

Placzek R, Drescher W et al. Treatment of Chronic Radial Epicondylitis with Botulinum Toxin A. JBJS 2007;89A:255-260.

Design: Randomized clinical trial

Population/sample size/setting:

- 130 patients (69 women, 61 men, mean age 47) treated for lateral epicondylitis in a University orthopedics department in Hamburg, Germany
- Eligible if they had symptoms for at least 4 months following the diagnosis, with at least 3 conservative therapies failing to resolve the problem, no other musculoskeletal diseases, and availability of a routine x-ray or MRI within 12 months previously
- Exclusion criteria included inability to work or current compensation claims due to epicondylitis, x-ray evidence of osseous changes in affected elbow, known allergy or antibodies to botulinum toxin A, known muscle disease, prior surgery of the affected elbow, cervicobrachial syndrome, and depression

Main outcome measures:

- Randomized to injection of 60 mouse units of Dysport botulinum toxin A (n=68) or placebo (n=62); 100 U of Dysport=20 to 40 U of Botox
- Single injection administered with standard 25 gauge needle about 3-4 cm distal to the tender epicondyle, with infiltration of the muscle at 2 locations
- Physical therapy was withheld for 6 weeks after injection; the only pain treatment allowed was diclofenac 50 to 150 mg qd prn
- Examinations were done at baseline and at 2, 6, 12, and 18 weeks, and evaluated pain, grip strength, and global improvement
- Main outcome was a "clinical pain score" developed by the authors for the evaluation of lateral epicondylitis severity with 5 items, each scored 0 if negative, 1 if undefined, and 2 if positive, for a scale from 0-10
- "Clinical pain score" items were pain on isometric extension of wrist, pain on isometric extension of third finger, pain on passive flexion of the wrist with the elbow extended, pain on passive flexion of the third finger with the elbow extended, and localized tenderness at the lateral epicondyle
- Two other pain scores were recorded, also on a scale of 0-10: continuous pain in past 48 hours, and maximum pain in past 48 hours
- Grip strength (fist closure strength) was measured with a Martin vigorimeter (bulb resembles a blood pressure cuff); wrist and third finger resisted extension strength was measured on a scale of 0 to 5
- Global assessment of improvement was done by the patient and the attending doctor as substantially better (4 points), slightly better (3 points), unchanged (2 points), slightly worse (1 point), or substantially worse (0 points)
- The botulinum group showed more improvement than the placebo group in the clinical pain score beginning at two weeks after the injection and continuing through week 18; the mean baseline pain scores for the Botulinum and placebo group were 8.43 and 8.55 respectively, while the mean 18 week scores were 2.88 and 4.29

- Third finger extension was weaker in the botulinum group at weeks 2, 6, and 12, but was equal at week 18; wrist extension was equal between groups at all examinations
- Fist closure strength was weaker in the botulinum group at week 2 (was 101% of baseline for botulinum and 114% of baseline for placebo); the strengths then were equal at weeks 6, 12, and 18, with the final measurements being 156% of baseline for botulinum and 142% of baseline for placebo

Authors' conclusions:

- Botulinum toxin A is an effective treatment for chronic lateral epicondylitis, and does not impair a patient's ability to work
- The 60 U of Dysport used in this study represents a smaller paralyzing dose than the 50 U of Botox used in some other studies, and maintains the working capacity of patients

Comments:

- Clinical pain score developed by authors has 5 items which appear to cover a satisfactory spectrum of manifestations of lateral epicondylitis and may be sensitive to change in the condition
- Global assessment of improvement (reported to be better in the botulinum group than the placebo group) was done "by the patient and by the attending doctor" and may have been influenced by the doctor
- For fist closure, Table VII gives strength at week 2 and later, but no baseline data
- Because workers' compensation patients were excluded from the study, application of results to a WC population will require careful consideration
- Strength measurements were not blinded and may have been influenced by the examiner, but weakness was still detected in the botulinum group
- Third finger extension weakness appears to be a more sensitive indicator of motor inhibition than grip strength
- Dysport is recently approved by the FDA for cervical dystonia and for glabellar lines, similar to Botox, and both would be off-label for epicondylitis

Assessment: Adequate (blinded measurements of strength and global improvement would have been more persuasive)