Yoga Eased Pain in Women With Fibromyalgia

Patients in the yoga group also were more likely to use positive pain-management strategies.

BY HEIDI SPLETE

FROM PAIN

Women with fibromyalgia who participated in an 8-week yoga program reported significant improvements on measures of fibromyalgia symptoms and function, based on data from a pilot study of 53 women.

The positive findings have become the basis of a grant proposal to the National Institutes of Health to fund a larger clinical trial, said lead investigator James Carson, Ph.D.

VITALS

Major Finding: An 8-week yoga program significantly reduced symptoms in women with fibromyalgia.

Data Source: A randomized, controlled trial of 53 women with fibromyalgia.

Disclosures: None reported.

Many fibromyalgia patients find standard medical care ineffective for reducing their symptoms, including pain and fatigue, Dr. Carson of Oregon Health and Science University in Portland said in an interview.

More effective treatments for fibromyalgia are needed, said Dr. Carson. "Exercise is often prescribed for fibromyalgia, but for many patients it is hard to find an exercise program that is tolerable for them. Yoga poses done in a gentle way may be a good option," he said.

Dr. Carson and colleagues randomized 53 women who met the American College of Rheumatology criteria for fibromyalgia in an 8-week Yoga of Awareness program (25 women) or standard care (28 women). The program consisted of gentle yoga poses, modified as needed to accommodate conditions such as knee osteoarthritis or carpal tunnel syndrome (Pain 2010;151:530-9).

The primary outcome measure was the total score on the Fibromyalgia Impact Questionnaire Revised (FIQR). After 8 weeks, the mean FIQR total score dropped from 48.32 at baseline to 35.49 in the yoga group (a statistically significant difference), compared with a change from 49.26 at baseline to 48.69 in the control group.

More than half (56%) of the yoga group had at least a 30% reduction in overall FIQR scores, which is slightly more than twice the 14% reduction that is recommended to show clinical significance, the researchers noted. In addition, 50% of patients in the yoga group had at least a 30% reduction in the pain subscale of the FIQR.

The Patient Global Impression of Change (PGIC) scale scores for overall improvement in fibromyalgia symptoms were significantly higher in the yoga group vs. the control group (5.05 vs. 3.69). The PGIC was measured only once, at the end of the study.

As part of the PGIC, approximately 90% of the patients in the yoga group reported feeling "a little better," "much better," or "very much better," compared with 19% of the controls.

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On average, patients spent 40 minutes practicing yoga at home, including about 13 minutes of seated meditation.

The average age of the participants was 54 years, and 68% had been symptomatic for more than 10 years. Patients who were already engaged in a yoga practice, those who were too disabled for meaningful participation in the yoga program, and those who were scheduled for elective surgery were excluded from the study.

"The most surprising finding for us was that most patients became so fully engaged in the home yoga practices they were assigned," Dr. Carson said.

On average, the patients spent 40 minutes practicing yoga at home, including about 19 minutes of postures, 13 minutes of seated meditation, and 8 minutes of breathing exercises. Those who practiced more had better results on several of the study outcomes, he noted.

"This finding suggests that yoga practices, if taught in a tailored, accessible manner, are not only well tolerated and effective; they are practiced with an unexpected degree of enthusiasm," he said.

The results also showed that patients in the yoga group were more likely to use positive pain-management strategies such as problem solving, religion, acceptance, and relaxation, and less likely to resort to negative pain-management strategies such as self-isolation, disengagement, and catastrophizing.

"We are preparing a grant proposal to the National Institutes of Health to fund a larger clinical trial that will include comparison with another active treatment, so that we can make sure that the improvements seen in this first study can be reliably replicated in another group of patients, and that the improvements are not attributable to simply receiving extra attention from caregivers or to a placebo effect," Dr. Carson said.

"We also are planning to study important changes that the yoga program may produce in neurally based abnormal pain processes that are key to the pathophysiology of fibromyalgia," he said. ■

Advisory Panel Rejects Sodium Oxybate for Fibromyalgia

BY ELIZABETH MECHCATIE

FROM A JOINT MEETING OF THE FDA'S ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT COMMITTEE

BETHESDA, MD. – Advisors to the Food and Drug Administration voted 20-2 that the risk-benefit profile of sodium oxybate did not support approval of the sedative-hypnotic drug as a treatment for fibromyalgia, citing concerns that included the lack of long-term data and the potential for illicit use of the drug.

At the meeting, panelists generally agreed that the data from clinical trials showed that sodium oxybate, which is approved for treating cataplexy and daytime sleepiness associated with narcolepsy, was effective in treating fibromyalgia.

Panelists said the effect was modest, and that treatment may benefit only a subset of patients. They also said that it was unclear whether the results could be generalized to the typical fibromyalgia population and that more studies were needed, including those directly comparing sodium oxybate to other treatments for the disorder.

Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB), an endogenous neurotransmitter synthesized from gamma aminobutyric acid, and is also known as the "date rape" drug. Sodium oxybate in an oral solution was approved in 2002 for narcolepsy and has been marketed as Xyrem by Jazz Pharmaceuticals, with a risk evaluation and mitigation (REMS) program that tightly controls availability of the drug and includes restricted distribution of the agent through one centralized pharmacy and other measures.

A main concern voiced by the panelists and FDA reviewers was if the drug were approved to treat fibromyalgia, its use would increase substantially—and its availability as a street drug could increase markedly, despite the controlled distribution.

Panelists and FDA reviewers were concerned that an indication for fibromyalgia would increase use substantially—and availability as a street drug could increase markedly.

The panelists were strongly against the company's proposal to use a different commercial name (Rekinla), concentration, and dose. They also opposed a different REMS for the fibromyalgia indication, with distribution through 15 specialized pharmacies, which they said was confusing and would increase the likelihood of medication errors.

The company proposed that patients would take two doses, one before going to sleep and the second in the middle of the night, which was also cited as a disadvantage for patients.

In two phase 3 randomized, double-blind, controlled 14-week studies, two different doses of sodium oxybate were compared to placebo in about 1,000 fibromyalgia patients aged 18 and older, who discontinued opiates, benzodiazepines, muscle relaxants, and other medications or devices before enrollment. A significantly greater proportion of those treated with sodium oxybate (36%-46%) met the primary end point, at least a 30% reduction in pain from baseline to the end of treatment, compared with those on placebo (20%-27%). Adverse events were similar to those observed in Xyrem trials.

Xyrem is also approved in the European Union and Canada for the treatment of symptoms associated with narcolepsy. The company anticipates that the drug would be used to treat up to 120,000 people with fibromyalgia in the United States.

The other drugs approved by the FDA for treating fibromyalgia are milnacipran (Savella), pregabalin (Lyrica), and duloxetine (Cymbalta).

The FDA usually follows the recommendations of its advisory panels. Panelists have been cleared of potential conflicts related to the topic of the meeting, although in some cases, a waiver is granted to a panelist. ■