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Effects of milnacipran on the multidimensional aspects of fatigue and the relationship of fatigue to pain and function: pooled analysis of 3 fibromyalgia trials.

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Abstract

BACKGROUND:

Fatigue is a core symptom in fibromyalgia that can negatively affect a patient's quality of life.

OBJECTIVE:

The objective of this study was to analyze fatigue-related data from 3 randomized, placebo-controlled trials of milnacipran (n = 3109) in fibromyalgia patients.

METHODS:

Fatigue was assessed with the Multidimensional Fatigue Inventory (MFI). Treatment effects were evaluated by changes in MFI total scores and identifying patients with improvement of 30% or greater from baseline. Path analyses were conducted to evaluate direct and indirect effects of treatment on fatigue.

RESULTS:

Patients had high levels of baseline fatigue; mean MFI total score was 68.1 (of 100). After 3 months of stable-dose treatment, patients receiving milnacipran 100 and/or 200 mg/d had significant improvement in MFI total and subscale scores ($P < 0.05$ vs placebo). The largest treatment effect was found in patients with equal to or greater than 20% to 40% fatigue improvement. Significantly more patients met the threshold of 30% or greater with milnacipran (100 mg/d, 17.6%; 200 mg/d, 15.2%) than with placebo (9.9%); odds ratios for this responder status were 1.93 and 1.63, respectively ($P < 0.05$ for both doses). Path analyses indicated that up to 28% of fatigue improvement may be attributed to direct milnacipran effects (ie, not indirectly through effects on pain or other symptoms).

CONCLUSIONS:

Fibromyalgia patients in the milnacipran studies had high levels of baseline fatigue. Patients receiving milnacipran had statistically significant and clinically meaningful reductions in fatigue that were not completely attributable to indirect treatment effects through pain reduction. Evaluating and managing fatigue are an important clinical concern when treating patients with fibromyalgia.