Fibromyalgia Care Varies Among Specialties

BY SHERRY BOSCHERT
San Francisco Bureau

SAN FRANCISCO — Rheumatologists and primary care physicians tend to use different diagnostic tests and prescribe different treatments for fibromyalgia syndrome, survey results indicated.

A large fraction of physicians in both groups did not follow the American College of Rheumatology (ACR) 1990 criteria for diagnosing fibromyalgia, Dr. Terence W. Starz and his associates reported in a poster presentation at the annual meeting of the American College of Rheumatology.

"I don't know what that means," conceded Dr. Starz, a rheumatologist at the University of Pittsburgh Medical Center. "We've got to adhere to criteria" to develop standards of care, he said in an interview during the poster session.

Questionnaires e-mailed to 199 rheumatologists throughout Pennsylvania and 183 primary care physicians in the southwestern portion of the state were returned by 74 (37%) of the rheumatologists and 89 (49%) of the primary care physicians. Both groups agreed that it takes more time to manage patients with fibromyalgia than other patients.

Rheumatologists were significantly more likely to use ACR criteria to diagnose fibromyalgia (56, or 76%) compared with primary care physicians (50, or 56%). The two groups also differed significantly in the use of tests to measure levels of vitamin D, rheumatoid factor, antinuclear antibody, and anti–cyclic citrullinated peptide (anti-CCP) antibody. They reported similar rates of testing for thyroid function, metabolic profile, and human leukocyte antigen B27.

"We need to determine which ones of those should be utilized, because they're very expensive. A vitamin D level can cost up to $250. Anti-CCP is very expensive. They're not included" in the current ACR diagnostic criteria, Dr. Starz said. "We, as a discipline, need to set out standards for diagnosis."

Vitamin D levels were ordered by 36 rheumatologists (49%) and 15 primary care physicians (17%). Tests for rheumatoid factor were ordered by 43 (58%) and 68 (76%), respectively. Rheumatologists were more likely to measure anti-CCP level (24, or 32%) than were primary care physicians (5, or 6%) but less likely to test for antinuclear antibody (45, or 61%, compared with 68, or 76%, of primary care physicians).

The two groups reported similar perceptions about the pathophysiology of fibromyalgia. Approximately three-fourths said fibromyalgia is both a medical and psychological condition, less than 20% said it's solely a medical condition, and less than 10% said it's solely a psychological condition, judging from the findings in the research, which was recognized as a "notable poster" by the ACR.

Nearly all physicians in both groups prescribed exercise and physical therapy to treat fibromyalgia, but their use of most other therapies differed significantly.

Cognitive therapy was prescribed by 39 rheumatologists (52%) and 26 primary care physicians (29%). NSAIDs were prescribed by 42 (57%) of the rheumatologists and favored by primary care physicians (75, or 84%). "The data on NSAIDs, though, are not very good for fibromyalgia," Dr. Starz said.

The primary care physicians also were significantly more likely to use SSRIs (68, or 76%) compared with rheumatologists (42, or 57%).

Rheumatologists were more likely to treat with cyclobenzaprine (64, or 86%), or alpha-2-delta ligands such as gabapentin or pregabalin (64, of 86%), compared with primary care physicians (50, or 56% and 59, or 66%, respectively).

The use of selective norepinephrine reuptake inhibitors for fibromyalgia was similar between groups.

"What's interesting to me is there's not nearly enough focus on sleep hygiene and sleep treatment" for patients with fibromyalgia, Dr. Starz commented.

An estimated 5 million people in the United States have fibromyalgia syndrome, more than the combined total of patients with rheumatoid arthritis (1.3 million), systemic lupus erythematosus (322,000), scleroderma (49,000), polymyalgia rheumatica (228,000), and gout (3 million), he said.

The investigators reported no conflicts of interest. ■

Drug May Improve Sleep in Patients With Fibromyalgia

BY SHERRY BOSCHERT
San Francisco Bureau

PHOENIX — Preliminary data on the off-label use of sodium oxybate suggest that it improved sleep in a randomized, placebo-controlled study of 151 patients with fibromyalgia who completed 8 weeks of treatment at 21 medical centers.

The study enrolled 195 patients who were randomized to 8 weeks on sodium oxybate 4.5 g/day or 6 g/day or placebo. Doses were split; patients took a half-dose at bedtime, then awoke 4 hours later for the other half.

Forty-four patients (23%) withdrew before completion, mostly from the higher-dose group and primarily because of side effects, including headache, dizziness, and nausea, Dr. Harvey Moldofsky reported at a meeting of the New Clinical Drug Evaluation Unit sponsored by the National Institute of Mental Health.

Both objective and subjective measures of sleep improved in the drug groups, compared with placebo—for those who finished the study—more so with the 6 g/day dose, said Dr. Moldofsky, president and director of the Centre for Sleep and Chronobiology, Toronto, and professor emeritus of medicine at the University of Toronto. The study was funded by Jazz Pharmaceuticals, the company that makes sodium oxybate. Dr. Moldofsky is a consultant to and an advisory board member for the company.

Many patients with fibromyalgia have sleep disturbances, he noted.

Sleep polysomnography showed significant objective improvements in the high-dose group in the amount of time spent sleeping, in sleep efficiency (the proportion of time spent sleeping, compared with time in bed), and in the amount of deep or slow-wave sleep, he reported.

Subjective results from patient self-reports on several scales showed improvements with either dose, compared with placebo, in pain and fatigue (Visual Analog Scale), daytime sleepiness (Epworth Sleepiness Scale), impaired sleep (Jenkins Scale), and daytime functioning (Functional Outcome of Sleep Questionnaire, SF-36 Vitality scale, and Fibromyalgia Impact Questionnaire).

The study provides a proof of concept, but more research is needed before the drug is used by patients with fibromyalgia, he said.

Besides headache, dizziness, and nausea, other side effects that occurred more frequently in the drug groups than in the placebo group included vomiting, nasopharyngitis, extremity pain, muscle cramp, nervous system disorders, restlessness, and incontinence or other renal/urinary disorders.

In 2002 sodium oxybate was approved in the United States to reduce cataplexy attacks in patients with narcolepsy, but the drug is under tightly restricted distribution from Jazz Pharmaceuticals alone—not from pharmacies. The agent, more commonly known as gamma hydroxybutyrate, or GHB, entered the U.S. market as a dietary supplement in the early 1990s. It subsequently gained favor as a party drug, was used to perpetrate date rape because of its intoxicating effects, and caused many serious adverse events and some deaths from its use and misuse.

More research would be needed to determine whether the improvements in sleep seen in the current study were independent of subjective improvements in pain and functionality, Dr. Moldofsky said. ■

Two Antidepressants Show Promise for Fibromyalgia

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

BARCELONA — The antidepressants milnacipran and trazodone appear to relieve pain and improve sleep and overall quality of life for fibromyalgia patients.

Neither drug is approved in the United States for fibromyalgia, but the Food and Drug Administration is considering a New Drug Application for milnacipran jointly submitted by Forest Laboratories Inc. and Cypress Bioscience, Anne Cazorla said at the annual congress of the European College of Neuropsychopharmacology.

"If this is approved, as we expect, then U.S. physicians will have a third approved choice for treating patients with fibromyalgia," said Ms. Cazorla, a manager with Pierre-Fabre Medicament, Boulogne, France, developer of the drug.

The results of the large European randomized, controlled trial were presented in a poster. The mean age of the 884 patients was 49 years; 94% were female. They were randomized to placebo or 200 mg/day milnacipran.

Patients taking milnacipran reported significant improvements in pain, quality of life, fatigue, sleep quality, and cognition.

"For all parameters, the efficacy of milnacipran vs. placebo was observed as soon as the first on-treatment assessment visit at week 4 and was maintained up to the end of treatment," wrote principal investigator Dr. Jaime C. Branco, chief of rheumatology at the Hospital Egas Moniz, Lisbon.

Trazodone, a drug fibromyalgia patients usually receive to improve sleep, also appears to have an impact on a wide range of fibromyalgia symptoms, Rocio Molina-Barea concluded in another poster. But the drug's side effects made the researcher question its clinical usefulness in fibromyalgia.

Patients who received the drug had an "unusually high frequency of palpitations," wrote Mr. Molina-Barea, a researcher at the University of Granada, Spain. "Globally, our data do seem to support the use of trazodone in fibromyalgia management."

The 12-week open-label study included 44 patients with a mean age of 50 years. Patients were started on 25 mg trazodone given at bedtime; the final dose ranged from 50 to 300 mg/day.

By the study's end, patients experienced significant improvements in sleep, pain, and global pain interference with daily activities. Both depression and anxiety showed significant improvements.

At the end of the study, 51% of patients reported mild improvement and 15% reported much or very much improvement.

Mr. Molina-Barea reported that he had no conflicts to declare. ■