POEMs

Gabapentinoids for Chronic Low Back Pain: Limited Evidence, More Harm Than Benefit

Clinical Question

Are gabapentinoids safe and effective in treating patients with chronic low back pain?

Bottom Line

The existing data on gabapentinoids for chronic low back pain are limited in number and quality. The amount of pain reduction is low to moderate, and the rate of adverse effects is high. The few studies that assessed function found no improvement. (Level of Evidence = 2a–)

Synopsis

These authors searched two databases and the Cochrane clinical trials register to identify randomized trials of gabapentinoids (gabapentin [Neurontin], pregabalin [Lyrica]) for treating adults with back pain lasting at least three months. Two authors independently assessed the inclusion of articles, and they resolved disagreements by consensus or through third-party adjudication. Ultimately, they included eight small studies with three different comparison treatments. Most of the studies had methodological quality issues, including selection bias and inadequate concealment of randomization. Three studies with 185 patients compared gabapentin with placebo, finding minimal improvement in pain. Three studies with 332 patients compared pregabalin with other analgesics, finding pregabalin was more effective in average pain response. The remaining studies, which assessed pregabalin as an adjunct to pain management, were heterogeneous, and the authors chose not to pool the data. The largest of these studies, however, found that adding pregabalin did not improve pain.

We have commented often on the inconsistent reporting of treatment harms in clinical trials, and these studies are no exception. However, the authors were able to pool data and estimate the number needed to treat to harm (NNTH) for several adverse effects: dizziness (NNTH = 7; 95% confidence interval [CI], 4 to 30), fatigue (NNTH = 8; 95% CI, 4 to 44), altered mentation (NNTH = 6; 95% CI, 4 to 15), and vision disturbance (NNTH = 6; 95% CI, 4 to 13). The studies generally did not report on functional outcomes.

Study design: Meta-analysis (randomized controlled trials)

Funding source: Government

Setting: Various (meta-analysis)

Reference: *Shanthanna H, Gilron I, Rajarathinam M, et al. Benefits and safety of gabapentinoids in chronic low back pain: a systematic review and meta-analysis of randomized controlled trials.* PLoS Med. *2017;14(8):e1002369.*

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Home Glucose Monitoring Offers No Benefit to Patients Not Using Insulin

Clinical Question

Does home monitoring of blood glucose levels improve glycemic control or quality of life in patients with type 2 diabetes mellitus who are not using insulin?

Bottom Line

Home glucose monitoring of patients in primary care does not improve A1C scores or quality of life over one year in patients who are not taking insulin. Patients did not feel more empowered or satisfied as a result of home monitoring, nor did they have fewer hypoglycemic episodes, and their physicians did not seem to respond to the home glucose levels to any beneficial effect. (Level of Evidence = 1b)

Synopsis

These researchers identified adults (average age = 61 years) with type 2 diabetes not treated with insulin and who had A1C levels between 6.5% and 9.5%. Most of the patients (75%) monitored their blood glucose levels

at home before the study but had not been treated by an endocrinologist. The 450 patients (who had type 2 diabetes for an average of eight years) were randomly assigned, using concealed allocation, to one of three arms: (1) no home glucose monitoring; (2) standard once-daily monitoring; and (3) enhanced once-daily monitoring, consisting of glucose values immediately reported to the patient plus automated, tailored messaging delivered via the meter. The patients' physicians were given the home glucose monitoring results but were not asked to follow a specific protocol to respond to them. After both six months and one year, there were no differences, on average, among the groups in A1C levels, hospitalizations, episodes of severe hypoglycemia, or quality-of-life scores. Similarly, there was no difference among groups in treatment satisfaction or feelings of empowerment.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (any)

Reference: *Young LA, Buse JB, Weaver MA, et al.; Monitor Trial Group. Glucose self-monitoring in non-insulin-treated patients with type 2 diabetes in primary care settings: a randomized trial.* JAMA Intern Med. *2017;177(7):920-929.*

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In Hospitalized Patients with Influenza and an Infiltrate, Adding Clarithromycin and Naproxen to Oseltamivir Improves Outcomes

Clinical Question

For patients with confirmed influenza and an infiltrate consistent with pneumonia, does adding clarithromycin (Biaxin) and naproxen to oseltamivir (Tamiflu) improve outcomes?

Bottom Line

Adding clarithromycin and naproxen to oseltamivir significantly lowered all-cause mortality at 30 days and at 90 days. This study was limited by its open-label design. The outcome of mortality would not be subject to observer bias, though, and the groups were balanced. These findings are consistent with other studies of hospitalized patients with community-acquired pneumonia that concluded that adding a macrolide to amoxicillin/clavulanate (Augmentin) or a cephalosporin improves outcomes. (Level of Evidence = 1b)

Synopsis

These researchers recruited adults hospitalized with laboratory-confirmed influenza A (H3N2) within 72 hours of the onset of symptoms. All patients had an infiltrate on chest radiography, fever, and at least one typical symptom of influenza. Of 334 patients screened for inclusion, 217 were randomized to receive oseltamivir (75 mg twice daily), or oseltamivir plus clarithromycin (500 mg twice daily) and naproxen (200 mg twice daily). The oseltamivir was given for five days, whereas the naproxen and clarithromycin were given for three days. Groups were balanced at baseline. All patients also received amoxicillin/clavulanate and esomeprazole (Nexium). The mean age of patients was 80 years, and 57% were men. Approximately 50% were previously in good health, and despite extensive testing, only approximately 5% in each group had a bacterial coinfection.

All-cause mortality was significantly lower at 30 days in the group who received clarithromycin and naproxen (0.9% vs. 8.2%; $P = .01$; number needed to treat [NNT] = 14); it was also lower at 90 days (1.9% vs. 10%; $P = .01$; NNT = 13). The researchers hypothesized based on in vitro studies that naproxen and clarithromycin have antiviral properties, and they found that viral titers and the pneumonia severity index scores also declined faster in the combination therapy group. The median length of hospitalization was shorter for those in the combination therapy group (two vs. three days; $P < .001$), as was the likelihood of admission to the high-dependency unit, which is something between a regular ward and intensive care.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Inpatient (any location)

Reference: *Hung IFN, To KKW, Chan JFW, et al. Efficacy of clarithromycin-naproxen-oseltamivir combination in the treatment of patients hospitalized for influenza A(H3N2) infection: an open-label randomized, controlled, phase IIb/III trial.* Chest. *2017;151(5):1069-1080.*

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