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Duloxetine for treating painful neuropathy, chronic pain or fibromyalgia.Lunn MP¹, Hughes RA, Wiffen PJ.**+ Author information****Abstract**

BACKGROUND: Duloxetine is a balanced serotonin and noradrenaline reuptake inhibitor licensed for the treatment of major depressive disorders, urinary stress incontinence and the management of neuropathic pain associated with diabetic peripheral neuropathy. A number of trials have been conducted to investigate the use of duloxetine in neuropathic and nociceptive painful conditions. **This is the first update of a review first published in 2010.**

OBJECTIVES: To assess the benefits and harms of duloxetine for treating painful neuropathy and different types of chronic pain.

SEARCH METHODS: On 19th November 2013, we searched The Cochrane Neuromuscular Group Specialized Register, CENTRAL, DARE, HTA, NHSEED, MEDLINE, and EMBASE. We searched ClinicalTrials.gov for ongoing trials in April 2013. We also searched the reference lists of identified publications for trials of duloxetine for the treatment of painful peripheral neuropathy or chronic pain.

SELECTION CRITERIA: We selected all randomised or quasi-randomised trials of any formulation of duloxetine, used for the treatment of painful peripheral neuropathy or chronic pain in adults.

DATA COLLECTION AND ANALYSIS: We used standard methodological procedures expected by The Cochrane Collaboration.

MAIN RESULTS: We identified 18 trials, which included 6407 participants. We found 12 of these studies in the literature search for this update. Eight studies included a total of 2728 participants with painful diabetic neuropathy and six studies involved 2249 participants with fibromyalgia. Three studies included participants with depression and painful physical symptoms and one included participants with central neuropathic pain. Studies were mostly at low risk of bias, although significant drop outs, imputation methods and almost every study being performed or sponsored by the drug manufacturer add to the risk of bias in some domains.

Duloxetine at 60 mg daily is effective in treating painful diabetic peripheral neuropathy in the short term, with a risk ratio (RR) for $\geq 50\%$ pain reduction at 12 weeks of 1.73 (95% CI 1.44 to 2.08). The related NNTB is 5 (95% CI 4 to 7). **Duloxetine at 60 mg daily is also effective for fibromyalgia** over 12 weeks (RR for $\geq 50\%$ reduction in pain 1.57, 95% CI 1.20 to 2.06; NNTB 8, 95% CI 4 to 21) and over 28 weeks (RR 1.58, 95% CI 1.10 to 2.27) as well as for painful physical symptoms in depression (RR 1.37, 95% CI 1.19 to 1.59; NNTB 8, 95% CI 5 to 14). There was **no effect on central neuropathic pain in a single, small, high quality trial.** In all conditions, adverse events were common in both treatment and placebo arms but more common in the treatment arm, with a dose-dependent effect. **Most adverse effects were minor, but 16% of participants stopped the drug** due to adverse effects. **Serious adverse events were rare.**

AUTHORS' CONCLUSIONS: There is **adequate amounts of moderate quality evidence** from eight studies performed by the manufacturers of **duloxetine that doses of 60 mg and 120 mg daily are efficacious for treating**

pain in diabetic peripheral neuropathy but lower daily doses are not. Further trials are not required. In fibromyalgia, there is lower quality evidence that duloxetine is effective at similar doses to those used in diabetic peripheral neuropathy and with a similar magnitude of effect. The effect in fibromyalgia may be achieved through a greater improvement in mental symptoms than in somatic physical pain. There is low to moderate quality evidence that pain relief is also achieved in pain associated with depressive symptoms, but the NNTB of 8 in fibromyalgia and depression is not an indication of substantial efficacy. More trials (preferably independent investigator led studies) in these indications are required to reach an optimal information size to make convincing determinations of efficacy. Minor side effects are common and more common with duloxetine 60 mg and particularly with 120 mg daily, than 20 mg daily, but serious side effects are rare. Improved direct comparisons of duloxetine with other antidepressants and with other drugs, such as pregabalin, that have already been shown to be efficacious in neuropathic pain would be appropriate. Unbiased economic comparisons would further help decision making, but no high quality study includes economic data.

Comment in

ACP Journal Club. Review: In neuropathy, fibromyalgia, or chronic pain, duloxetine reduces pain but increases adverse events. [Ann Intern Med. 2014]

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