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FPIN's Clinical Inquiries

Medications for Insomnia Treatment in Children

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Clinical Question

Are there safe and effective medications for the treatment of insomnia in children?

Evidence-Based Answer

Melatonin may be effective for treating insomnia in healthy children and in those with physical or learning disabilities (Strength of Recommendation [SOR]: B). Short-term use of melatonin is safe in children, but there is insufficient evidence to evaluate its long-term effects and optimal dosage (SOR: B).

Diphenhydramine (Benadryl) is no more effective than placebo (SOR: B). The safety and effectiveness of benzodiazepines and newer hypnotic agents in children with insomnia have not been studied.

Evidence Summary

Insomnia that is associated with delayed sleep onset and sleep maintenance problems has been reported in as many as 10 percent of healthy children and in even higher rates in children with physical and emotional disabilities.¹ There is limited evidence regarding the effectiveness and safety of pharmacologic agents for sleep promotion in children.

Several researchers have studied the effectiveness of melatonin in healthy children. These studies had small numbers of participants (27 to 62 children) and varied in the measurements used to assess improvements in sleep. One four-week, randomized, double-blind, placebo-controlled trial of 38 healthy children six to 12 years of age found that 5 mg of melatonin taken at 6 p.m. improved sleep onset compared with placebo (14 versus 63 minutes; $P < .05$) and total sleep time (+41 versus +4 minutes; $P < .05$). Lights-off time was 34 minutes earlier in the melatonin group versus eight minutes earlier in the placebo group ($P < .05$). No significant differences were seen in sleep latency (amount of time between going to bed and falling asleep) or wake-up time.² Another four-week randomized controlled trial (RCT) of 62 Dutch children six to 12 years of age showed that 5 mg of melatonin at 7 p.m. advanced sleep onset by 57 minutes, advanced wake-up time by nine minutes, and decreased sleep latency by 17 minutes compared with placebo ($P < .05$).³

There have been fewer studies in children with physical or emotional disabilities. One RCT of 27 Indian children three to 12 years of age who were receiving sodium valproate monotherapy for epilepsy showed

that 6 to 9 mg of melatonin given one hour before bedtime for four weeks significantly improved the total sleep score as measured by the Sleep Behavior Questionnaire compared with placebo⁴; however, there were no significant effects on daytime drowsiness scores or sleep fragmentation scores. Another RCT of 27 children six to 14 years of age with stimulant-treated attention-deficit/hyperactivity disorder who had not responded to sleep hygiene intervention showed that 5 mg of melatonin administered 20 minutes before bedtime over 30 days significantly improved sleep latency, decreasing it from 62.1 minutes with placebo to 46.4 minutes with melatonin ($P < .05$).⁵

Short-term use of melatonin is thought to be safe. Adverse effects seen with four weeks of treatment included headache, chills, decreased appetite, and dizziness, all of which resolved during the first week.³ Long-term safety of melatonin is unknown.⁶ One child developed epilepsy after four months of treatment with melatonin; however, the child was then started on sodium valproate and continued on melatonin without any further seizures.²

We found no studies addressing the use of benzodiazepines or newer hypnotics (e.g., zolpidem [Ambien]) for children with insomnia. In the only RCT on diphenhydramine, 44 children six to 15 months of age were given 1 mg per kg of diphenhydramine 30 minutes before bedtime for one week, with follow-up at two and four weeks. The study showed that diphenhydramine was no more effective than placebo at reducing nighttime awakening or improving overall parental happiness with their child's sleep.⁷

Recommendations from Others

The American Academy of Pediatrics and the National Sleep Foundation recognize that there are inadequate data to guide pharmacologic treatment of insomnia in children.⁸

Clinical Commentary

This review is interesting, given the lack of information on insomnia in children. My initial thought when I see a child with insomnia is to determine the amount of caffeine or other dietary stimulants the child is ingesting, as well as whether there is a calming and consistent bedtime routine in place. It is concerning that pharmacologic solutions are so often sought for dietary or parenting deficiencies. That being said, it is useful to know that there may be some evidence supporting the use of melatonin for those parents who feel that their child may need medication. I also find it helpful to know that diphenhydramine is not effective for treating insomnia. In my experience, treatment with diphenhydramine has often had the opposite desired effect and led to even more parental dismay.

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