Lamotrigine reduces painful diabetic neuropathy: a randomized, controlled study.

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Abstract:

Objective: To study the efficacy of lamotrigine in relieving the pain associated with diabetic neuropathy.

Methods: The authors randomly assigned 59 patients to receive either lamotrigine (titrated from 25 to 400 mg/day) or placebo over a 6-week period. Primary outcome measure was self-recording of pain intensity twice daily with a 0 to 10 numerical pain scale (NPS). Secondary efficacy measures included daily consumption of rescue analgesics, the McGill Pain Questionnaire (MPQ), the Beck Depression Inventory (BDI), the Pain Disability Index (PDI), and global assessment of efficacy and tolerability.

Results: Twenty-four of 29 patients (83%) receiving lamotrigine and 22 of 30 (73%) patients receiving placebo completed the study. Daily NPS in the lamotrigine-treated group was reduced from 6.4 +/- 0.1 to 4.2 +/- 0.1 and in the control group from 6.5 +/- 0.1 to 5.3 +/- 0.1 (p < 0.001 for lamotrigine doses of 200, 300, and 400 mg). The results of the MPQ, PDI, and BDI remained unchanged in both groups. The global assessment of efficacy favored lamotrigine treatment over placebo, and the adverse events profile was similar in both groups.

Conclusions: Lamotrigine is effective and safe in relieving the pain associated with diabetic neuropathy.

Comments:

Strengths/Uniqueness:
This investigation fulfils all the key criteria for a well-designed study: randomisation, concealment of allocation, intent-to-treat analysis, balanced treatment group characteristics, and completeness of follow-up.

Weaknesses:
The study was conducted at a single centre and the number of subjects was relatively small. However, the results are consistent with two other small randomized double-blind placebo-controlled trials of lamotrigine conducted in patients with painful HIV-associated neuropathy and central post-stroke pain. The trial was supported by the manufacturer of the drug.

Relevance to Palliative Care: This study was conducted in a population of patients with chronic non-cancer pain, which limits applicability of the results to the palliative setting. Lamotrigine appears to be well tolerated. However, the titration process takes weeks. Therefore, lamotrigine would only be useful for palliative patients who are relatively early in the trajectory of their illness.