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Increased use of benzodiazepines among older adults: Bambuí Project

Aumento da utilização de benzodiazepínicos entre idosos mais velhos: Projeto Bambuí

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ABSTRACT: ***Background:*** Benzodiazepines are the most widely used psychoactive drugs, despite the risks associated with their prolonged use, especially among older adults. ***Objective:*** To investigate the use of benzodiazepines among community-dwelling people aged ≥ 75 years. ***Methods:*** The study was conducted among members of the baseline (in 1997) and survivors (in 2012) of the Bambuí Project cohort. The prevalence of benzodiazepine use was estimated separately for each year, and the comparison between them was performed using the Poisson regression model with robust variance. ***Results:*** The prevalence of benzodiazepine use was higher in 2012 (33.9%) compared to 1997 (24.9%). After multiple adjustments, the difference in prevalence did not remain significant in study population (PR = 1.25; 95%CI 0.99 – 1.60), unlike that observed in the female stratum (PR = 1.38; 95%CI 1.04 – 1.84). Clonazepam was the strongest-growing drug between the two years (PR = 4.94; 95%CI 2.54 – 9.62). ***Conclusion:*** This study showed an important increase in benzodiazepine use in an older adult population. These results are concerning as these drugs are contraindicated for use in older adults, mainly if used chronically, and are available in the national list of essential medicines. Health professionals should be aware of the risks involved in its use regarding this population.

Keywords: Benzodiazepines. Aged. Medication use. Pharmacoepidemiology. Inappropriate prescribing.

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RESUMO: ***Introdução:*** Os benzodiazepínicos são os psicofármacos mais utilizados globalmente, apesar dos riscos associados ao seu uso prolongado, especialmente entre os idosos. ***Objetivo:*** O estudo teve como objetivo investigar a tendência do uso de benzodiazepínicos entre idosos mais velhos (75 anos ou mais) residentes em comunidade. ***Métodos:*** Trata-se de um estudo realizado com idosos com idades entre 75 e 89 anos, integrantes da linha base (em 1997) e sobreviventes (em 2012) da coorte idosa do Projeto Bambuí. A prevalência do uso de benzodiazepínicos foi estimada separadamente para cada ano, e a comparação entre elas foi realizada por meio de regressão de Poisson com variância robusta. ***Resultados:*** A prevalência do uso de benzodiazepínicos foi maior em 2012 (33,9%) em comparação a 1997 (24,9%). Após o ajuste múltiplo, a diferença de prevalências não permaneceu significativa na população total de estudo (razão de prevalência (RP) = 1,25; intervalo de confiança de 95% (IC95%) 0,99 – 1,60), diferentemente do observado no estrato feminino (RP = 1,38; IC95% 1,04 – 1,84). O clonazepam foi o medicamento que apresentou o mais forte crescimento (RP = 4,94; IC95% 2,54 – 9,62) entre os dois anos. ***Conclusão:*** O presente estudo evidenciou um importante aumento no uso de benzodiazepínicos em uma população idosa mais velha. Esses resultados preocupam, pois são medicamentos contraindicados para idosos, especialmente se utilizados cronicamente, e estão disponíveis na relação nacional de medicamentos essenciais. Os profissionais de saúde devem estar atentos para os riscos envolvidos no seu uso por essa população.

Palavras-chave: Benzodiazepínicos. Idoso. Uso de medicamentos. Farmacoepidemiologia. Prescrição inapropriada

INTRODUCTION

Benzodiazepines (BZD) are the most widely used psychiatric drugs and have pharmacological properties that provide sedative, hypnotic, anxiolytic, anticonvulsant and muscle relaxant action[1,2]. Although they are considered effective in the management of sleep and anxiety disorders, they have been related to the occurrence of adverse events, and their prescription to the older adults is potentially inadequate, especially for prolonged use[3]. BZDs have been associated with psychomotor impairment and cognitive decline[4], increased risk of Alzheimer's disease, stroke and malignant brain tumors[5].

Despite the risks associated with the prolonged use of BZD, especially among the older adults, its use remains frequent. In higher-income countries, the trend of this use among the older adults has been investigated, sometimes showing an increase[6-8], sometimes a decrease[9-11] of its prevalence. In Brazil, local scope studies have assessed the prevalence of BDZ use among the older adults in smaller cities[12,13] and in metropolises[14-16], but the trend of the event's behavior on a population basis, especially among older older adults, remains unknown.

Thus, this study aimed to investigate the trend regarding the use of BZD among older adults (75 years or more) community residents.

METHODS

STUDY AREA AND POPULATION

This investigation is part of the Bambuí Project, a longitudinal population-based study developed in the city of the same name, located in southwest Minas Gerais state,

Brazil, which had 15,000 inhabitants in 1997, when the baseline of the older adults cohort was established. Among the 1,742 older adults living in the urban area of the municipality on January 1st, 1997, 1,606 (92.0%) agreed to participate in the study. The profile of the baseline participants was similar to the older adults living in Bambuí in terms of sex, age, marital status, education and income. More details can be seen in a previous publication[16].

The present study sample consisted of two groups of older adults aged between 75 and 89 years:

- baseline members in 1997 (called the 1997 cohort);
- survivors in 2012 (called the 2012 cohort).

The age limit for the eligibility criterion was established to guarantee the independence of the samples, preventing any older adults aged 75 years or older in 1997 and survivor in 2012 from being simultaneously part of the two cohorts under comparison.

DATA COLLECTION AND STUDY VARIABLES

In both years, data were collected through the same standardized questionnaire, applied at home by interviewers who were thoroughly trained by the researchers responsible for the Bambuí Project. The dependent variable was the report of BZD use in the last 90 days, obtained from the answer to a general question about medication use. To minimize bias or memory problems, medical prescriptions and medication packages were checked. The drugs referred by the participants were identified, broken down into their chemical substances and classified according to Anatomical Therapeutic Chemical (ATC)[17]. The drugs listed in ATC under the codes N05B (anxiolytics) and N05C (hypnotic-sedatives) were considered BZD. Clonazepam, classified by ATC as an anticonvulsant (code N03AE01), was considered as an anxiolytic due to its usual prescription for this purpose.

The adjustment variables included sociodemographic characteristics, health conditions and use of health services. In the first set, sex, age, education (none; 1 to 3; 4 or more years of regular school attendance), marital status (married; widowed; divorced/single), monthly family income in minimum wages (< 2.0; 2.0–3.9 and 4.0 or more).

The health conditions investigated were self-rated health (good; very good; reasonable; poor; or very poor), number of chronic diseases, depressive symptoms and insomnia. Chronic diseases included coronary heart disease (angina and/or myocardial infarction), hypertension, diabetes, Chagas disease and arthritis, all based on a medical diagnosis report. The presence of depressive symptoms was assessed using the General Health Questionnaire, in its simplified 12 item version (GHQ-12), using a cut-off point equal to or greater than 5 for categorization[18]. The presence of insomnia was defined by reports of difficulty in initiating or maintaining sleep and/or waking up in the morning on at

least three days a week, in the last 30 days[19]. The variables that describe the use of health services were the number of medical consultations in the last 12 months and the coverage per health plan.

DATA ANALYSIS

The prevalence of BDZ use (overall, by therapeutic group and by drug) was calculated separately for each cohort. The therapeutic groups analyzed were anxiolytic and hypnotic/sedative. Regarding drugs, diazepam, lorazepam, bromazepam and clonazepam, the most frequently used, were analyzed.

The two cohorts were compared in relation to the distribution of the adjustment variables. Differences in prevalence of BZD use between years were investigated in the total study population and within the male and female strata, with the stratified analysis being restricted to overall use only. All adjustment variables were included in the multivariate models, regardless of any statistical criteria. The level of significance adopted to identify associations was $p < 0.05$. The statistical software Stata®, version 14 was used in the analyses.

All ethical principles regarding research in human beings were respected. The Bambuí Project was approved by the Oswaldo Cruz Foundation Ethics Committee.

RESULTS

There was a total of 769 older adults in the studied population; among the total eligible (n = 882), 113 were excluded (48 from the 1997 cohort and 65 from the 2012 cohort) due to the lack of information for at least one of the variables included in the investigation. Losses were not differentiated by cohort ($p = 0.882$).

Table 1 compares the two cohorts in relation to the study variables. They were similar in relation to sex, age and the presence of sleep disorders. Significant differences were observed for the other characteristics investigated, with the 2012 cohort having higher education and family income, worse self-reported health, greater number of chronic diseases and a higher frequency of depressive symptoms. This cohort had more medical appointments in the last 12 months and had higher coverage per health plan.

The prevalence of overall BZD use increased between 1997 and 2012, from 24.9 to 33.9% ($p = 0.007$). In this period, BZD use increased among women (27.1% in 1997 and 39.9% in 2012) and remained stable among men (21.3% in 1997 and 22.0% in 2012).

With regard to therapeutic subgroups, the use of anxiolytics was more common, with an increase in the use of anxiolytics (from 21.5% to 32.6%; $p = 0.001$), while use of hypnotics / sedatives decreased (from 3.7% to 1.6%; $p = 0.055$) between 1997 and 2012. Regarding drugs, there were significant changes in the prevalence of clonazepam (an increase from

Table 1. Distribution (%) of the characteristics of the study population and comparison of baseline older adults (1997) and survivors (2012), Bambuí Project

Characteristics	Total Population (n = 769)	1997 (n = 321)	2012 (n = 448)	pValue *
Sex				
Male	35.4	38.0	33.5	0.196
Female	64.6	62.0	62.5	
Age				
75 – 79	52.3	53.0	51.8	0.847
80 – 84	32.9	31.8	33.7	
≥ 85	14.8	15.3	14.5	
Schooling (in years)				
None	30.3	37.4	25.2	0.001
1 – 3	33.4	29.6	36.2	
≥ 4	36.3	33.0	38.6	
Family income in MW				
< 2	26.8	34.6	21.2	< 0.001
2 – 3.9	39.5	33.0	44.2	
≥ 4	33.7	32.4	34.6	
Health self-assessment				
Very bad/bad	46.2	34.9	54.2	< 0.001
Reasonable	40.3	45.2	36.8	
Good/Very good	13.5	19.9	8.9	
Number of chronic diseases				
≥ 2	17.0	24.3	11.8	< 0.001
0	34.3	39.9	30.4	
1	48.6	35.8	57.8	
Depressive symptoms				
No	45.4	56.4	37.5	< 0.001
Yes	54.6	43.6	62.5	
Insomnia				
No	60.1	63.2	57.8	0.130
Yes	39.9	36.8	42.2	
Number of medical visits in the last 12 months				
0 – 1	27.6	33.3	23.4	0.010
2 – 4	44.3	40.2	47.3	
≥ 5	28.1	26.5	29.2	
Health insurance coverage				
No	72.2	80.1	66.5	< 0.001
Yes	27.8	19.9	33.5	

*P value obtained by Pearson's χ^2 test; MW: minimum wage, equivalent to US$120 in 1997 and US$333 in 2012.

3.1 to 16.3%; p <0.001) and bromazepam (a decrease from 9.0 to 2.9%; p <0.001); the use of lorazepam increased (from 4.4 to 6.0%; p = 0.311), but not significantly, while diazepam use remained stable, around 4.0%.

After multiple adjustment for sociodemographic variables, health conditions and use of health services, the prevalence of overall BZD use was 25% higher in 2012, but the association lost its statistical significance (prevalence ratio (PR) = 1.25; 95% confidence interval (95% CI) 0.99 –1.60). The analysis of the association between cohort and use of therapeutic subgroups showed different results for anxiolytics and hypnotics/sedatives. The use of the former was significantly higher in 2012 (PR = 1.42; 95% CI 1.10 – 1.84), while that of the latter decreased significantly (PR = 0.32; 95% CI 0.13 – 0, 84). In relation to drugs, the prevalence of the use of clonazepam increased strongly and significantly (PR = 4.94; 95% CI 2.54 – 9.62), unlike the prevalence of the use of bromazepam, which showed the opposite trend, significantly decreasing (PR = 0.29; 95% CI 0.15 – 0.26). There were no significant differences between the two cohorts for the use of diazepam and lorazepam. The complete results of the univariate and multivariate analyzes of the association between the use of BZD and the birth cohort can be seen in Table 2.

Multivariate analyzes stratified by sex showed that the overall BZD use among older adults men did not differ between the two cohorts (PR = 1.03; 95% CI 0.63 – 1.69), however, the overall BZD use was significantly higher in the 2012 cohort among older adults females (PR = 1.38; 95% CI 1.04 – 1.84).

Table 2. Results of crude and adjusted analyzes for association between year of cohort and use of benzodiazepines (global, therapeutic subgroups and drugs) among older adults, Bambuí Project (1997 and 2012).

Use Of benzodiazepines	1997 (%)	2012 (%)	Crude PR (95%CI)	Adjusted PR (95%CI)
Overall	24.9	33.9	1.36 (1.08 – 1.71)	1.25 (0.99 – 1.60)
Therapeutic subgroups				
Anxiolytics	21.5	32.6	1.52 (1.18 – 1.94)	1.42 (1.10 – 1.84)
Hypnotics / Sedatives	3.7	1.6	0.42 (0.17 – 1.05)	0.32 (0.13 – 0.84)
Drug				
Diazepam	4.1	4.0	0.99 (0.49 – 2.00)	0.89 (0.39 – 2.08)
Lorazepam	4.4	6.0	1.38 (0.74 – 2.59)	1.35 (0.71 – 2.54)
Bromazepam	9.0	2.9	0.32 (0.17 – 0.61)	0.29 (0.15 – 0.26)
Clonazepam	3.2	16.3	5.23 (2.74 – 9.98)	4.94 (2.54 – 9.62)

PR: prevalence ratio adjusted for sex, age, education, monthly family income, self-reported health, number of chronic diseases, depressive symptoms, sleep disorder, number of medical appointments and coverage by health insurance; 95% CI: 95% confidence interval; estimated by the Poisson regression model, with robust variance.

DISCUSSION

Although the difference in the overall prevalence has not been shown to be statistically significant, the present study showed a higher consumption of BZD in older older adults in 2012, compared to that observed in 1997. On the other hand, BZD use increased significantly among women, but the same did not occur among men. This increase reflected the increment in the use of anxiolytics (regarding the therapeutic subgroup) and clonazepam (regarding the drug).

In higher-income countries, trend studies on BZD prescription and use among the older adults have shown divergent results. In Canada[9], a population-based study based on prescription records showed a significant reduction in the prevalence of BZD use between 1998 and 2013, from 23.2 to 14.8%, a trend similar to that seen in Germany[11] in two national health surveys (3.7% in 1997–99 and 2.5% in 2008–11), as well as in the United States (9.2 to 7.3%) and Australia (20.2 to 16.8%), both between 2010 and 2016[10]. In terms of trend, our results are in line with that observed in Spain (17.0% in 2003 and 24.9% in 2009)[7], in the United States (from 5.6 to 8.7%, between 2003 and 2012)[6] and in Finland (29.6% in 1998 and 31.3% in 2004)[8]. Regarding the magnitude, the prevalence detected in Bambuí are higher than those of the aforementioned studies, with the exception of the Finnish study carried out with an older adults population of similar age to that of Bambuí[8].

The change in the pattern of prescription and use of drugs in a population over time can be influenced by factors that are interconnected, such as medical preferences and the advancement of biomedical knowledge, namely, changes in treatment guidelines and the development of new drugs, in addition to the policies defined for pharmaceutical assistance. The decrease of BZD use has been attributed to controversies related to the safety of these drugs: BZDs have been associated with the occurrence of adverse events, such as cognitive impairment, falls and addiction[3].

In richer countries, health authorities have implemented programs to monitor the prescription of BZD and have disseminated and applied protocols for deprescribing these agents[20,21], in order to reduce their use by older adults[1], who have been in favor of this change[22]. In line with recent therapeutic guidelines, other drugs are replacing BZDs in treating anxiety disorders, such as the newest and safest antidepressants in geriatrics (eg sertraline)[23], as well as the institution of non-pharmacological measures in the management of sleep disorders and insomnia symptoms, such as cognitive behavioral therapy[24].

The trend of increasing BZD use among older adults in Bambuí is unsettling, as it is contrary to what has been seen recently in more developed countries[9-11] and disregards the growing concern about the risks involved in the use of these drugs, which are also considered potentially inappropriate for the older adults, according to the Beers Criteria[3]. It is possible that the trend of increasing prevalence is largely due to the chronic use of the medication, reflecting the preferences of prescribers or even users[25].

The chronic use of BZD in this population is evidenced in quantitative[13] and qualitative[26,27] studies. In 1997, two thirds of older adults aged between 60 and 69 years old (and who would have been between 75 and 84 years old in 2012) had used BZD for at least 1 year and

a third of them for at least 5 years[13]. Evidence of chronic BZD use (for more than a decade) by this population appears in more recent qualitative studies. For this, different factors that mutually potentiate contribute, such as the meanings of the medication for the user, ease of access and medical practice.

For the older adults, BZD is an effective solution for the relief of mental suffering resulting from life problems, loneliness and lack of sleep, becoming as indispensable as food. The risks involved in using the drug are minimized and there is no fear of addiction. The health professional is valued because of the prescription, which is obtained without the assessment of its clinical relevance and due professional guidance. In these studies, there is a stronger link between the older adults and the medication than with the professional[26,27].

Another issue is the more frequent prescription of BZD by general practitioners, compared to psychiatrists[6]. In this context, the difficulty of access to specialized care can contribute to the growth in the prescription of BZD. In Bambuí, there was no psychiatrist available and almost all prescriptions were made by professionals other than the mental health specialist. In addition, the prescription may seem like a demonstration of the physician's empathy towards his suffering. This valorization of the medication by the user is an additional source of concern in the perspective of trying to reverse this trend, as inhibiting the chronic BZD use (which impacts the prevalence of use) can be more difficult than curbing new prescriptions (which affect the incidence of use)[10].

In Bambuí, the increase in BZD use was mostly due to the use of anxiolytics and clonazepam, which was the most used drug in 2012. Although ATC considers clonazepam to be an anticonvulsant, in the present study, it was classified as anxiolytic, given that its use for this purpose is frequent in Brazil. The growth trend in the use of clonazepam is similar to that observed among Canadian older adults[9] and raises particular concern, since it is a benzodiazepine with a long half-life, exposing the older adults to even more considerable risks as a result of its slow elimination.

Apparently, in Bambuí, clonazepam became the preferred BZD prescription, replacing bromazepam, which was the most used in the oldest cohort (1997). The reasons for this are not sufficiently clear, but, it is possible that the former is a standardized drug by the National Essential Medicines List (RENAME) since 2000[28] and is a factor that contributes to its prescription and diazepam, another BZD widely used in Bambuí. A large part of the study population has low income and is probably primarily served by the Unified Health System (SUS). Additionally, clonazepam is a low-cost drug to purchase even in private pharmacies[29] and its availability in liquid pharmaceutical form tends to provide greater user acceptance and tolerability in relation to the medication[27]. On the other hand, it is important to highlight that safer, or even more effective, therapeutic alternatives for the older adults, such as the antidepressant sertraline, are not standardized by RENAME. This raises the need for SUS to review the availability of psychiatric drugs for this population, increasingly and often affected by mental health problems[30].

The most frequent use of BZD by women, verified in the present investigation, has been consistently documented in older adults populations in several countries[6,9-11,31,32]. The upward trend in the use of these drugs among women, observed here, is paralleled in the literature[7,8]. This is usually

due to the higher frequency of mental disorders among women, as they tend to recognize and report psychological symptoms in medical appointments, when compared to men[33]. Also, there is evidence that women more commonly accept and use psychotropic drugs to treat these health problems[34] and that doctors are more willing to prescribe psychotropic drugs to women[30].

This study has both limitations and advantages. Among its limitations, there is the absence of relevant information, which would guarantee greater precision of the results and a less speculative interpretation. As an example, we cite the absence of more detailed information regarding the indication and the time of use of the medication, which prevents the assessment of the suitability and quality of use. The lack of information on the presence of anxiety disorders (one of the indications for the BZD use) may have affected the accuracy of the results, if the variation observed in the prevalence BZD use results from changes in the magnitude of this health problem in investigated population. Finally, although the internal validity of the study contributes to the robustness of the results obtained, these are not generalizable to other older adults populations.

On the other hand, the strength of this research derives from methodological care and the character of originality. Data collection, separated by 15 years, was performed with the same instrument (questionnaire) by interviewers trained by the same group of researchers, thus guaranteeing the excellent data comparability. It is worth highlighting the advantage of the present study concerning to the specific measurement procedures for the use of medications. Data collection was carried out at home and was accompanied by the presentation and verification of the packages and prescriptions of the drugs mentioned. This approximates the measurements obtained from the actual use of the referred medication, when compared to those generated in studies that use prescription banks or medication dispensing, as this does not guarantee use. Regarding its originality, it appears that this is the first population-based Brazilian study to investigate the trend in BZD use among older older adults (75 years or more).

In summary, the present study showed an important (although not significant) increase in BZD use in an older adult population, especially among women, which was basically due to the use of anxiolytics and clonazepam. These results are worrisome, as they are, in principle, contraindicated for older adults, especially if used chronically. Further trend studies are needed to verify whether these findings are restricted to this population or whether the same trend is observed in other older Brazilian populations. In light of the risks involved in the use of BZD by older adults, it is essential to raise the awareness of health professionals regarding its prescription as well as monitoring its users.

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