

Efficacy of Duloxetine in Chronic Low Back Pain with a Neuropathic Component: A Randomized, Double-blind, Placebo-controlled Crossover Trial

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1st [Regina Patricia Schukro](#)  
6.03 · Medical University of Vienna

2nd [Matthias J Oehmke](#)

3rd [Angelika Geroldinger](#)

+ 2

Last [Sibylle Pramhas](#)  
18.87 · Medical University of Vienna

Show more authors

Abstract

**Background:**  
Among patients with chronic low back pain (CLBP), approximately 37% show signs of a neuropathic pain component (radicular pain). Treatment of this condition remains challenging. Therefore, the current study aimed to investigate the efficacy of duloxetine in the treatment of CLBP patients with neuropathic leg pain.

**Methods:**  
The study was conducted as a prospective, randomized, placebo-controlled, double-blind crossover trial. CLBP with a visual analog scale (VAS) score greater than 5 and a neuropathic component that was assessed clinically and by the painDETECT questionnaire (score > 12) were required for inclusion. Patients were randomly assigned to either duloxetine or placebo for 4 weeks followed by a 2-week washout period before they crossed over to the alternate phase that lasted another 4 weeks. Duloxetine was titrated up to 120 mg/day. The primary outcome parameter was mean VAS score during the last week of treatment in each phase (VASweek4).

**Results:**  
Of 41 patients, 21 patients completed both treatment phases. In the intention-to-treat analysis (n = 25), VASweek4 was significantly lower in the duloxetine phase compared with placebo (4.1 ± 2.9 vs. 6.0 ± 2.7; P = 0.001), corresponding to an average pain reduction of 32%. The painDETECT score at the end of each treatment phase was significantly lower in the duloxetine phase compared with placebo (17.7 ± 5.7 vs. 21.3 ± 3.6 points; P = 0.0023). Adverse events were distributed equally between the duloxetine (65%) and placebo phases (62%) (P = 0.5).

**Conclusion:**  
In this crossover study, duloxetine proved to be superior to placebo for the treatment of CLBP with a neuropathic leg pain.

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