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ORIGINAL RESEARCH

Treatment of insomnia in primary care services in the southern region of Bogotá. 2019-2021

Manejo del insomnio en los servicios de atención primaria de la región sur de Bogotá. 2019-2021

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Abstract

Introduction: Insomnia is a prevalent sleep disorder in Colombia. Its treatment is challenging since there are no clinical practice guidelines (CPG) developed or adapted for the country.
Objective: To evaluate the treatment of insomnia in primary care services in the southern region of Bogotá between 2019 and 2021.
Materials and methods: Analytical cross-sectional study conducted using data from 247 adults with insomnia treated in the outpatient service of the primary health care centers of the Subred Sur E.S.E. of Bogotá, Colombia (southern region), between 2019 and 2021. The treatment was classified as adequate, partially adequate and inadequate following adherence to the recommendations of the European and American CPGs for the treatment of insomnia. Univariate and multivariate logistic regressions were performed to establish the correlation between receiving pharmacological prescription for insomnia and age, sex, and history of mental illness.
Results: Among the patients, 70.04% were women and 48.18% were between 29 and 59 years of age. Regarding insomnia treatment, 14.17%, 17.40% and 68.42% received adequate, partially adequate and inadequate treatment, respectively. Furthermore, 14.17% (95%CI: 9.54-18.80) were referred to psychiatric or psychological therapy, while 40.48% (95%CI: 32.8-48.2) were prescribed a drug to treat insomnia; however, none of the prescribed drugs were included in the reference CPGs. The most commonly prescribed drugs were trazodone (45.45%; 95%CI: 36.7-55.5) and amitriptyline (35%; 95%CI: 24.9-45.1), and a slight correlation was found between receiving pharmacological treatment and age (univariate: OR: 1.02; p=0.017; multivariate: OR: 1.02; p=0.021).
Conclusions: The treatment for insomnia was inadequate in most patients, as few were referred to psychiatric or psychological therapy, while none of the drugs prescribed for pharmacological treatment were recommended by the reference CPGs for the treatment of this sleep disorder.

Resumen

Introducción. El insomnio es un trastorno del sueño prevalente en Colombia, cuyo tratamiento representa un desafío al no contar con guías de práctica clínica (GPC) desarrolladas o adaptadas para este país.
Objetivo. Evaluar el manejo del insomnio en los servicios de atención primaria de la región sur de Bogotá entre 2019 y 2021.
Materiales y métodos. Estudio transversal analítico realizado con datos de 247 adultos con insomnio atendidos en el servicio de consulta externa de los centros de atención primaria en salud de la Subred Sur E.S.E. de Bogotá, Colombia (región sur) entre 2019 y 2021. El manejo del insomnio se clasificó según su adherencia a las recomendaciones de las GPC europea y estadounidense para el tratamiento de este trastorno en: adecuado, parcialmente adecuado e inadecuado. Se realizó una regresión logística univariada y multivariada para determinar la correlación entre haber recibido prescripción farmacológica para el insomnio y edad, sexo y presencia de enfermedad mental.
Resultados. 70.04% de los pacientes eran mujeres y 48.18% tenían entre 29 y 59 años. Respecto al manejo del insomnio, 14.17%, 17.40% y 68.42% recibieron un manejo adecuado, parcialmente adecuado e inadecuado, respectivamente. Además, 14.17% (IC95%: 9.54-18.80) fueron remitidos a terapia con psicología o psiquiatría, y en 40.48% (IC95%: 32.8-48.2) se prescribió un medicamento como tratamiento para el insomnio; sin embargo, ningún medicamento está incluido en las GPC de referencia. Los medicamentos más comúnmente prescritos fueron trazodona (45.45%; IC95%: 36.7-55.5) y amitriptilina (35%; IC95%: 24.9-45.1), y se encontró una correlación leve entre haber recibido tratamiento farmacológico y la edad (univariado: OR: 1.02; p=0,017; multivariado: OR: 1.02; p=0,021).
Conclusiones. El manejo del insomnio fue inadecuado en la mayoría de las pacientes, pues pocos fueron remitidos a terapia con psicología o psiquiatría, y en los que se prescribió tratamiento farmacológico, ninguno de los medicamentos es recomendado por las GPC de referencia para el manejo de este trastorno del sueño.

Introduction

Insomnia is a sleep disorder defined as frequent and persistent difficulty initiating or maintaining sleep, which impacts daytime sleep and cannot be attributed to environmental circumstances or lack of adequate opportunities for sleep.[1] The fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) describes the diagnostic criteria for insomnia, which include increased sleep latency, difficulty maintaining sleep (frequent awakening), impairment of daily living activities due to sleep disturbances, among others.[2]

Insomnia has been recognized as a prevalent disorder worldwide, with frequencies varying between 10% and 23.9% among the general population, being more frequent in older adults, women, people with a history of mental disorders, and subjects with socioeconomic difficulties.[3-5]

There are few studies in Colombia that address this disorder, for example the SUECA II study, which interviewed adults in Manizales and found an overall prevalence of 43.9%, with the chronic phenotype accounting for 33%.[6] Another study conducted in 1505 adults in Bucaramanga, Rueda-Sánchez *et al.*[7] found that 63.6% of the participants reported at least one symptom of insomnia which had no impact on the following day, while 26.2% reported having at least one symptom of insomnia with consequences during the following day, although it should be noted that the study by Rueda-Sánchez *et al.*[7] did not apply diagnostic criteria or long-term follow-up as the SUECA II study.[6]

The Subred Integrada de Servicios de Salud Sur E.S.E. (SubRed Sur E.S.E.) is a group of hospitals and health care centers that operate in a standardized manner to serve the inhabitants of the southern region of Bogotá (Colombia). Between 2019 and 2021, the average population enrolled in this network was 1 314 780 people, of which 50.4% were women. This service provides health care to some of the most vulnerable population of the city, from low socioeconomic sectors. It has a main unit for general emergency care, hospitalization and high complexity patients (Hospital El Tunal), two medium complexity units (Hospital Meissen and Unidad de Servicios de Atención en Salud Vista Hermosa), and 47 derived units serving as health points that focus on low complexity patient care and initial care to the community through outpatient services.[8]

The European Clinical Practice Guideline for the Diagnosis and Treatment of Insomnia (CPG-IE)[9] states that the approach to this disorder should first include recommendations for sleep hygiene, followed by an assessment to approach it from a cognitive behavioral therapy perspective. It also suggests providing symptomatic relief with pharmacological alternatives to patients who cannot be guaranteed prompt access to psychotherapy or patients whose work activity requires adequate rest (pilots, surgeons, among others).

Both the CPG-IE[9] and the American Academy of Sleep Medicine's Guidelines for the Pharmacologic Treatment of Chronic Insomnia (CPG-IA)[1] recommend pharmacologic treatment with cardinal medications such as Z-drugs, orexin receptor antagonists, melatonin receptor agonists, and, as a last resort, gamma-aminobutyric acid derivatives and melatonin.

There have also been reports of the use of drugs not indicated in the CPGs for this disorder, such as antihistamines (hydroxyzine, loratadine), antidepressants, anxiolytics (amitriptyline, trazodone, levomepromazine, among others), and benzodiazepines.[10,11] These drugs are listed in these CPGs with a recommendation against their use (weak recommendation according to the GRADE classification), taking into account that clinical studies and meta-analyses have shown that their use is associated with a higher incidence of adverse effects without a significant improvement in sleep latency or sleep duration.[1,9]

The treatment of insomnia is a therapeutic challenge given the wide variety of drugs available on the market with sedative capacity and the lack of CPGs adapted to each country and population.[5,10,11] In Colombia, this problem is particularly interesting given the prevalence of this disorder in the country, so the objective of this study was to evaluate the treatment of insomnia in primary care services in the southern region of Bogotá between 2019 and 2021.

Materials and methods

Study design

Analytical cross-sectional study.

Sample

The study sample comprised all patients over 18 years of age with a diagnosis of insomnia according to the ICD-10 (G47.9-G47.8-F51.9) who were treated in the outpatient services of the primary health care centers of the Subred Sur E.S.E. between 2019 and 2021 (n=247).

Procedures and variables

A review of the medical records yielded data on the following variables: sex, age, ICD-10 codes for diagnosis of insomnia, history of comorbidities (including mental disorders), and information on the treatment of insomnia (whether pharmacological treatment was prescribed, including the medication prescribed and dosage, and whether the patient was referred to psychiatric or psychological therapy). Age was classified according to the age groups defined by the Colombian Ministry of Health (18-28 years, 29-59 years, and ≥60 years).[12] It should be pointed out that, at the time of conducting the study, the Subred Sur E.S.E. did not have a protocol for the treatment of insomnia.

Classification of insomnia treatment

A search of the available evidence for the treatment of insomnia was performed in PubMed and LILACS using the terms "Clinical practice AND guidelines insomnia," and the filters for guidelines. As of November 2022, 37 related articles were found, of which CPG-IE[9] and CPG-IA[1] were the most recent (both published in 2017).

Both CPGs were evaluated by two reviewers using the AGREE II instrument.[13] The overall assessment of the quality of the guidelines was high according to the two reviewers, and their domain ratings ranged from 80.6% to 100%. It was also found that both CPGs made the same recommendations for pharmacological treatment, which suggests consistency. Therefore, the recommendations of these guidelines were considered appropriate for the classification of insomnia treatment in the present study, and the following criteria were established:

- *Adequate treatment:* referral of the patient to psychiatric or psychological therapy and/or prescription of pharmacological therapy with drugs recommended in the CPG-IE[9] or CPG-IA[1].
- *Partially adequate treatment:* prescription of any medication that has been approved by the Food and Drug Administration for the treatment of insomnia or whose off-label use has

been reported in the Dymamed evidence-based medicine database[14] and no referral to the mental health service for assessment.

- *Inadequate treatment:* patients who did not receive any treatment for insomnia or who were prescribed drugs that are not listed in the CPG-IE[9] or CPG-IA[1] recommendations or that are not indicated for the treatment of this disorder.

Statistical analysis

Data are described as absolute frequencies and percentages with their respective 95% confidence intervals (CI).

In addition, univariate and multivariate logistic regressions were performed to determine the correlation between receiving pharmacological prescription for insomnia and the variables age, sex and history of mental disorder, with a statistical significance level of $p<0.05$.

Analyses were performed using the statistical software JASP version 0.17.0.0.[15]

Ethical considerations

The study followed the ethical principles for biomedical research involving human subjects established in the Declaration of Helsinki[16] and the scientific, technical and administrative standards for health research of Resolution 8430 of 1993 of the Colombian Ministry of Health.[17] Furthermore, it was approved by the Research Ethics Committee of the SubRed Sur E.S.E. through Minutes No. 213 of February 24, 2023.

Results

Of the total number of outpatient consultations completed in the health institutions of the Subred Sur E.S.E between 2018 and 2021 (n=791 299), only 0.03% were related to insomnia. The annual proportion of consultations (total and related to insomnia) can be seen in Table 1.

Table 1. Proportion of outpatient consultations (total and related to insomnia) in primary care services of the Subred Integrada de Servicios de Salud Sur E.S.E de Bogotá, Colombia. 2019-2021.

Year	Number of consultations per year	Patients diagnosed with insomnia	Incidence of primary care consultations for insomnia
2019	283 610	80	0.03%
2020	233 278	63	0.03%
2021	274 411	104	0.04%
Total	791 299	247	0.03%

Of the 247 patients who sought medical care for insomnia during the study period, 70.04% were women and 48.18% were between 29 and 59 years of age. The most common comorbidities were dyslipidemia (27.94%; 95%CI: 19.37-34.07) and functional dyspepsia and/or gastritis (26.72%; 95%CI: 21.76-34.08). Regarding mental health disorders, 11.34% (95%CI: 7.47-15.21) of the patients had anxiety and 8.95% (95%CI: 4.91-12.91) had mixed anxiety–depressive disorder. Table 2 summarizes the clinical and sociodemographic characteristics of the sample.

Table 2. Sociodemographic characteristics of the sample (n=247).

Variable		Percentage	95%CI
Sex	Male	29.96%	25.21-34.71
	Female	70.04%	64.91-75.17
Age (years)	18-28	12.15%	11.11-13.19
	29-59	48.18%	42.01-54.35
	≥60	39.67%	33.48-45.86
Comorbidities	Functional dyspepsia and/or gastritis	26.72%	19.37-34.07
	High blood cholesterol levels (dyslipidemia)	27.92%	21.76-34.08
	Arterial hypertension	14.98%	10.53-19.42
	Hypothyroidism	9.31%	2.95-15.67
	Sleep apnea and sleep hypopnea syndrome	7.69%	1.37-14.01
	Diabetes	7.29%	1.00-13.58
	Unspecified cardiomyopathy	6.07%	0.05-11.59
	Cardiac arrhythmia	3.64%	2.50-4.78
	Kidney failure	2.83%	2.26-3.40
Mental disorders	Anxiety	11.34%	7.47-15.21
	Mixed anxiety–depressive disorder	8.92%	4.91-12.91
	Other	8.53%	6.29-10.71

Regarding insomnia treatment, 35 (14.17%; 95%CI: 9.54-18.80) patients were referred to psychiatric or psychological therapy and 100 (40.48%, 95%CI: 32.8-48.2) were prescribed drugs intended to treat insomnia. In the latter subgroup, the most frequently prescribed drugs were trazodone (46.04%; 95%CI: 36.7-55.5), amitriptyline (35.35%; 95%CI: 24.9-45.1), and levomepromazine (9.09%; 95%CI: 3.27-14.73). The distribution of the prescribed drugs is presented in Figure 1.

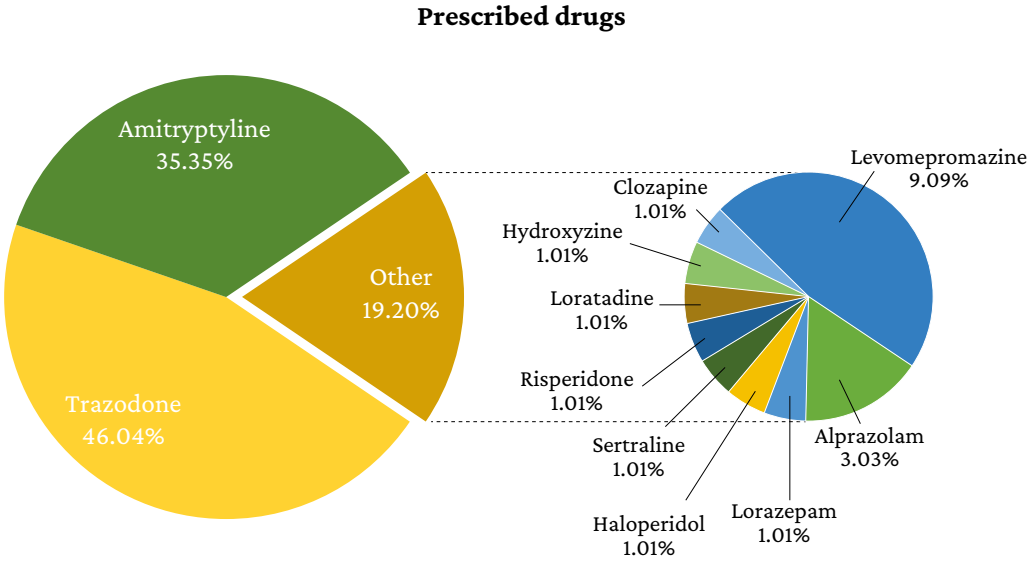

Figure 1. Drugs prescribed to patients with insomnia included in the study (n=100).

Furthermore, according to logistic regression analyses, both univariate and multivariate, there is a statistically significant, although slight, association between age and being prescribed pharmacological treatment for insomnia (univariate: OR: 1.02; p=0.017; multivariate: OR: 1.02; p=0.021). In contrast, sex and having a diagnosis of mental disorder were not significantly associated with being prescribed a drug for the treatment of insomnia.

Regarding treatment, it was found that no patient was prescribed any of the drugs recommended in the reference CPGs.[1,9] Thus, adequate treatment of insomnia occurred only in patients referred to psychiatric or psychological therapy, who accounted for 14.17% (95%CI: 8.89-19.44). Moreover, 17.40% (95%CI: 11.32-23.48) of patients received partially adequate treatment as all of them were prescribed trazodone, a drug that has off-label use for the treatment of insomnia. Finally, 68.42% (95%CI: 59.78-77.06) of the patients received inadequate treatment, given that the drugs prescribed in this group (i.e., amitriptyline, levomepromazine, etc.) are not included in the recommendations of the reference CPGs[1,9] for the treatment of insomnia, nor are they recognized for off-label use.

Discussion

This study describes the characteristics of insomnia treatment in primary health care services in the south of Bogotá, being the first research in Colombia that addresses this issue. Even though we found a low incidence of consultation due to insomnia (0.03%) during the study period, it is noteworthy that in most cases (68.42%) the treatment was inadequate and that only 14.17% were treated according to the recommendations of the CPGs considered.[1,9]

This study also found that the patients who consulted for insomnia were mainly women (70.04%), which is consistent with the findings of other studies such as the one conducted by Torrens *et al.*[18] in 467 adult patients (18 to 80 years old) treated in Spain between 2010 and 2011, which found that insomnia was more common in women (69.7%) than in men, and the one conducted by Chaput *et al.*[19] in Canadian population aged 6 to 79 years old (21 826 respondents of the 2007 - 2015 Canadian Health Measures Survey), in which a higher prevalence of insomnia symptoms was observed in women. This could be attributable to multiple factors, such as a higher prevalence of anxiety and depression in this population, the presence of hormonal alterations (menstrual syndrome and perimenopause), and a greater susceptibility to stressful life changes (widowhood, separation, care of the elderly, etc.).[20]

In the present study, most patients were between 29 and 59 years old (48.18%) or were older adults (39.67%), which is in line with the findings of Chaput *et al.*,[21] who reported that insomnia symptoms are more prevalent in adults than in adolescents and children. It should be noted that insomnia may be common in young people and adults due to inadequate sleep habits stemming from socioeconomic conditions, while in older adults it may be due to age-related alterations in the circadian cycle.[3]

On the other hand, the most common comorbidities in our study were high blood cholesterol levels (27.92%) and functional dyspepsia and/or gastritis (26.72%), which differs from what has been reported in the literature, in which it has been found that the most common comorbidities in patients with primary insomnia are diabetes, obesity, cardiovascular diseases (hypertension and ischemic heart disease), among others.[5,18,19] This may be the result of differences in the distribution of comorbidities in Colombia and developed countries, as well as the characteristics of the study population.

One of the main problems found in the present study is the low rate of referral to psychological therapy (14.17%) to initiate cognitive behavioral therapy. This implies that the population studied has limited access to this therapy, which has been recognized as a safe and effective option for the treatment of insomnia.[20] Some systematic reviews, such as those by Hertenstein *et al.*[20] and Matthews *et al.*,[21] have found that adherence to this type of therapy is directly associated with improved sleep quality. However, behavioral theoretical models, such as the theory of planned behavior or the health benefit model, do not seem to be successful in explaining why there is often a lack of adherence to this therapy. To date, there is no information available on the degree of access to cognitive behavioral therapy for patients with insomnia in other contexts, so it is necessary to study it in depth in order to suggest further solutions.

Concerning the use of medications for the treatment of insomnia, Begum *et al.*,[22] in a study of 1 773 525 patients treated between 2011 and 2018 in Australian general practices to explore changes in the pattern of benzodiazepine prescriptions, found that benzodiazepines, Z-drugs, and non-benzodiazepines were the most commonly prescribed drugs for the treatment of insomnia (prescribing rate of 56.6, 4.4, and 15.5 per 1 000 consultations in 2011 and 41.8, 3.5, and 21.5 per 1 000 consultations in 2018, respectively). In turn, Okuda *et al.*,[23] in a study involving 516 216 patients in Japan who were prescribed ≥1 hypnotic associated with a diagnosis of insomnia between April 1, 2009, and March 31, 2020, found that between 2018 and 2019, the most prescribed drug group was Z-drugs (40.2%), followed by benzodiazepines (32.1%), orexin receptor antagonists (18.7%), and melatonin receptor agonists (6.1%). These findings differ from those of our study, in which the most commonly prescribed drugs were trazodone (45.45%), amitriptyline (35.35%) and levomepromazine (9.09%), while benzodiazepines, represented by alprazolam and lorazepam, were prescribed in only 3.00% and 1.00%, respectively.

The foregoing demonstrates how the pharmacological treatment of insomnia varies substantially in different regions of the world, which may be related to differences in the trade and regulations of the pharmaceutical sector, in the training of prescribers, or in the culture of the societies in which the phenomenon occurs.

The failure to prescribe the drugs recommended by the reference CPGs[1,9] for insomnia shown in the present study is noteworthy. However, the information collected does not allow us to identify the possible causes of this phenomenon, and, to the best of our knowledge, there are no studies in other contexts that evaluate adherence to treatment recommendations. It can be inferred that this is a consequence of the lack of treatment guidelines that adapt the CPG-IE[9] and CPG-IA[1] to the local context and that physicians prefer drugs with a longer history in the market and without additional procedures for their prescription, such as trazodone and amitriptyline, since Z-drugs are subject to special regulations by the National Narcotics Fund, which involves additional procedures for their prescription in Colombia. In this regard, Walsh[24] reported that in the United States some physicians refrain from prescribing controlled drugs for insomnia, such as benzodiazepines, due to the regulations for prescribing them.

As for drugs not recommended by the CPGs considered[1,9] but with off-label use for the treatment of insomnia, trazodone was the most prescribed (45.45%). Even though it is not indicated for insomnia, according to studies conducted in other countries,[22-27] trazodone is commonly formulated for this purpose. In this sense, although there are no studies on the subject in Colombia, this drug could be a short-term option with an apparently adequate safety profile; however, further studies are needed to fully establish its safety.[25,26]

Despite the lack of studies comparing the prescription of drugs for insomnia by patient age, a slight correlation between age and receiving pharmacological treatment was observed in the present study. This may be so because older adults tend to achieve symptomatic relief more quickly due to the morbidity of daytime symptoms, whereas the waiting time for nonpharmacologic interventions to work in younger patients tends to be longer.[1,9]

The main limitation of the present study is that since only one moment of therapy is evaluated, there is no follow-up information on the patients or their medical records, so it is not possible to know the reasons that led to the choice of the treatment prescribed by the treating physician. Moreover, due to its retrospective nature, it was not possible to include information that would allow a more in-depth analysis of the reasons that led the treating physician to choose one or another type of treatment, such as the socioeconomic status of the patients or the availability of drugs in pharmacies at that time. Finally, it should be considered that the data obtained from the sample may not be extrapolated to other populations in the country, such as people covered by private health insurance plans or the rural population.

Conclusion

The recommendations of the reference CPGs for the treatment of insomnia were not followed in most of the participants, since less than one-fifth were referred to psychiatric or psychological therapy and the drugs prescribed were not recommended in the CPGs for this condition. This demonstrates the need, first, to develop or adapt the CPG on insomnia treatment to the Colombian context and, second, to improve the knowledge of current CPGs on the treatment of this disorder among physicians working in primary care services in Bogotá and Colombia. In addition, it is necessary to conduct studies that delve deeper into the factors that influence the physician's decisions on the treatment of insomnia, in order to generate interventions that promote the well-being of patients with this disorder in the country.

Conflicts of interest

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