Duloxetine Effective for Fibromyalgia in Women

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VANCOUVER, B.C. — Duloxetine is a safe and effective treatment for fibromyalgia symptoms in both depressed and nondepressed women, Lesley Arnold, M.D., reported at the annual meeting of the American Psychosomatic Society.

Duloxetine (Cymbalta) is approved for the treatment of both major depression and diabetic neuropathic pain. The drug's efficacy in treating both pain and depression—which often co-occur in fibromyalgia—is probably due to its dual action as a selective serotonin and norepinephrine reuptake inhibitor, said Dr. Arnold, a psychiatrist who is director of women's health research at the University of Cincinnati.

In one of two 12-week studies funded by Lilly Research Laboratories, a total of 354 adult women who met the American College of Rheumatology's criteria for primary fibromyalgia were randomized to receive 60 mg of duloxetine once a day (118), 60 mg twice daily (116), or placebo (120).

Significant differences in the Brief Pain Inventory (BPI) average 24-hour pain score and the Fibromyalgia Impact Questionnaire (FIQ) were seen within 1 week in both the 60 mg/day and 120 mg/day duloxetine groups compared with placebo, with no significant difference between the two dosages.

In the low- and high-dose groups, 41% of patients experienced a 50% reduction in overall pain, compared with 23% of patients on placebo, Dr. Arnold reported.

Significant improvements over placebo were also seen in the FIQ total, pain, fatigue, and restfulness upon awakening scores; in the mean tender point threshold and number of tender points; in the Clinical Global Impression (CGI) and Patient Global Impression of Improvement (PGI) scores; in other BPI subscale measures of pain severity and interference; and in several quality of life and functional measures.

This study replicated several findings from a previously published trial of 207 fibromyalgia patients that included a small number of men. Dr. Arnold presented the findings of both trials together in a poster at the meeting.

In the earlier study, 104 patients (89% women) were randomized to 120 mg/day of duloxetine, and 103 (89% women) to placebo. Duloxetine patients improved significantly more than did placebo-treated patients on the FIQ total score, but not significantly more on the FIQ pain score (Arthritis Rheum. 2004;50:2974-84).

Duloxetine-treated patients also had significant reductions compared with placebo-treated patients in BPI scores for average pain severity and interference from pain, number of tender points, and FIQ stiffness, as well as several other fibromyalgia-specific and quality of life measures. The differences were only significant for women, but the number of men was quite small, Dr. Arnold noted.

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Major depression was present in approximately 40% of the subjects in the earlier single-dose study and in about one-fourth of the subjects in the two-dose study. In both studies, there were no differences between depressed and nondepressed patients in duloxetine efficacy in alleviating pain and fibromyalgia symptoms, suggesting that these effects are not simply due to an improvement in mood, she noted.

In the first study, duloxetine was significantly more likely than placebo to be associated with side effects including constipation, dry mouth, insomnia, and a small mean increase in heart rate. These were typically mild to moderate in severity. Also in that study, anxiety was reported significantly less often with duloxetine than with placebo.

In the more recent study, nausea, dry mouth, constipation, diarrhea, somnolence, decreased appetite and weight, and a small mean increase in systolic and diastolic blood pressure were among the side effects reported more frequently by duloxetine-treated patients than by those on placebo. These side effects were also generally mild to moderate in severity. In all, the drug was safely administered and well tolerated, Dr. Arnold said. ■

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