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ORIGINAL ARTICLE

Diagnosed or prescribed only? A national analysis of initial evaluation and management of insomnia among older adult Medicare beneficiaries

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Abstract

Study Objectives: To describe initial insomnia-related encounters among a national sample of Medicare beneficiaries, and to identify older adults at risk for potentially inappropriate prescription insomnia medication usage.

Statement of Significance

Despite clear risks associated with sedative hypnotics among older adults, these medications are very commonly prescribed in this population. Using a national database of Medicare beneficiaries, results of this study demonstrate that the majority of older adults who are prescribed an FDA-approved insomnia medication do not receive a concurrent sleep-related diagnosis. Importantly, beneficiaries who were seen by a board-certified sleep medicine provider were more likely to receive an insomnia diagnosis and less likely to receive medication only. Future research should continue to examine prescribing patterns and provider education including specialty training in effort to encourage safe prescribing of insomnia medications among older adults.

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Methods: Our data source was a random 5% sample of Medicare administrative claims data (2006–2013). Insomnia was operationalized as International Classification of Disease, Ninth Revision, Clinical Modification diagnostic codes. Insomnia medications included FDA-approved insomnia-related medication classes and drugs. Logistic regression was employed to identify predictors of being "prescribed only" (i.e., being prescribed an insomnia medication without a corresponding insomnia diagnosis).

Results: A total of *N* = 60 362 beneficiaries received either an insomnia diagnosis or a prescription for an insomnia medication as their first sleep-related encounter during the study period. Of these, 55.1% (*n* = 33 245) were prescribed only, whereas 44.9% (*n* = 27 117) received a concurrent insomnia diagnosis. In a fully adjusted regression model, younger age (odds ratio (OR) 0.98; 95% confidence interval (CI) 0.98, 0.99), male sex (OR 1.15; 95% CI 1.11, 1.20), and several comorbid conditions (i.e., dementia [OR 1.21; 95% CI 1.15, 1.27] and anemia [OR 1.17; 95% CI 1.13, 1.22]) were positively associated with being prescribed only. Conversely, black individuals (OR 0.83; 95% CI 0.78, 0.89) and those of "other" race (OR 0.89; 95% CI 0.84, 0.94) were less likely to be prescribed only. Individuals who received care from a board-certified sleep medicine provider (BCSMP) were less likely to be prescribed only (OR 0.27; 95% CI 0.16, 0.46).

Conclusions: Fewer than half of Medicare beneficiaries prescribed insomnia medications ever received a formal sleep-related diagnosis.

Key words: sleep; sleep medicine; health services; board certification; Medicare; older adults

Introduction

Despite well-documented risks, sedative hypnotic medication usage remains very common among older adults. One of the most common indications for many such medications is insomnia disorder, defined as a persistent difficulty initiating or maintaining sleep with associated daytime consequences. Among older adults, insomnia is highly prevalent[1] and associated with increased medical (e.g., cardiovascular disease, diabetes) and psychiatric (e.g., depression, anxiety, substance abuse, and dementia) consequences, as well as diminished quality of life and adverse economic outcomes.[2–4] Major international societies including the American College of Physicians,[5] American Academy of Sleep Medicine,[6] and European Sleep Research Society[7] consistently recommend cognitive behavioral treatment of insomnia (CBTI) as first-line treatment for chronic insomnia, with medications being considered when CBTI is unavailable or ineffective. Even so, due to convenience, availability, and short-term clinical effectiveness, pharmacotherapy is the most common treatment for insomnia. Numerous FDA-approved compounds are available, included in a broad range of medication classes.[8] However, many insomnia medications (including benzodiazepines, newer "z-drugs" such as eszopiclone and zolpidem, and others such as antipsychotics frequently used off-label to treat insomnia) incur unfavorable risk/benefit ratios among older adults and can increase risk for falls, fractures, and cognitive side effects.[9–12] Notably a recent meta-analysis evaluated risks of insomnia medications among older adults and suggested additional research to evaluate doxepine, suvorexant, and ramelteon as possible options among older adults[13] (other agents lacked data for this meta-analysis). As a result, sleep medications should be used with caution and require thoughtful oversight among older adults. At minimum, benzodiazepines should be avoided whenever possible.[14, 15]

Despite the known need for caution when prescribing insomnia medications to older adults, few studies have evaluated issues pertaining to sleep-related care in the context of insomnia medication use among this population.[16] We recently performed a time-series analysis of Medicare claims data (2006–2013) and found that 1) insomnia medication use was very common and increased over time, and 2) the majority of beneficiaries using FDA-approved insomnia medications were not actually diagnosed with insomnia.[16] These results raised important questions regarding how sleep complaints are evaluated and treated in real-world clinical settings. From a population health perspective, such data are vital because rates of both physician-diagnosed insomnia as well as prescriptions of insomnia medications are increasing.[16] Given the aging US populace and rising prevalence of sleep problems, knowledge regarding insomnia medication prescribing patterns (and potentially inappropriate usage, such as prescribing medications without comprehensive assessment) could provide valuable insights regarding quality of care to payers, policy-makers, and health systems leaders charged with optimizing outcomes and managing health for the future.[17]

To address this known gap in the literature, the purpose of the present study was to advance understanding regarding initial evaluation and management of sleep problems among older adults. Specifically, we sought to describe initial insomnia-related encounters (i.e., diagnosis and medication prescription) and to identify older adults at risk for potentially inappropriate prescription insomnia medication usage among a nationally representative sample of older adult Medicare beneficiaries. The Medicare population is of particular interest as Medicare is the largest payer for health care for older adults in the US and a leading developer of public and private health policy. In addition to this primary goal, we sought to evaluate the impact of board certification in sleep medicine on sleep-related care in this context.

Materials and Methods

Study design and data source

This was a retrospective cohort study performed using a 5% random sample of Medicare administrative claims data for years 2006–2013, created by and obtained from the Center for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse (CCW). Using these data, we created a cohort of Medicare beneficiaries whose first sleep-related event (i.e.,

index date) was either an insomnia diagnosis or a prescription fill for an FDA-approved insomnia medication. Next, to identify older adults at risk for potentially inappropriate prescription insomnia medication usage, we followed individuals whose first sleep-related event was a prescription fill forward in time from the index date to assess subsequent sleep-related diagnoses. Finally, we identified independent factors associated with receipt of an insomnia medication without an insomnia diagnosis, including board-certification in sleep medicine (BCSMP) status.

Study participants

We searched for the first claim for either an insomnia diagnosis (International Classification of Disease, Version 9, Clinical Modification [ICD-9-CM] codes 307.41, 307.42, 307.49, 327.00, 327.01, 327.09, 780.52, or V69.4) and/or a prescription fill for US Food and Drug Administration (FDA) approved medications for the treatment of insomnia (i.e., butabarbital, doxepin, estazolam, eszopiclone, flurazepam, quazepam, ramelteon, secobarbital, temazepam, triazolam, zaleplon, zolpidem) during the study period following a 12-month period with no previously observed sleep-related diagnoses, testing, or treatment. Beneficiaries who received both a prescription fill and insomnia diagnosis on the same date of service were included in the "diagnosed" group. This first date was considered the index date. Continuous enrollment in Medicare Parts A, B, and D—with no Part C (Medicare Advantage) coverage for 12 months before and 24 months after the index date—was required, and beneficiaries under 65 years of age were excluded from analysis. For clarity, throughout this manuscript, we refer to these groups as "diagnosed" and "prescribed only."

Other sleep disorders

Table 1 presents other sleep disorder diagnoses that might have been received following the initial insomnia diagnosis or prescription medication fill. These disorders were operationalized using ICD-9-CM diagnostic codes and included sleep-related breathing disorders (i.e., obstructive sleep apnea [OSA] and central sleep apnea [CSA]), narcolepsy, circadian rhythm sleep-wake disorders, parasomnias, hypersomnia, and restless legs syndrome (RLS).

Identification of board-certified sleep medicine providers

Our methodology for the identification of BCSMPs has been described in detail elsewhere.[18] Briefly, we linked lists of BCSMPs obtained from the American Board of Sleep Medicine and the American Board of Medical Specialties to the CCW using Unique Physician Identifier Numbers (UPINs; prior to June 2007) and National Provider Identifiers (NPIs; after June 2007) available on the individual claims. We used the NPI matched to the index date to determine whether a beneficiary was initially seen by a BCSMP. It should be noted that Medicare policy does not require a specific referral in order to see specialist providers, including BCSMPs.

Covariates

Demographic and clinical characteristics were obtained from the claims files. The CCW contains information on 27 comorbid conditions, with an annual flag for each condition as well as the date of first diagnosis for that condition. We combined the five cancer flags to create an "any cancer" variable and selected to report the Alzheimer's disease and related dementias flag rather than the Alzheimer's disease (only) flag. In addition, we created indicators for anxiety (ICD-9-CM 293.84, 300.x, 308.x, 309.81, 313.x) and fibromyalgia (ICD-9-CM 338.2x, 338.3, 338.4, 780.7x, 729.x). We used the date of first diagnosis to determine if a condition was present at the date of insomnia diagnosis or prescription fill (i.e., index date). Any diagnoses received prior to insomnia diagnosis were assumed to be present at the index date.

Data analysis

First, we compared distributions of demographic and clinical characteristics between the diagnosed and prescribed-only groups using Student's t-tests and Pearson's chi-squared test. Next, to better understand the care that beneficiaries received following an FDA-approved prescription insomnia medication fill, we searched for sleep-related diagnoses (i.e., insomnia, as well as additional diagnoses listed in Table 1) received during the 24 months following the index date.

To identify beneficiary characteristics associated with receiving a prescription-only, we used logistic regression. First, covariates that differed significantly between groups in bivariate analysis were added to the model. Next, we eliminated covariates whose p-value was >.001 in the final model. Analyses were performed with SAS Studio Enterprise Edition 3.71 (SAS Institute, Cary, NC). This study was approved by the Institutional Review Board at the University of Maryland, Baltimore.

Results

We identified 60 362 beneficiaries aged 65 and older who received either an insomnia diagnosis or a prescription for an FDA-approved prescription insomnia medication between 2007–2011 and met continuous coverage criteria. Of these, 27 117 (44.9%) received a diagnosis and 33 245 (55.1%) were only prescribed medication. Of beneficiaries who were prescribed-only, zolpidem was most commonly prescribed medication (78.6%), followed by doxepin (6.2%), eszopiclone (5.5%), and temazepam (5.3%).

Characteristics of study participants are reported in Table 2. Relative to diagnosed beneficiaries, prescribed-only beneficiaries were more likely to be male (30% vs. 25%, $p < .001$). They were also more likely to have cardiovascular disease or cardiovascular risk factors, including heart failure (33% vs. 28%, $p < .001$), diabetes (37% vs. 32%, $p < .001$), and ischemic heart disease (58% vs. 52%, $p < .001$). On the other hand, beneficiaries who were prescribed only were less likely to experience psychological health problems such as anxiety (18% vs. 25%, $p < .001$). Although the number of beneficiaries initially treated by BCSMPs was very low, relative to beneficiaries who were diagnosed, those who were prescribed only were much less likely to have been treated by a BCSMP (0.06% vs. 0.20%, $p < .001$).

Diagnoses following an FDA-approved insomnia medication fill

Among beneficiaries whose first sleep-related event was receipt of an FDA-approved prescription insomnia medication, 14 347

Table 1. Operational definition of sleep disorders

Sleep disorder	ICD-9-CM codes
Insomnia	307.41, 307.42, 307.49, 327.00, 327.01, 327.09, 780.52, V69.4
Obstructive sleep apnea	327.23, 780.57, 780.51, 780.53
Central sleep apnea	327.21, 327.22, 327.27, 327.29, 768.04
Hypersomnia	307.43, 307.44, 327.10, 327.11, 327.12, 327.13, 327.14, 327.15, 780.54
Narcolepsy	347.0, 347.00, 347.01, 347.1, 347.10, 347.11
Circadian rhythm disorders	307.45, 327.3x, 780.55
Parasomnia	327.40, 307.46, 307.47, 327.4x, 780.56
Restless leg syndrome	333.94

(43.1%) received a subsequent sleep-related diagnosis during the two-year follow-up (median time to diagnosis = 553 days [interquartile range = 844]). Among these, 71% of those treated by non-BCSMPs and 80% of those treated by BCSMPs were eventually diagnosed with insomnia.

Predictors of being prescribed only

Table 3 presents results of our final logistic regression model to identify independent predictors of being prescribed only. Younger age (odds ratio (OR) 0.98; 95% confidence interval (CI) 0.98, 0.99) and male sex (OR 1.15; 95% CI 1.11, 1.20) were significantly associated with increased risk for being prescribed only. Based on the Medicare categories for race, relative to white beneficiaries, those who were black (OR 0.83; 95% CI 0.78, 0.89) and those of "other" race (OR 0.89; 95% CI 0.84, 0.94) were less likely to be prescribed only. Several comorbid conditions were also associated with being prescribed only, including dementia (OR 1.21; 95% CI 1.15, 1.27) and anemia (OR 1.17; 95% CI 1.13, 1.22). Receiving care from a BCSMP was associated with significantly decreased likelihood of being prescribed only (OR 0.27; 95% CI 0.16, 0.46).

Discussion

In this national analysis of Medicare beneficiaries, more than half of patients with insomnia were prescribed an insomnia medication without a corresponding diagnosis during their initial sleep-related encounter. These results suggest that, despite well-documented risks of sedative hypnotic medication use among older adults, most prescribing providers do not document sleep complaints prior to prescribing, let alone perform comprehensive sleep assessment. Further, several risk factors for being prescribed-only were identified, including older age and dementia—a condition with dramatically heightened risk for cognitive side effects, falls, and other adverse sequelae from potentially inappropriate use of insomnia medications, such as prescribing medications without comprehensive assessment. However, it should be noted that Cognitive Behavioral Therapy for Insomnia (CBTI) has been shown as an effective treatment modality for older adults and thus offers a safer alternative to sedative hypnotic medication for this population. Importantly, board certification in sleep medicine was associated with reduced likelihood of being prescribed only, suggesting that provider training may help ensure appropriate prescribing practices, and potentially the pursuit of other treatment approaches, when caring for older adults with insomnia.

Present data demonstrate that treatment from board-certified sleep medicine physicians (BCSMPs) was robustly associated with reduced likelihood for being prescribed only at the initial encounter. On the one hand, this result makes sense, as BCSMPs would be expected to administer and document sleep care carefully and thoroughly. Another possibility, although speculative, is that relative to non-specialists, BCSMPs are more likely to perform a comprehensive assessment, ensure accurate diagnosis and coding, and adhere to clinical recommendations regarding safe use of sedative hypnotic insomnia medications among older adults. Thus, future research should seek to replicate this finding and examine insomnia evaluation and management practices using additional data sources and research methods. Second, BCSMPs might be under-involved in delivering insomnia-related care among older adults. For example, our group recently reported that of all sleep disorders among older adults, insomnia was least likely to be associated with receiving care from a BCSMP.[19] Of course, although BCSMPs provide a substantial proportion of sleep medicine care among older adult Medicare beneficiaries,[18] requiring board-certification is not a realistic requirement for treating insomnia among older adults. Even so, increased provider education regarding sleep disorders management and safe prescribing practices seems prudent.

In addition to older age, dementia, and provider certification, sociodemographic characteristics were found to be associated with prescription-only status. Specifically, male sex, as well as black and "other" race, were associated with decreased likelihood of being prescribed only. Interestingly, in univariate comparisons, few racial differences were observed, but after controlling for covariates, race-based differences in treatment patterns were evident. To our knowledge, these results have not previously appeared in the literature and warrant further investigation in future studies, particularly from a health disparities perspective.

Given the high frequency of sleep complaints among older adults, several clinical considerations warrant mention. First, because CBTI is often not available or not convenient, pharmacotherapy remains by far the most common treatment for insomnia disorder and is highly common among older adults.[16] Thus, it is important to consider what safe prescribing practices might look like in this population, especially given formulary restrictions that often require older-generation insomnia medications as first-line treatments.

Insomnia medication management among older adults requires a detailed risk/benefit discussion with the patient and careful shared decision-making. On the one hand, health providers are cognizant of the very high prevalence of insomnia and its adverse consequences among their older adult patients. On the other hand, thoughtful providers also recognize

Table 2. Baseline characteristics of medicare beneficiaries with insomnia by status of index date 2007–2011, *n* = 60 362

	Insomnia diagnosis first, *n* = 27 117	**FDA-approved medication for insomnia first, *n* = 33 245**	***p*-value[1]**
Age, mean (SD)	76.7 (7.6)	76.3 (7.5)	<.001
Sex, *n*(%)			<.001
Female	20 234 (75)	23 293(70)	
Male	6883 (25)	9952 (30)	
Race, *n*(%)			.14
White, non-Hispanic	23 023 (85)	28 408 (85)	
Black, non-Hispanic	1726 (6)	2007 (6)	
Other	2368 (9)	2830 (9)	
Comorbid Conditions, *n*(%)			
Alzheimer's and Related Dementias	4125 (15)	5687 (17)	<.001
Anemia	14 457 (53)	19 360 (58)	<.001
Anxiety	6910 (25)	6123 (18)	<.001
Asthma	3359 (12)	4571 (14)	<.001
Atrial fibrillation	3801 (14)	5430 (16)	<.001
Chronic Kidney Disease	4682 (17)	6883 (21)	<.001
Cancer	3957 (15)	5458 (16)	<.001
Chronic obstructive pulmonary disease	7603 (28)	10 180 (31)	<.001
Depression	6631 (24)	7517 (23)	<.001
Diabetes	8790 (32)	12 451 (37)	<.001
Fibromyalgia	5967 (22)	6706 (20)	<.001
Glaucoma	6585 (24)	8098 (24)	.83
Heart failure	7641 (28)	10 992 (33)	<.001
Hip fracture	1346 (5)	1745 (5)	.12
Hyperlipidemia	20 934 (77)	25 921 (78)	.02
Hypertension	22 658 (84)	28 020 (84)	.02
Hyperplasia	3362 (12)	4714 (14)	<.001
Hypothyroidism	6956 (26)	9049 (27)	<.001
Ischemic Heart Disease	14 084 (52)	19 238 (58)	<.001
Myocardial infarction	1282 (5)	1995 (6)	<.001
Osteoporosis	12 100 (45)	14 432 (43)	.003
Rheumatoid arthritis	16 714 (62)	20 889 (63)	.008
Stroke/transient ischemic attack	4483 (17)	6107 (18)	<.001
Treated by a BCSMP2 at index date, *n*(%)	55 (0.20)	19 (0.06)	<.001

Table 3. Independent factors associated with being prescribed-only (receiving an FDA-approved insomnia medication without concurrent diagnosis), *n* = 60 362

	Odds ratio (95% Confidence interval)
Age in years	0.98 (0.98, 0.99)
Sex	
Female	Reference
Male	1.15 (1.11, 1.20)
Race, *n*(%)	
White, non-Hispanic	Reference
Black, non-Hispanic	0.83 (0.78, 0.89)
Other	0.89 (0.84, 0.94)
Alzheimer's and Related Dementias	1.21 (1.15, 1.27)
Anemia	1.17 (1.13, 1.22)
Anxiety	0.65 (0.62, 067)
Chronic Kidney Disease	1.11 (1.06, 1.20)
Cancer	1.11 (1.07, 1.17)
Diabetes	1.13 (1.09, 1.17)
Fibromyalgia	0.89 (0.85, 0.92)
Heart failure	1.15 (1.11, 1.20)
Hypothyroidism	1.08 (1.0.4, 1.12)
Ischemic Heart Disease	1.18 (1.14, 1.22)
Treated by a BCSMP at index date	0.27 (0.16, 0.46)

the substantial risk of side effects of common insomnia medications in this population. The American Academy of Sleep Medicine provides a clinical guideline for pharmacologic management of insomnia.[15] In our view, safe prescribing practices for insomnia medications among older adults requires a thorough sleep history, consideration of comorbid conditions

and medication interactions, and regular follow-up to monitor response to treatment. Although face-to-face CBTI might not always be accessible, health providers can certainly recommend subjective sleep diaries or internet/smartphone-based applications to monitor response to therapy. Indeed, adaptations and evaluation of internet/mobile health CBTI applications among older adults is a high research priority.

Our study possesses several strengths. First, we employed a large, national sample representative of the Medicare fee-for-service population. Second, our operational definitions were based on a comprehensive set of insomnia diagnoses and FDA-approved medications. Finally, we employed a logical, highly detailed approach to identify BCSMPs in this national dataset. At the same time, our administrative methodology has limitations. Most importantly, we were unable to ascertain whether, despite not assigning diagnoses, providers documented sleep complaints elsewhere in the electronic health record (EHR). Future studies should seek to evaluate insomnia care within the context of linked administrative claims and EHR data, as well as other data sources. Related to this, we were unable to determine insomnia severity, sleep parameters, or other clinical variables of interest. Of note, insomnia itself is underdiagnosed.[16] Third, we were unable to examine long-term outcomes of initial insomnia-related encounters; examining downstream health and economic outcomes is a vital future direction. Fourth, in addition to FDA-approved insomnia medications, off-label medications (e.g., low dose trazodone) and over-the-counter agents (e.g., melatonin) should be examined in future research. Fourth, although polypharmacy among older adults could influence prescribing, our dataset did not include additional medications to assess polypharmacy. Finally, although our sample was large and representative of Medicare fee-for-service beneficiaries, it is unknown how well this randomly generated 5% sample generalizes to all older adults, or to individuals in Medicare advantage plans.

In summary, results from our study highlight an important discrepancy between prescription of insomnia medication versus actual diagnosis of insomnia among older adults who are at high risk for adverse sequelae from sedative medications. Future research should further evaluate sleep assessment and treatment patterns among older adults, with emphasis on patient-centered comprehensive assessment, safe prescribing practices, and careful management to optimize sleep treatment outcomes among older adults.

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