

CBT More Effective Than Zopiclone for Insomnia

BY JOHN R. BELL
Associate Editor

Cognitive-behavioral therapy led to greater improvements in a variety of sleep measures than did zopiclone in adults with insomnia, Norwegian researchers report.

Børge Sivertsen, Psy.D., of the University of Bergen, Norway, and his colleagues found in a randomized, double-blinded, placebo-controlled trial that among older patients randomly assigned to CBT, sleep efficiency, total wake time, and duration of slow-wave sleep were all significantly more improved by 6 weeks and 6 months than were patients taking zopiclone (JAMA 2006;295:2851-8).

A total of 45 patients enrolled from a Norwegian clinic received either CBT (18 patients), zopiclone (15 patients), or a placebo (12 patients). The mean age of the patients was 61 years.

Sleep measures were assessed at 6 weeks, which was the end of the treatment protocol. These measures were also assessed at 6 months, via polysomnography (PSG) and patient-reported sleep diaries filled out each morning for 2 weeks, at baseline, and at the two subsequent assessment points.

At 6 weeks, PSG data showed that subjects on CBT had a mean 52% improvement in total wake time, which rose to 56% at 6 months; those on zopiclone had a 4% and 10% improvement, respectively. Diary-reported data showed that the subjects believed the efficacy of both treatments to be even greater, with self-reported wake-time reductions in the CBT group of 34% and 51% at the two time points, and 16% and 27% for the zopiclone group.

Similarly, mean sleep efficiency, the ratio of total sleep time to time spent in bed multiplied by 100, improved by 9% and

11% at 6 weeks and 6 months, as assessed by PSG. The investigators found that efficiency actually decreased by 1% at both points among the zopiclone group. PSG-measured time spent in slow-wave sleep was improved by a mean of 34 minutes by 6 months in the CBT group, versus a loss of 23 minutes at 6 months in the zopiclone group.

Total sleep time as assessed via PSG actually decreased among both groups (and in the placebo group), even though the

participants recorded improvements in their diaries. However, none of these data reached statistical significance.

"We found that CBT was more effective immediately and long-term, compared with both zopiclone and placebo in older adults with chronic primary insomnia," the investigators concluded. This finding comes despite the clinical dominance of medications to treat insomnia in primary care, they noted.

The CBT arm underwent five treat-

ment modules. Sleep hygiene education addressed exercise, diet and alcohol use, and environmental factors conducive to sleep. Sleep restriction imposed a schedule of when a patient could be in bed. The stimulus control module restricted bedroom activities to those compatible with sleep. The therapy addressed patient beliefs and fears about sleep, and the progressive relaxation techniques aimed to teach patients to control muscular tension via exercises. ■

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selectivity for inhibiting only MAO-B—not MAO-A—in humans, and a sensitivity to tyramine during treatment with rasagiline at any dose have "not been sufficiently characterized to avoid restriction of dietary tyramine and amines contained in medications."

Dr. Litvan was not involved in clinical trials of the drug, and has no ties to the manufacturer, other than having received an education grant. Several of her patients who acquired the drug in Europe or Israel have done well on it, she said.

The FDA is also recommending that patients on the drug be checked regularly for signs of melanoma because people treated with rasagiline during its development were diagnosed with melanoma at a rate greater than that seen in the general population. However, the risk was comparable to that seen in some epidemiologic studies of Parkinson's patients; at this point, whether the greater melanoma rate is a result of the disease or the drug treatment is unclear. Teva will evaluate the relative risk of melanoma in a 6-month postmarketing study of rasagiline added to standard treatment in about 5,000 patients. ■

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