

Duloxetine decreases pain of diabetic neuropathy

Clinical question Does duloxetine reduce pain in patients with diabetic peripheral neuropathy?

Bottom line In this study, duloxetine (Cymbalta) 60mg daily was more effective than placebo in reducing pain from neuropathy in patients with diabetes. Higher doses of duloxetine did not provide much additional benefit. The biases in this study favour treatment, so it is likely that the real benefit is less than that observed by these investigators. Finally, we do not know if duloxetine is any more effective than other treatments used for painful diabetic neuropathy.

Synopsis Patients with diabetic peripheral neuropathy, and glycosylated haemoglobin levels no higher than 12 per cent, were randomly assigned (double blinded, allocation concealed) to receive placebo (n = 108), duloxetine 60mg daily (n = 114) or duloxetine 60mg twice daily (n = 112). The patients recorded their assessment of pain severity (on a scale from 0 to 10) in a daily diary. The main outcome — the weekly average pain score from the diary — was evaluated by a modified intention-to-treat analysis. In other words, they only included patients who completed the study. In general, this tends to bias the results in favour of the interventions. The patients had comparable pain levels at the beginning of the study. Patients in each group improved by the end of the study: those taking placebo improved by 1.4 points, those taking duloxetine 60mg daily improved by

2.7 points and those taking duloxetine 60mg twice daily improved by 2.8 points. The largest reduction in pain was seen by the second week of treatment. In general, a reduction of two points is considered clinically important. This degree of reduction was observed in 42 per cent of patients taking placebo, 63 per cent of patients taking duloxetine 60mg daily, and 69 per cent of patients taking twice-daily duloxetine. Compared with placebo, five patients would need to be treated with once-daily duloxetine (95 per cent confidence interval, 3–17) for one patient to benefit. The number needed to treat for twice-daily duloxetine is four (CI 3–8). A large proportion of patients dropped out of the study (21 per cent in the placebo group and 25 per cent and 30 per cent in the two duloxetine groups), which reinforces concerns about bias.

Level of evidence 2b– (low quality randomised controlled trial with less than 80 per cent follow-up or wide confidence interval).

Reference Wernicke JF, Pritchett YL, D'Souza DN, et al. A randomized controlled trial of duloxetine in diabetic peripheral neuropathic pain. *Neurology* 2006;67:1411–20.

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