Botulinum Toxin for Diabetic Neuropathic Pain: A Randomized Double-Blind Cross-over Trial

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摘要

Abstract

Background: Diabetic neuropathy is a common complication in diabetes, with patients typically experiencing diverse sensory symptoms including dysesthesias in the feet and usually accompanied by sleep disturbance. There is still no comprehensive understanding of the underlying biologic processes responsible for diabetic neuropathic pain. Thus, the current symptomatic therapy remains unsatisfactory. Recent experimental evidence suggests that botulinum toxin type A (BoNT/A) may not only inhibit the release of acetylcholine at the neuromuscular junctions, but also modulate afferent sensory fiber firing, thereby relieving neuropathic pain.

Methods: A double-blind crossover trial of intradermal BoNT/A for diabetic neuropathic pain in 18 patients was conducted to evaluate the effectiveness.

Results: We find significant reduction in visual analog scale (VAS) of pain by 0.83 ± 1.11 at 1 week, 2.22 ± 2.24 at 4 weeks, 2.33 ± 2.56 at 8 weeks, and 2.53 ± 2.48 at 12 weeks after injection in the BoNT/A group, as compared to the respective findings for a placebo group of 0.39 ± 1.18, −0.11 ± 2.04, 0.42 ± 1.62, and 0.53 ± 1.57 at the same timepoints ($p < 0.05$). Within the BoNT/A group, 44.4% of the participants experienced a reduction of VAS 3 within 3 months after injection, whereas there was no similar response in the placebo group. At the 4-week postinjection stage, improvement in sleep quality was measured using the Chinese version of the Pittsburgh Sleep Quality Index.

Conclusions: This pilot study found that botulinum toxin type A significantly reduced diabetic neuropathic pain and transiently improved sleep quality. Further large-scaled study is warranted.