European Group Issues Fibromyalgia Guidelines

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Fibromyalgia guidelines issued by the European League Against Rheumatism represent a work in progress on a field "that is very much in evolution," Dr. Philip J. Mease said in an interview.

The recommendations were formulated by a European working group that included specialists from various fields including rheumatology, pain medicine, and neurology, who reviewed all the available trials through 2005.

"They have done a good job with a difficult challenge, because the trials are so different, both in terms of the outcome measures used and the treatment approaches tried," said Dr. Mease, a rheumatologist who is clinical professor of medicine, University of Washington, Seattle, and chief of rheumatology clinical research, Swedish Hospital Medical Center, Seattle.

"Moreover, they used a balanced way of looking at both pharmacologic and nonpharmacologic approaches, to give the managing physician a choice of therapeutic approaches," he said.

Among the general recommendations of the EULAR investigators were the concepts that fibromyalgia requires a comprehensive assessment of pain, function, and psychosocial context, and that treatment should be multidisciplinary, combining various modalities tailored to pain intensity, function, and associated features such as depression and fatigue. While recommendations were evidence based whenever possible, these general recommendations regarding the heterogeneity of fibromyalgia and the need for multidisciplinary treatment were based on expert opinion.

Among the recommendations for nonpharmacologic measures were for the use of heated pool treatment, with or without exercise. This modality was found to be effective in improving pain and function in several "fairly high quality" trials, according to the investigators.

They also suggested that cognitive-behavioral therapy may be beneficial for some patients. This recommendation was based on expert opinion, but the only two studies identified that evaluated this approach were of poor quality. However, they wrote, "This is another area in which the poor quality of trials has masked what experts believe to be a realistic reflection of possible benefits," and cited potential improvements in pain and function (Ann. Rheum. Dis. July 20, 2007 [Epub doi:10.1136/ard.2007.071522]).

With regard to pharmacologic treatments, the working group recommended tramadol for the management of pain, based on two randomized controlled trials. They also favored the use of acetaminophen and other weak opioids.

However, they advised against the use of corticosteroids and strong opioids, because of their potential for significant long-term side effects and a scarcity of clinical trial data.

Antidepressants should be considered, the recommendations state, because of their ability to reduce pain and often to improve function. Amitriptyline, for example, was found to be beneficial in four of five trials that assessed pain according to a visual analogue scale (VAS).

The amitriptyline data exemplify a difficulty the investigators faced in their analysis when there were multiple trials evaluating the same drug, in that they averaged the effect sizes in these trials. With some trials being of high quality and others not, this may have skewed in an adverse way the effect size for amitriptyline, Dr. Mease observed.

Other antidepressants that have shown benefits in varying numbers and sizes of trials were fluoxetine, duloxetine, milnacipran, moclobemide, and pirlindole.

Finally, the investigators stated that tropisetron, pramipexole, and pregabalin reduce pain and should be considered for the treatment of fibromyalgia. This recommendation illustrates a further difficulty faced by EULAR. "Both pregabalin and pramipexole are recommended, but if you look at the specific trials they are vastly different," Dr. Mease said. Pregabalin was evaluated in a multicenter, 500-plus patient trial that was very well controlled and excluded all other drugs that might influence fibromyalgia. In contrast, the pramipexole trial took place in a single center and, importantly, permitted the use of background drugs including opioids, he said.

The recommendations will be updated every 5 years, with the hope that clinical trials of good quality will add to the available evidence, according to the investigators. ■