NIH INSOMNIA ABSTRACT

Treatment Epidemiology

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There have been significant advances in the therapeutic modalities used to treat insomnia over the past decade.^{1,2} While numerous studies have examined the efficacy and safety of these agents, a smaller number of studies have examined the patterns of use for these treatments (see Table 1). These studies offer several insights into the epidemiology of insomnia treatments. First, selftreatment methods relying on over-the-counter (OTC) medications and alcohol are some of the most commonly cited insomnia treatments. The use of alcohol is particularly concerning because of the increased risk of alcohol abuse in insomniacs.³ However, in general, 88 percent of individuals believe that alcohol is not beneficial for sleep.⁴ Furthermore, while frequently mentioned, both OTC medications and alcohol are used on a less-consistent basis relative to prescription drugs. Roehrs et al. noted that 65-70 percent of patients using OTC medications/alcohol as a sleep aid used it for less than 1 week, while 62 percent of patients taking prescription drugs used them for more than 1 week.5 OTC medications were used an average of 5.2 nights per month and alcohol an average of 6.8 nights per month. Second, there is very little data available regarding the use of behavioral/psychological treatments for insomnia, with the current data suggesting that they are largely underutilized. "Mental relaxation," for example, was recommended to chronic insomniacs by physicians only 6 percent of the time.6 Nonprescription medication use has rarely been examined in detail as well, despite its high prevalence.⁷ Third, the most commonly used prescription drugs for insomnia appear to be antidepressants and anxiolytics (U.S. Food and Drug Administration [FDA] off-label use).8 Three of the five most commonly used drugs for insomnia drawn from a pharmaceutical database were antidepressants (trazodone [27.5 percent], amitriptyline [7.8 percent], and mirtazapine [6.7 percent]) and only two were FDA-approved drugs for insomnia (zolpidem [20.9 percent] and temazepam [5.6 percent]).8

Research examining trends in insomnia treatments has observed that the relatively low rate of prescription medication use has continued, with an overall decline of 24.4 percent from 1987 to 1996. Specifically, there has been a 53.7 percent decline in the use of FDA-approved insomnia drugs. In contrast, there has been a marked increase in the off-label use of antidepressants for insomnia during this same time period.⁹ While these developments run counter to current treatment guidelines, several possible explanations have been proposed that are largely related to the regulatory environment in the United States.⁸

As noted earlier, the frequency of use and duration vary by treatment type. Prescription medications (e.g., hypnotics, anxiolytics, or antidepressants) were used for an average of 26 months, and within that time, the average number of consecutive nights of use was 35.⁶ In Europe, nearly 30 percent of insomniacs using prescription hypnotics have used them for more than 4–5 years.^{10,11} When comparing specific prescription medications, anxiolytics and antidepressants have even longer periods of use than hypnotics.¹²

Epidemiology studies have also examined the influence of demographic and comorbid factors on the use of insomnia treatments. Roehrs et al. noted that prescription drug users were more likely to be older than those using alcohol or OTC agents; alcohol users were mostly male, not married, and more likely to have rotating work schedules; and prescription medication users reported more severe insomnia, had higher scores on neuroticism scales, and were more likely to have lost days from work and social activities. There were no differences in racial, educational, or socioeconomic measures or in the nature of their insomnia.⁵ Another study found that subjects with higher levels of chronic disease were more likely to use prescription drugs for their insomnia.¹³ When comparing patient characteristics across different types of prescription drugs used to treat insomnia, gender and age were found to be significant: Females were more likely to receive antidepressants and less likely to receive hypnotics, while patients receiving hypnotics were older.12

A limited body of work has examined the epidemiology of insomnia treatments in special populations, such as children. The National Sleep Foundation's 2004 Sleep in America Survey focused on pediatric sleep and noted that parents who felt that their child had a sleep problem used medications 11 percent of the time.¹⁴ Owens et al. surveyed primary care pediatricians regarding their management strategies for sleep disorders (not limited to insomnia) and observed the following: (1) medications were used with behavioral strategies in half of the cases; (2) 75 percent of pediatricians had recommended nonprescription medications; and (3) less than 50 percent had recommended a prescription medication. The mean duration of use for nonprescription medications was less than 1 week, while prescription drugs were more likely to be used for more than 1 month.¹⁵

Of all prescription and OTC drugs used to treat insomnia, 31 percent are consumed by patients aged 65–79, thus, making the elderly the most common users of insomnia medications.¹⁶ In addition, the duration and frequency of use of insomnia treat-

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	Subjects			
Study	(Response Rate)*	Characteristics/Year	Method	Findings
National Sleep Foundation, 2004 ⁽¹⁴⁾	1,473 (26%)	U.S., families with a child younger than 10 years old, 2003	Random digit dial tele- phone calls	Rates of medication use in children (irrespec- tive of sleep quality): 5% for those less than 3 years old and 3% for those 3 years of age or older. Types of medications used: 1–3% used OTC medications and 1% used prescription medications.
Roehrs et al., 2002 ⁽⁵⁾	1,325 (68%)	U.S. (Metropolitan Detroit area), ages 18–65, 2000	Random digit dial tele- phone calls	In all subjects (insomniacs and noninsomni- acs): 8% used prescription medications, 10% used OTC medications, and 10% used alcohol. Five percent used both prescription medica- tions and alcohol.
Hatoum et al., 1998 ⁽²¹⁾	3,447 (46%)	U.S. (from five diverse managed care organization clinics), all ages, 1997	Mailed survey	In those with insomnia: 5.5% used prescription medications for sleep (hypnotics and others) and 11.2% used OTC medications. In those with insomnia and daytime sleepiness: 11.6% used prescription medications and 21.4% used OTC medications.
Simon and Von- Korff, 1997 ⁽¹³⁾	373 (61%)	U.S. (Puget Sound, WA, managed care primary care clinics), ages 18–65, 1996	Face-to-face interview	In those with insomnia ("nearly every night"): 28% were on some type of psychotropic medi- cation (14% used benzodiazepines and 19% used antidepressants). Most antidepressant use occurred in those with depression and insom- nia: 38% of them were on antidepressants as compared to 13% of those with insomnia only.
Gallup Organiza- tion, 1995 ⁽⁴⁾	1,027	U.S., population-based, ages 18 and older, 1995	Random digit dial telephone calls with oversampling of insomniacs	In those with insomnia: 15% used a prescrip- tion sleep medication, 22–37% used OTC medications, and 16% used alcohol. Self-help techniques included: 64% reading, 50% warm bath, and 40% reduced caffeine and/or relax- ation techniques.
Asplund, 1995 ⁽¹⁹⁾	6,143 (60.8%)	Sweden, ages less than 65, 1992	Mailed survey	In all subjects: 13.5% of men and 22.3% of women used hypnotic medications. Usage rates increased with age (34.9% of women younger than 80). Twenty percent of hypnotic users used them every night. In insomniacs: 47.0% of men and 51.6% of women.
Ancoli-Israel and Roth, 1999 ⁽⁶⁾	1,000 (51%)	U.S., population based, ages 18 and older (15% were over 65), 1991	Random digit dial telephone calls with oversampling of insomniacs.	Amongst occasional and chronic insomniacs: 21% used prescription medications, 23% used OTC medications, and 28% used alcohol. In chronic insomniacs only: more than 21% used prescription medications, 25% used physical exercise, 19% used reading, 17% used mental relaxation, and 11% used OTC medications. Thirty-nine percent had used some other kind of prescription sleeping medication (e.g., anxiolytics, etc.).

*"Subjects" refers to the number of subjects who completed the survey/interview and on whom the study data is available.

Note: Percentages indicate subjects who have tried or used a given method for their insomnia at some point; OTC = over-the-counter.

ments tends to be longer in the elderly.⁷ While most studies of elders have found similar rates of use, one study of rural elders found lower rates of treatment with only 0.4 percent using OTC agents (primarily diphenhydramine) and 1.8 percent using prescription hypnotics (data on antidepressants/ anxiolytics was not obtained).¹⁷ The elderly may also engage in counter-productive measures while attempting to self-treat their insomnia—59.1 percent watch television or listen to the radio to help themselves fall

asleep.¹⁸ To determine factors associated with treatment, Asplund conducted a study of 6,143 Swedish pensioners and noted that elders with poor health, cardiovascular disease, or chronic pain were more likely to use hypnotic drugs (odd ratio equals 1.6–2.3). There were no gender differences in the use of hypnotics.¹⁹

Another important observation highlighted by the treatment epidemiology data is that less than half of all chronic insomniacs have discussed their sleep disorder with their health care provider.^{4,6} This has significant ramifications for interpreting the epidemiology of insomnia treatment. For example, of those patients who have spoken with a physician, only 1 percent discussed it with a sleep specialist, 8 percent with a psychiatrist, and the remainder spoke to their primary care doctor.⁶ Many chronic insomniacs, especially the elderly, may tend not to discuss sleep problems with their health care providers because they view insomnia as a natural part of aging (34.8 percent) or are concerned they may be given a prescription sleeping pill by their physician (18.9 percent).²⁰ Lack of education is clearly a factor, with 72 percent of insomniacs stating that they did not understand the treatment options for insomnia.⁴

Several areas of significant research need can be identified from the preceding treatment epidemiology data:

1. Research on patient and physician factors that underlie the pervasive use of treatments that are not FDA-approved for insomnia, such as OTC agents, anxiolytics, and antidepressants—most of these agents have rarely, if at all, been rigorously studied as insomnia treatments, and the high prevalence of their use is concerning.

2. Examination of modifiable factors underlying the use of alcohol for insomnia with the ultimate goal of developing education/outreach programs to reduce inappropriate alcohol consumption for insomnia.

3. Investigation of the epidemiology of insomnia treatment in special populations (e.g., children, institutionalized and noninstitutionalized elders, ethnic and racial groups). For example, the largest consumers of insomnia medications are older adults, especially those with multiple comorbidities, but relatively little is known about what factors motivate their treatment decisions.

4. Research on the use of nonpharmacologic treatments (e.g., exercise, relaxation techniques) and nonprescription treatments. While there is evidence to suggest that as a category they are the most commonly used treatment modalities, there is very little information regarding the use of specific treatments, such as diphenhydramine (which may be overutilized), or cognitive-behavioral therapies (which, from our limited data, are significantly underutilized).

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