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| Item Type     | Journal article   |
| Authors       | Kar, Nilamadhab;Ohri, Lakshmi;Mahil, Jasmin;Merlici, Sorina   |
| Citation      | Kar N, Ohri LR, Mahil J, Merlici S (2023) Use of hypnotics for the management of insomnia in psychiatric patients: A clinical audit and review on Z#drugs. Odisha Journal of Psychiatry, 19(1), pp. 8-13. |
| DOI           | <a href="https://doi.org/10.4103/OJP.OJP_17_23">10.4103/OJP.OJP_17_23</a>   |
| Publisher     | Medknow Publications  |
| Journal       | Odisha Journal of Psychiatry  |
| Download date | 2025-05-21 19:57:42   |
| License       | <a href="https://creativecommons.org/licenses/by-nc-sa/4.0/">https://creativecommons.org/licenses/by-nc-sa/4.0/</a>   |
| Link to Item  | <a href="http://hdl.handle.net/2436/625376">http://hdl.handle.net/2436/625376</a>   |

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| DOI:<br>10.4103/OJP.OJP_17_23   |

# Use of hypnotics for the management of insomnia in psychiatric patients: A clinical audit and review on Z-drugs

Nilamadhab Kar, Lakshmi Radhica Ohri, Jasmin Mahil, Sorina Merlici

## Abstract:

**BACKGROUND:** Insomnia is a common condition in patients with mental illness, for which hypnotic medications are regularly prescribed.

**AIM:** It was intended to study the clinical practice of using hypnotic medications including Z-drugs for insomnia and compare it with treatment guidelines.

**METHODS:** In this clinical audit, data were collected from the clinical records of patients who attended outpatient department in adult and old age psychiatric units in a mental health service.

**RESULTS:** Out of the consecutive 203 patients screened, 50 (24.6%) were prescribed hypnotic/sedative drugs. It was observed that around half (54%) received nonpharmacological interventions for insomnia, 42% had psychoeducation, and 24% sleep hygiene. Zopiclone (56%) and promethazine (26%) were more commonly prescribed; however, lorazepam (14%) and diazepam (16%) were also used. In the majority of cases, these were prescribed on a "if required" basis. Duration of hypnotic prescription was specified in only 36%, whereas many patients continued these medications for months (26%) and years (26%).

**CONCLUSION:** There is a scope to increase the use of nonpharmacological treatments for insomnia. Reviewing the period of use of hypnotic medications is essential as many patients continue them for longer durations than recommended. Treatment of insomnia needs focused attention in psychiatric clinics.

## Keywords:

Benzodiazepine, hypnotics, insomnia, outpatients, psychiatry, sedatives, Z-drug

## Introduction

Insomnia is the most common sleep disorder, with a prevalence of up to 30% among the general adult population worldwide.<sup>[1]</sup> It is characterized by abnormal sleeping patterns, including reduced time asleep, delay in onset of sleep, and early morning waking.<sup>[2]</sup>

Treatment of insomnia is of high importance due to its association with impaired daily function and quality of life.<sup>[3,4]</sup> Insomnia has also been linked with a range of morbidities, including diabetes, ischemic heart disease,

hypertension, chronic pain, poor mental health, and cognitive problems.<sup>[5,6]</sup> All of these have the potential to have an economic burden due to reduced productivity and work absences.<sup>[7]</sup>

The first line of treatment for insomnia should take the form of nonpharmacological measures, namely good sleep hygiene. Psychological interventions such as cognitive behavioral therapy (CBT) are also helpful; however, these are not readily available in many areas. When the nonpharmacological methods fail or the insomnia causes significant distress, hypnotics can be used.<sup>[5]</sup> In clinical

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**How to cite this article:** Kar N, Ohri LR, Mahil J, Merlici S. Use of hypnotics for the management of insomnia in psychiatric patients: A clinical audit and review on Z-drugs. *Odisha J Psychiatry* 2023;19:8-13.

Department of Psychiatry,  
Black Country Healthcare  
NHS Foundation Trust,  
Wolverhampton, UK

## Address for correspondence:

Prof. Nilamadhab Kar,  
Steps to Health,  
Showell Circus, Low  
Hill, Wolverhampton  
WV10 9TH, UK.  
E-mail: n.kar@nhs.net

Submitted: 28-Sep-2023

Revised: 17-Oct-2023

Accepted: 18-Oct-2023

Published: 09-Nov-2023

practice, various drugs are prescribed which include antihistamines (e.g. promethazine); shorter-acting benzodiazepines (loprazolam, lormetazepam, and temazepam) along with triazolam, estazolam, quazepam, flurazepam, lorazepam, alprazolam and diazepam; Z-drugs (zaleplon, zolpidem, zopiclone, and eszopiclone) and melatonin. Only a few of these compounds have approval for use in insomnia.<sup>[8,9]</sup> It is common to observe many patients use dietary supplements, over-the-counter sleep aids, and off-label sedating medications for their sleep problems.<sup>[8]</sup>

### Literature review on Z-drugs

Z-drugs are benzodiazepine agonists, which act specifically on the alpha-1 subclass of GABA-A receptors to produce hypnotic effects.<sup>[10,11]</sup> These were developed in the 1990s to optimize the pharmacological benefits of benzodiazepines. Their succession of the older benzodiazepines has mostly been attributed to their greater efficacy and safety profile, particularly in the elderly.<sup>[12]</sup> The Z-drugs used for the treatment of insomnia include zolpidem, zopiclone, zaleplon, and eszopiclone.<sup>[13]</sup> In the UK, currently, only zopiclone and zolpidem are licensed,<sup>[14]</sup> and of these zopiclone is the most frequently prescribed hypnotic.<sup>[12]</sup>

Z-drugs produce a quicker clinical effect and have a more rapid rate of clearance compared to benzodiazepines. Their better pharmacodynamics and pharmacokinetic profiles minimize their scope for drug abuse. They are less harmful in overdose compared to benzodiazepines. Although Z-drugs were developed to reduce the risk of developing tolerance, dependence, and withdrawal symptoms,<sup>[10]</sup> abuse, dependence, and withdrawal-related adverse drug reactions have been reported.<sup>[15]</sup>

It has been reported that adverse effects were less common and severe for Z-drugs. Therapeutic doses of zopiclone have a high risk of psychomotor and cognitive impairment as well as poor mental alertness and motor coordination, within the first 12 h. There is a comparable risk of hangover effects between zopiclone and short-acting benzodiazepines. Zolpidem can, dose-dependently, impair word recall and recognition 6–8 h postadministration, and zaleplon may cause significant, dose-independent psychomotor impairment immediately after administration. In addition, there is a risk that Z-drugs, especially zolpidem, can cause complex behaviors such as sleep-walking, sleep-driving, and hypnopompic hallucinations.<sup>[16]</sup> However, at typical doses, it was found that the Z-drugs do not cause as much cognitive impairment compared to the benzodiazepines.<sup>[7]</sup>

Both benzodiazepines and Z-drugs can cause unpredictable paradoxical reactions, namely, acute

excitement, hyperactivity, vivid dreams, sexual disinhibition, and an increase in hostility, anxiety, and aggression. Patients with a learning disability, neurological disorder, central nervous system (CNS) degenerative disease, or a history of aggression, as well as young and older age patients, are at greater risk of these effects.<sup>[10]</sup>

The use of benzodiazepines and Z-drugs can lead to respiratory depression; however, the myorelaxant effect is 10–40 times greater in benzodiazepines.<sup>[17]</sup> Z-drugs have not been found to exacerbate comorbid respiratory impairments, e.g., chronic obstructive pulmonary disease (COPD) or obstructive sleep apnea.<sup>[7]</sup> Unlike benzodiazepines, CNS depression is not likely with Z-drugs unless they are taken with alcohol.<sup>[5]</sup>

One major patient safety concern is impaired driving performance.<sup>[16]</sup> The risk of road traffic accidents is more than doubled in zopiclone and zolpidem users compared with unexposed drivers. Residual effects are also pertinent, i.e., zopiclone can induce driving impairment the next morning or afternoon following a 15 mg dose.<sup>[18]</sup>

Benzodiazepines and Z-drugs are associated with similar risks in elderly patients. Elderly patients are more likely to have reduced renal and/or hepatic function, which can alter drug pharmacodynamics, namely, prolonged drug metabolism, elimination, and action. In addition, their receptors tend to be of greater sensitivity and even short-acting GABA-ergic drugs can compromise balance and decision-making during the night.<sup>[16]</sup> The ability of hypnotics to impair mental or psychomotor function increases the risk of falls and injury, resulting in increased morbidity and consequent health-care costs.<sup>[10]</sup>

Z-drugs do cause acute, reversible cognitive dysfunction such as slurred speech and transient amnesia in many patients, to which older individuals are more sensitive. Beyond acute drug effect, an association extending to progressive, neurodegenerative diseases such as dementia has been raised.<sup>[10]</sup> In recent years, benzodiazepine and Z-drug exposure has been linked with the development of dementia, infections, respiratory disease exacerbation, pancreatitis, and cancer.<sup>[13]</sup>

Although all hypnotics have abuse potential, the risk is increased with the prolonged use of shorter-acting hypnotics at higher doses, a history of substance dependency, personality disorders, and a lack of medical supervision. The prolonged use of Z-drugs can reduce the hypnotic effect and create a degree of dependence. Duration of use is therefore restricted to 4 weeks for zopiclone and zolpidem and 2 weeks for zaleplon. The risk of tolerance, dependence, and abuse varies among the Z-drugs.<sup>[19]</sup>

The view that Z-drugs are safer than benzodiazepines is not completely accurate. Despite having a quicker rate of onset and shorter duration of action they do produce similar side effects, and so are not necessarily suitable alternatives, if the aim of treatment is for these to be avoided altogether. Hypnotics with shorter half-lives tend to be safer because they produce fewer residual problems and adverse effects, but conversely do have higher risks of withdrawal, meaning they should only be used on a short-term basis. Benzodiazepines still carry a greater risk of tolerance and abuse when compared with Z-drugs. It is important to take into consideration individual patient characteristics as well as pharmacokinetic differences between drugs before choosing which hypnotic to prescribe. All hypnotics should be used short-term or intermittently and be reviewed regularly. The mechanism of action as well as the cautions and side effects of the prescribed hypnotic should be explained to the patient to limit the abuse potential of the drug.<sup>[10]</sup>

### Guidance on Z-drugs

National Institute for Health and Care Excellence (NICE) guidance on Z-drugs outlined the standards for the use of zolpidem, zopiclone, zaleplon (not available in the UK), and short-acting benzodiazepine hypnotics including loprozepam, lormetazepam, and temazepam in the short-term management of insomnia.<sup>[19]</sup> The NICE standards state that only after careful consideration of nonpharmacological interventions should pharmacological agents be prescribed for a short period as per their licensing agreement; and this should be adhered to in all patients being treated for insomnia. Second, when pharmacological agents are required, the most cost-effective pharmacological agent should be prescribed. Third, patients who have not responded to one of these hypnotic drugs should not be prescribed any of the others. However, switching from one of these hypnotics to another should only occur if a patient experiences adverse effects considered to be directly related to a specific agent.

### Objectives

The main aim of this clinical audit was to explore the use of Z-drugs in mental health setup, in the short-term management of insomnia using NICE guidance. In particular, it was intended to identify the pharmacological agents being used in clinical practice for the treatment of insomnia and in turn, whether they were being utilized on a short-term basis.

## Methods

### Site

The clinical audit was conducted in a mental health trust covering a population of around a million, having four

bases in the West Midlands region of England. This is a secondary care level psychiatric facility where patients are referred from primary care mostly by the general practitioners (GP), and from various departments of local general hospitals in secondary care settings.

### Sample

All the patients seen in a 1-week period in the psychiatric outpatient departments in the adult and older adult teams of the mental health trust were screened for the audit. Patients who had hypnotic/sedative drugs prescribed were included in the audit. Information for the previous 1 year was sourced from the letter to GP and case notes. Data collection was done in July 2019. Data were collected by the psychiatrists in different teams.

### Audit tool

A data collection form was prepared which included demographic variables (age and gender), clinical variables (psychiatric diagnosis, physical diagnoses, and substance use), and treatment (psychotropic and hypnotic/sedative drugs). Documentation regarding insomnia and its management was checked. Specific information about whether nonpharmacological measures were considered before the prescription of drug therapy for insomnia; the nonpharmacological intervention that was provided, e.g., psychoeducation, sleep hygiene, etc.; the hypnotic/sedative drug prescribed, both as regular and if required basis were collected.

We also checked when hypnotic drug therapy was prescribed, if the drug with the lowest purchase cost was chosen, and whether the doctors were aware of the cost of the hypnotic drugs. Regarding prescribing information, we noted any specific reason mentioned why a particular hypnotic drug was chosen, whether the duration of prescription for the hypnotic drug was documented; and if it was, the duration (<2 weeks, <4 weeks, 1–3 months, 3–6 months, >6 months) was noted.

We checked if the hypnotic drug was prescribed for a short period as indicated in the guidelines, e.g. zolpidem and zopiclone for 4 weeks. In addition, we found out for how long the patient was continuing the current hypnotic drug. We also explored if the patient had switched from one hypnotic drug to another in the last year and whether the reason for the switch was mentioned.

### Ethics

The project was considered a clinical audit by the trust. Ethical principles were followed. Any identifiable information was not collected.

## Analysis

Data were entered into the Excel sheet and quality was checked. It was analyzed using SPSS (version 25, IBM Corporation, Armonk, NY, USA). Missing values were mentioned separately. Results were presented with percentages, mean, and standard deviation. A comparison of the age in years was done with *t*-test, and the significant value was kept at <0.05 as standard.

## Results

### Sample characteristics

Out of the 203 patients screened, 50 (24.6%) patients had been prescribed hypnotic drugs. The sample characteristics are given in Table 1. More than half of the patients involved in the audit were females (56%); the average age for women was  $51.6 \pm 20.2$  years old, in contrast with men with  $42.8 \pm 15.0$  years old ( $t = 1.7, P = 0.095$ ).

### Psychiatric diagnoses

In terms of the primary diagnoses, there was a range of psychiatric conditions associated with sleep problems. These included depressive disorders, followed by anxiety disorders, and psychotic disorders. Comorbid psychiatric diagnoses were common, almost half (46%) had a second diagnosis, and a further five patients (10%) had a third psychiatric diagnosis. Comorbid psychiatric diagnoses were depression and mood disorders (12%), psychotic disorders (8%), anxiety disorder (16%), cognitive disorder (2%), substance abuse (4%), personality disorder (12%), and learning disability (2%).

### Substance use

Nearly half of the patients (46%) reported substance use; the distribution of substances used was alcohol (30.0%), tobacco (22.0%), cannabis (20%), and other drugs (4%). However, substance use disorder as a primary diagnosis was present in only 6%.

### Physical diagnoses

Twenty-two patients (44%) had physical illnesses, such as diabetes, hypertension, chronic pain syndromes (fibromyalgia, sciatica) and lung problems (asthma and COPD). Most of these patients (68%) had just a single physical diagnosis.

### Insomnia

Symptoms of insomnia were documented in 42 (84%). Details of sleep management are given in Table 2. Before they were prescribed a sleeping tablet, more than half (54%) of the patients included in the audit had been offered a nonpharmacological solution to their sleep problem. The most common measure recommended was psychoeducation in 42% of cases, followed by sleep hygiene in 24% of patients.

**Table 1: Sample characteristics**

| Variables                                   | n (%)     |
|---|-----------|
| Gender                                      |           |
| Female                                      | 28 (56.0) |
| Male  | 22 (44.0) |
| Primary psychiatric diagnoses               |           |
| Depression and other mood disorders         | 17 (34.0) |
| Schizophrenia and other psychotic disorders | 8 (16.0)  |
| Anxiety disorders                           | 10 (20.0) |
| Dementia and cognitive disorders            | 6 (12.0)  |
| Substance use disorders                     | 3 (6.0)   |
| Personality disorders                       | 6 (12.0)  |
| Substance use                               |           |
| No  | 27 (54.0) |
| Yes   | 23 (46.0) |
| Physical diagnosis                          |           |
| Absent                                      | 28 (56.0) |
| Present                                     | 22 (44.0) |

**Table 2: Clinical practice status related to insomnia**

| Variables  | Categories      | n (%)     |
|--|-----------------|-----------|
| Symptoms of insomnia documented                      | No              | 8 (16.0)  |
|  | Yes             | 42 (84.0) |
| Nonpharmacological measures considered               | No              | 21 (42.0) |
|  | Yes             | 27 (54.0) |
|  | Data missing    | 2 (4.0)   |
| Nonpharmacological measures provided                 | Psychoeducation | 21 (42.0) |
|  | Sleep hygiene   | 12 (24.0) |
|  | Other           | 2 (4.0)   |
| Current hypnotic drug                                | Zopiclone       | 28 (56.0) |
|  | Zolpidem        | 2 (4.0)   |
|  | Promethazine    | 13 (26.0) |
|  | Lorazepam       | 7 (14.0)  |
|  | Diazepam        | 8 (16.0)  |
|  | Melatonin       | 1 (2.0)   |
| Hypnotic drugs prescribed "if required" basis        | No              | 15 (30.0) |
|  | Yes             | 35 (70.0) |
| Lowest-cost hypnotic was chosen                      | No              | 13 (26.0) |
|  | Yes             | 9 (18.0)  |
|  | Unknown         | 28 (56.0) |
| Aware of the cost of the hypnotic drugs              | No              | 45 (90.0) |
|  | Yes             | 5 (10.0)  |
| The reason for choosing the hypnotic drug mentioned  | No              | 38 (76.0) |
|  | Yes             | 10 (20.0) |
|  | Data missing    | 2 (4.0)   |
| Prescription duration of the hypnotic drug specified | No              | 32 (64.0) |
|  | Yes             | 18 (36.0) |
| Prescribed for a short period                        | No              | 29 (58.0) |
|  | Yes             | 20 (40.0) |
|  | Data missing    | 1 (2.0)   |
| Length of hypnotic treatment continuing              | Weeks           | 13 (26.0) |
|  | Months 1–12     | 13 (26.0) |
|  | Year+           | 13 (26.0) |
|  | Not documented  | 6 (12.0)  |
|  | Unknown         | 5 (10.0)  |
| Hypnotic changed last year                           | No              | 44 (88.0) |
|  | Yes             | 6 (12.0)  |



### Prescribed hypnotic/sedative

In terms of pharmacological treatment for sleep disorders, the most common choice was zopiclone, which was prescribed to 56% of all patients. This was followed by promethazine (26%), and benzodiazepines, such as diazepam and lorazepam, with 16% and 14%, respectively. The observation that benzodiazepines were the least preferred could be explained by their high potential for dependence if used for long periods. There were no patients on zaleplon, loprazolam, lormetazepam, temazepam, or other hypnotics. It was observed that the majority of all patients (70%) were given the sedative drugs only on an occasional or as-required basis, and not as a regular treatment. The doses were within the British National Formulary recommendations.<sup>[14]</sup>

In only 20% of all cases, the reason for prescribing a particular hypnotic drug was mentioned in the medical notes. These included agitation, anxiety, efficacy, improved sleep, less addictive, side effects, and tolerability, no benefit with promethazine, and it was not clear in a small proportion (4.0%).

### Psychotropic medications prescribed

In terms of pharmacotherapy for mental health problems, almost half of the patients (42%) were taking an antipsychotic drug as their main treatment, followed by antidepressants, taken by 32% of all patients. A smaller number of patients were taking a second psychotropic medication, mostly represented by an antipsychotic or antidepressant drug, and in a few cases a mood stabilizer.

## Discussion

This clinical audit evaluated the current practice of prescribing hypnotic/sedative medications, including the Z-drugs in patients attending outpatient departments of adult and old age subspecialties in a mental health trust.

### Major findings

Almost a quarter of psychiatric patients were prescribed

hypnotic drugs. More than half of the sample had depressive or anxiety disorders, and a considerable proportion had substance use and physical illnesses. Indication of insomnia was documented in the majority (84%), nonpharmacological interventions were considered in more than half (54%), which were mostly psychoeducation in 42% and sleep hygiene in 24%. Zopiclone was the most commonly prescribed hypnotic drug, followed by promethazine. A majority (70%) were prescribed on an if-required basis. Most doctors did not know about the cost of the medications. The reason for choosing a particular drug was not noted as well in most cases, so also prescription duration. In a minority of cases, the prescriptions were specified for short periods. It was a concern to observe that most patients had these medications for months or years.

### Findings against standards

The findings were compared with the NICE standards.<sup>[19]</sup> A summary of the comparison related to standards is given in Table 3.

It appears that there is a scope to increase the offer of nonpharmacological interventions to more psychiatric patients. Psychoeducation and sleep hygiene could be utilized more and a leaflet describing these can be given. In addition to these, there are scopes for CBT for insomnia and other psychotherapeutic interventions; which can be considered in appropriate cases. CBT in insomnia has been found to be effective, in both short and long-term, and is understandably an underutilized intervention.<sup>[20-22]</sup>

It is important to document the specific duration of the hypnotic prescription. In addition, how to taper it after that duration should be explained to the patient and GP should be informed about it. Considering that many patients continued the hypnotics for months and years, it needs to be reemphasized that hypnotics should be prescribed for a short duration, according to guidelines,<sup>[14,19]</sup> and the period of prescription reviewed regularly.

**Table 3: Summary result of this clinical audit**

| Criterion   | Standard  | Exception   | Findings (%) |
|---|---|---|--------------|
| Nonpharmacological measures are considered before the prescription of drug therapy for insomnia   | 100% of patients being treated for insomnia                   | None  | 54.0         |
| When hypnotic drug therapy is used, the drug used is prescribed for a short period only, in strict accordance with the licensed indications | 100% of patients for whom hypnotic drug therapy is prescribed | None  | 40.0         |
| When hypnotic drug therapy is prescribed, the drug with the lowest purchase cost is chosen  | 100% of patients for whom hypnotic drug therapy is prescribed | A. The patient experiences adverse effects considered to be directly related to the first-line choice | 18.0         |
| A patient is switched from one hypnotic drug to another   | 0% of patients for whom hypnotic drug therapy is prescribed   | A. The patient experiences adverse effects considered to be directly related to a specific agent      | 12.0         |

As benzodiazepines could be given for different reasons, whenever these are prescribed it is better to specify the indication. It is important to record the reason for choosing a specific hypnotic or when changing to a different hypnotic drug. This will help to clarify any issues related to efficacy, side effects, dependence issues, etc.

In only 18% of cases, the drug with the lowest cost was chosen, and 90% of medics did not know about the cost of hypnotic medications. However, the hypnotics were mostly from the low-cost categories: 56.0% zopiclone; 4% zolpidem and 26% promethazine. It is recommended that the cost of these medications should be provided periodically to the doctors. Keeping the costs of the interventions down is not only important in state-sponsored health programs but also when patients pay for their prescriptions in different parts of the world.

## Conclusion

Hypnotic/sedative drugs were commonly prescribed for psychiatric patients. It appeared that nonpharmacological interventions were offered in around half of the psychiatric patients with sleep problems; and included mainly psychoeducation and discussions on sleep hygiene. This suggests that there is a greater scope for nonpharmacological treatments for insomnia, and these should be routinely available for psychiatric patients. Although in the majority of cases, the indication of insomnia was mentioned, it is essential to record this in all cases while prescribing for insomnia. The prescription should also mention the specific duration of hypnotic drugs, and the duration should be monitored in clinical practice. The majority of the doctors were not aware of the cost of the medications, appraising that may reduce the cost of the prescriptions. It is important to review the clinical practice regarding the management of insomnia periodically.

## Acknowledgment

The authors wish to thank Natalie Jackson, Lindsay Phillips, Clinical Effectiveness Team; Black Country Healthcare NHS Foundation Trust for their support in conducting the clinical audit; The Institute of Insight, and the Quality of Life Research and Development Foundation for their support in the project.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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