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Sedative use and incidence of falls and hip fractures among older adults in an outpatient geriatric clinic

Perfil de uso de sedativos e ocorrência de quedas e fratura de fêmur entre idosos em um ambulatório de geriatria

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Abstract

Objective: To investigate the use of sedatives by older adults attending a private outpatient geriatric clinic in Belo Horizonte (MG), Brazil, and its association with falls and hip fractures.

Methods: Using a longitudinal design, the prevalence of benzodiazepine and nonbenzodiazepine (“z-drugs”) intake by older adults was described and their association with the incidence of falls and fractures (30 days after the initial visit) was evaluated through logistic regression.

Results: A total of 7821 older adults were included in the study, most of them women (72.50%), with a mean age of 77.5 years and a mean Clinical-Functional Vulnerability Index (IVCF-20) score of 16.5. The overall prevalence of sedative use (any sedative) was 6.19%, with 4.48% benzodiazepines and 1.98% z-drugs. The most widely used sedatives were clonazepam (29.04%), zolpidem (28.65%), and alprazolam (23.44%). Falls were reported for 182 patients (2.33%), with a higher incidence among users of any sedatives (4.34; $p = 0.002$; OR = 1.94, adjusted for sex, age, and IVCF-20) and benzodiazepines (5.14%; $p < 0.001$; OR = 2.28) than among non-users (2.19%). Hip fractures occurred in 33 patients (0.42%), and again were more frequent among users of sedatives (1.03%; $p = 0.032$; OR = 2.57) and benzodiazepines (1.43%; $p = 0.003$; OR = 3.45) than among non-users (0.38%).

Conclusions: The use of sedatives, especially benzodiazepines, is associated with an increased incidence of falls and hip fractures in older adults.

KEYWORDS: aged; hypnotics and sedatives; benzodiazepines; accidental falls; femoral fractures; longitudinal studies.

Resumo

Objetivo: Investigar a utilização de sedativos entre idosos atendidos em ambulatório privado de geriatria em Belo Horizonte (MG), bem como sua associação com quedas e fraturas de fêmur.

Metodologia: Trata-se de estudo longitudinal, no qual foi descrita a prevalência de uso de benzodiazepínicos e drogas Z entre idosos (60 anos ou mais) e avaliada sua associação com a incidência de queda e fratura (30 dias após consulta inicial) por meio de regressão logística.

Resultados: Foram incluídos no estudo 7821 idosos, com maioria feminina (72,50%), idade média de 77,5 anos e Índice de Vulnerabilidade Clínico Funcional (IVCF-20) médio de 16,5 pontos. A prevalência de uso de sedativos em geral foi de 6,19%, sendo 4,48% de benzodiazepínicos e 1,98% de drogas Z. Os medicamentos sedativos mais utilizados foram clonazepam (29,04%), zolpidem (28,65%) e alprazolam (23,44%). Relatou-se queda para 182 idosos (2,33%), com incidência maior entre usuários de sedativos (4,34; $p = 0,002$; OR = 1,94 ajustada por sexo, idade e IVCF-20) e de benzodiazepínicos (5,14%; $p < 0,001$; OR = 2,28) do que entre não usuários (2,19%). Identificou-se fratura de fêmur em 33 idosos (0,42%), sendo mais frequente entre usuários de sedativos (1,03%; $p = 0,032$; OR = 2,57) e de benzodiazepínicos (1,43%; $p = 0,003$; OR = 3,45) do que entre não usuários (0,38%).

Conclusão: Concluiu-se que a incidência de quedas e fraturas de fêmur em idosos possui associação com o uso de medicamentos sedativos, em especial os benzodiazepínicos.

PALAVRAS-CHAVE: idosos; hipnóticos e sedativos; benzodiazepinas; acidentes por quedas; fraturas do fêmur; estudos longitudinais.



INTRODUCTION

Medicines are the most important health technology for disease prevention, treatment, and control.¹ However, their use is also associated with adverse events, especially among the growing geriatric population, which, in addition to experiencing changes in physiology that cause changes in the pharmacokinetics and pharmacodynamics of any drugs to which they are exposed, usually have multiple comorbid chronic diseases and take multiple medications.^{2,3}

The use of benzodiazepines and nonbenzodiazepine sedatives (also known as “z-drugs”) in geriatrics has been the subject of specific research interest because it carries more risks than benefits in this population; sedatives are thus considered potentially inappropriate medications (PIMs) for older adults. These drugs have been associated with an increased incidence of cognitive impairment, delirium, motor vehicle accidents, falls, and fractures among the geriatric population.^{4,5}

Among these adverse outcomes associated with the use of benzodiazepines and z-drugs, falls and fractures are particularly consequential for older adults, as they contribute to loss of confidence, pain, reduced mobility, increased dependency, and even mortality. Some studies have shown an increase in emergency department visits and hospitalization due to falls and femoral fractures associated with the use of benzodiazepines and z-drugs.⁶⁻⁸

Benzodiazepine use has increased markedly in the Brazilian geriatric population.⁹⁻¹¹ However, the profile of z-drugs utilization by older adults is still relatively unexplored. Characterizing the use profile of these agents, as well as the adverse outcomes related to such use, including falls and hip fractures, would help improve geriatric health care and reduce harm related to prescribing practices in this population.

However, to our knowledge, there are no longitudinal studies investigating the association between use of sedatives and incidence of falls and fractures among older adults treated at outpatient geriatric clinics, which usually provide care for an even more fragile geriatric population. Thus, the aim of this study is to investigate the longitudinal association between the use of sedative drugs and the incidence of falls and hip fractures among older adults treated at a private geriatric clinic in Belo Horizonte, Minas Gerais, Brazil.

METHODS

This is a longitudinal study carried out at a private outpatient geriatric clinic in a large urban area. The outpatient clinic serves older adults (i.e., aged 60 years or older according

to current Brazilian legislation), who pay for their care out of pocket or who are insured and for whom the clinic is an in-network provider. The patients most commonly referred to the outpatient clinic by their insurers or primary health care professionals are older adults showing signs of frailty and/or the oldest old.

The clinic is staffed by a multidisciplinary team of geriatricians, cardiologists, nephrologists, endocrinologists, family physicians, psychiatrists, nurses, pharmacists, physical therapists, speech therapists, dietitians, and psychologists. This team, using a holistic, horizontal, and comprehensive approach, monitors patients through face-to-face visits, telemonitoring, support groups, and matrix meetings.

The study population consisted of all older adults first seen at the outpatient clinic between May 2019 and January 2022. The eligibility criteria were:

1. Remaining registered with the clinic for at least 30 days after the initial visit.; and
2. Having data available for all variables of interest.

Data collection was carried out through the clinic’s health management platform, “LifeCode – Inteligência & Saúde”.

Two event variables were defined: incidence of at least one fall and incidence of hip fracture within up to 30 days after the first visit to the outpatient clinic. The incidence of falls is monitored weekly through active case-finding (by phone or in person) by clinic staff, and is also recorded on the health management platform whenever a fall is reported by patients themselves or by a family member. For the purpose of this research, we defined a fall as an event which results in a person coming to rest inadvertently on the ground or floor or other lower level, according to World Health Organization (WHO)¹².

Data on fractures are retrieved from providers’ records automatically by the management platform.

Based on the patients’ current medications at the time of their first clinic visit, the following exposure variables were defined: use of at least one benzodiazepine or nonbenzodiazepine sedative, regardless of class (exposure variable 1); use of at least one benzodiazepine sedative (exposure variable 2); and use of at least one nonbenzodiazepine sedative (exposure variable 3).

Benzodiazepine sedatives were defined as those in WHO Anatomical Therapeutic Chemical (ATC) class N05BA plus clonazepam, which is classified as an antiepileptic by WHO but widely used as a sedative in Brazil. Nonbenzodiazepine sedatives (“z-drugs”) were defined as those belonging to ATC class N05CF. All identified drugs were recorded by their nonproprietary names.

The following data were also collected at the first clinic visit for subsequent construction of adjustment variables: sex (female or male), age (in years, completed, and dichotomized at 75 years), and Clinical-Functional Vulnerability Index (IVCF-20) (scored from 0 to 40, dichotomized at 15 points). The IVCF-20 is a frailty screening instrument, developed and validated in Brazil, which assesses the main dimensions associated with functional decline and/or death in older adults: age, self-perceived health status, activities of daily living, cognition, mood, mobility, communication, and presence of multiple comorbidities.¹²

A descriptive analysis of the data was performed by determining absolute and relative frequencies for qualitative variables and by calculating the mean and standard deviation (SD) for quantitative variables.

Medication use was analyzed from two perspectives:

- a. profile; and
- b. prevalence.

To characterize profile of sedative use, medications were selected as the unit of analysis, and the absolute and relative frequency of sedative use was described per active pharmaceutical ingredient in relation to the total number of sedatives used. To characterize prevalence of sedative use, the proportion of participants on sedatives relative to the total number of study participants was calculated.

Associations between qualitative variables were analyzed using Pearson's chi-square test. The association between exposure variables and outcome variables was measured by estimating crude odds ratios (OR_{crude}) and their 95% confidence intervals (95% CI). Furthermore, adjusted ORs (OR_{adj}) were calculated by adjusting the logistic regression models, with sex, age, and IVCF-20 score as control variables.

All analyses were performed in the Stata® version 12 software environment; statistical significance was accepted at the 5% level ($p=0.05$).

This study is an integral part of a research project ("Perfil de uso de medicamentos e desprescrição em um ambulatório de geriatria" [Medication use profiles and deprescribing at an outpatient geriatric clinic]) approved in 2021 by the Research Ethics Committee of Universidade Federal de Minas Gerais (UFMG) (opinion number 52595821.1.0000.5149).

RESULTS

A total of 7821 older adults were included in the study. The sample was predominantly female ($n = 5671$, 72.50%), with a mean (SD) age of 77.5 (9.0) years and a mean (SD) IVCF-20 score of 16.5 (7.1).

A total of 484 participants (6.19%; 95% CI 5.65–6.72) were on at least one sedative drug, with 350 (4.48%; 95% CI 4.00–4.90) taking at least one benzodiazepine and 155 (1.98%; 95% CI 1.67–2.29) taking at least one nonbenzodiazepine or z-drug.

Among sedative users, 456 (94.21%) took only one sedative, 27 (5.58%) took two sedatives simultaneously, and one (0.21%) took three sedatives.

Of the 513 sedatives reported, clonazepam was most widely used ($n = 149$; 29.04% of prescriptions), followed by zolpidem ($n = 147$; 28.65%) and alprazolam ($n = 120$; 23.44%). Eight other sedative agents were reported, all accounting for less than 10% of prescriptions (Table 1).

Sedative use overall was more common in women, those under the age of 75, and those with an IVCF-20 score above 15. Benzodiazepine use was more frequent among women and older adults with an IVCF-20 score above 15, while the use of z-drugs was more frequent only among the younger old (under age 75) (Table 2).

Falls were reported for or by 182 participants (2.33%). They were more prevalent among those over the age of 76 and among those with an IVCF-20 score above 15. Hip fractures occurred in 33 participants (0.42%), also with a higher frequency among those over 76 years of age or with an IVCF-20 score above 15 (Table 2).

The incidence of falls was higher among users of sedatives overall (4.34; $p = 0.002$; $OR_{adj} = 1.94$) and among those on benzodiazepines (5.14%; $p < 0.001$; $OR_{adj} = 2.28$) than among those not receiving any sedatives (2.19%) (Table 3).

Similarly, hip fractures were more frequent among users of sedatives overall (1.03%; $p = 0.032$; $OR_{adj} = 2.57$) and of benzodiazepines (1.43%; $p = 0.003$; $OR_{adj} = 3.45$) than among those not on sedatives (0.38%) (Table 3).

TABLE 1. Types of sedative agents used by older adults attending the study clinic.

Sedative	n	%
Clonazepam	149	29.04
Zolpidem	147	28.65
Alprazolam	120	23.44
Bromazepam	46	8.960
Lorazepam	27	5.26
Diazepam	9	1.75
Midazolam	5	0.97
Zopiclone	5	0.97
Eszopiclone	3	0.58
Flunitrazepam	1	0.19
Sulpiride/bromazepam	1	0.19
Total	513	100

The very small number of falls and fractures among participants using z-drugs alone did not allow for an adequate assessment of the statistical significance of potential associations, which makes our findings for this class of drugs inconclusive.

DISCUSSION

This longitudinal study provides important insights on the association between use of sedatives (particularly benzodiazepines) by older adults and the incidence of falls and hip fractures in this population. In addition, it is one of the few such studies to have been conducted at a private outpatient geriatric clinic, a setting which is becoming increasingly relevant as the Brazilian population ages and a type of facility which usually serves the most fragile and oldest old, among whom safe use of medications is even more critical. To the authors' knowledge, no other longitudinal study has sought to evaluate our outcomes of interest (falls and hip fractures)

among older adults treated at an outpatient geriatric clinic and with sedative use as the exposure variable.

The use prevalence of at least one benzodiazepine in the studied population (4.48%) was lower than that identified at a public outpatient geriatric clinic in Rio Grande do Sul (10.00%)¹³ and much lower than in another such clinic in the Netherlands (41.00%).¹⁴ The prevalence of nonbenzodiazepine use was about half of the prevalence of benzodiazepine use (1.98%), but no other study carried out in outpatient geriatric clinics evaluated use of this class of drugs. Even considering use of any sedative overall (6.19%), the prevalence was comparatively lower than that identified in Rio Grande do Sul and the Netherlands, as noted above.

Although the reasons for this low prevalence of benzodiazepine use in the studied population are unclear, it can be considered a positive indicator of the quality of prescribing in the outpatient geriatric clinic where the study was conducted, especially when considering the advanced mean age (77.5 years) and high mean IVCF-20 score (16.5 points) of the

TABLE 2. Overall distribution of any sedative use, benzodiazepine use, z-drug use, incidence of falls, and incidence of hip fracture stratified by categories of sex, age, and Clinical-Functional Vulnerability Index.

Variable	Overall n (%)	Sedative use n (%)	BZD use n (%)	Z-drug use n (%)	Incidence of falls n (%)	Incidence of hip fracture n (%)
Sex		*	*	*	*	*
Male	2150 (27.50)	105 (4.88)	75 (3.49)	36 (1.67)	55 (2.56)	8 (0.37)
Female	5671 (72.50)	379 (6.68)	275 (4.85)	119 (2.10)	127 (2.24)	25 (0.34)
Age (years)		*	*	*	p < 0.001	*
60–75	3210 (41.05)	225 (7.01)	159 (4.95)	76 (2.37)	49 (1.53)	5 (0.16)
76–106	4611 (58.95)	259 (5.62)	192 (4.14)	79 (1.71)	133 (2.88)	28 (0.61)
IVCF-20 (points)		*	p < 0.001	*	p < 0.001	p < 0.001
0–14	3463 (44.27)	180 (5.20)	123 (3.55)	64 (1.85)	36 (1.04)	2 (0.06)
15–40	4358 (55.73)	304 (6.98)	227 (5.21)	91 (2.09)	146 (3.35)	31 (0.71)

BZD: benzodiazepine; IVCF-20: Clinical-Functional Vulnerability Index.

*p-value statistically insignificant.

TABLE 3. Association of any sedative use, benzodiazepine use, or z-drug use with the incidence of falls or hip fractures among older adults within 30 days of first visit at the outpatient geriatric clinic.

Variable	n	Incidence of falls			Incidence of hip fracture		
		Yes, n (%)	OR _{crude} (95%CI)	OR _{adj} (95%CI)	Yes, n (%)	OR _{crude} (95%CI)	OR _{adj} (95%CI)
Sedative		*			*		
Yes	484	21 (4.34)	2.02 (1.27–3.22)	1.94 (1.22–3.11)	5 (1.03)	2.73 (1.05–7.09)	2.57 (0.98–6.75)
No*	7337	161 (2.19)			28 (0.38)		
BZD		p < 0.001			*		
Yes	350	18 (5.14)	2.42 (1.47–3.98)	2.28 (1.38–3.78)	5 (1.43)	3.78 (1.45–9.86)	3.45 (1.31–9.08)
No*	7337	161 (2.19)			28 (0.38)		
Z-drug		*			*		
Yes	155	3 (1.94)	0.88 (0.28–2.79)	0.88 (0.28–2.80)	0 (0)	†	†
No*	7337	161 (2.19)			28 (0.38)		

OR_{crude}: odds ratio calculated by logistic regression, without adjustment for covariates; OR_{adj}: odds ratio calculated by logistic regression and adjusted for sex, age, and Clinical-Functional Vulnerability Index; BZD: benzodiazepine. *No sedative; †Number of events insufficient for calculation.

*p-value statistically insignificant.

participants. The frailest and oldest old are more vulnerable to the adverse effects of sedatives, as they tend to experience more physiological alterations that alter the pharmacokinetic and pharmacodynamic profiles of these drugs.¹⁵ Considering the safety profile of sedatives, which are considered potentially inappropriate medicines (PIMs) for older adults, the prevalence identified in this study is still significant.⁵ Furthermore, it should be noted that use of sedatives and benzodiazepines was even more frequent among participants with an IVCF-20 score above 15, who are more fragile and thus more liable to experience adverse effects.

The most commonly used sedative in the present study was clonazepam, accounting for 29.04% of prescriptions. A previous study by Cuentro et al.¹⁶ was the only one to date to describe the profile of benzodiazepine use by older adults (treated at a public, university-affiliated outpatient geriatric clinic in the Brazilian state of Pará) stratified by active pharmaceutical ingredient, with diazepam being the most often used benzodiazepine in their sample. A systematic review demonstrated that long-acting benzodiazepines, such as clonazepam and diazepam, are those most frequently prescribed to older adults.¹⁷

Clonazepam is a low-cost drug, marketed in the form of oral drops, and is widely available in Brazilian retail drugstores and public dispensaries, which may explain why it was the most commonly used benzodiazepine in the present study. However, as noted above, clonazepam has a long half-life when compared, e.g., to alprazolam, which was the third most frequently used sedative in the studied population (23.44%). This longer half-life is associated with an even higher incidence of adverse effects among older adults.¹⁵

Zolpidem was the second most commonly used sedative drug in the studied population (28.65%). Despite a lack of studies with investigating the use of nonbenzodiazepine sedatives in outpatient geriatric populations, which precluded any comparative analyses, use of this class of medication by older adults is on the rise. Despite a lower dependence potential, z-drugs can cause the same adverse effects expected for benzodiazepines.^{18,19} Furthermore, the U.S. Food and Drug Administration (FDA) recently recommended the addition of boxed warnings for an increased risk of serious injury and death due to complex sleep behaviors, including sleepwalking, to the prescribing information and package inserts of drugs in this class. This adverse effect can occur even at low doses and even after a single dose, with or without concomitant intake of alcohol or other central nervous system depressants.²⁰

Regardless of the half-life of a benzodiazepine or the specific type of “z-drug” taken, the well-established association

of these medications with cognitive impairment, delirium, motor vehicle accidents, falls, and fractures make these drugs PIMs. PIMs are drugs which have a negative risk-benefit ratio when used by older adults.⁵

Regarding falls, we were unable to find any other longitudinal studies investigating the impact of sedatives on this outcome in older adults treated at an outpatient geriatric clinic, which precluded comparative analyses. However, an association between incidence of falls and use of benzodiazepines was identified in a cross-sectional study carried out in a Dutch outpatient clinic,¹⁴ and a similar association with the use of tranquilizers, in a cross-sectional study carried out at a university-affiliated outpatient geriatric clinic in Paraíba, Brazil.²¹ A meta-analysis has also already identified an association of this group of drugs with falls in older adults.²² In the present study, both the use of sedatives overall and the use of benzodiazepines specifically were associated with an increased incidence of falls (OR = 1.94 for sedatives overall and OR = 2.28 for benzodiazepines specifically), highlighting the risks posed by this medication class. In older adults, falls can cause loss of confidence, loss of independence, pain, trauma, depression, and even death.²³

On the other hand, considering the very small number of users of z-drugs in our sample (approximately 2.00%), no association could be identified between incidence of falls and this specific class of sedatives. It is important to stress that this finding is limited to our specific population, and that previous studies have already identified such an association in other settings.¹⁸

Regarding hip fractures, again we found no other longitudinal studies in the literature which investigated the potential association of this outcome with sedative use among older adults in the outpatient geriatrics context. In the present study, use of sedatives, including benzodiazepines, was associated with an increased incidence of hip fractures within 30 days (OR = 2.57 for sedatives and OR = 3.45 for benzodiazepines). Systematic reviews have also reported an association between the use of benzodiazepines and nonbenzodiazepine “z-drugs” and hip fracture in older adults.¹⁹ Patients who have recently started these drugs are at even greater risk for such fractures.^{24,25}

Hip fractures have a major impact on the life of older adults. They are associated with recurrent fractures and a substantial increase in morbidity and mortality.²⁶ Furthermore, many older adults who survive a fracture then face reduced ability to perform the activities of daily living, with some studies showing that about a third subsequently require institutionalization.²⁷ Approximately 25% of hip fracture survivors die within the first year after the event.²⁸

The recently published *World guidelines for falls prevention and management for older adults: a global initiative* provides recommendations on a multidisciplinary approach to reduce concerns about falls in community-dwelling older adults. Among them is the need to review pharmacotherapy and deprescribe any drugs that increase the risk of falls, such as sedatives.²⁹ Deprescribing is defined as the planned process of reducing or discontinuing drugs that no longer offer therapeutic benefit or are causing harm.³⁰ It thus bears stressing that reducing the dose of sedative medications also has the potential to reduce negative patient outcomes.

The process of patient intake at the specialized, multidisciplinary geriatrics service in which this study was conducted, which includes active involvement of physicians, nurses, and pharmacists, can contribute to the deprescribing process and facilitate its follow-up, contributing to even greater prospective reductions in the frequency of sedative use. In addition, other providers, such as occupational therapists and physical therapists, work at the facility and have the potential to strengthen implementation of nonpharmacological measures for these patients, including sleep hygiene and fall prevention strategies.

One limitation of the present study is that sedative dosages were not evaluated. The short observation time for detection of falls and fractures is another limitation; further studies with longer follow-up are warranted. Finally, the fact that the study was carried out in the highly specific setting of a private outpatient geriatric clinic precludes extrapolation of any inferences to other populations.

However, to our knowledge, this is the first study to evaluate the use of sedatives in the outpatient geriatrics setting and the longitudinal outcome of falls and hip fractures in a large population, providing additional evidence of the unsafe use of this class of medications

in the specific context of older adults with more complex medical needs.

CONCLUSION

The present study identified an association between use of sedatives overall and benzodiazepines specifically with an increased incidence of falls among older adults, and an even stronger association with the incidence of hip fractures.

Our findings provide additional evidence of the negative consequences of sedative use in the geriatric population, and suggest that multidisciplinary strategies should be developed to reduce use of these medications.

Conflict of Interest

The authors report no conflicts of interest.

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Author Contributions

NMCJ: project administration, formal analysis, conceptualization, data curation, writing – original draft, writing – review & editing, investigation, methodology, software, validation, visualization. EAR: formal analysis, writing – review & editing, methodology, validation, visualization. AILF: formal analysis, writing – review & editing, methodology, validation, visualization. EAV: data curation, writing – review & editing, software, supervision, validation, visualization. DCA: data curation, writing – review & editing, software, supervision, validation, visualization. MMGN: project administration, formal analysis, conceptualization, data curation, writing – original draft, writing – review & editing, investigation, methodology, software, supervision, validation, visualization.

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