

Elizondo-Rodriguez J, Araujo-Lopez Y, et al. A comparison of botulinum toxin a and intralesional steroids for the treatment of plantar fasciitis: a randomized, double-blinded study. Foot Ankle Int. 2013;34(1):8-14.

Design: Randomized clinical trial

Study question: Is botulinum toxin injected into the calf an effective treatment of plantar fasciitis?

Population/sample size/setting:

- 36 patients (16 men, 20 women, mean age 43) treated for plantar fasciitis at a university orthopedics department in Monterey, Mexico
- Eligibility criteria were heel pain at the insertion of the plantar fascia in skeletally mature patients who had failed NSAIDs and ordinary shoe pads for three months or longer
- Exclusion criteria were associated knee/ankle dysfunction and associated pathologies such as other rheumatologic conditions, neurological abnormalities, psychiatric abnormalities, previous injection of the affected heel, recent infection of the heel, and adverse reactions to the materials which were to be used in the study

Interventions:

- All patients had an injection followed 7 days later by stretching exercises for the plantar fascia, and no patient was immobilized
- Randomization was to which injection was done, either botulinum toxin a (BTX-A, n=19) or steroid injection (n=17)
 - o BTX-A was given in a dose of 100 U the lateral and 100 U in the medial thickest part of the muscular mass of the calf, and 50 U into the soleus, for a total of 250 U
 - o Steroid was injected into the medial plantar surface of the foot, with 2 ml of 2% lidocaine and 2 ml of 8 mg dexamethasone

Outcomes:

- Followup was done at 15 days after the injection and again at 1, 2, 4, and 6 months
- Several scales were used to evaluate outcomes
 - o Pain VAS on scale from 0 to 10
 - o The Maryland Foot Score on a scale from 0 (incapacity to work) to 45 (no pain)
 - o The American Orthopaedic Foot and Ankle Society (AOFAS) scale (highest score 100)
 - o The Foot and Ankle Disability Index (FADI, best score 100)

- The two groups were similar at baseline, and both groups improved from the start of the study until the final followup at 6 months, but the BTX-A scores began to be more favorable than the steroid scores beginning at the first followup visit and continuing to be more favorable at the ensuing followup visits
 - o For example, the AOFAS scores in the BTX-A and steroid groups at baseline were 46.0 and 46.8, and at 6 months the scores were 93.2 and 74.8 respectively
 - o The pain VAS scores for BTX and steroid were 7.1 and 7.7 at baseline and were 1.1 and 3.8 at 6 months
- No adverse reactions were reported with either intervention

Authors conclusions:

- In plantar fasciitis patients who are doing stretch exercises, an injection of BTX-A leads to better symptomatic and functional scores than an injection of lidocaine plus dexamethasone

Comments:

- Although the authors did not declare a primary outcome, all four outcomes were reported and all favored the BTX group, making it unlikely that selective outcome reporting has occurred
- Measures of foot dorsiflexion, although not designated as outcomes, would have been of interest as the study progressed
- While the injection of different sites makes participant blinding impractical, it would not necessarily preclude blinding of outcome assessors, especially for the Maryland Foot score, which has a component involving motion and the shape of the foot
- Duration of action of BTX beyond six months would be needed to ascertain whether this leads to a lasting resolution of a condition whose clinical course is expected to be self-limiting, making BTX a candidate for a definitive treatment
- The case definition of plantar fasciitis required for entry did not specify that the heel pain occur in the morning or that it be reproduced with pressure over the calcaneal tuberosity, criteria which are commonly specified for study eligibility for plantar fasciitis interventions, and a trial of stretching was not required before study entry as part of the conservative treatment

Assessment: Adequate for some evidence that in the setting of plantar fasciitis which lasts more than 3 months, a single injection of botulinum toxin into the gastrocnemius and soleus, in combination with plantar stretching exercises is likely to lead to better pain and functional improvement lasting up to six months than an injection of dexamethasone into the plantar surface of the foot