

Yuan R-Y, Sheu J-J et al. Botulinum toxin for neuropathic pain. Neurology 2009;72:1473-1478.

Design: Crossover randomized trial

Brief summary of results:

- 18 patients with diabetic neuropathy (6 men, 12 women, mean age 66) participated in a clinical trial of intradermal botulinum toxin (BTX) at a university neurology clinic in Taipei
- Eligible patients had a minimum of 3 years of diabetes and neuropathic pain in both feet, and had had no change in medication for neuropathic pain in the previous month
- Exclusion criteria included peripheral arterial occlusion, infection, motor deficit, lumbosacral radiculopathy, and neuropathic pain from other causes
- Each participant had an injection of 50 units of BTX into each foot and an injection of saline placebo; the injections were given in random order, with a 12 week washout between injections
- Pain VAS was measured at 1 week, and again at 4, 8, and 12 weeks
- BTX and placebo pain scores differed at 4, 8, and 12 week stages, with the mean pain reduction at 12 weeks of 2.53 points for BTX but only 0.53 for placebo

Authors' conclusions:

- Intradermal BTX is safe and effective in relieving neuropathic pain due to diabetes in the feet

Comments:

- The study has a crossover design, but lacks essential information to interpret its results
- For example, the authors refer to "the" BTX group and "the" placebo group as if these were separate groups; each participant in fact was a member of both groups
- The authors probably intend to refer to the effects of BTX and placebo separately, but there ought to be separate mentions of treatment effect, period effects, and carryover effects, with efforts to distinguish between them
- The washout period of 12 weeks is probably too short, and makes a significant carryover effect very likely, but this effect is only vaguely described

Assessment: Inadequate for evidence of botulinum toxin effect (essential features of crossover trials are not described sufficiently)