Pharmacologic or behavioural therapy for elderly people's insomnia

Which is better?

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Morin CM, Colecchi C, Stone J, Sood R, Brink D. Behavioral and pharmacological therapies for late-life insomnia. A randomized controlled trial. *JAMA* 1999;281:991-9.

Research question

How effective are behavioural and pharmacologic therapies alone, or in combination, for treating elderly people's insomnia?

Type of article and design

Eight-week randomized placebo-controlled clinical trial with follow up conducted at 3, 12, and 24 months after treatment.

Relevance to family physicians

Sleep disturbance is very common among elderly people. Between 12% and 25% of healthy seniors report chronic insomnia with a higher prevalence among those with coexisting medical or psychiatric illnesses.[1] Insomnia, the most common sleep disorder, can involve trouble falling asleep, frequent or prolonged wakening at night, or wakening in the early morning and not being able to return to sleep.[2] If left untreated, chronic insomnia can increase risk of depression and, in elderly people with cognitive impairment, could hasten nursing home placement. Only about one in six seniors with insomnia receive treatment, and most of these are prescribed drug therapy. Short-term hypnotic therapy is both useful and indicated for acute insomnia, but there is little evidence on its long-term efficacy or whether changes in sleep are maintained when drug therapy is stopped.

Evidence indicates that seniors could be receiving a disproportionate number of prescriptions for sedative hypnotics.[3] Evidence also indicates increased risk of falls, hip fractures, and motor vehicle accidents among seniors taking these medications. Good evidence suggests that behavioural therapy is effective treatment for insomnia, yet it is underused by primary care physicians. Few studies have compared the efficacy of drug and behavioural therapy for insomnia. This study was designed to compare the separate and combined effects of behavioural and pharmacologic therapy for elderly people's insomnia.

Critical Appraisal reviews important articles in the literature relevant to family physicians. Reviews are by family physicians, not experts on the topics. They assess not only the strength of the studies but the "bottom line" clinical importance for family practice. We invite you to comment on the reviews, suggest articles for review, or become a reviewer. Contact Coordinator Michael Evans by e-mail michael.evans@utoronto.ca or by fax (416) 603-5821.

Overview of study and outcomes

Patients aged 55 and older were recruited through newspaper ads and letters to primary care physicians and were included in the study if they had sleep-onset or maintenance insomnia at least 3 nights weekly, had insomnia lasting at least 6 months, and complained of at least one negative effect during waking hours (eg, fatigue, impaired functioning, mood disturbance). Patients were excluded if their insomnia was directly related to a medical disorder or the adverse effects of a medication, if they had sleep apnea or periodic limb movements during sleep, if they regularly used hypnotic or other psychotropic drugs and were unable or unwilling to discontinue them, if they had a major depression or other severe psychopathologic condition, and if they were cognitively impaired as indicated by a Mini-Mental State Examination score lower than 23.

Patients enrolled in the study were randomly assigned to either cognitive behavioural therapy (CBT); pharmacotherapy (PCT), combined CBT and PCT, or placebo. All participants kept daily sleep diaries for 2 weeks before treatment, during the 8 weeks of treatment, and for 2 weeks before each of the follow-up appointments (3, 12, and 24 months). All subjects had 3 consecutive nights of sleep and laboratory evaluation both before and at the end of treatment. Outcome measures were based on the average of pretreatment nights 2 and 3 and post-treatment nights 5 and 6. Finally, all subjects completed a Sleep Impairment Index, a 7-item scale that provides a quantitative index of the severity of insomnia.

Those receiving CBT were divided into groups of four to six. Subjects attended eight

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90-minute therapy sessions weekly. Treatment was a structured multifaceted intervention involving behavioural, cognitive, and educational components aimed at various facets of late-life insomnia. The components were very well described in the Methods section of the paper. Pharmacotherapy was temazepam (Restoril) taken 1 hour before bedtime. Initial dose was 7.5 mg/night, gradually increased to a maximum of 30 mg based on treatment response and adverse effects. Subjects were instructed to use medication 2 to 3 nights per week, but the medication was available 7 nights if they wished to use it.

Subjects in the placebo group were treated according to a protocol identical to the group receiving the active medication. Subjects in the placebo group were offered active treatment after completing the 3-month follow up.

Results

Of 163 subjects recruited for initial screening and baseline assessment, 78 were eligible for the study and were randomized into the four treatment arms; 71 completed the protocol. There were no significant differences between those who withdrew and those who completed the study, and subjects in the four treatment arms were essentially similar.

The investigators compared sleep diary data (waking after sleep onset, sleep efficiency, total waking time, and total sleep time), polysomnography results, and Sleep Impairment Index scores before and immediately after treatment. All three treatment groups had significant improvements compared with the placebo group according to sleep diary data (less total waking time, improved sleep efficiency, less waking after sleep onset) and polysomnography results (less waking after sleep onset, better sleep efficiency, less total waking time, and increased total sleep time after treatment).

Perhaps the most important outcome assessed was self-rating for sleep quality, which was incorporated into the Sleep Impairment Index. Subjects in the CBT and combined groups rated themselves as significantly more improved (and less impaired) than subjects in either the PCT ($P = .01$) or placebo ($P = .002$) groups. Patients in the combined and CBT groups were more satisfied, were less distressed, and felt less impaired in daytime functioning than patients in the PCT or placebo groups ($P < .05$ for all). Comparisons of the ratings of subjects' significant others showed that all three active treatment groups were perceived as more improved than control subjects ($P < .05$ for all).

Since polysomnographic assessment was conducted only at baseline and immediately after 8 weeks' treatment, the 3-, 12-, and 24-month follow ups were based on sleep diary data only. For the CBT group, there were no significant changes on any of the sleep variables (total waking time, waking after sleep onset, and sleep efficiency), suggesting improvements achieved after 8 weeks' therapy were well maintained. For the PCT group, there was significant worsening on all these parameters between the 8-week post-treatment period and the 24-month follow up ($P = .04$ for total waking time; $P = .03$ for sleep efficiency; $P = .03$ for waking after sleep onset). For combined therapy, there was significant deterioration at 3, 12, and 24 months for all three parameters ($P < .05$ for all).

The investigators examined the clinical significance of the various treatments using the proportion of individuals reaching >85% sleep efficiency. This value is used to distinguish normal from clinically impaired sleep. Proportion of subjects meeting this criterion 8 weeks after treatment assessment were 55.6% for CBT, 47.1% for PCT, 68.4% for combined therapy, and 22.2% for placebo.

Bottom line

- This well designed study shows that cognitive behavioral therapy (CBT) is at least as effective as pharmacotherapy for short-term treatment of insomnia and is more effective in the long term.
- Pharmacotherapy is effective and safe treatment for acute, situational insomnia, but is less effective than CBT for chronic insomnia.
- Some risks are associated with elderly people's long-term use of benzodiazepine hypnotics, including increased risk of falls, hip fractures, and motor vehicle accidents.
- Where available, family physicians should strongly consider referring their motivated elderly patients with chronic insomnia for CBT.

Points saillants

- Cette étude bien conçue démontre que la thérapie cognitivo-comportementale (TCC) est à tout le moins aussi efficace que la pharmacothérapie dans le traitement à court terme de l'insomnie et se révèle plus efficace à long terme.
- La pharmacothérapie est un traitement sûr et efficace pour l'insomnie aiguë situationnelle, mais s'avère moins efficace que la TCC pour l'insomnie chronique.
- Certains risques sont associés à l'usage à long terme des hypnotiques à la benzodiazépine chez les personnes âgées, notamment le risque de chutes, de fractures de la hanche et d'accidents d'automobile.
- Lorsque c'est possible, les médecins de famille devraient considérer fortement l'orientation vers une TCC de leurs patients âgés souffrant d'insomnie chronique qui sont motivés à la suivre.

Analysis of methodology

Double blinding was not possible in this study. Bias was reduced by blinding those analyzing sleep diary and polysomnographic data to subjects' treatment. Treatment groups were well described, including treatment of the CBT group, which would allow physicians to duplicate the intervention and adopt elements of it into their practices. The main limitations of the study are that subjects were predominantly white and well educated and that recruitment was not from a primary care setting. This makes it difficult to generalize results to primary care settings.

Application to clinical practice

This study adds to the mounting evidence that CBT can be safe, effective, and durable treatment for insomnia in later life. Over the long term, CBT appears to be more effective therapy than hypnotic medication alone. Currently, primary care physicians use hypnotic medication more often than anything else. It is difficult, however, to generalize results of this efficacy study to primary care settings. The study was carried out at a single academic medical centre and subjects were recruited through newspaper ads and letters to physicians, rather than through family physicians' practices.

A serious concern with this study from a primary care point of view is that, while PCT is readily accessible to most physicians and their patients, CBT of the type described in this study is likely available only in larger centres. Furthermore, seniors must be highly motivated to participate in CBT programs and might have to bear the costs directly.

References

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