Original Article

Pharmacists' Counseling and Benzodiazepines Dispensing for Sleep Disorders: A Simulated Patient Study in Iran

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ABSTRACT

Objective: Sleep is critical for good health and quality of life, but many people struggle with sleep disorders. Pharmacists are on the front lines, helping patients manage these problems. However, there is growing concern that some pharmacists are dispensing benzodiazepines over-the-counter and failing to provide proper counseling. This study examined how pharmacists in Iran performed in these areas. **Methods:** Between January and April 2022, we conducted a cross-sectional study in three major Iranian cities, using a "simulated patient" to observe how pharmacists interacted with them. In total, 431 pharmacies participated, and we used detailed forms to record the pharmacists' behavior. We then analyzed the data using descriptive statistics and the Chi-square tests. **Findings:** Of 549 visits, 78.5% were managed by pharmacists, whereas the remainder were managed by other pharmacy staff. 79.7% of pharmacists evaluated the patient before deciding whether or not to prescribe the medication and 58.9% provided a kind of counseling for their offered medication, but just 10.6% of pharmacies had a private counseling area. Despite regulations that require a valid prescription for benzodiazepines, 9.2% of pharmacies dispensed diazepam, and 13.2% dispensed alprazolam without requesting one, and when counseling was offered, it often lacked critical details. **Conclusion:** These findings raise serious concerns. There are deficiencies in how pharmacists and patients interact, with many pharmacists spending minimal time assessing patient needs. The high rates of benzodiazepine dispensing without valid prescriptions and inadequate counseling point to a need for stricter protocols and more training. To address these issues, health-care professionals and policymakers must collaborate to improve the quality and safety of sleep disorder treatment in community pharmacies.

KEYWORDS: *Benzodiazepines, patient counseling, patient education, pharmacists' performance, simulated patient, sleep disorders*

INTRODUCTION

Sleep is a crucial aspect of human life that helps restore the body and mind and promotes overall well-being. However, millions worldwide suffer from sleep disorders, which can negatively affect their health as well as their quality of life.[1] Insomnia is the most common sleep disorder, characterized by difficulty in falling or staying asleep, waking up too early, and feeling tired on arousal.[2] Other sleep disorders include sleep apnea, restless leg syndrome, and narcolepsy.[3]

Various factors, including lifestyle habits, medical conditions, and medication use, can cause sleep disorders. Insomnia, for example, can be triggered by stress, anxiety, depression, caffeine or alcohol consumption, or chronic pain.[4] Sleep apnea is often associated with obesity, smoking, and alcohol use,[5] and narcolepsy is a rare disorder caused by the loss of brain

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cells that produce a chemical called hypocretin, which regulates sleep and wakefulness.[6]

Treatment options for sleep disorders include medication, behavioral therapy, and lifestyle changes. Sleeping medications, such as benzodiazepines and nonbenzodiazepine hypnotics, are commonly prescribed for insomnia but can have side effects such as drowsiness, confusion, and memory problems.[7] These medications are also associated with an increased risk of falls, especially in older adults.[8] Antidepressants, antipsychotics, and anticonvulsants can also be used in the treatment of insomnia and other sleep disorders, but their effectiveness varies depending on the underlying cause.[9] Behavioral therapy, such as cognitive behavioral therapy for insomnia, is also a nonpharmacological treatment option that can be effective for people with chronic insomnia.[10]

Sleep medications, such as benzodiazepines and nonbenzodiazepine hypnotics, can effectively treat short-term insomnia.[11] However, they can cause adverse effects such as daytime drowsiness, cognitive impairment, and dependency.[12] Long-term use of sleep medications can also lead to rebound insomnia and withdrawal symptoms.[13] Therefore, physicians should carefully weigh the risks and benefits of sleep medications and closely monitor patients who use them.[14,15] Nonpharmacological interventions such as cognitive behavioral therapy and sleep hygiene should also be considered first-line treatments for chronic insomnia.[16]

Pharmacists play a crucial role in the management of sleep disorders. With their extensive knowledge of different types of sleep disorders, symptoms of insomnia, and treatment options, they are well-positioned to educate patients on proper sleep hygiene and nonpharmacological interventions to improve the quality of sleep.[17] According to the World Health Organization, pharmacists bear the responsibility of recognizing common minor symptoms within the population. It is incumbent on them to develop strategies for self-medication and promote responsible self-care practices.[18] Moreover, pharmacists can recommend over-the-counter sleep aids or prescribe medications when necessary, ensuring proper dosing and monitoring potential drug interactions.[19] They also collaborate with health-care providers to optimize treatment plans and adjust medications as needed.[20] Furthermore, pharmacists provide counseling and support, addressing concerns and reassuring patients struggling with sleep disorders.[21] The pharmacist's expertise significantly contributes to effective sleep disorder management and improves patients' quality of life.[22]

In Iran, pharmacists are permitted to offer counseling on sleep disorders as part of their professional responsibilities, enabling them to assist patients with sleep-related concerns.[23] Existing literature indicates that both pharmacy students and practicing pharmacists possess insufficient understanding regarding sleep-related disorders.[24,25] A cross-sectional study conducted in Jordan in 2019, which involved a simulated patient (SP) scenario with 67 pharmacists, indicated that community pharmacists in the region typically fail to provide sufficient counseling to patients requesting guidance concerning insomnia.[26] Another study conducted in Isfahan, Iran, focused on asthma management using metered-dose inhalers and showed that the provision of pharmaceutical care services is frequently inadequate. It was found that pharmacists working in community settings typically do not gather enough information and fail to provide appropriate counseling regarding patients' medical histories.[27] Another cross-sectional study in Mazandaran, Iran, in 2017, which involved a SP scenario showed pharmacists usually focus on dispensing the correct medication and pay less attention to patient counseling.[28] The present study was conducted to document and compare the process of case management for insomnia at community pharmacies in three major cities of Iran, namely, Mashhad (Capital of Razavi Khorasan province), Isfahan (Capital of Isfahan province), and Qom (Capital of Qom province).

Methods

A cross-sectional study was conducted in three major cities of Iran from January to April 2022, using a SP approach. The SP approach involved a trained individual, also known as an affected patient or mystery shopper, enacting a scenario to evaluate a specific behavior of a health-care professional. This approach is advantageous as it focuses on actual conduct rather than proxy measures. The study was conducted across pharmacies of three provincial capitals in the northeast (Mashhad, 648 pharmacies) and central parts (Isfahan, 480 and Qom, 140 pharmacies) of Iran, with a total of 1268 community pharmacies based on the Iranian Ministry of Health information. All the three mentioned cities are provincial capitals and also large and populous cities in different parts of Iran. At a 95% confidence level and a 5% margin of error with a 50% response distribution, the minimum sample size was calculated to be 549 pharmacies (Mashhad = 242, Isfahan = 216, and Qom = 91) using the Cochran formula.

The study employed a cluster, stratified sampling strategy based on locations in the three mentioned capitals, and any information related to the pharmacy or pharmacy staff was kept confidential and treated with strict confidentiality. The study included any community pharmacy in the Mashhad, Qom, and Isfahan cities, and any hospital and university pharmacies were excluded from this study.

The SP in this study was a female pharmacy student in her early thirties. A single scenario was employed, where the SP sought treatment for insomnia and requested assistance in falling asleep. The SP did not provide any information unless specifically requested. The scenario was developed by conducting an extensive review of the published literature and guidelines about insomnia treatment, and the first draft was refined through multiple discussions among experts. The SP evaluated the visit using a predesigned data collection form.

A 1-day training session was provided to the SP (pharmacy student) to focus on enacting the scenarios in a standardized way, evaluating the visits, filling out the questionnaire after the visit, and responding to unexpected situations during the visit. The SP also consented to the ethical code designed for this study to maintain the anonymity of participating individuals and protect the integrity of the data obtained and used either a pharmacist identification label or direct question to identify the pharmacist from the pharmacy staff. Six pharmacies were visited for the pilot study and were not included in the analysis as the pilot study location was different from the rest of the study.

The predesigned data collection form of this study was developed based on previous surveys,[26,29-33] with a total of 25 questions to collect information about sociodemographic information, pharmacist knowledge, and practice regarding sleep disorders and provide recommendations for this condition as well as pharmacological and nonpharmacological suggestions.

This project was approved on November 2, 2021, by the Research Ethics Committee of Tehran Medical Sciences Islamic Azad University (IR.IAU.PS.REC.1400.286).

The collected data were reviewed, organized, tabulated, and analyzed using the Statistical Package for the Social Sciences (SPSS) version 27.0 (SPSS Inc., IBM, Chicago, IL, USA). Descriptive statistics, frequencies, and percentages were used to present the data. To compare knowledge scores and attitude scores among respondents, they were grouped based on the city of practice. The Chi-square test was used to test statistical significance, and the limit for statistically significant differences was $P < 0.05$.

Results

All 549 planned SP visits (242 in Mashhad, 216 in Isfahan, and 91 in Qom) were completed. Based on the obtained results, the prevalence of pharmacists in the studied cities was 431 cases (78.5%), categorized by city; in Mashhad, there were 200 cases (46.4%, 83% of city pharmacies), in Isfahan – 167 cases (38.75%,

78% of city pharmacies), and Qom – 64 cases (14.85%, 62% of city pharmacies). Despite requesting to speak with the pharmacist, 21.5% ($n = 118$) of the encounters were managed by a pharmacy staff member. Majority of The visited pharmacies were limited-time pharmacies ($n = 301$, 69.8%), with no more than three customers waiting to be served, and visits were mostly ($n = 357$, 82.8%) during afternoon shifts and all on weekdays. The majority of the visited pharmacists were females ($n = 233$, 54.6%) and aged between 25–40 years ($n = 163$, 37.82%). Furthermore, we learned that only 13.7% ($n = 59$) of visited pharmacies had private counseling areas, categorized by city, 21% in Mashhad, 15% in Qom, and 14% in Isfahan city. Table 1 summarizes the general demographic characteristics of visited pharmacies.

79.7% ($n = 326$) of pharmacists evaluated the patient before deciding whether or not to prescribe the medication. Among them, 67.8% ($n = 292$) evaluated the patient <5 min, 4.6% ($n = 20$) between 5 and 10 min, and 3.2% ($n = 14$) more than 10 min [Table 1].

The information about the content and nature of the pharmacist's questions during the patient assessment, the types of questions asked, and the collected data were gathered using a checklist and are presented in Table 2.

Table 1: Demographic details of participants (n=431)	
Characteristics	Frequency (%)
Gender of pharmacist	
Female	233 (54.6)
Male	198 (45.4)
Location of pharmacy	
Mashhad	200 (46.4)
Isfahan	167 (38.7)
Qom	64 (14.85)
Estimated age of the pharmacist (years)	
25–40	163 (37.82)
40–55	148 (34.34)
>55	120 (27.84)
Time of visit by simulated patient	
Morning shift (9 am–3 pm)	74 (17.2)
Afternoon shift (4–10 pm)	357 (82.8)
Type of pharmacy	
24/7 pharmacy	130 (30.16)
Limited time pharmacy	301 (69.84)
Time for assessing and counseling	
No assess or counsel	105 (24.4)
<5 min	292 (67.8)
5–10 min	20 (4.6)
>10 min	14 (3.2)
Availability of a private counseling area in the pharmacy	
Yes	59 (13.7)
No	372 (86.3)

The range of questions posed to the patient varied from one to eight, with the majority typically asking two to five questions. The majority of pharmacists did not ask about pregnancy ($n = 43$, 10%), whereas the duration of insomnia ($n = 106$, 24.6%) and consumption of caffeinated beverages after 4 PM ($n = 91$, 21.1%) were the most asked questions.

The next step of the study examined the over-the-counter availability of diazepam or alprazolam, which are the most widely used benzodiazepine medications in Iran.[34] In total, 9.2% of pharmacists ($n = 40$) offered diazepam and 13.2% ($n = 57$) provided alprazolam to the SP. According to the reported statistics, the largest amount of drug delivery of mentioned medications (diazepam and alprazolam) was provided by the pharmacists practicing in Isfahan, followed by Qom and Mashhad. There was no significant difference among cities ($P > 0.05$) as well as genders ($P > 0.05$) and ages ($P > 0.05$) regarding delivery of OTC diazepam or alprazolam to the SP.

Furthermore, our study demonstrated that 15.1% of pharmacists ($n = 65$) referred patients to doctors in case of nondelivering of medication, among which the most referrals were related to Mashhad city by

21.5% ($n = 43$) followed by Qom – 9.4% ($n = 6$) and Isfahan – 9.5% ($n = 16$). Our study also revealed that 280 pharmacists (65%) delivered either an OTC medication or offered a traditional or herbal medication to the SP. The most recommended nonprescription medication was melatonin by 22.3% ($n = 96$), which was mostly recommended in the city of Mashhad, whereas 9% ($n = 39$) recommended some herbal medication again mostly in Mashhad city [Table 3].

Among the pharmacists who delivered either diazepam or alprazolam without a prescription to the patients, 38.2% counseled about the offered medication, mostly in Mashhad ($n = 16$, 41%) followed by Qom ($n = 3$, 23.1%) and Isfahan ($n = 9$, 20%).

The frequency of essential counseling for any offered medication was 165 (58.9%) which is depicted in Table 4. None of the consultations were adequate. In all 165 consultations, only partial information was provided to the SP, while the rest of the pharmacists provided no information to the SP after delivering the medication to them. The most consulted items were the dosage ($n = 108$, 65.5%) and the correct time to take the medicine ($n = 103$, 62.4%), while the least consulted

Table 2: The types of questions asked and information gathered by the pharmacist

The types of information gathered	All 3 cities (*n*=431)	Mashhad (*n*=200)	Isfahan (*n*=167)	Qom (*n*=64)
History of insomnia	71 (16.5)	49 (24.5)	13 (7.8)	9 (14.1)
Pattern of insomnia	72 (16.7)	50 (25)	13 (7.8)	9 (14.1)
Duration of insomnia	106 (24.6)	68 (34)	26 (15.6)	12 (18.7)
Sleeping conditions	91 (21.1)	60 (30)	28 (16.7)	3 (4.7)
Medicines used by the patient	67 (15.5)	47 (23.5)	13 (7.8)	7 (11)
The last consumed caffeinated beverage in the day	77 (17.9)	47 (23.5)	13 (7.8)	7 (11)
Use of cell phone or tablet at bedtime	60 (14)	34 (17)	18 (10.8)	8 (12.5)
Pregnancy	43 (10)	25 (12.5)	15 (9)	3 (4.7)

Data are presented as *n* (%) of participants

Table 3: Most recommended nonprescription option

Recommended medications	All 3 cities (*n*=431)	Mashhad (*n*=200)	Isfahan (*n*=167)	Qom (*n*=64)
Melatonin	96 (22.3)	54 (27)	30 (18)	12 (18.8)
Herbals	39 (9.1)	28 (14)	5 (3)	6 (9.4)
Traditional medications	155 (36)	80 (40)	50 (30)	25 (39.1)

Data are presented as, *n* (%) of participants

Table 4: The frequency of essential counseling for any offered medication

Essential counseling	All 3 cities (*n*=165)	Mashhad (*n*=100)	Isfahan (*n*=42)	Qom (*n*=23)
Dosage	108 (65.5)	63 (63)	30 (71.4)	15 (65.2)
The correct time to take medication	103 (62.4)	63 (63)	24 (57.1)	16 (69.6)
Drug interactions	0	0	0	0
Cautions	1 (0.6)	0	1 (2.3)	0
Drug adverse reactions	18 (10.9)	17 (17)	0	1 (4.3)
Maximum recommended dose	13 (7.9)	8 (8)	2 (4.8)	3 (13)
Safe storage of medicine	5 (3)	2 (2)	3 (7.1)	0

Data are presented as *n* (%) of participants

item was the cautions ($n = 1$, 0.6%) followed by storage conditions ($n = 5$, 3%).

DISCUSSION

The presented study provides valuable insights into the process of case management for insomnia in community pharmacies across three major cities in Iran. Using a SP approach, the researchers evaluated various aspects of pharmacist–patient interactions, including clinical assessment, provision of information and medication, and counseling practices. The findings shed light on the current practices and challenges in managing insomnia within community pharmacy settings.

One notable aspect of the study is its methodology, employing a cross-sectional design with SP s. This approach allows for the assessment of real-world behaviors and practices without the influence of observer bias. The use of standardized scenarios and data collection tools enhances the reliability and validity of the findings.[32]

The results highlight several important findings regarding pharmacist–patient interactions. Despite the majority of encounters being managed by pharmacists themselves, a significant proportion involved pharmacy staff members, indicating potential gaps in pharmacist availability or delegation of responsibilities. This raises concerns about the consistency and quality of care provided in community pharmacies, particularly in addressing complex health issues such as insomnia.

Furthermore, the study reveals variations in pharmacist clinical assessment practices, with a significant percentage of pharmacists spending <5 min assessing patients. This aligns with the findings by Wazaify *et al*. who noted that pharmacists often spent <5 min assessing patients for insomnia and provide inadequate counseling, especially regarding benzodiazepines.[26] However, Mulder *et al*. found that most pharmacists spent 5–15 min discussing sleep disorders, with a maximum of 10 min on sleep hygiene.[35]

This may reflect the time constraints commonly faced in busy pharmacy settings. It also underscores the importance of efficient yet thorough clinical assessments to ensure appropriate treatment decisions.

The study also investigated pharmacist provision of medication, particularly benzodiazepines such as diazepam and alprazolam, commonly used to treat insomnia.[34] The findings suggest a concerning trend of medication dispensing without proper prescription, with a notable percentage of pharmacies offering these medications to SPs. This raises questions about adherence to regulatory guidelines and the potential for inappropriate use or misuse of controlled substances.

Moreover, the study highlights the role of pharmacists in providing information and counseling to patients. While a significant proportion of pharmacists delivered medication to SPs, the adequacy of counseling provided varied, with many consultations lacking essential information on dosage, administration, and precautions. The absence of patient counseling might stem from various factors, including insufficient knowledge or low self-esteem on the part of the pharmacist.[35] This underscores the need for standardized protocols and training programs to enhance pharmacist communication skills and ensure comprehensive patient education.[36]

Comparing the findings of this study with existing literature reveals several common themes and challenges in the management of insomnia within community pharmacy settings. Previous studies conducted in Iran and UAE on pharmacists' role in counseling asthmatic patients[27,37] and different countries, such as Swiss,[35] Jordan,[27] and Pakistan, on insomnia counseling[38] as well as Slovenia on paracetamol counseling in headaches[39] have also highlighted issues related to pharmacist knowledge and practices regarding different disorders.

Overall, while the specific challenges and regulatory contexts may vary across different countries, the findings of this study resonate with broader themes identified in the international literature on the management of insomnia in community pharmacies. These findings underscore the need for collaborative efforts among health-care professionals, policymakers, and regulatory agencies to address systemic issues and improve the quality and safety of sleep disorder management in community pharmacy settings.

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Conflicts of interest

There are no conflicts of interest.

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