

Report

Nationwide Trends in Insomnia Medication Use Among Older Adults in Japan: NDB Open Data Analysis (2019–2023)

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Insomnia is highly prevalent among older adults, and hypnotics are widely prescribed in Japan. As older individuals are vulnerable to hypnotic-related adverse events, such as falls and cognitive impairment, monitoring national prescription trends is essential for safer pharmacotherapy. Using the National Database Open Data from fiscal years 2019–2023, we examined nationwide prescription trends of hypnotics indicated for insomnia (or insomnia with pre-anesthetic medication). We calculated the annual total dispensed quantity, the dispensed quantity attributable to adults aged ≥ 65 years, and the proportion (%) of dispensed quantity among older adults. Conventional hypnotics (benzodiazepines and Z-drugs) and newer agents, including dual orexin receptor antagonists (DORAs), were evaluated. Zolpidem remained the most frequently used hypnotic, increasing from 506 million dispensed dosage units in 2019 to 685 million in 2023. However, the proportion of dispensed quantity attributable to adults aged ≥ 65 years declined from 64.7% to 60.2%. Brotizolam exhibited a similar utilization trend, with stable overall use but a reduction from 66.6% to 62.1% in the older adult population. In contrast, lemborexant, introduced in 2020, demonstrated a rapid uptake, reaching 504 million dispensed dosage units in 2023, whereas its proportion of use among older adults increased from 38.9% to 51.1%. Insomnia medication prescription trends are shifting in Japan, with the increasing adoption of DORAs along with a relative decline in conventional hypnotics among older adults. Continued monitoring is warranted to support safer prescription practices in geriatric insomnia care.

Key words insomnia, hypnotics, prescription trends, dual orexin receptor antagonists

INTRODUCTION

Insomnia is among the most prevalent sleep disorders in older adults, associated with reduced quality of life, depressive symptoms, cognitive decline, and increased risk of falls.¹⁻³ In Japan, where population aging is rapidly accelerating, insomnia has become an increasingly important clinical and public health concern. Insomnia might impair daytime functioning and limit social participation, thereby contributing to increased caregiver burden and healthcare resource use.⁴ Hypnotic medications remain central to the pharmacological management of insomnia. Benzodiazepines and non-benzodiazepine hypnotics (Z-drugs) have traditionally been widely prescribed. However, these agents are associated with adverse outcomes in older adults, including falls, delirium, dependence, and cognitive impairment.⁵⁻⁷ Age-related changes in drug metabolism and excretion might further increase susceptibility to residual next-day effects such as dizziness and impaired balance, even at low doses.⁸ Therefore, ensuring safer prescription practices for geriatric populations represents a major clinical challenge. Recently, new hypnotics have been introduced with

distinct mechanisms of action, including melatonin receptor agonists and dual orexin receptor antagonists (DORAs). Orexin is a neuropeptide involved in maintaining wakefulness, and orexin receptor blockade promotes physiological sleep.⁹ Compared to conventional hypnotics, DORAs might retain a more favorable safety profile, making them potentially safer alternatives for older adults at risk of falls.¹⁰ Despite these developments, nationwide evaluations of prescribing trends restricted to hypnotics indicated for insomnia remain limited, particularly those among adults aged ≥ 65 years. The National Database (NDB) Open Data provide a valuable resource for monitoring population-level medication utilization trends in Japan.

Therefore, in this study, we aimed to examine nationwide trends in insomnia medication use, focusing on changes among older adults.

METHODS

This study was designed as a repeated cross-sectional drug utilization analysis using the NDB Open Data, where the unit of observation was aggregated dispensing quantities (e.g.,

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number of tablets or capsules) rather than individual patients.

We analyzed the most recent NDB Open Data published by the Ministry of Health, Labour and Welfare (MHLW), covering the fiscal years 2019–2023.¹¹⁾ The NDB Open Data are publicly available datasets that can be accessed through the official MHLW website without individual-level data application procedures. The database provides aggregated information on dispensed quantities derived from health insurance claims, enabling evaluation of nationwide medication utilization trends. These data reflect quantities claimed for reimbursement rather than actual patient-level consumption. In this study, the reported values represent dispensed dosage units (e.g., tablets or capsules), not the amount of active ingredient or prescribed daily dose.

Target medications were hypnotics with indications restricted to “insomnia only” or “insomnia and pre-anesthetic medication,” including suvorexant and lemborexant (dual orexin receptor antagonists [DORAs]), ramelteon (melatonin receptor agonist), zolpidem, zopiclone, and eszopiclone (Z-drugs), and brotizolam, triazolam, and flunitrazepam (benzodiazepines). Hypnotics with multiple indications, such as anxiolytics, were excluded because the NDB Open Data do not allow identification of prescriptions specifically intended for insomnia treatment. Drug selection was based on approved indications in Japan, and when a drug had multiple formulations with different indications (e.g., oral vs injectable), only formulations relevant to insomnia treatment were included. The dataset contains aggregated dispensing quantities derived from both medical institutions and dispensing pharmacies. These values represent finalized reimbursement-based quantities compiled at the national level; therefore, summing these sources does not result in double counting. For each medication, we calculated the annual total dispensed quantity, the dispensed quantity attributable to adults aged ≥ 65 years, and the proportion (%) of dispensed quantity among older adults. Year-to-year changes were assessed to evaluate the diffusion of newly introduced agents and shifts in prescription trends.

The NDB Open Data are fully anonymized and aggregated prior to publication, and individual patients cannot be identified. Therefore, informed consent from patients was not required.

RESULTS

Table 1 summarizes the annual utilization trends of hypnotics. Suvorexant remained stable at approximately 260–300 million dispensed dosage units from 2019 to 2023, with older adults accounting for more than 65% of the total dispensed quantity. Lemborexant displayed a rapid uptake after 2020, increasing from 15.36 million to 504 million dispensed dosage units in 2023. Moreover, the proportion of its dispensed quantity attributable to adults aged ≥ 65 years increased from 38.9% to 51.1%, suggesting its expanding adoption in geriatric care. Ramelteon maintained relatively stable utilization (approximately 130–150 million dispensed dosage units annually), remaining consistently high among older adults (approximately 70%). Among conventional hypnotics, zolpidem remained the most frequently prescribed agent, increasing from 506 million to 685 million dispensed dosage units, whereas the proportion attributable to adults aged ≥ 65 years declined from 64.7% to 60.2%. Benzodiazepines showed a similar reduction in the proportion of use in older adults dur-

ing the study period.

DISCUSSION

This nationwide analysis using NDB Open Data clarified recent prescription trends for hypnotics indicated for insomnia in Japan and highlighted notable shifts among older adults. The overall use of conventional hypnotics, such as zolpidem and brotizolam, was maintained or increased, whereas their relative share among adults aged ≥ 65 years declined. These findings may suggest a potential shift in prescribing practices; however, the interpretation of “safer prescribing” should be made with caution. In particular, the rapid and substantial increase in the use of lemborexant, reaching a scale comparable to major conventional hypnotics, complicates the interpretation of “safer prescribing.” Although DORAs are considered to have a more favorable safety profile, the large-scale adoption of these agents requires careful evaluation, as their real-world safety outcomes in older adults remain to be fully established. Similar increasing trends in the use of DORAs have also been reported in other countries, suggesting a broader shift in insomnia pharmacotherapy.^{12,13)}

According to national statistics, the number of individuals aged ≥ 65 years increased modestly from approximately 35.8 million in 2019 to 36.2 million in 2023,¹⁴⁾ corresponding to about a 1 percentage point increase in population proportion. Therefore, demographic changes alone are unlikely to fully explain the observed trends in dispensed quantities. One possible explanation is the increasing awareness of hypnotic-related risks, including falls and cognitive impairment,⁵⁻⁷⁾ together with guideline recommendations encouraging cautious use of benzodiazepines and Z-drugs in older adults.¹⁵⁾

In contrast, lemborexant demonstrated rapid diffusion following its introduction, accompanied by a rising proportion of older adult users. Because the data are based on aggregated dosage units, differences in dosing regimens, treatment duration, and drug potency (e.g., defined daily doses) cannot be accounted for. These factors may introduce bias when comparing across drugs, and the direction and magnitude of such bias are uncertain. The study period overlapped with the COVID-19 pandemic, which may have influenced sleep disorders and prescribing trends of psychotropic medications. Therefore, part of the observed trends may reflect pandemic-related effects.

This study has strengths in restricting the analysis to hypnotics with insomnia-specific indications and improving the specificity by excluding multi-indication anxiolytics. However, several benzodiazepine anxiolytics with broader indications, such as etizolam and diazepam, were not included in this analysis. Previous studies in Japan have suggested that short-acting benzodiazepines are frequently prescribed and may be used for long periods, sometimes for sleep-related purposes.¹⁶⁾ In addition, some studies have suggested that bedtime prescriptions of anxiolytics may indicate their use as hypnotics.¹⁷⁾ Therefore, it is possible that some prescriptions of these anxiolytics might have been intended for insomnia management.

This study has several limitations. First, the NDB Open Data do not contain information on dosing time or prescribing instructions, making it impossible to identify whether certain medications were prescribed specifically for sleep. Second, because the NDB Open Data consist of aggregated data, patient-level factors, treatment duration, and clinical outcomes

Table 1. Annual Utilization Trends of Hypnotics ($\times 10^6$ Dispensed Dosage Units)

Drug Class	Drug Name	Fiscal Year	Total dispensed quantity	Dispensed quantity (≥ 65 years)	Proportion of dispensed quantity in adults aged ≥ 65 years (%)
Orexin receptor antagonists (DORAs)	Suvorexant	2019	268.4	177.1	66.0
		2020	299.8	198.6	66.2
		2021	290.0	196.7	67.8
		2022	257.6	176.1	68.4
		2023	260.7	170.6	65.4
	Lemborexant	2019	-	-	-
		2020	15.4	6.0	38.9
		2021	140.3	61.9	44.1
		2022	300.5	148.6	49.5
		2023	503.8	257.6	51.1
Melatonin receptor agonists	Ramelteon	2019	134.0	94.9	70.8
		2020	140.9	99.2	70.4
		2021	142.9	100.6	70.4
		2022	139.8	97.4	69.7
		2023	154.1	103.8	67.3
Z-drugs	Zolpidem	2019	506.3	327.5	64.7
		2020	514.4	327.4	63.6
		2021	550.8	345.8	62.8
		2022	658.7	406.1	61.6
		2023	684.9	412.3	60.2
	Zopiclone	2019	79.1	54.3	68.7
		2020	74.9	51.4	68.6
		2021	68.7	47.3	68.8
		2022	67.9	45.5	67.0
		2023	67.9	44.4	65.3
Eszopiclone	2019	213.9	128.9	60.2	
	2020	238.1	141.4	59.4	
	2021	186.6	114.2	61.2	
	2022	265.3	151.3	57.1	
	2023	302.0	163.9	54.3	
Benzodiazepines	Brotizolam	2019	522.4	348.1	66.6
		2020	498.3	328.2	65.9
		2021	488.3	318.2	65.2
		2022	480.5	309.7	64.4
		2023	499.6	310.5	62.1
	Triazolam	2019	190.3	116.3	61.2
		2020	195.5	114.0	58.3
		2021	171.4	100.1	58.4
		2022	202.6	115.6	57.1
		2023	217.7	117.6	54.0
Flunitrazepam	2019	262.2	97.7	37.3	
	2020	255.9	93.3	36.5	
	2021	249.0	89.6	36.0	
	2022	249.5	87.3	35.0	
	2023	290.9	94.8	32.6	

such as falls or hospitalization could not be evaluated. Third, the data represent dispensed quantities rather than actual consumption. Future studies are needed to determine whether the increasing adoption of newer hypnotics is associated with improved safety outcomes among older adults.

Conflict of interest The authors declare no conflict of interest.

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