When is medication appropriate for chronic insomnia?

Evidence-Based Answer

Medications are an appropriate second-line treatment if a behavioral intervention is not effective and any comorbid conditions, medications, or substances that might interfere with sleep have been identified and addressed (SOR **C**, based on expert opinion).

A 2008 evidence-based guideline was developed by a panel of sleep medicine experts convened by the American Academy of Sleep Medicine (AASM). The panel reviewed existing AASM practice parameter papers (each based on a systematic literature search) and obtained additional evidence through a Medline search from 1999 to 2006.[1] The guideline recommends that initial treatment of insomnia should include at least 1 behavioral intervention, based on a level of evidence (LOE) designated as "standard," and that cognitive behavioral therapy (CBT) should be used alongside long-term pharmacotherapy when possible, based on an LOE designated as "consensus."

- A "standard" LOE is defined as "a generally accepted patient-care strategy that reflects a high degree of clinical certainty. The term *standard* generally implies the use of Level 1 Evidence, which directly addresses the clinical issue, or overwhelming Level 2 Evidence."[1]
- A "consensus" LOE denotes the opinion of the expert panel when evidence is limited or inconclusive.

Other recommendations when considering treatment of insomnia that are not assigned a specific LOE include treating comorbid conditions such as depression and chronic pain, addressing caffeine and alcohol use, and considering current medications that may impair sleep.

The short-term efficacy of behavioral therapy was shown to be slightly better than pharmacotherapy in a meta-analysis comparing 14 studies (250 participants) of stimulus control and sleep restriction therapies with 8 studies (220 participants) of benzodiazepine and benzodiazepine receptor agonists.[2] English language studies of chronic, primary insomnia were found through Medline and psycINFO searches from 1966 to 2000. The weighted effect size for improvement in sleep latency in studies of behavioral therapy (1.05) was significantly larger than in studies of pharmacotherapy (0.45, P=.01). (An effect size of 0.2 is considered small, 0.6 moderate, and 1.2 large.) Otherwise, total sleep time, number of awakenings, sleep quality, and wake time after sleep onset were similar.

Three subsequent randomized controlled trials including 46 to 77 participants have directly compared CBT with zolpidem,[3] zopiclone,[4] or temazepam,[5] and have shown superior long-term efficacy with CBT. Adults with chronic, primary insomnia were randomized to CBT, pharmacotherapy, or placebo for 6 to 8 weeks and then followed for 6 to 12 months. Two of the studies also included a combined CBT and pharmacotherapy treatment arm,[3,5] and 1 of the studies allowed patients randomized to pharmacotherapy to continue treatment through the 6-month follow-up.[4] Only 1 of the studies reported intent-to-treat analysis.[4]

In the first study, CBT and combination therapy both showed a significant 52% reduction in self-reported sleep-onset latency at the end of treatment, compared with a 14% reduction with pharmacotherapy (P=.003).[3] These changes persisted at the 1-month follow-up with CBT, but not with combination therapy.[3]

In the second study, CBT was significantly better than pharmacotherapy for decreasing self-reported total wake time at the 6-month follow-up (51% vs 27% decrease, P=.03).[4] In the last study, self-reported sleep-onset latency with pharmacotherapy and combined therapy was significantly better than with CBT at the end of treatment (73%, 75%, and 54% reductions, respectively), but after treatment the CBT group continued to improve and the other groups worsened. At the 8-month follow-up, CBT had a significantly better 61% reduction, compared with a 28% reduction with pharmacotherapy (P<.001).[5]

Nam Ho, MD
Thomas Satre, MD
U of MN/St. Cloud Hospital FMR
St. Cloud, MN

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