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Sleeping pill use in Brazil: a population-based, cross-sectional study

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ABSTRACT

Objectives This study aimed to assess the prevalence of sleeping pill use in Brazil.

Design A population-based cross-sectional study with a three-stage cluster sampling design (census tracts, households and adult residents) was used.

Setting The Brazilian 2013 National Health Survey was used.

Participants The study population consisted of household residents aged ≥18 years. A total of 60 202 individuals were interviewed, including 52.9% women, and 21% reported depressive symptoms.

Outcomes The primary outcome was sleeping pill use, which was self-reported with the question, 'Over the past two weeks, have you used any sleeping pills?' The prevalence was calculated and stratified according to sociodemographic characteristics. The associated factors were identified from prevalence ratios (PRs) obtained through a Poisson regression with robust variance and adjusted for sex and age.

Results The prevalence of sleeping pill use was 7.6% (95% CI 7.3% to 8.0%), and the average treatment duration was 9.75 (95% CI 9.49 to 10.00) days. Self-medication was found in 11.2% (95% CI 9.6% to 12.9%) of users. The following factors were associated with sleeping pill use: female sex (PR=2.21; 95% CI 1.97 to 2.47), an age of ≥60 years (PR=5.43; 95% CI 4.14 to 7.11) and smoking (PR=1.47; 95% CI 1.28 to 1.68). Sleeping pill use was also positively associated with the severity of depressive symptoms (p<0.001), whereas alcohol intake was inversely associated (PR=0.66; 95% CI 0.56 to 0.77).

Conclusions One in every 13 Brazilians adults uses sleeping pills. There is a lack of information about the reasons for this use. Actions are required to raise awareness about the risks. The results could assist programmes in targeting rational sleeping pill use and the identification of factors demanding intervention.

Strengths and limitations of this study

- ► This is an analysis of a representative sample of 60 202 adults living in Brazil.
- ► Sleeping pill use was self-reported by the interviewees and may be an underestimate.
- ► This survey did not provide the pharmacological class of the sleeping pills.

INTRODUCTION

A more stressfull pace of life is the main caractheristic of modern lifestile. Factors such as work, new technologies and sociocultural tendencies influence the speed of change in human behaviour.[1] Chronic diseases like hypertension, diabetes and depression also follow these paradigms. These elements are closely involved with changes in an individual's daily routine, including sleeping habits. Thus, the use of sleeping pills is sought as a strategy by people who find it difficult to fall asleep. Sleeping pill use has been addressed in a variety of contexts, and the most relevant aspect is the relationship between sleep disturbances, particularly insomnia.[2 3]

Insomnia is the most prevalent sleep disorder, afflicting 6%–10% of persons with some sleep disturbance.[4] Sleep is a physiological process that is central to an individual's normal functioning and development.[5] Sleep disruption caused by insomnia has an effect on human physiology and is reflected in significant daytime afflictions such as sleepiness, fatigue and mood swings, in addition to greatly compromising quality of life.

Investigations of sleep disturbances, particularly insomnia and its relationship to sleeping pill use, rely primarily on findings of nationwide surveys.[6] These instruments, which are widely used in developed countries, assist in the characterisation of populations and the identification of factors demanding some form of intervention.

Studies in several countries have associated the frequency of sleeping pill use with work-related problems, mental disorders and lifestyle habits. Between 2008 and 2010, a Spanish study reported the concomitant use of alcoholic beverages (wine, beer and others) and sleeping pills in individuals >60 years of age.[7] In Finland, a study revealed problems such as work absenteeism due to sleep disorders in 2000.[8] The need for sedatives, hypnotics or psychoactive drugs increased the risk of suicide in adults with short sleep (<6 hours/night) or those who had trouble falling asleep in Taiwan.[9] In China, a study highlighted specific aspects of sleep behaviour and its association with increased involuntary injury

in school-age children.[10] An investigation in Lebanon revealed the off-label use of sleeping pills, concomitant with tobacco (through narghile), to relieve symptoms of anxiety and depression.[11] In the USA, there are investigations associating sleeping pill use with parasomnias[12] and excessive daytime sleepiness in adults in three major cities.[13]

In Latin America and Brazil, information about sleeping pill use is scarce. Its relationship is little explored with sleep disturbances, chronic diseases or psychiatric disorders. The publications found refer to populations of certain cities or states with specific characteristics and provide little information about medicines.[14–16] In Brazil, there is an increase in the consumption of benzodiazepines, with an emphasis on the prescription of clonazepam as a sleep inducer.[17]

Considering that multiple studies have highlighted the harmful effects of such use, knowing the profile of sleeping pill users and the effect on this segment of the population and of society in general is a necessity. In this context, the aim of the present study was to assess the prevalence and factors associated with sleeping pill use in Brazil.

METHODS

Study design and sample

The present study was an analysis of data from the 2013 National Health Survey (*Pesquisa Nacional de Saúde* (PNS)), a population-based, cross-sectional study conducted in Brazil by the Brazilian Institute of Geography and Statistics (*Instituto Brasileiro de Geografia e Estatística*) in partnership with the Ministry of Health.[18]

The PNS consisted of household interviews conducted with adult residents with the aim of collecting data on health status, accessibility to public services, participation in prevention programmes and lifestyles of the population.[18]

A three-stage cluster sampling design was chosen for the survey. The first stage was the random selection of census tracts, also referred to as primary sampling units. Areas with special characteristics or small populations were excluded. The second stage involved the random selection of households belonging to the selected units. Finally, the third stage involved the random selection of an adult resident (age ≥18 years) at each chosen address.[18]

The final PNS sample comprised 69 954 occupied households, with 64 348 interviews administered. At each household, only one resident was selected for the individual interview concerning health status, lifestyle patterns and chronic diseases. In all, 60 202 persons were included in the prevalence calculations.[18] Sample losses occurred for the following reasons: closed or empty houses, refusal of residents to answer the interviewer and failure to interview the resident after three or more attempts, even with previously scheduled visits.[18]

The survey response rate was 86.0%.[19] Methodological details, including the conception and development process of the PNS, have been described elsewhere.[18 19]

Data collection

The primary outcome analysed in the present study was related to the following question concerning the use of sleep medications: 'Over the past two weeks, have you used any sleeping pills?' Two related questions were also asked: 'Over the past two weeks, for how many days have you used the sleeping pills?' and 'Were the sleeping pills prescribed to you?'

Factors that might be associated with sleeping pill use were extracted from the survey data set and analysed: sex (male, female), age group in years (18–24, 25–39, 40–59, 60 or older), marital status (single, married, separated/divorced, widowed), ethnicity (black, brown (mixed race)/indigenous, white/Asian descent) and level of education (no formal education and less than primary education, primary education and less than high school education, high school education and less than higher education, higher education).

The following lifestyle characteristics were analysed: smoking (smoker, ex-smoker, non-smoker), alcohol consumption (non-drinker, less than once a month, more than once a month), physical activity (active, inactive), salt intake (moderate, excess) and body mass index (BMI) (normal weight, overweight, obese).

The present study also examined questions about depressive symptoms based on the Patient Health Questionnaire for depression (PHQ-9) (no symptoms, minimal symptoms, moderate symptoms, severe symptoms, very severe symptoms) and their relationship to sleeping pill use.

Statistical analysis

The data analysis was performed using the STATA statistical software V.14.2. All calculations considered the weights allocated in the complex sampling process. Statistical significance was considered for p values<0.05. A descriptive analysis was performed with data stratified according to sleeping pill use. To determine whether the frequency of sleeping pill use was related to the independent variables, prevalence ratios (PRs) adjusted for sex and age were calculated with their respective 95% CIs using a Poisson regression model with robust variance.[20] A sensitivity analysis was performed through the bootstrap resampling technique by simulations with subsamples from the same data set.[21] We also implemented a Wald test to a second Poisson model adjusted for sex, age, smoking status, alcohol intake and depression symptoms.

Ethical considerations

The selected participants provided written informed consent in which they agreed to participate in the study and complete the questionnaire. Participation was voluntary and confidentiality of information was ensured in compliance with the National Health Council (*Conselho*

Table 1 Sociodemographic characteristics of the sample and prevalence ratios (PRs) of sleeping pill use in Brazil, 2013 (n=60 202)

Variables	Sample (%)	Sleeping pill use (%)	PR*	95% CI	p Value†
Sex					<0.001
Male	47.1	4.5	1.00	–	
Female	52.9	10.4	2.21	1.97 to 2.47	
Age group (years)					<0.001
18–24	15.9	2.5	1.00	–	
25–39	31.8	4.8	1.89	1.42 to 2.51	
40–59	34.2	9.1	3.53	2.70 to 4.62	
≥60	18.1	14.3	5.43	4.14 to 7.11	
Marital status					0.104
Single	42.5	5.2	1.00	–	
Married	44.3	8.5	1.07	0.95 to 1.21	
Separated	6.5	10.5	1.17	0.98 to 1.39	
Widowed	6.7	14.6	1.02	0.86 to 1.21	
Ethnicity					<0.001
Black	9.2	5.8	1.00	–	
Brown/indigenous	42.4	7.4	1.36	1.11 to 1.66	
White/Asian descent	48.4	8.2	1.38	1.13 to 1.68	
Level of education					0.010
Higher education	14.3	7.2	1.00	–	
High school education	36.7	5.2	0.89	0.76 to 1.05	
Primary education	36.8	9.3	1.18	1.01 to 1.38	
No formal education	12.2	10.7	1.14	0.95 to 1.36	

*PR adjusted for sex and age.
†p Values for the Wald test adjusted by sex, age, smoking status, alcohol intake and depressive symptoms.

Nacional de Saúde) Resolution no. 466 of 12 December 2012.[18]

RESULTS

The profile of respondents is shown in table 1. Most participants were female, and the mean age of the interviewed population was 42.9 years (95% CI 42.7 to 43.2). Most participants had primary to high school education level, were married and reported being of white ethnicity.

With respect to lifestyle characteristics, approximately 25% of the respondents consumed alcoholic beverages more than once a month, the great majority reported sedentary behaviour and nearly 20% were obese (table 2).

The prevalence of sleeping pill use was 7.6% (95% CI 7.3% to 8.0%), and the duration of treatment was 9.75 (95% CI 9.49 to 10.00) days. Of the users, 11.2% (95% CI 9.6% to 12.9%) reported taking sleep medications without medical guidance.

The frequencies for sleeping pill use and PRs are shown in table 1. The sociodemographic profile shows increased use associated with females, an age of ≥25 years, brown and white ethnicity, and education level. Regarding lifestyle patterns, smoking was related to the increased use of sleep medication, while alcohol consumption was associated with decreased use. In a sensitivity analysis, physical inactivity was associated with less sleeping pill use.

Of the respondents, 21% reported depressive symptoms, with 9.42% of those reporting sleep complaints almost daily and 3.76% declaring suicidal ideation and/or some form of self-aggressive behaviour. The mean PHQ-9 score was 2.7 (95% CI 2.6 to 2.8). Sleeping pill use was positively associated with the severity of depressive symptoms. A higher PR was found with increasing depressive symptom severity (table 2).

DISCUSSION

Roughly 1 in every 13 Brazilian adults uses sleeping pills. This behaviour was more frequent among women, older individuals, smokers and persons with depressive symptoms. Approximately 10% of users were self-medicating. Marital status, level of education, physical activity, salt intake and BMI were not related to sleep medication use.

The PNS was developed using a design of its own, and no distinction was made between pharmacological classes; only information regarding sleeping pill use versus no use was included. Two strengths of the present study are the

Table 2 Lifestyle characteristics of the sample and prevalence ratios (PRs) of sleeping pill use in Brazil, 2013(n=60 202)

Variables	Sample (%)	Sleeping pill use (%)	PR*	95% CI	p Value†
Smoking					0.004
Non-smoker	67.8	6.7	1.00	–	
Ex-smoker	17.5	9.8	1.28	1.14 to 1.44	
Smoker	14.7	9.4	1.47	1.28 to 1.68	
Alcohol intake					<0.001
Non-drinker	59.6	9.6	1.00	–	
Less than once a month	13.9	5.7	0.78	0.66 to 0.93	
More than once a month	26.5	4.2	0.66	0.56 to 0.77	
Physical activity					0.007
Active	31.5	6.4	1.00	–	
Inactive	68.5	8.2	1.03	0.92 to 1.15	
Salt intake					0.300
Moderate	86.4	7.8	1.00	–	
Excess	13.6	6.6	1.06	0.91 to 1.23	
Body mass index					0.823
Normal weight	45.9	6.7	1.00	–	
Overweight	35.6	7.3	0.99	0.86 to 1.14	
Obese	18.5	8.9	1.08	0.92 to 1.26	
Depressive symptoms					<0.001
No symptoms	78.9	3.9	1.00	–	
Minimal	13.2	15.8	3.62	3.21 to 4.07	
Moderate	4.8	24.6	5.36	4.66 to 6.16	
Severe	2.1	38.2	7.85	6.77 to 9.11	
Very severe	1.0	50.4	10.42	8.74 to 12.44	

*PR adjusted for sex and age.
†p Values for the Wald test adjusted by sex, age, smoking status, alcohol intake and depressive symptoms.

sample size and the use of probability sampling, which ensured greater national representativeness.[19] In addition, special attention was given to the preparation of the questionnaire, which included internationally validated instruments such as PHQ-9, which is a specific measure for depressive symptoms. Before the fieldwork was initiated, a pilot study was performed in March of 2013. In all, 46 census tracts and 644 households were selected from six Brazilian states: Acre, Espírito Santo, Goiás, Mato Grosso do Sul, Rio de Janeiro and Sergipe. This approach was used to minimise or prevent potential problems and errors that might occur during the full-scale study interviews.[18] Despite the various preventive measures, the reported results may have been influenced by some form of bias and should thus be interpreted with caution. Weaknesses were also identified in the present study. Sleeping pill use was self-reported. The interviewer took note of the answers without checking any source or reliable record such as medical prescriptions, medication boxes, information sheets or medication packaging (eg, blister packs and vials). Moreover, the questionnaire provided no detail as to the pharmacological class of the medication, whether the intention was for the treatment of symptoms of sleep disturbances or whether drugs were used with a different indication that also had sedative effects, such as antihistamines. Sleep medications with hypnotic/sedative effects cause concentration and comprehension deficits. Given the circumstances, some respondents might have had difficulties responding to the interview coherently. Another consideration is the possibility that a proportion of respondents who reported using sleeping pills were depressed, which may have compromised their commitment to the survey. Persons with depressive symptoms typically lose interest or have no pleasure in performing any activity. This fact could have influenced the results due to the unwillingness of those individuals to answer the questions. Other potentially influential factors that could be associated with sleeping pill use were also left out of the questionnaire, such as 'burnout syndrome', a family history of insomnia and the lack of an environment conducive to nightly rest.[22–24] The use of illicit drugs such as marijuana, in addition to anxiety disorders, could also lead to insomnia and stimulate the use of sleep medication.[25 26] Some other lifestyle-related variables that might

have a bearing on sleeping pills use, such as caffeine intake and internet use, were also absent from the questionnaire.[1 27]

Studies conducted in a variety of countries have shown frequencies of sleeping pill use ranging from 3% to 20%. The frequency rate of 7.6% found in the present study is consistent with the results of studies from three large Latin American cities[2] and one study from Germany.[28] However, it was lower than the frequency of use revealed by a study in the USA, which was 21%.[29] The variation in frequency values demonstrates the heterogeneity of approaches to sleeping pill use in each setting. Factors such as sleep disorders,[2] depression,[29] medication intake[30] and work absenteeism[8] were related to the use of medications. The data reflect the cultural diversity of each country, the characteristics of the samples and the location (urban or rural areas) where the studies were performed, all of which can influence the final study results. Comparing frequencies between studies is difficult because of methodological differences. Distinct methods were used in each study according to its goals, such as measures to assess sleep complaints (either validated[31] or designed ad hoc[2 30]) and statistical analyses and classification criteria[30 31] or not[2 7 28] for the sleeping pills. Among the cited medications were pharmacological classes with central action (benzodiazepines, non-benzodiazepine hypnotics, antidepressants and anxiolytics) and over-the-counter sleeping pills such as antihistamines and phytomedicines.

The present study shows a higher frequency of sleep medication use by women and older individuals. In fact, both are regarded as demographic risk factors for the insomnia disorder.[32 33] Furthermore, depression and anxiety have been reported to be predominant factors among women.[25 34] With advancing age, health complications become more frequent, which further supports the relationship between age and medication use. Senility also promotes changes in sleep architecture, resulting in a significant impact on the quality of life of older individuals.[35] However, a review on insomnia in older populations found that age alone is not responsible for sleep alterations. Rather, multiple factors are related to ageing such as psychiatric disorders, comorbidities and polypharmacy.[36] Studies assessing the prevalence of insomnia in different age groups have reported increased rates with advancing age.[28 31] In an investigation of sleep-related issues in a population >60 years of age, conducted in the municipality of Bambuí, Minas Gerais state, Brazil, the prevalence of insomnia was nearly 40%, mostly among women. The frequency of sleeping pill use was 25%.[16] The use of sleep medications among respondents aged ≥40 years in the present study was likely related to a lack of sleep or another prevalent comorbidity such as depression or substance abuse.[37] Sleep disturbances and their relationship to depression have been widely explored.[25 38 39] The findings of the present study highlight the association between depression and sleep alterations, particularly insomnia. Approximately 10% of Brazilians who reported any depressive symptoms have difficulty sleeping nearly every day. This fact likely explains the relationship found between depressive symptoms and sleeping pill use. Lifestyle patterns are constantly changing, influenced by new behaviours and economic and technological developments. Countless factors have an effect on daily routine and lead to changes in everyday behaviour, including sleep habits.[1] There is growing evidence that inadequate sleep (insufficient duration and poor quality) is associated with lifestyle-related factors, including alcohol, nicotine, obesity, lack of physical activity and use of substances such as caffeine.[40] In the present study, alcohol consumption was shown to be inversely associated with sleeping pill use. A study conducted in the USA revealed that individuals with insomnia are more susceptible to alcohol consumption due to its hypnotic effects,[41] supporting the findings of the present study. Consistently, several published articles have shown the use of alcohol for inducing sleep because of its depressive action on the central nervous system.[40 42] However, one complication of alcohol intake is dependence, which develops with prolonged use, and a 'rebound effect', as alcohol provokes multiple awakenings and makes it more difficult to resume sleep. With respect to cigarette smoking, being an ex-smoker or current smoker increased the frequency of sleeping pill use. Nicotine is considered a stimulant, and although it improves some cognitive functions such as focused attention, recognition memory and reasoning, it impairs sleep quality.[43] High amounts of nicotine result in rapid eye movement sleep suppression, increased latency time and a reduction in total sleep time.[44] Even after smoking cessation, nicotine remains in the body for a long time. Ex-smokers, depending on the duration of abstinence, may have sleep problems, particularly multiple awakenings and overactive dreaming. In addition, there may be a relationship between smoking and depressive symptoms, with the cigarette being used as a resource to mitigate depression.[45] Smoking is implicated in a variety of complications affecting sleep, among many others. It is likely that sleeping pill use is related to sleep deprivation caused by nicotine.

The present analysis determined the frequency and factors associated with sleeping pill use in Brazil. Those issues, including duration of use and source of prescription, have rarely been studied in Brazil to date. The aspects surveyed in the PNS show the concern of the Brazilian government regarding the health of the population. However, some issues such as sleep-related problems were not directly addressed in the nationwide survey. International studies have examined sleep disturbances in view of their implications to health status, quality of life and sleeping pill use.[46 47] This subject and accompanying impacts should be explored more thoroughly by government agencies.

In conclusion, the analyses of the PNS data showed that sleeping pill use by the population is still insufficiently explored by the Brazilian scientific community and government agencies. A considerable number of

people were found to take sleep medications without medical guidance. Women and older individuals are the most prevalent users. Regarding behavioural factors, being a smoker increases the frequency of sleeping pill use whereas alcohol consumption reduces the need for such medications. Finally, persons with severe depressive symptoms are more likely to use sleeping pills. The results of this study could assist in guiding initiatives and programmes targeting rational sleeping pill use, sleep-related disturbances and potentially associated factors.

Contributors KK performed substantial contributions to the analysis and interpretation of data for the work and drafted the manuscript. MTS delineated the work and critically reviewed the important intellectual content.

Competing interests None declared.

Patient consent Obtained.

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