Abundance of Insomnia Therapies in the Pipeline

BY BRUCE JANCIN  Denver Bureau

DENVER — The pharmaceutical industry envisions the insomnia market as a field of dreams, judging by the sizable array of agents moving through the developmental pipeline.

And there aren’t “me-too” drugs, either. They involve a wealth of new therapeutic targets and novel mechanisms of action.

“This is an exciting time in insomnia. There’s a lot of movement in terms of how people are conceptualizing the problem clinically, there are new treatments coming up, and I think we’re really going to have some better options for our patients in the near future,” Daniel J. Buysse, M.D., said at a satellite symposium held with the annual meeting of the Associated Professional Sleep Societies.

The opportunity for new agents to make a big splash stems from the fact that insomnia is extremely common, with 6% of the population, by some estimates, meeting formal diagnostic criteria for the disorder.

In addition, although numerous drugs are commonly prescribed off label for insomnia, the benzodiazepine receptor agonists and the newly approved melatonin receptor agonist ramelteon (Rozerem) are the only medications with Food and Drug Administration approval for this indication.

And only two agents—the benzodiazepine receptor agonist eszopiclone (Lunesta) and ramelteon—are approved for long-term use. The rest of the benzodiazepine receptor agonists carry an indication for a maximum of 30 days of use or less, a restriction frequently ignored in clinical practice.

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Dr. Buysse offered his own suggested approach. It begins with behavioral measures: Restrict time in bed, set a regular wake-up time, don’t go to bed until sleepy, and don’t stay in bed when unable to sleep.

“I treat a lot of patients with medication, but I always spend some time on behavioral approaches as well,” the psychiatrist stressed.

His first-line pharmacotherapy, used in combination with behavioral measures, is a short-acting benzodiazepine receptor agonist. If the patient still wakes up too early, he’ll switch to one with a longer half-life.

His second-line therapy is low-dose trazodone, oxazepam, or amitriptyline. Third-line therapy, reserved for desperate cases, is gabapentin or tiagabine.

One of the few situations where he doesn’t use a benzodiazepine receptor agonist as first-line therapy is in patients with a history of substance abuse. “Although there are very few true benzodiazepine addicts out there, I just don’t feel that lucky. So if I know that a person has a history of alcohol abuse, I’ll start with something else,” he said.

Dr. Buysse said he prefers to treat insomnia with combined medical or anxiety with separate medications—usually a benzodiazepine receptor agonist and a selective serotonin reuptake inhibitor—that causes the disorders often don’t follow the same time course.

Dr. Buysse is a consultant to Sepracor Inc., sponsor of the satellite session, as well as to numerous other pharmaceutical companies.

Home Diagnosis of Obstructive Sleep Apnea: Far from Costly

BY BRUCE JANCIN  Denver Bureau

DENVER — Home ambulatory peripheral arterial tonometry is an accurate, convenient, and far less costly alternative to polysomnography in the sleep laboratory for diagnosis of obstructive sleep apnea, Donald Townsend, Ph.D., said at the annual meeting of the Associated Professional Sleep Societies.

He reported on 103 consecutive patients who presented to a sleep clinic with symptoms suggestive of obstructive sleep apnea.

The patients were randomized to receive overnight home peripheral arterial tonometry (PAT) or standard polysomnography in the sleep clinic, Dr. Townsend reported.

Test results were available the next morning, and the 86% of patients who were in each study arm who were diagnosed with obstructive sleep apnea then received continuous positive airway pressure.

The cost of diagnosis was $653 per patient in the PAT group, compared with $2,181 in the polysomnography group, according to Dr. Townsend, who is with the Metropolitan Sleep Disorders Center, St. Paul, Minn.

Obstructive sleep apnea was deemed sufficiently severe in eight patients, based upon PAT results that they required confirmatory testing via polysomnography, which is considered the standard for diagnosing the disorder.

In a follow-up survey, patients in both study groups indicated a high degree of satisfaction with the testing procedures.

At 8 weeks, patients in both groups showed similar significant improvements in scores on the Epworth Sleepiness Scale and Beck Depression Inventory.

PAT measures changes in peripheral arterial tone in response to bursts of sympathetic nervous system activity.

The spikes in sympathetic activity are triggered by arousals from sleep as a result of apneic episodes. PAT is recorded using a device worn on the wrist.

A practical obstacle to wider diagnostic use of PAT is that insurance coverage for the ambulatory test is mixed.

Many insurers continue to be reluctant to reimburse for anything other than overnight polysomnography in the sleep laboratory, although this situation is changing in light of the significant cost savings obtained with PAT, Dr. Townsend explained.

Dr. Townsend’s study received no external funding.

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