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INSOMNIA & *Chronic Pain*

2:30 AM

- Exploring Link Between Pain and Sleep
- Guides to Treating Your Patient's Insomnia

- Editorial Board Outlines Strategies for Getting Patients to Sleep

PPM Editorial Board Outlines Management Strategies for Chronic Pain Patients With Insomnia

Educate, Then Let Patient Choose

C. Norman Shealy, MD, PhD
Fair Grove, MO

As with all medical problems, I list the best options I see and then let the patient choose. Here are some of the measures typically discussed:

- 1. No caffeine after 3 p.m., and no alcohol within 3 hours of sleep.** This may seem obvious, but it is important to review with patients because caffeine and alcohol abuse are so common: Excess caffeine is seen in more than 50% of patients with chronic pain, and alcohol abuse is present in 15% to 20%.
- 2. Dietary supplements.** I often recommend timed-release melatonin plus 0.5 g of taurine and 20 mg of lithium orotate (a salt of orotic acid and lithium). Regarding melatonin, only timed-release melatonin seems of use. I have patients begin with 1 mg just before bed. They may increase that dosage slowly up to 6 mg. Just today I had a patient who had gone up to 10 mg and was delighted with her response. Still, about 10% of patients do not experience a satisfactory response with melatonin, and non-timed-release formulations fail in a majority of patients.
- 3. Cranial electrotherapy stimulation (CES),** one hour each morning. CES devices deliver microcurrent levels of electrical stimulation directly to the brain and are used to treat anxiety, insomnia, and depression. To date, I have treated approximately 30,000 patients with the Liss CES device (now licensed to Fisher Wallace Laboratories). Used alone, the stimulator significantly reduces depression in 50% of patients. If I add the Shealy RelaxMate, a photostimulator, 85% of my patients with depression respond well. As noted, the CES device also is excellent for insomnia—but it needs to be used in the morning for that problem. Indeed, I prefer that patients not use the Liss device in the afternoon.
- 4. Acupuncture/acupressure stimulation.** There have been many studies done on this nonpharmacologic approach to treating insomnia. I recently completed

Editor's Note:

We recently surveyed our editorial board members and asked them what they recommend for the management of the chronic pain patient who complains of insomnia. What is your view on this topic? Let us know; please send comments to ppmeditorial@verticalhealth.com.

an unpublished study of an approach that seems to have promise: LifeWave Silent Nights acupuncture patches. These patches use a variety of modalities, including acupressure, to stimulate acupuncture points and enhance sleep. In the study, I saw an 88% improvement in length of sleep, with improved quality of sleep and decreased daytime sleepiness. I am currently completing a double-blind study with the patches, and those initial promising results appear to be holding up: So far, about half of the study subjects who have used these patches for a month have reported improved sleep.

Diet, Exercise, and Good Sleep Hygiene Are Crucial

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My approach is to first have a solid understanding of the physiologic basis of sleep disturbances in patients with chronic pain. Abnormalities in sleep are thought to disorder the processing of painful stimuli by the central nervous system (CNS). The CNS is capable of modifying the way it processes a variety of impulses (neuronal plasticity). These abnormalities can lower pain thresholds. Substance P levels in the CNS (not in serum) are higher in fibromyalgia patients, for example, than in control subjects.^{1,2} In patients with fibromyalgia, a condition that often has sleep disturbances as a comorbidity, these elevated levels of substance P may be associated with nonrestorative sleep, in which a disorder of serotonin metabolism results in musculoskeletal pain.

In terms of therapeutic interventions, I have had some positive experience with chlorpromazine, a drug that increases delta sleep and decreases patients' pain and tender points in fibromyalgia. But there are nonpharmacologic options as well. The use of nonoverexertional aerobic exercise, flexibility exercises, good dietary habits, avoidance of misuse of habituating medications, and regulation of sleep schedules are fostered in my clinic, with emphasis on interventional pain-modulating procedures and nonhabituating medications to control pain conditions.

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2. Vaerøy H, Helle R, Førre O, Kåss E, Terenius L. Cerebrospinal fluid levels of beta-endorphin in patients with fibromyalgia (fibrositis syndrome). *J Rheumatol*. 1988;15(12):1804-1806.

First, Diagnose the Problem

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Washington, DC

Control of chronic pain is difficult, if not impossible, without restorative sleep. First, determine if it is falling asleep, staying asleep, or getting back to sleep that is troublesome. Second, is “restless” sleep with daytime tiredness a problem? If so, that might imply sleep apnea. Third, consult an internist, psychopharmacologist, or “sleep clinic” for advice on control of sleep patterns and insomnia.

Behavioral Approach a Core Strategy

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First, you have to get the pain under control. From a behavioral perspective, I use relaxation augmented by biofeedback to teach patients to lower their arousal levels; this will lower their pain level and promote sleep. I have reviewed a number of sleep studies of patients with pain and found a predictable pattern of stage 1 and 2 sleep with no stage 3 and 4 or slow-wave sleep. The goal is to improve stages 3 and 4; that will have a positive effect on mood and pain and will result in less daytime fatigue. In terms of pharmacologic interventions, I would add a note of caution about prescription sleep aids; these medications can have a negative influence on REM sleep, which is important for both sleep and mood. A natural alternative that I recommend is extended-release melatonin, which helps regulate the sleep clock. If patients continue to awaken, I encourage them to try more relaxation

techniques, including self-hypnosis, to lower their arousal levels. I also recommend an additional small dose of melatonin 1 mg sublingual.

Editor’s note: For more of Dr. Olson’s views on sleep and chronic pain, see his editorial on page 46.

“Audio Drugs” and Other Alternative Methods for Enhancing Sleep

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Because we’re usually trying to reduce the amount of medications that our patients with chronic pain are taking, we begin with a trial of alternative approaches to determine if they can reduce sleep latency (the length of time between closing their eyes and entering stage 1 of sleep); increase sleep duration; minimally affect sleep architecture (little or no REM suppression); avoid nightmares, night terrors, and multiple awakenings; and minimize hangover effects the next morning. Only if these alternatives are ineffective do we use hypnotics, anxiolytics (especially the benzodiazepines), anti-seizure medications, antidepressants, and β -blockers. We never recommend opiates for insomnia.

Here are the three classes of alternative or complementary therapies that we have found most helpful to date:

Nutritional and Herbal Supplements

- L-tryptophan 500 mg every afternoon + 500 mg at bedtime (with low-dose niacin and pyridoxine). This is the amino acid precursor of serotonin, an important neurotransmitter for sleep. It is particularly effective when taken on an empty stomach and combined with niacin (a tryptophan pyrrolase inhibitor that prevents conversion of tryptophan to kynurenine) and pyridoxine (which facilitates the conversion of 5-HTP to serotonin).

GABA (g-aminobutyric acid) 500 mg every afternoon + 500 mg at bedtime. This is another neurotransmitter that is thought to be important for sleep. The benzodiazepines act on the GABA receptor, producing a significant reduction in sleep latency, anxiety, and muscle tension. Chronic administration of benzodiazepines, however, can ultimately convert insomnia with anxiety into even worse insomnia with depression. This does not tend to occur with long-term GABA supplementation.

- Dietary supplements. There are many over-the-counter products that contain melatonin, valerian root, hops, skullcap, chamomile, passionflower, l-taurine, calcium, magnesium, and a host of other ingredients. Surprisingly, we find that many are quite effective and can be used regularly without much concern about dependence, habituation, or tolerance.

Cranial Electrotherapy Stimulation

- Alpha-Stim (see www.alpha-stim.com). This cranial electrotherapy stimulation (CES) device generates a unique microcurrent through two ear clips attached to the patient’s earlobes. It has a rapid onset (less than a minute) and produces light sedation. The FDA has cleared Alpha-Stim for the treatment of insomnia, depression, and postoperative pain, and many of our patients report that it has helped with all three problems.
- Fisher Wallace (see www.fisherwallace.com). This CES device uses a headband to hold two electrodes in place over the temples. Cleared by the FDA in 1991 for the treatment of depression, anxiety, insomnia, and chronic pain, the device appears to increase the brain’s production of serotonin, GABA, and endorphins. About 70% of our patients with chronic pain who have used it for insomnia report significant benefits with sleep.

Guided imagery CDs, DVDs, and Other Alternatives

There are several other alternative therapies that may help improve sleep, including acupuncture, biofeedback, guided imagery, eye movement desensitization and reprocessing (EMDR), homeopathy, chiropractic, massage, Pilates, Reiki, and variety of other mind-body approaches. However, these are usually costly, labor-intensive interventions that most chronic insomniacs can't afford over a long period of time. For greater cost-effectiveness, we have developed and continue to use a variety of guided imagery CDs for reducing stress and anxiety, increasing pain tolerance, and for quieting the mind in order to invite restful sleep. We call them "audio drugs" and tell patients that their content is injected directly into their brains using headphones attached to their ears.

Nearly half of our patients with chronic pain who listen to our Restful Sleep CD at bedtime report that they have never heard what's on the end of the recording. We believe that the suggestions on these CDs modify brain chemistry to enhance sleep without the many complications that can arise from psychopharmacologic interventions. For more information about pain relief CDs, see www.breslercenter.com.

Cranial Electrical Stimulation A Safe, Effective Therapy

**Daniel L. Kirsch, PhD, DAAPM, FAIS
Mineral Wells, TX**

I use a number of different approaches to treat insomnia in my patients with chronic pain, but the modality that I've had the most experience with is CES. The procedure, which employs microcurrent levels of electrical stimulation delivered directly to the brain via transcutaneous electrodes, is simple: Ear-clip electrodes, moistened with an appropriate conducting solution, are applied at a comfortable current level for 20 minutes to an hour. Initially,

it should be used on a daily basis for a week or two, followed by a reduced schedule of two or three treatments a week until the insomnia is resolved, and then further reduced to an as-needed basis.

CES has achieved some of its most impressive results in military applications. The US Army, for example, uses CES for insomnia at many Army medical centers and currently has two major studies under way in the United States and Germany researching CES for sleep-related disorders. Colonel Kathy Platoni, chief psychologist for the US Army Reserves, stated, "I'm not surprised at that level of interest; CES has proved invaluable in my own practice and during my three overseas deployments in support of Operations Iraqi Freedom and Enduring Freedom. In the latter case, when productive sleep or any degree of sleep was elusive, Alpha-Stim CES was an extremely effective solution. In fact, when anxiety and panic prevented soldiers from being able to perform critical missions, the response to CES was rapid and entirely effective, acting as an unequivocal force multiplier. In the face of desperately depressed soldiers consumed with overwhelming misery and despair, the rapid and progressive effects of CES made it possible for these soldiers to perform their missions and to exceed standards and expectations."

The evidence for CES's safety and efficacy is considerable. In one recent survey of patients conducted by mail between 2006 and August 2011, 1,745 of 4,590 respondents provided adequate data for analysis.¹ Overall, 99.9% reported that they considered Alpha-Stim CES to be effective (ie, either yes or no) for their identified indication for its use. Respondents also were asked to rate their perceived improvement since beginning treatment. One percent of respondents reported complete recovery; 59%

reported having either moderate (50%-74%) or marked improvement (75%-99%) from baseline or starting treatment. Twenty-three percent of respondents reported only fair improvement, whereas 16% of respondents reported slight improvement. One percent reported no change. The final question asked was whether CES was more effective than anything else they had used for their reported indication; 36% of respondents reported that CES was more effective than anything else they had used for anxiety, 35% for pain, 17% for depression, and 11% for insomnia.

In a recent government study, veterans were trained in and offered use of five complementary/alternative care modalities at a walk-in pain clinic at the Michael E. DeBakey Veterans Affairs Medical Center Pain Management Program in Houston. Of the five choices, they chose Alpha-Stim CES 73% of the time and reported an overall improvement in their sleep of 54%.² As an added benefit, a paired t test indicated an average decrease of 1.02 units (standard deviation = 1.10) on the 0-to-10 Numerical Rating Scale of pain intensity during the study period ($P < 0.001$). Given the strong relationship between pain and insomnia, this finding is significant and bodes well for clinicians looking to offer patients relief of both conditions. In my view, it is absolutely worth a trial for patients with sleep-related disorders, especially to avoid polypharmacy effects in the typically medicated patient with pain.

For a complete review and meta-analyses of CES research for insomnia, see *Pract Pain Manage.* 2007;7(8):30-43. ■

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Cranial Electrotherapy Stimulation

The US Army is turning to cranial electrotherapy stimulation (CES) as a nonpharmaceutical way to help service members battle insomnia, among other ailments. “Our biggest customers in terms of sales outside of China are the US Army and Veterans Administration,” said Daniel L. Kirsch, PhD, chairman of Electromedical Products International, based in Mineral Wells, outside Fort Worth, Texas.

In CES, a low-level electrical current is delivered to the brain via transcutaneous electrodes, attached to the ears by clip electrodes, for up to an hour daily. Dr. Kirsch, who also is a member of the *PPM* Editorial Board, said the device works something like a tuning fork, seeking to activate relaxing alpha brain waves by sending out various electrical frequencies. The FDA allows the machines to be sold only with a prescription as a Class III medical device. Dr. Kirsch said that more than 50 studies have demonstrated the safety and efficacy of CES. He points to a pilot study at the University of North Texas that showed significant increases in alpha activity after a single 20-minute session of electrotherapy, which left users in an “alert yet relaxed” state.⁷

More studies are under way, including two by the US Army, which currently uses CES for treatment of insomnia at several of its medical centers. In a recent unpublished, Web-based survey conducted by Texas State University—San Marcos and Electromedical Products International, 72% of the 1,514 service members who were using Alpha-Stim, a CES device sold by Dr. Kirsch’s company, reported that their insomnia was improved to some degree.⁸

Acupuncture and Acupressure

Acupuncture involves the insertion of tiny needles into specific points of the body with the goal of improving health, whereas acupressure involves applying pressure to those areas. C. Norman Shealy, MD, PhD, president of Holos Institutes of Health, Fair Grove, MO, and a board member of *PPM*, recently conducted an acupuncture study on the treatment of insomnia using LifeWave patches. The patches are designed to stimulate acupuncture points using acupressure. Dr. Shealy said his small study of 25 individuals suffering from chronic insomnia found significant improvements in length and quality of sleep.⁹ “There’s a slight warming effect because the patches trap the heat from the skin. And you can certainly activate acupuncture points with heat,” said Dr. Shealy. “The nontransdermal patches also contain a small amount of amino acids that the company says reflect heat back into the body.”

Dr. Shealy said preliminary results of the double-blind study he completed in October showed that a year later, half of the study subjects who used the patches for a month were still sleeping well. The unpublished, noncontrolled trial is based primarily on patient-reported outcomes.⁹ “There’s not a drug in the world that works that well for that long—and with no complications,” he said.

More research is needed to prove the effectiveness of treating sleep disorders with acupuncture. According to a recent study, 10 systematic reviews of acupuncture used in the treatment of insomnia were published between 2003 and 2010. The report states, “The evidence...is plagued by important limitations, eg, the poor quality of most primary studies.”¹⁰

The Case for Sleep Medications

Dr. Spielman has his concerns about the effectiveness of acupuncture along

with other nontraditional sleep disorder treatments such as acupressure, energy medicine, and cranial stimulation. But he does not rule out the possibility that they may help. “There are small studies and anecdotal evidence in favor of the alternative treatments, so I don’t doubt they can be useful for some patients,” he said. But he is not convinced that their effectiveness will be proven anytime soon. “Drug companies spend millions developing a drug, so they have a stake in getting them to market. But these alternative approaches don’t have huge companies behind them to fund big studies,” he added. “So, at least for now, there just isn’t evidence that shows these approaches are as systematically effective as many sleep medications or CBT-I.”

As to the argument against some insomnia medications because they reduce REM sleep, Dr. Spielman said it’s irrelevant. “The end point is for the patient to regain the restorative value of sleep and functional capacity. That’s what I’m aiming for.” He pointed out that it is possible to mitigate some of the other negative side effects of sleep medications by taking a lower dose or taking them earlier at night to avoid the “hangover” effect the next day. And he pointed out a disadvantage of certain behavioral treatments, such as CBT-I—learning them can involve much time and effort. “If you need help tonight, drugs will work the fastest.”

Depending on the patient, Dr. Spielman recommended taking 2 to 3 mg of eszopiclone (Lunesta), 5 to 10 mg of zolpidem (Ambien), 2 to 6 mg of doxepin, or 15 to 30 mg of temazepam—either nightly or up to three times a week. He said that some patients benefit from long-term drug therapy, whereas others may need treatment for only a month before they’re able to sleep well again. (For a complete review of sleep medications, see page 48.)

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