A randomized, double-blind, placebo-controlled phase III trial of duloxetine in Japanese fibromyalgia patients.

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Abstract

INTRODUCTION:

Fibromyalgia is characterized by widespread pain and is often accompanied by accessory symptoms. There are limited treatment options for this condition in Japan. Therefore, we conducted a phase III study to assess the efficacy and safety of duloxetine in Japanese patients with fibromyalgia.

METHODS:

This randomized, double-blind, placebo-controlled, parallel-group trial was conducted in Japan. Outpatients who met the American College of Rheumatology 1990 criteria for fibromyalgia and whose Brief Pain Inventory (BPI) average pain score was ≥4 were randomized to duloxetine 60 mg or placebo once daily for 14 weeks. The primary efficacy measure was the change in the BPI average pain score from baseline. Secondary efficacy, quality of life (QoL), and safety outcomes were also evaluated. Mixed-effects model repeated-measures (MMRM) analysis and last observation carried forward (LOCF) analysis of covariance were used to evaluate the primary efficacy measure.

RESULTS:

Overall, 393 patients were randomized to receive either duloxetine (n = 196) or placebo (n = 197). The MMRM analysis revealed no significant difference between duloxetine and placebo regarding the change in BPI average pain scores at week 14. Based on LOCF analysis, a statistically significant improvement in the change in BPI average pain scores at week 14 was observed for patients treated with duloxetine compared with placebo. Duloxetine treatment was associated with improved outcomes in nearly all secondary and post hoc analyses. The treatment was generally well tolerated. Somnolence, nausea, and constipation were the most common treatment-emergent adverse events in the duloxetine group. The discontinuation rates due to treatment-emergent adverse events were similar in both groups.

CONCLUSIONS:

Although the MMRM analysis did not demonstrate superiority of duloxetine over placebo, duloxetine treatment was associated with improved outcomes in secondary and post hoc analyses of the mean change in the BPI average pain score and most of the secondary outcomes, including analgesia and QoL. Duloxetine treatment was safe and well tolerated. These results suggest that duloxetine treatment could be associated with improvements in pain relief and QoL in Japanese patients with fibromyalgia.