INBRIEF | Summarizing the Evidence

Clinical Evaluation of Interventions for the Management of Insomnia

Key Messages

- The comparative effectiveness and safety of drug or non-drug interventions versus other drug or non-drug interventions for the management of insomnia is unclear.
- Cognitive behavioural therapy for insomnia appears to be effective in improving sleep outcomes and likely has minimal harm.
- Short-duration treatment (i.e., treatment that is typically less than or equal to 16 weeks) with zolpidem, triazolam, and doxepin appear to improve sleep outcomes. The long-term effectiveness and safety of these interventions is unknown.

Context

Insomnia is a sleep disorder characterized by dissatisfaction with sleep quantity or quality, difficulty falling asleep, maintaining sleep, or early morning awakening. It can be acute (i.e., lasting less than three months) or chronic in nature. Approximately 40% of Canadian adults 18 years of age and older report at least one symptom of insomnia three times per week, and about 13% of the general Canadian population meet the criteria for an insomnia disorder. Persistent insomnia can have negative effects such as problems with attention, and memory and mood disturbances; it can impact relationships; and it can affect a person's ability to work or carry out normal daily activities. Insomnia may be a risk factor for other mental health disorders.

Technology

Both drug therapies and non-drug (psychological and behavioural) therapies have been used in the management of insomnia, either alone or in combination. Many hypnotic and sedative medications are indicated for the treatment of insomnia including benzodiazepines (e.g., temazepam, bromazepam); "Z-drugs" (e.g., zopiclone, zolpidem); and doxepin, a sedating antidepressant. There are other medications commonly prescribed for insomnia despite not being approved for use for the condition (e.g, quetiapine, trazodone, and anxiety-reducing benzodiazepines). An example of non-drug therapy for insomnia is cognitive behavioural therapy for insomnia (CBT-I), which is a multimodal intervention combining many techniques (e.g., sleep restriction, relaxation training, sleep education) and can be delivered in many formats (e.g, online, in person, self-guided).

Issue

Medications for insomnia can be easily accessed and are widely reimbursed by public and private payers. They are commonly used for longer durations than indicated and have known associated adverse effects (e.g., dependence, morning sedation). CBT-I is considered generally safe and is recommended as a first-line therapy by clinical practice guidelines; however, its availability in Canada is limited and it can be expensive for individuals, as it is not routinely covered by insurance. A review of the clinical effectiveness, comparative effectiveness, and safety of drug and non-drug interventions in patients with insomnia will help guide treatment decisions for this patient population.

Methods

A review of systematic reviews (SRs) was conducted to assess the clinical effectiveness, comparative effectiveness, and safety of the interventions for insomnia. The quality of the reviews was determined using the A MeaSurement Tool to Assess systematic Reviews (AMSTAR) 2 tool. An analysis of current prescriber practice and a report of patients' and caregivers' perspectives and experiences were conducted separately.

Results

The literature search identified 64 SRs that met the criteria for inclusion in this review, 35 of which included a meta-analysis (SR+MA). A meta-analysis is a method for combining data from multiple studies into a single estimate or result, which is a statistical way of integrating the findings from multiple sources. SRs included data for 11 different drugs and eight different non-drug interventions. Nine effectiveness and seven harms outcomes were assessed.

The review came to the following conclusion based on comparisons among different interventions:

- Because of limited moderate or high-quality comparative data, this review could not conclude if any drug or non-drug intervention was more effective compared with other drug or non-drug interventions. More high-quality research is needed to assess comparative efficacy and safety.

The review came to the following conclusions based on the comparison of an intervention to an inactive control (i.e., those who received no treatment or a placebo):

- CBT-I (alone or combined with other non-drug interventions) and multi-component behavioural therapy demonstrated improvement in more than one sleep outcome compared with inactive controls across moderate or high-quality SRs+MAs. These non-drug measures are expected to have infrequent and non-serious harms, if any at all.
- Short durations (less than or equal to 16 weeks on average) of zolpidem, triazolam, and doxepin improved more than one sleep outcome in adults with insomnia when compared with placebo, based on moderate or high-quality SR+MAs.
- All other medications assessed impacted one or zero sleep outcomes compared with placebo, based on moderate or high-quality SR+MAs.
- There is an absence of robust safety data for drug interventions, including serious harms such as mortality. Long-term effectiveness and safety data for drug interventions is unknown because of the lack of trials extending beyond 16 weeks. More research is needed to assess long-term effectiveness and the safety of drug interventions for insomnia.

It should be noted that the clinical significance of observed improvements in insomnia symptoms is poorly understood and lacks definition, resulting in the inability to interpret the meaningful impact of sleep outcomes in patients. Comparing the intervention to inactive control does not allow for the determination of which intervention is the most effective. Additional comparative data are required to make that determination. There is limited data on interventions for insomnia in specific populations, such as the elderly. Also, in the SRs reviewed, there were few or no comparisons on dose or method of administration among interventions. Not all efficacy and safety outcomes were assessed in each review and more than 50% of included SRs were of low or critically low quality. Therefore, the results of this review should be interpreted with caution.

The bottom line: CBT-I appears effective, with expected minimal harm. A few drugs (zolpidem, triazolam, and doxepin) appear effective in the short term (less than or equal to 16 weeks), with unknown long-term effectiveness or safety.

Read more about CADTH and its review of interventions for insomnia at:

https://cadth.ca/interventions-insomnia-disorder

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