

Medscape Conference Coverage, based on selected sessions at the:

American Association of Pain Management (AAPM) 20th Annual Clinical Meeting

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Sodium Oxybate Reduces Fibromyalgia Pain and Fatigue

Nancy A. Melville

October 27, 2009 (Phoenix, Arizona) — Sodium oxybate (*Xyrem*, Jazz Pharmaceuticals Inc.), a novel sleep medication approved by the US Food and Drug Administration (FDA) for the treatment of narcolepsy and cataplexy, offers safe and significant reduction of pain and fatigue in patients with fibromyalgia, according to a study presented here at the American Association of Pain Management 20th annual clinical meeting.

Sodium oxybate, the sodium salt of gamma-hydroxybutyrate, a metabolite of gamma-aminobutyric acid (GABA), is used specifically for the treatment of deep sleep pattern disturbances, and because studies have shown that fibromyalgia patients commonly have deep sleep disturbances, scientists suspected that the drug could help treat the condition's symptoms.

Previous proof-of-concept studies offered evidence that sodium oxybate can reduce pain and fatigue and provide polysomnographic improvements in sleep in patients with fibromyalgia, compared with placebo.

The current phase 3 randomized double-blind study evaluated the treatment in 548 patients with the condition.

The patients were assigned to receive sodium oxybate 4.5 g/night, sodium oxybate 6.0 g/night, or placebo in divided doses at bedtime and 2.5 to 4 hours later, over the course of 14 weeks.

The 334 patients completing the study reported reductions in pain as early as the first week of the study. The percentage of patients in the sodium oxybate 4.5 g and 6.0 g groups reporting reductions in pain of 30% or more were significantly higher than that in the placebo group (54.2% and 58.5% vs 35.2% respectively; $P < .001$).

Those reporting pain reductions of 50% or more were also higher in the sodium oxybate groups than in the placebo group (44.7% and 43.3% vs 22.7%, respectively; $P < .001$).

Mean fatigue scores were significantly reduced in the sodium oxybate 4.5 g and 6.0 g groups, compared with the placebo group, throughout the study, beginning in week 1 ($P < .01$) and at the study's end point (-27.94 and -30.02 vs -17.57, respectively; $P < .001$).

The percentage of patients reporting global impression of change scores of "much better" or "very much better" were also significantly higher in the sodium oxybate 4.5 g and 6.0 g groups than in the placebo group (48.3% and 45.4% vs 27.2%, respectively; $P < .001$) at the study's end point.

The most common adverse events were headache (15% in the 4.5 g group; 23% in the 6.0 g group), nausea (14% in the 4.5 g group; 21% in the 6.0 g group), and dizziness (13% in the 4.5 g group; 17% in the 6.0 g group).

With mechanisms that aren't directly related to sleep, the 3 drugs that are currently approved in the United States for the treatment of fibromyalgia — pregabalin, duloxetine, and milnacipran — might fall short in addressing a hallmark of the condition, said Victor Rosenfeld, MD, a principle investigator on the study and a neurologist at the Samsun Clinic in Santa Barbara, California.

"Surveys of fibromyalgia patients, in fact, show pain to be the fourth most common complaint," he said. "Sleep problems, fatigue, and cognitive dysfunction are actually more prominent complaints in this population, so we know that fibromyalgia is much more than a pain disorder."

The study underscores how the treatment of sleep problems, with a mechanism that isn't currently understood, can help reduce pain, he said.

"Not only do the studies show that sodium oxybate treatment improves patients' sleep and fatigue complaints, interestingly enough, there's a very significant improvement in their pain," he said.

"The data look stronger in terms of pain reduction with this sleep drug than it does with the other FDA-approved medications for fibromyalgia at this time," he said.

Daniel J. Clauw, MD, professor of medicine in the Division of Rheumatology at the University of Michigan, Ann Arbor, said he felt that sodium oxybate represents an exciting new approach to fibromyalgia, addressing an important part of the brain that is not targeted by other therapies.

"This uniqueness of this drug is probably not simply that it is working in part by improving sleep, because other drugs, such as tricyclics and gabapentin/pregabalin, are also likely working in part by improving sleep," he said. "The more exciting property is that this drug is likely working by elevating GABA levels, and that makes it somewhat unique because none of the other drugs that are approved or commonly used for fibromyalgia are likely to be primarily working on this neurotransmitter, which is one of the key inhibitory neurotransmitters in the brain."

An advantage of the drug is that it appears to have a lower risk for nausea as an adverse effect than duloxetine, but a drawback is that, as a potent central nervous system depressant, sodium oxybate comes with a high risk for abuse. But Dr. Clauw said that, in a managed setting, it should gain acceptance as a useful modality in the treatment of fibromyalgia.

"I think that it will be helpful to have this drug approved for use in fibromyalgia," he said. "Most physicians, myself included, will not likely prescribe it initially because of it being a tightly controlled substance, but it is already being prescribed by sleep physicians for narcolepsy, and these same physicians will likely be very comfortable prescribing it for fibromyalgia. So initially, it will likely be used for refractory cases of fibromyalgia."

The study received funding from Jazz Pharmaceuticals Inc. Dr. Rosenfeld reports receiving research support from Jazz Pharmaceuticals Inc. Dr. Clauw reports being a consultant for multiple pharmaceutical companies working in fibromyalgia.

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Authors and Disclosures

Journalist

Nancy A Melville

Nancy Melville is a freelance writer for Medscape.

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