Grade 1	**45 (22%)**
Grade 2	18 (8.6%)
Grade 3	4 (1.9%)
Grade 4	12 (5.7%)
BAS3 Score	
Zero	65 (31%)
Risk 1	56 (27%)
Risk 2	**30 (14%)**
Risk ≥ 3	**58 (28%)**
NO	91 (51%)

1 Median (AIQ); n (%), 2 Anticolinergic Risk Scale, 3 Brazillian Anticolinergic Scale (n) = 209 patients (100%)

A total of 30 medications classified as grade 1 (moderate according to ARS or with a score of 1 according to BAS) were identified and were prescribed a total of 219 times. In fewer cases, 4 medications were classified as grade 2 (strong according to ARS or with a score of 2 according to BAS) and were prescribed 30 times. Only 14 medications classified as grade 3 (very strong according to ARS or with a score of 3 according to BAS) were prescribed, totaling 27 prescriptions. It is worth noting that some medications listed in BAS are not present in ARS, as the former includes a broader range of drugs (125 vs. 48). Medications found in only one of the two scales are listed in Table 3.

Table 3 - Difference in Anticholinergic Medications Included in Both Scales

	Medications included in BAS but not listed in ARS
A	Atropine alkaloids; Azathioprine; Alprazolam; Ampicillin; Atenolol;
B	Biperiden; Brompheniramine; Buclizine; Bromocriptine; Butylscopolamine bromide; Bupropion;
C	Carbamazepine; Chlorzoxazone; Carbinoxamine; Captopril; Lithium carbonate; Cefoxitin; Cyclosporine; Clemastine; Citalopram; Clomipramine; Clonazepam; Chlordiazepoxide; Chlorthalidone; Codeine; Colchicine;
D	Darifenacin; Desloratadine; Dexbronpheniramine; Dexamethasone; Dexchlorpheniramine; Diazepam; Digoxin; Dimenhydrinate; Diltiazem; Doxylamine; Dipyridamole; Domperidone;
E	Escitalopram;
F	Famotidine; Phenobarbital; Fentanyl; Fexofenadine; Fluoxetine; Fluvoxamine; Furosemide;
G	Gentamicin;
H	Homatropine; Hydralazine; Hydrocortisone;
I	Ipratropium; Isosorbide;
L	Levocetirizine; Loratadine; Lorazepam; Levomepromazine;
M	Maprotiline; Methylprednisolone; Metoprolol; Midazolam; Morphine; Methadone;
N	Nifedipine;
O	Orphenadrine; Oxycodone; Oxcarbazepine;
P	Pethidine; Pimozide; Piperacillin; Prednisolone; Prednisone;
S	Sertraline; Solifenacin;
T	Theophylline; Tramadol; Triamcinolone; Triamterene; Tiotropium; Trihexyphenidyl; Triprolidine;
V	Vancomycin; Venlafaxine; Valproic acid;
W	Warfarin.
	Medications included in ARS but not listed in EBA
	Benztropine; Dicyclomine; Perphenazine; Tiotixene; Prochlorperazine; Methocarbamol; Ziprasidone.

DISCUSSION

The ARS scale highlights a prevalence of 38% of anticholinergic burden, whereas EBA identified a prevalence of 69%. The findings indicate a high use of drugs with anticholinergic potential in the studied population, particularly when using the EBA scale. This discrepancy may be explained by the broader range of medications included in this scale. In this context, three key points deserve attention in the discussion.

First, the study population consists of very elderly individuals (median age of 80 years), who are at high risk of experiencing adverse drug effects and present a high prevalence of conditions associated with the use of such medications[18]. Indeed, anticholinergic drugs are commonly prescribed for various conditions, whether chronic, acute, or sporadic[18,19]. In this study, the most frequently used anticholinergic medications were antidepressants (sertraline, mirtazapine, amitriptyline, citalopram, venlafaxine, trazodone, among others), antipsychotics (quetiapine, olanzapine, clozapine, risperidone), cardiovascular agents (furosemide, atenolol, hydralazine, isosorbide), medications for urinary

incontinence (oxybutynin), and antiparkinsonian drugs (levodopa, biperiden, pramipexole). All these conditions are highly prevalent among the elderly population, which justifies the frequent use of these medications in the study.

Several references in the literature highlight this situation as a matter of concern in the context of public health[20]. Lee et al.[21] and Miranda et al[22], the latter being a Brazilian study, report a prevalence of approximately 60% in the use of drugs with anticholinergic potential among the elderly population. This finding aligns with the 69% prevalence observed in the present study when applying BAS[21,22]. Miranda et al. emphasize that anticholinergic drugs are primarily used by patients over 80 years old and those with lower levels of education - characteristics that match the sample profile of the current study - as well as by individuals who have experienced hospitalization in the past year or require caregiver support.

All these characteristics suggest a state of vulnerability, and studies indicate that in more fragile populations, the use of anticholinergic medications is even higher[22,23,24]. Arrechea et al., in a study involving institutionalized elderly individuals with dementia, reported that 83.7% of the sample used anticholinergic drugs, with the highest burdens associated with conditions such as polypharmacy, falls, hospitalizations, and frequent emergency department visits[23]. Similarly, Al-Azayzih et al., when evaluating elderly oncology patients, observed a high prevalence (84.3%) of anticholinergic medication use, with drugs such as metoclopramide, furosemide, and tramadol being the most prescribed 24. In this group, 46.2% of patients had an anticholinergic burden classified as high (score ≥ 3). Conversely, in younger populations, the prevalence of anticholinergic drug use tends to be significantly lower[24]. Pinto et al. found a prevalence of 31.0% for anticholinergic use among individuals aged 40 years or older, with only 20.7% presenting a high burden (score ≥ 3)[25].

In the present study, anticholinergic burden was classified as high (risk ≥ 3) in 28% of the sample, according to BAS. These findings position the analyzed sample at an intermediate level compared to the results of studies with a younger population, such as the one by Pinto et al.[25], and studies with more frail elderly groups, such as oncological patients. Although the use of medications with anticholinergic burden is common among the elderly population in general, the accumulated burden and its associated risks are likely more pronounced in populations with greater clinical frailty. These findings highlight the importance of cautious prescribing of anticholinergic drugs, particularly for older adults with multiple comorbidities and increased functional vulnerability[22,23,24].

In the study by Pinto et al.[25], conducted with adults and elderly individuals in southern Brazil, a higher anticholinergic burden was associated with the occasional use of two or more medications, including self-medication. Older adults frequently attempt to manage common symptoms such as insomnia, pain, or gastrointestinal discomfort on their own, often resorting to anticholinergic drugs - such as antihistamines and muscle relaxants - without full awareness of their potential risks[26]. This phenomenon can be attributed to the accessibility of over-the-counter medications and the widespread practice of using pharmaceuticals without continuous medical supervision, which increases the risk of inadequate management of both chronic and acute conditions. In a vulnerable population such as the elderly, this behavior may amplify the risks of drug interactions and adverse effects. Therefore, the importance of stricter surveillance strategies and pharmacological interventions is underscored, particularly for populations more exposed to the risks of iatrogenesis.

Secondly, the present study was conducted in a specialized geriatric outpatient clinic, where patients receive care from a highly trained and attuned team that is specifically tailored to the needs of the elderly population. The geriatric approach emphasizes particular caution regarding the use of medications with anticholinergic effects, as their indiscriminate use may have deleterious consequences for this population. The Brazilian Society of Geriatrics and Gerontology recommends deprescrib-

ing anticholinergic drugs whenever possible, prioritizing the substitution for alternatives with a lower anticholinergic burden[27,28]. This recommendation is based on the potential negative impact of these medications on the quality of life and morbidity/mortality of the elderly population. It was observed that, despite the high prevalence of prescribed anticholinergic medications in the evaluated outpatient clinic, the majority had a low anticholinergic burden - 30 grade 1 medications, prescribed a total of 219 times. One possible hypothesis is that both the frequency and the anticholinergic potency of the prescribed medications are lower than those typically observed in primary care outpatient settings, where awareness of the risks associated with anticholinergic burden may be less rigorous. However, further studies are necessary to confirm this assumption.

It is, therefore, essential to adequately train and empower primary care services to raise awareness among caregivers regarding the specificities of the elderly and the risks of polypharmacy and iatrogenesis. Moreover, the use of tools such as checklists for potentially inappropriate medications for older adults, such as the Beers Criteria [8], can assist in reducing the prescription of drugs with high iatrogenic potential. Continuing education and responsible deprescribing can contribute to improving the quality of life for elderly individuals, minimizing complications such as delirium, falls, and cognitive decline, as well as reducing mortality associated with the inappropriate use of medications in this age group[8,27].

As the third key point of this study, the sample examined is part of an outpatient service from SUS, the Brazilian unified health care system. Several medications available through SUS possess strong anticholinergic properties and are widely used by elderly individuals, particularly those who rely exclusively on this system. Ideally, some of the medications with high anticholinergic burden could be substituted with alternatives that have a lower burden; however, many of these options are not available through SUS. An example is the tricyclic antidepressants amitriptyline and nortriptyline, which could be replaced by sertraline, venlafaxine, citalopram, and escitalopram. The same applies to oxybutynin, the only medication provided by SUS[29] for the treatment of overactive bladder (a type of urinary incontinence). Safer alternatives are already available on the market for this condition, including those with lower central nervous system penetration or even beta-adrenergic activity instead of antimuscarinic. In this context, a policy of reviewing and expanding the list of medications available through SUS, with a focus on the needs of the elderly population, could significantly improve the safety and efficacy of treatments for common conditions in this age group[29,30].

It is important to note that this research has some limitations, such as the fact that it is a retrospective study based on medical records, which introduces the risk of underreporting data and prevents a detailed assessment of certain variables (chronic health conditions, the prevalence of self-medication, medication dosage, and duration of use). Additionally, it is a descriptive, cross-sectional study that does not aim to establish direct causal associations between anticholinergic burden and its complications. Furthermore, the fact that the sample represents a specific outpatient service for elderly patients within the SUS limits the generalizability of the results.

Finally, it is worth reflecting on the selection of the most appropriate tool to assess anticholinergic burden in the Brazilian elderly population. To date, there are no well-validated scales available in the literature for this specific population. The Brazilian Anticholinergic Scale (BAS) includes a larger number of medications in its assessment compared to ARS and was specifically developed for the national population, but it has not yet been validated. Nevertheless, it is noteworthy that the prevalence data obtained with BAS were more consistent with global statistics when compared to those found using ARS. Additional studies are needed to validate this and other tools, enabling more precise and reliable analyses, as well as their applicability in various contexts

CONCLUSION

This study confirmed a high prevalence of anticholinergic medication use among the elderly, particularly when BAS was applied. Given the extensive evidence that anticholinergic burden adversely impacts health, leading to both central and peripheral side effects[5], including unfavorable clinical outcomes such as cognitive and functional decline, hospitalization, and death, there is a clear need to minimize anticholinergic burden in at-risk populations. The implementation of these preventive strategies at primary healthcare levels is a crucial step toward mitigating the risks of iatrogenesis and providing more effective and safer care for the elderly population[27].

National literature still lacks well-validated scales that consider both the pharmacopoeia and the demographic and clinical characteristics of the Brazilian elderly population. The creation and validation of such tools would be pivotal for clinical practice, allowing healthcare professionals to accurately assess the anticholinergic potential of medications before prescribing them to older adults. The scarcity of specific data and tailored tools for the local context is becoming increasingly relevant as the Brazilian population ages rapidly, leading not only to heightened health risks for the elderly but also to increased healthcare costs, including those associated with hospitalizations, home care, and other services.

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