

Waseem Z, Boulias C, et al. Botulinum toxin injections for low-back pain and sciatica. Cochrane Database of Systematic Reviews 2011, Issue 1, Art No. CD008257.

Design: Systematic review of randomized trials

PICOS:

- **Patient population:** Adults with nonspecific low back pain (LBP)
 - o LBP defined as pain between the 12th rib and inferior gluteal fold
 - o Sciatica defined as pain radiating from buttock into leg and/or foot
 - o Non-specific LBP defined as pain
- **Interventions:** Any botulinum toxin (BoNT) serotype injected intramuscularly (IM) at sites in the lumbar region, sacral region, or both
- **Comparison:** Sham or placebo IM injections, other therapeutic injections (epidural steroid, acupuncture), other medical interventions, or no intervention
- **Outcomes:** Primary outcomes were pain, disability (return to work), overall improvement, back-specific functional status (Oswestry, Roland-Morris), or well-being (SF-36, Sickness Impact Profile, etc)
- **Study types:** Completed randomized clinical trials, published or unpublished, in any language

Study selection:

- Databases included MEDLINE, EMBASE, CINAHL, and the Cochrane Library
- Grey (unpublished) literature was searched by search engines such as Google and Yahoo
- One author who was fluent in Chinese translated an article published in Chinese
- Two authors independently rated articles for relevance and for risk of bias
 - o Relevance was assessed by whether the patients in the study were described in detail to enable the reader to judge whether they were comparable to those seen in their practice; similarly, the interventions were judged by whether they were described in enough detail to enable the reader to provide the same care, whether all important outcomes were reported, whether the effect size was clinically important, and whether the benefits outweigh the harms
 - o Risk of bias was judged by the description of randomization, allocation concealment, blinding, dropouts/attrition, intention to treat analysis, similarity of co-interventions

Results:

- Only three RCTs were identified for analysis, one of which had to be translated from Chinese
- Only one RCT had a low risk of bias
- Because of different kinds of comparison among the three studies, meta-analysis was not attempted

- The single study with a low risk of bias reported pain and function measures at 8 weeks after BoNT injection; it had only 31 patients
 - o At 8 weeks, the percentage of patients with 50% pain relief was greater for BoNT (11/15) than for a placebo (4/16)
 - o At 8 weeks, improvement in the Oswestry score was reported in 10/15 BoNT patients and in 3/14 placebo injected patients
- Injection site pain was the only adverse outcome reported
- None of the studies discussed costs of treatment

Authors' conclusions:

- There is a lack of high-quality studies evaluating BoNT for LBP
- The current body of evidence does not support use of BoNT for LPB
- In addition to larger and improved methodological studies of the effects of BoNT, further studies need to report on costs in relation to benefits

Comments:

- One more recent study (de Andres 2010) met most of the Cochrane criteria for control of bias; it enrolled only 28 patients, and did not report significant differences between BoNT and control (saline or local anesthetic) injections at 15, 30, and 90 days after treatment
- The data from de Andres cannot be combined with the data from Foster 2001 (the only RCT considered by the Cochrane authors to be at low risk of bias), because Foster did not report the Oswestry results in numerical form
- Although a large RCT with clear results in favor of BoNT could change the overall estimate of its effectiveness, the authors' conclusions that the current body of evidence does not support its use appears reasonable

Assessment: A high-quality systematic review which can support a statement that current evidence does not support the use of BoNT for chronic low back pain

References:

De Andres J, Adsua VM, et al. A Double-Blind, Controlled, Randomized Trial to Evaluate the Efficacy of Botulinum Toxin for the Treatment of Lumbar Myofascial Pain in Humans. *Reg Anesth Pain Med* 2010;35:255-260

Foster M, Clapp L, et al. Botulinum Toxin A and chronic low back pain: a randomized, double-blind study. *Neurology* 2001;53(10):1290-3