

Diaz-Llopis IV, Rodriquez-Ruiz CM, et al. Randomized controlled study of the efficacy of the injection of botulinum toxin type A versus corticosteroids in chronic plantar fasciitis: results at one and six months. Clin Rehabil 2011;26(7):594-606.

Design: randomized clinical trial

Purpose of study: to compare the effects of injecting botulinum toxin type A (BTX) versus the effects of injecting corticosteroids into the intrinsic muscles of the foot in patients with chronic plantar fasciitis

Reasons not to cite as evidence:

- Although the design of the study is adequate in terms of proper randomization and blinding to control biased comparisons, there are significant problems with the analysis of the results
- The comparison groups consisted of patients randomized to plantar muscle injection with BTX (n=28) or corticosteroid (n=28)
- The outcomes were initially compared at one month, and consist of changes in four separate foot health status questionnaires
- The differences between intervention groups were not statistically different at one month
- After the one month evaluation, due to ethical considerations likely required by the IRB for the study, patients who had failed to improve on one injection were crossed over to the other injection (i.e., steroid injection to BTX and BTX to steroid injection), and at six months these groups were compared
- The authors report that the improvement in the foot health questionnaires for 34 patients (who originally responded to BTX plus patients who failed on steroid but crossed over to BTX) were greater than for 22 patients who responded to steroid plus patients who failed on BTX but crossed over to steroid injection
- Table 5 presents the means, medians, and standard deviations for the improvement scores between one month and six months for these two groups
- The two groups are said to differ in their improvement scores, evidenced by a low p value in the right hand column of Table 5, where an unpaired t-test was used to compare the improvement scores
- Although there appear to be improvements in the scores for the BTX group and deteriorations for the steroid group, the standard deviations (SD) are quite large, meaning a very wide variation in the scores for the two groups
- For example, in Table 5, the mean change for the BTX group is 19.1 with SD of 24.76; the mean change for the steroid group is -6.84 with SD of 31.95; the difference in means is 25.94 in favor of the BTX group, but the pooled SD for the difference is

- 27.78, the value of the t statistic for this difference is $25.94/27.78$, which is 0.983, and the p value for this difference is 0.354
- The other group differences in Table 5 are similarly not statistically different between the two groups
 - Similarly, Table 4, which compared “therapeutic failures” at one month for BTX versus steroid, appears to favor BTX, but the p value of 0.61 is consistent with a chance difference between the intervention groups
 - Therefore, the differences between group improvement scores are consistent with what would be expected by chance, unless there is a major error in the reporting of the standard deviations in Table 5

Assessment: inadequate for evidence that an injection of BTX into the muscles of the foot is significantly more effective than an injection of corticosteroid for patients with plantar fasciitis lasting longer than six months