

McMillan AM, Landorf KB, et al. Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial. BMJ 2012;344:e3260.

Design: Randomized clinical trial

Study question: Does a single injection of dexamethasone reduce heel pain from plantar fasciitis more effectively than saline, and does this benefit last longer than one month?

Population/sample size/setting:

- 82 patients (39 women, 43 men, mean age 52) treated for plantar fasciitis at La Trobe University in Melbourne, Australia
- Eligibility criteria were at least 8 weeks of inferior heel pain at least 20 points on a 100 point VAS, reproduced by palpation of the medial calcaneal tubercle or proximal plantar fascia, confirmed by diagnostic ultrasonography with a plantar fascial thickness of 4 mm or more
- Exclusion criteria were pregnancy, steroid injection for plantar fasciitis within the previous six months, diabetes, posterior heel pain, skin or soft tissue infection near the injection site, previous local surgery, local trauma, starting any treatment for plantar fasciitis in the previous four weeks, or inability to walk household distances without the use of an aid

Interventions:

- Randomization was to plantar injection following a tibial nerve block to either saline (n=41) or 4 mg of dexamethasone sodium phosphate (n=41)
- All injections were done under ultrasound guidance into the proximal plantar fascia using a medial oblique approach in the region of maximal fascial thickening
- Patients with bilateral plantar fasciitis had injections into both feet, but were asked to report a single pain score so that they would be analyzed with a single outcome value
- All participants were given a daily stretching program during the first 8 weeks and were asked to complete a daily log of their adherence to the exercise program

Outcomes:

- Primary outcomes were the pain component of the foot health status questionnaire at 4, 8, and 12 weeks, and plantar fascial thickness at the same time points
 - o In the foot health status questionnaire, a score of 0 represents the worst outcome and 100 points represent the best outcome
- Secondary outcomes were function on the foot health status questionnaire and “first step” pain at 4, 8, and 12 weeks
- Foot pain scores on the foot health status questionnaire were equal at baseline (36.8 in the steroid group and 35.8 in the saline group)

- Plantar fascial thickness had a mean of 6.67 mm in the steroid group and 6.29 mm in the saline group, a non-statistically greater thickness in the steroid group
- At 4 weeks, the foot pain scores had improved in both groups, but the steroid group had a higher (better) score of 58.9 compared to 47.5 in the saline group, with an adjusted (for baseline scores) group difference of 10.9 points (95% confidence interval from 1.4 to 20.4)
- At 4 weeks, the plantar fascia thickness, adjusted for the baseline thickness, was lower in the steroid than in the saline group with an adjusted difference of 0.35 mm (95% CI from 0.03 to 0.67)
- At 8 and 12 weeks, the foot pain scores remained greater (better) in the steroid group than in the saline group, but the differences were no longer statistically significant
- At 8 and 12 weeks, the group differences in plantar fascial thickness remained statistically lower in the steroid than in the saline group
- For the secondary outcomes, there was an 11.37 point difference in “first step” pain in favor of the steroid group at 4 weeks, but later group differences were not significant
 - o The functional score differences were not significant at any of the followup times

Authors’ conclusions:

- A single ultrasound-guided injection of dexamethasone is a safe and effective short term treatment for plantar fasciitis, providing better pain relief than placebo for at least 4 weeks
- The adjusted group difference for pain on the foot health status questionnaire was, however, suboptimal, with a mean difference of 11 points, which only approaches the minimal important difference of 13 points for this outcome
- The measurements of plantar fascial thickness suggest that it is a useful objective method for monitoring the progress of treatment, but the interrater reliability of this measure has not been investigated in detail
- Dexamethasone sodium phosphate may have been safer than for steroid compounds such as methylprednisolone acetate; the lack of adverse effects such as post-injection flare and plantar fascia rupture supports this idea

Comments:

- Apparently adverse effects of the steroid injection did not occur, although this information is presented in the discussion rather than in the results section
- The authors made special efforts to preserve blinding of patients and physicians, and the analysis of group differences by adjustment for baseline differences is also appropriate
- Although details are not presented in any of the tables, it appears that there was not a significant functional advantage of dexamethasone over saline

- The thickness of the plantar fascia was measured, but the thickness of the plantar fat pad was not; since there is some concern about the effects of steroid injection on this structure, it appears that an opportunity was missed to assess that effect
- Although a correlation between fascial thickness and pain relief was observed, this correlation is not necessarily beneficial, since attenuation of the plantar fascia could increase the risk of fascial rupture
 - o Past reports of fascial rupture from steroid injection (Sellman 1994 and Acevado 1998) were associated with triamcinolone in a dose of 20 to 40 mg
 - o The correlation coefficient of -0.3, while different from 0, would have a squared value of 0.09, meaning that fascial thickness captures only 9% of the variation in pain scores; this is almost a trivial amount and fascial thickness is a weak surrogate measure for what is important to patients

Assessment: Adequate for some evidence that a single ultrasound guided injection of dexamethasone into the plantar fascia reduces pain in the short term compared to saline injection

References:

Acevado JI, Beskin JL. Complications of Plantar Fascia Rupture Associated with Corticosteroid Injection. *Foot Ankle Int* 1998;19(2):91-97

Sellman JR. Plantar Fascia Rupture Associated with Corticosteroid Injection. *Foot Ankle Int* 1994;15(7):376-381.