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## Randomized, Placebo-Controlled Comparison of Amitriptyline, Duloxetine, and Pregabalin in Patients With Chronic Diabetic Peripheral Neuropathic Pain: Impact on pain, polysomnographic sleep, daytime functioning, and quality of life.

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### Abstract

**OBJECTIVE** Chronic diabetic peripheral neuropathic pain (DPNP) is difficult to treat, with treatment regimens often inadequate at controlling pain and limited by side effects and drug tolerance. Secondary parameters, such as quality of sleep and mood, may also be important for successful DPNP management. The objectives of this study were to compare the analgesic efficacy of pregabalin, amitriptyline, and duloxetine, and their effect on polysomnographic sleep, daytime functioning, and quality of life in patients with DPNP. **RESEARCH DESIGN AND METHODS** This was a double-blind, randomized, parallel group investigation of type 1 and 2 diabetic subjects with DPNP. Each treatment group had a single-blind, 8-day, placebo run-in followed by 14 days of lower-dose and 14 days of higher-dose medication. At the end of each dose titration period, subjective pain, sleep, and daytime functioning were assessed during a 2-day residential period. **RESULTS** All medications reduced pain when compared with placebo, but no one treatment was superior to any other. For sleep, pregabalin improved sleep continuity ( $P < 0.001$ ), whereas duloxetine increased wake and reduced total sleep time ( $P < 0.01$  and  $P < 0.001$ ). Despite negative effects on sleep, duloxetine enhanced central nervous system arousal and performance on sensory motor tasks. There were no significant safety findings; however, there was a significantly higher number of adverse events in the pregabalin treatment group. **CONCLUSIONS** There was no significant difference in analgesic efficacy between amitriptyline, duloxetine, and pregabalin. However, there were significant differences in the secondary parameters, which may be of relevance when deciding the optimal treatment for DPNP.

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