Sleep Diagnosis and Therapy Vol 7 No 7 November 2012, Russell Rosenberg

Insomnia: All About Awareness

Sleep apnea may capture more headlines these days, but sleep veteran Russell Rosenberg, PhD, points out that every good sleep center can capture the full slumber spectrum with a serious focus on insomnia.

It's not easy to find a clinical psychologist and board certified sleep specialist with more than 25 years experience in the sleep world. Russell Rosenberg, PhD, director and CEO, NeuroTrials Research, and Atlanta School of Sleep Medicine, fits that rare description and brings his considerable experience to international courses on a range of sleep medicine topics—including the occasionally neglected realm of insomnia.

The National Sleep Foundation estimates that about a third of Americans have symptoms of insomnia. It's a massive number, but it should not be confused with the disorder of insomnia. "Everybody has an occasional night of sleeplessness, or occasionally can't get back to sleep," says Rosenberg, who also serves as chairman of the National Sleep Foundation. "But that number does not represent the number of Americans who meet the criteria for a diagnosis of insomnia. About 6% of adults have diagnosable primary insomnia based on strict criteria from the Diagnostic and Statistical Manual of Psychiatric Disorders (DSM IV-TR)."

Insomnia has been a primary focus of Rosenberg's clinical work, along with research and teaching. Rosenberg has seen many insomnia patients who simply did not realize the sheer amount of available treatments.

Worse yet, far too many walking around with the disorder have yet to be evaluated, much less treated. Many sleep disorder centers do not have enough staff who feel comfortable treating insomnia. The situation is caused by an emphasis on sleep apnea, but Rosenberg maintains that sleep centers can successfully treat both disorders. After all, "There are far more people who have insomnia than who have sleep apnea," says Rosenberg.

Primary Care Practioners First Line of Defense

Primary care physicians (PCPs) are still the first line of treatment for most sleep disorders, including insomnia. Rosenberg does not necessarily have a problem with this phenomenon, but he points out that PCPs are more likely to be medically focused, and less likely to use behavioral approaches.

"Not every sleep center has someone who can provide cognitive behavioral therapy (CBT) for insomnia," he says. "I want more primary care providers to recognize poor sleep in their patients as a serious health problem—whether it be sleep apnea or insomnia—and whether the treatment is medication, a medical device, or behavior therapy."

Most of the time, says Rosenberg, PCPs will tend to prescribe a hypnotic or sleeping agent of some sort for insomnia. While these medications can be used long term, they can have side effects. Psychologically-based behavior treatments are also valid, but their use usually depends on the PCP establishing solid sleep center referral networks.

New Drug Fits "As Needed" Niche

The first and only FDA-approved drug for treating patients who have middle-of-the-night awakenings—and can't get back to sleep—was approved late last year. It's called Intermezzo, and Rosenberg is confident that the new offering can serve as a valid option for years to come.

Since most insomniacs do not have horrible sleep 7 nights a week, 365 days of the year, the new drug fits the "as needed" niche. "Previously, patients were given hypnotics in anticipation that they might not sleep well," explains Rosenberg. "When you wake up in the middle of the night, you can take Intermezzo only if you have 4 or more hours to remain in bed. It takes 4 hours to get it out of your system so it's safe to drive."

Administered under the tongue, the minty flavored tablet has a 3.5-milligram dose for men and 1.75 milligrams for women. "Drugs like intermezzo are not for everyone," cautions Rosenberg. "I don't think every insomnia patient should be on a sleeping pill. This is something that should be carefully considered by a patient's physician, whether it's a PCP or a specialist who has a lot of experience with these drugs. Remember that CBT has been shown to be quite effective—as effective as treatments with medications."

Too often, the problem is that CBT is not as widely available, largely because clinical psychologists and mental health professionals do not put in the time to study it. "Sleep specialists may do a more thorough evaluation to detect breathing disorders and movement disorders," adds Rosenberg. "They are more likely to use a combination approach of medication and CBT then PCPs. There are lots of sleep centers across the country that do have a specialist in CBT, but not all do at this point."

Where are the Insomniacs?

Why do sleep labs see so many apnea patients, but relatively few insomniacs? Rosenberg boils it down to the simple fact that insomniacs rarely, if ever, require a polysomnography. The American Academy of Sleep Medicine does not recommend the use of polysomnography as a routine evaluation for insomnia, and most insomniacs do not need a full sleep study.

Certainly there are those that are also suspected to have sleep apnea, but Rosenberg says these patients are not the "bread and butter" of sleep disorder centers. "If there is a sleep disorder center that wants to present itself as a full service center," he says, "it should have the capability, or at least a specialist for treating insomnia."

Rosenberg hopes the full spectrum approach will catch on nationwide, and he'll do his part to further that mission while he educates physicians in the clinical and basic science

of sleep medicine—and the therapeutic interventions for sleep disorders. "I'm also interested in is identifying an efficient way to integrate behavioral approaches with medication treatments for insomnia," muses Rosenberg. "In the last 15 years, there has been a tremendous amount of research on insomnia, but very few breakthroughs. The reason is that these things take time. We are in a bit of a lull in terms of advances—other than this new drug Intermezzo—which is probably the most exciting advance in at least the last 5 years."

Russell Rosenberg, PhD, D.ABSM, is the founder and director of the Atlanta School of Sleep Medicine and Technology. In addition to teaching, Rosenberg is actively involved in clinical research at NeuroTrials Research Inc. He currently serves on the board of directors of the National Sleep Foundation.

Intermezzo in Detail

According to the FDA, zolpidem tartrate (Intermezzo) was first approved in the United States in 1992 as the drug Ambien. Intermezzo is a lower dose formulation of zolpidem. The recommended and maximum dose of Intermezzo is 1.75 milligrams for women and 3.5 mg for men, taken once per night. The recommended dose for women is lower because women clear zolpidem from the body at a lower rate than men.

"For people whose insomnia causes them to wake in middle of the night with difficulty returning to sleep, this new medication offers a safer choice than taking a higher dose of zolpidem upon waking," said Robert Temple, MD, deputy center director for clinical science in the FDA's Center for Drug Evaluation and Research. "With this lower dose there is less risk of a person having too much drug in the body upon waking, which can cause dangerous drowsiness and impair driving."

Intermezzo was studied in two clinical trials involving more than 370 patients. In the studies, patients taking the drug had a shorter time to fall back asleep after waking compared to people taking an inactive pill (placebo). The most commonly reported adverse reactions in the clinical trials were headache, nausea, and fatigue.

Like other sleep medicines, Intermezzo may cause serious side effects, including getting out of bed while not fully awake and doing an activity that you do not know you are doing or do not remember having done. Reported activities while under the influence of sleep medicines include driving a car, making and eating food, having sex, talking on the phone, and sleep walking—without knowing at the time or remembering later.

For additional information, please read the Intermezzo Full Prescribing Information available at http://app.purduepharma.com/xmlpublishing/pi.aspx?id=i