INSOMNIA, OR THE DISSATISFACTION WITH THE QUANTITY, quality or timing of sleep, is a common complaint. Because the definition of “normal” sleep is not well established, the estimates of the prevalence and severity of insomnia vary widely. Insomnia is often secondary to underlying psychiatric and medical conditions, and these should be evaluated and treated as a first measure. Nonpharmacological interventions for insomnia including sleep hygiene manoeuvres and exercise are recommended, although the success of these interventions has not been well documented. Benzodiazepines have been the pharmacologic agents of choice for the treatment of insomnia, but there is reason to exercise caution with their use; their overall benefit compared with placebo appears to be minor, and they are often associated with adverse cognitive effects. Unfortunately, no other class of drugs has proven to be superior to the benzodiazepines in terms of benefit:risk ratio. Given the importance of sleep for health and normal daily functioning the diagnosis, prognosis and treatment of insomnia should be a research priority.

Insomnia, as classified in the DSM-IV in the sleep disorders, is associated with complaints about the quantity, quality or timing of sleep at least 3 times a week for at least 1 month. The word complaint should be emphasized here because there are often significant differences between what people perceive and report about their sleep and what is measured objectively (e.g., by EEG monitoring) and individuals vary widely in the amount of sleep they require for optimal functioning. The sleep disturbance must be of sufficient severity to produce noticeable impairment in daytime function or mood. The frequency, duration and intensity components of the definition attempt to exclude the sleep disturbances that occur in everyday life.

Insomnia has been classified in at least 3 different ways — by comorbidity, duration and severity (Table 1). Subtypes of extrinsic and intrinsic classifications for insomnia, proposed by the American Association of Sleep Disorders, await validation but some of the subtypes they have proposed, including inadequate sleep hygiene, insufficient sleep, altitude insomnia and environmental insomnia, should also be considered when classifying insomnia.

**Epidemiology and current practices**

Patterns of sleep vary with age; it is thought that the amount of time spent in deep sleep decreases and the number of awakenings through the night and total time awake increases with age. Studies have reported more complaints regarding insomnia from older respondents, and sleep apnea may also be more prevalent in the elderly. However, a standard definition of what constitutes normal sleep is lacking, and community-based epidemiologic studies of sleep patterns that use similar definitions of insomnia and control for physical health, mental health, age and socioeconomic variables are scarce. The insomnia literature is therefore difficult to summarize to formulate precise estimates of the burden of illness.

Insomnia is a subjective complaint, but when validated by sleep laboratory stud-
ies many insomniacs have been found to have more sleep difficulties than normal sleepers. Population-based estimates of the prevalence of insomnia in adults have varied considerably, from 10.2% to 37.8%. In one survey of noninstitutionalized adults, 17% of adults viewed their insomnia as significant (i.e., “had trouble and was bothered a lot in the past year”). The nature of difficulty with sleep in this sample was almost equally divided into 3 groups — difficulty getting to sleep but not maintaining sleep, difficulty maintaining sleep but not getting to sleep, and difficulty both getting to sleep and maintaining sleep. The prevalence of insomnia has also been reported to be higher in women, women in minority groups, people who are unemployed or separated, lower socioeconomic groups and in those with medical or psychiatric (particularly substance abuse) disorders.

In a survey of office-based physicians in the United States, patients with insomnia had also been diagnosed with comorbid depression (30% of total), other mental diseases (20%) and organic disorders (19%); thus, only 31% of the sample were determined to have primary insomnia. In the National Institute of Mental Health Epidemiologic Catchment Area Study, a population-based survey using a structured DSM-III-based diagnostic questionnaire, 811 (10.2%) of the 7954 respondents complained of insomnia, and of those, 328 (40.4%) had a comorbid psychiatric disorder — most met the criteria for either anxiety or depression. For those with insomnia that persisted over a 12-month period, compared with those without insomnia, the risk of developing new major depression (odds ratio [OR] 39.8; 95% confidence interval [CI] 19.8–80.0), anxiety disorder (OR 25.6) or alcohol dependence (OR 3.4) was much higher.

Support for the hypothesis that physical and psychological wellness may be more strongly associated with sleep quality than age alone is provided by a small study on exercise interventions in a sample of healthy older adults (mean age, 57 years) from California. Although approximately one-third of the sample reported not feeling well rested, 5% or fewer described frequent problems with sleep latency, total quantity of sleep or awakenings. Many older surveys on the correlation between insomnia and advanced age reported much higher values for the prevalence of insomnia in elderly people but did not control for confounding variables such as comorbidity and use of medications.

More recent studies suggest that insomnia is less correlated with age than conditions such as pain, nocturia, dyspnea, nocturnal myoclonus and psychopathology and their associated treatments. In evaluating these studies it should also be considered that a general decline in the amount of sleep obtained has been noted over the past 3 to 4 decades; this has been termed voluntary sleep restriction.

Information on the prognosis of insomnia is scant, although complications associated with insomnia are presumed to be limited to impairments related to sleep deprivation, both actual and perceived, and to medications taken to augment sleep or increase alertness. The higher prevalence of anxiety and major depression among those suffering with insomnia is well documented, but it may also be that insomnia is an early symptom rather than a cause of anxiety or depression. Without careful longitudinal cohort studies documenting the course of any comorbid condition, it will continue to be difficult to judge the prognosis of insomnia itself.

Results from a US-based study examining the performance of general practitioners in assessing and managing patients with insomnia suggest there is room for improvement in physicians’ history taking when evaluating elderly patients with insomnia; 53% of physicians neglected to elicit any sleep history, and after asking a mean of only 2.5 questions, 46% identified a prescription medication as the best therapy. Research in Canada shows wide regional variation in benzodiazepine prescribing rates, disproportionate prescribing to women and elderly patients and higher prescribing rates by physicians who spend less time with each patient. These data suggest a need for training in treatment alternatives for insomnia.

### Treatment recommendations

An adequate sleep history, including sleep and wakefulness patterns, history from the bed partner, family history of sleep disorders and previous treatments, should be obtained before a diagnosis of insomnia is made and treatment is considered. We suggest the following 3-step approach to treatment. These recommendations are intended for primary care settings where the vast majority of treatment decisions are made.

#### Consider an underlying cause of insomnia

It is recommended that insomnia be considered as a symptom in the initial assessment, rather than a diagnosis. Therefore, psychiatric (depression, anxiety or panic), medical (arthritis, hyperthyroidism, congestive heart failure, obstructive sleep apnea or pulmonary disease) and pharma-

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### Table 1: Classification schemes for insomnia

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<th>By comorbidity</th>
<th>By duration</th>
<th>By severity</th>
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<tr>
<td>Related to a psychiatric disorder (nonorganic)</td>
<td>Transient, 2–3 d</td>
<td>Mild, almost nightly, associated with little or no evidence of social or occupational impairment</td>
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<tr>
<td>Related to an organic factor (i.e., a medical condition)</td>
<td>Short-term, less than 3 wks</td>
<td>Moderate; nightly, mild to moderate impairment with associated symptoms</td>
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<tr>
<td>Related to substance use or abuse</td>
<td>Long-term, more than 3 wks</td>
<td>Severe; nightly, severe impairment, significant restlessness, fatigue, irritability and anxiety</td>
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<tr>
<td>Primary insomnia</td>
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cological (caffeine, alcohol, hypnotic withdrawal, akathesias secondary to psychotropics or antidepressants) causes should be explored and treated before any other steps are taken to treat insomnia.

**Nonpharmacological therapy**

Sleep hygiene manoeuvres have considerable face validity but have not been extensively tested for efficacy in alleviating insomnia. Common recommendations include: regular daytime exercise; avoiding large meals at night; avoiding caffeine, tobacco and alcohol; reducing evening fluid intake; limiting the use of the bedroom to sleep and sex; maintaining a consistent wake-up time; avoiding or limiting daytime napping and avoiding bright lights (including television), noise and temperature extremes.

These items can be variously grouped into 3 main forms of intervention — stimulus control, temporal control and sleep restriction. Stimulus control refers to the attempt to associate the bedroom with sleep rather than wakefulness. Temporal control measures recommend a constant time of waking with minimal daytime napping, and sleep restriction curtails slightly the time spent in bed and then gradually increases it as long as most of the time is spent sleeping. These behavioural therapies have been shown to be superior to placebo. Additional nonpharmacological interventions such as progressive muscle relaxation, biofeedback and cognitive-behavioural therapy may be of benefit as well but require additional expertise on the part of the provider. Many patients with insomnia do not recognize the important role that stress may play in their symptoms and, therefore, lose the opportunity to benefit from psychotherapy or behavioural therapy.

Exercise deserves special mention here; a recent small randomized controlled trial demonstrated that moderate intensity exercise improved self-rated sleep quality, sleep-onset latency and sleep duration for older adults. This study provides evidence that is consistent with other trials that have reported the benefits of exercise for other chronic conditions such as arthritis. Because the majority of elderly people, particularly women, report low levels of physical activity, exercise may be one of the most cost-effective health interventions for people with insomnia.

**Pharmacological therapy**

The principles of pharmacological therapy for insomnia are straightforward.

- Use only medications known to be efficacious and safe; efficacy and safety beyond that of placebo should be proven.
- Use the lowest effective dose for the shortest period of time (less than 2 weeks), and aim for intermittent dosing.
- If use is prolonged or the dose is high, the discontinuation of sedatives should be gradual unless the patient can be observed for withdrawal reactions.

Commonly used sedative medications that fail our first criterion of proven risk:benefit superiority when compared with placebo include over-the-counter sedatives and antihistamines, alcohol, chloral hydrate, tryptophan and barbiturates. Evidence is still weak for the efficacy of melatonin.

In the accompanying meta-analysis in this issue of CMAJ, randomized controlled trials of benzodiazepine use compared with placebo or alternative sedative medications for the treatment of insomnia were surveyed. Summary comparisons with placebo suggested only approximately a 11.7-minute reduction in patient estimates of sleep latency and a 48.4-minute increase in total sleep duration. Although statistically significant, the increase was of uncertain clinical importance. An estimate of clinical importance would require that placebo-controlled studies include outcomes such as patient quality of life, functional status and satisfaction with sleep. Notably, the improvement in sleep with exercise was virtually identical to the summary estimates for improvements noted with benzodiazepine use. There are currently few well-studied pharmacological alternatives to benzodiazepines; one such alternative is zopiclone (Imovane), often touted as a safer sedative, but our meta-analysis does not suggest any superiority of this agent.

The rational use of benzodiazepines has been controversial for years. Although their overall usage has declined in this decade, benzodiazepines are still frequently prescribed for the elderly and are often used for long periods of time. There appears to be virtually no evidence to support the chronic use of benzodiazepines for insomnia. Various studies have reported a higher risk for motor vehicle accidents, falls and fractures and fatal poisonings, a general decline in functional status and cognitive impairment associated with the use of benzodiazepines. Concern regarding the adverse effects of benzodiazepines was raised with reports of confusion, bizarre behaviour and amnesia associated with the use of triazolam; it was eventually withdrawn from the market in countries such as Norway, Denmark, Brazil and the United Kingdom.

Dependence on these medications is an important consideration and may explain the finding in our meta-analysis of a lower discontinuation rate among patients taking benzodiazepines than among those on placebo, despite a lack of evidence of clear-cut benefits. Unfortunately, studies that have demonstrated adverse effects generally employed a different design (cohort, case-control) and sampled different patient groups (older, often with comorbidity) than those in smaller controlled trials. These differences, plus a lack of any global measure of benefit:risk in any of these studies, make it very difficult to either condemn or endorse the use of benzodiazepines with any confidence.

A further difficulty in evaluating the appropriateness of
bendazepine use is its indication for use. Insomnia is a symptom rather than a disease, is highly prevalent in society and may be related to an underlying condition. Without better tools, such as sleep-related quality-of-life scales and objective measures of sleep deprivation, it is difficult to judge the impact of insomnia on people’s everyday lives. Even if those with insomnia judge their lives to be significantly impacted by their condition, the differentiation between age-related physiologic change and treatable pathology can be difficult.

The paucity of nonpharmacological comparison trials is disappointing given the concern about the adverse effects of benzodiazepines, the potential for tolerance, and the potential for rebound insomnia when the drugs are taken irregularly. There is a clear need for further research in the area of nonpharmacological interventions. The research that is available does indicate that cognitive behavioural therapies should be preferred over benzodiazepines. This will require an educational effort with physicians.

The difficulty in making strong evidence-based recommendations is heightened by the lack of a safe and superior drug alternative to treat insomnia. The current “common sense plus evidence” approach, which will be presented in the Canadian guideline on the use and safety of benzodiazepines in the treatment of anxiety and insomnia in an upcoming issue of *CMAJ*, highlights the lack of strong evidence of major benefits and the existing evidence for potential harm. Benzodiazepines should only be tried after sleep hygiene and nonpharmacological manoeuvres have been considered. For physicians faced with the rare patient where other treatments have been exhausted and they feel they must prescribe a benzodiazepine, the drug should be discontinued within 2 to 4 weeks because it is unlikely to remain effective in the long-term.

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References


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