

Lee JH, Lee S-H, Song SH. Clinical Effectiveness of Botulinum Toxin Type B in the Treatment of Subacromial Bursitis or Shoulder Impingement Syndrome. Clin J Pain 2011;27(6):523-528.

Design: Randomized clinical trial

Study question: In the setting of subacromial impingement shoulder pain, is botulinum toxin B (BTX) comparable in effectiveness to steroid injection?

Population/sample size/setting:

- 61 patients (25 men, 36 women, mean age 57) treated for symptoms consistent with subacromial impingement syndrome in a physical medicine clinic at the University of Ulsan, Korea
- Eligibility criteria were shoulder or lateral deltoid pain for at least 2 months not responsive to analgesics and PT, diagnosis of subacromial bursitis or impingement based on both Neer and Kennedy-Hawkins clinical tests being positive
- Exclusion criteria were fracture, glenohumeral osteoarthritis, bone tumor, osteonecrosis history of shoulder and cervical trauma, cervical radiculopathy, neurologic deficit of an upper limb, clinical and ultrasound evidence of a full thickness rotator cuff tear, laboratory evidence of an inflammatory or autoimmune disease, subacromial injection of BTX or steroid in the past 6 months

Main outcome measures

- Randomization was to ultrasound-guided injection with either BTX (n=31) or steroid (n=30)
 - o BTX group was treated with 2 ml of 0.5% lidocaine and 2500U of Myobloc
 - o Steroid group was treated with 2 ml of 0.5% lidocaine and 40 mg triamcinolone
 - o The injecting physician knew the treatment group, but the patients did not
- No other treatment was done during the study; patients were asked not to have PT or take analgesic medication during the followup period
- Clinic re-visits were scheduled at 1 and 3 months after injection; there were 4 BTX patients and 3 steroid patients who were lost to followup at 3 months
- Primary outcomes were the numeric rating scale (NRS) for pain, the Korean version of the Disability of Arm, Shoulder, and Hand (DASH) questionnaire: shoulder active abduction ROM was a secondary outcome
 - o In addition, proportion of patients with successful treatment was recorded, where successful treatment was a 50% decrease in the NRS or a 10 point improvement in the DASH
 - o Evaluations were done by a nurse blinded to treatment group

- Both groups experienced improvement in pain NRS and in DASH during the followup period, and at 1 month, the improvements were equal
 - o The mean NRS of the BTX group decreased from 7.0 to 3.0; that of the steroid group decreased from 6.9 to 3.4
 - o The DASH of the BTX group decreased from 65.5 to 41; that of the steroid group decreased from 62.4 to 41.6
- However, at 3 months, the BTX group had more favorable NRS and DASH scores than the steroid group
 - o For the BTX group, the NRS and DASH scores were 2.9 and 37.4; for steroid, the NRS and DASH scores were 4.5 and 46.2
 - o The proportion of successes for NRS were greater for BTX than for steroid (16/26 versus 6/25); for DASH, the successes for BTX were 23/26 versus 15/25 for steroid
- Mild discomfort at the injection site was reported by 2 patients in the BTX groups and 3 patients in the steroid group; other adverse effects were not reported

Authors' conclusions:

- BTX B showed more persistent benefits in pain reduction and shoulder function than triamcinolone in patients with subacromial bursitis or impingement syndrome
- BTX B could be useful to replace steroids as a treatment for these subacromial shoulder conditions

Comments:

- Most methodological requirements for control of bias appear to have been met
- The authors' discussion mentions the problems associated with repeat steroid injections, but there is an implication that BTX can be given repeatedly
 - o The formation of blocking antibodies with BTX deserves some discussion which it did not receive
- Rotator cuff tears were ruled out by ultrasound; it is not quite clear whether all patients had US on entry to the study, or whether it occurred when the injections were being given
- Neither group had physiotherapy; this is a departure from usual practice but its direction on the group comparisons cannot be inferred from the data
- Although the clinical benefits of steroid injection appear not to depend greatly upon the accuracy of the placement of the injection, there is no reason to assume that the same is true of BTX injections; ultrasound guidance was done in all patients, and it cannot be assumed that landmark-guided injections would be effective

Assessment: Adequate for some evidence that in patients with subacromial bursitis or subacromial impingement syndrome, a single ultrasound-guided subacromial injection of

botulinum toxin B may be more effective than a steroid injection in pain reduction and shoulder function 3 months after the injection , but the usefulness of repeated BTX injections is not known