

Porta M. A comparative trial of botulinum toxin type A and methylprednisolone for the treatment of myofascial pain syndrome and pain from chronic muscle spasm. Pain 2000;85:101-105.

Design: Randomized clinical trial

Population/sample size/setting:

- 40 patients (27 women, 13 men, mean age 48) treated for myofascial pain at a pan center in a neurology department in Italy
- Eligibility determined by duration of pain from chronic muscle spasm between 6 months and 2 years in the piriformis, iliopsoas, or anterior scalene muscles confirmed by CT or MRI and by EMG to rule out other diseases; pain was characterized by trigger points
- Exclusion criteria were history of disc or bone disease, prior surgery for disc disease, abdominal cavity tumors, abnormal anatomy, rheumatoid disease, or radiculopathy

Main outcome measures:

- All participants received a single site injection of 0.5% bupivacaine plus a depot of a study drug
- Randomization was on the study drug; this was either botulinum toxin A (BTX-A, n=20) or methylprednisolone (n=20)
- Injection was done with position confirmed by CT scan using a spinal epidural needle advanced into the belly of the involved muscle, either the piriformis (n=23), anterior scalene (n=10), or iliopsoas (n=7)
 - o BTX-A dose for piriformis was 100 U, for iliopsoas was 150 U, and for anterior scalene was 80 U; dose of methylprednisolone was 80 mg for each muscle
- All patients had the same post-injection physical therapy, which involved passive stretching 4-5 times per day for 30 days, followed by active stretching 2-3 times per day for the following 30 days
- Pain on VAS was assessed at baseline, at 30 days, and at 60 days, with changes from baseline as the main measure of effectiveness
- Pain scores were presented graphically, but appear to be about 7.9 for the BTX group and 7.2 for the methylprednisolone group
- Mean reduction in pain scores at 30 days was similar for the BTX (3.9 points) and methylprednisolone (3.5 points) intervention groups
- Mean pain reduction at the 60 day assessment was greater for BTX (5.5 points) than for methylprednisolone (2.5 points)
- Some transient (2-3 hour) adverse effects were recorded; two cases of mild dysphonia in the anterior scalene injection and 3 cases of leg weakness after piriformis injection
- 19 patients reported increased pain after the first 3-4 days of passive stretching, but this pain was reduced after 5-8 days

- Noncompliance with stretching exercises was reported for 7 patients, all of whom were in the methylprednisolone group, presumably because the stretching was more painful

Authors' conclusions:

- BTX-A in combination with stretching exercises was effective in reducing the pain from myofascial trigger points
- Compliance to the physiotherapy regimen is essential to maximize the efficacy of BTX-A therapy
- A single injection is expected to be effective; re-injection carries the risk of provoking an immune response

Comments:

- The description of the participants is fairly minimal; the reader is not told what kinds of interventions had been attempted prior to the trial, what kinds of medications were being taken, and whether any of the patients had previously had injections with either of the study drugs
- Baseline and follow-up pain scores are presented graphically in Figure 3 rather than in tabular form (with numerical data); baseline distribution of age, sex, and duration of symptoms are not in Fig. 3; the effect size in the bar graph appears to be appreciable, but actual data are more interpretable
- Method of randomization is not reported (allocation concealment not reported); this often represents a threat to internal validity
- The method of identifying the injection site could be clearer; it appears that an EMG signal was involved, in addition to CT, but the description is sketchy
- Method of determining trigger point diagnosis is unreported; since the piriformis can be difficult to palpate (and referral from a trigger point could be confused with piriformis syndrome nerve entrapment), there is a possibility of misclassification of the patients
 - o This is unlikely to inflate the treatment effect, since such misclassification would not be associated with treatment group
 - o The distinction may be irrelevant in any case, if it were the case that BTX could relax the piriformis and alleviate nerve entrapment
- Functional outcomes at the end of the study would have added pertinent information to the study
- Unlike several of the studies of BTX in lateral epicondylitis, where extensor motor strength was reported in the injected muscle groups, no motor strength is reported; and it appears to be assumed that there was no impact on strength
- The lower compliance in the steroid group is itself an outcome of interest, and may account for much of the observed differences in pain VAS
- The hypothesis that BTX is beneficial appears to be worth further study, but the information in this study does not support an evidence statement

Assessment: Inadequate for evidence statement that BTX in combination with daily stretching exercises can alleviate trigger point pain (description of participant characteristics is not adequate to decide who would benefit from the intervention);

baseline comparison of patient characteristics is sketchy, method of randomization not described, effect on motor function not reported)