
Design: Randomized clinical trial

Study question: Does an injection of prednisolone acetate into the plantar fascia alleviate the pain of plantar fasciitis, and does ultrasound guidance of the injection affect the pain relief response?

Population/sample size/setting:

-  65 patients (29 men, 36 women, mean age 49) treated for plantar fasciitis at a hospital rheumatology department in Belfast
-  Eligibility criteria were a history of at least 8 weeks of heel pain combined with point tenderness over the medial tubercle of the calcaneus
-  Exclusion criteria were a diagnosis of inflammatory arthritis, prior surgery or trauma of the heel, or a previous steroid injection into the heel fat pad

Interventions:

-  Randomization was to one of three groups: ultrasound-guided injection of 20 mg of methylprednisolone acetate (n=22), unguided injection of 20 mg of methylprednisolone acetate (n=22), or ultrasound-guided saline injection (n=21)
  -  The unguided injection was via the posterior approach parallel to the heel pad in the direction of the medial tubercle of the calcaneus
-  All patients were told to avoid weight bearing on the heel pad for 48 hours and were allowed to continue with their usual pain medications

Outcomes:

-  The primary outcome was the VAS pain score 12 weeks after the injection
  -  Secondary measures included the VAS score at 6 weeks and changes in the plantar fascia thickness measure by ultrasound at 6 and 12 weeks
-  The mean baseline thickness of the plantar fascia was 6.1 mm
-  At 6 and at 12 weeks, both steroid injection groups had lower pain scores, adjusted for baseline values, than the placebo group
  -  At 6 weeks, the ultrasound guided steroid group pain scores were 19.7 points less than the placebo group
  -  At 6 weeks, the unguided steroid group pain scores were 24.0 points less than the placebo group
  -  At 12 weeks, the ultrasound guided steroid group pain scores were 25.1 points less than the placebo group
  -  At 12 weeks, the unguided steroid group pain scores were 28.4 points less than the placebo group
- There was no difference in pain scores at any time between ultrasound guided and unguided injection groups
- Plantar fascial thickness was also lower in both steroid groups compared to the placebo group
- No adverse events occurred as a result of any of the interventions

Authors’ conclusions:

- Both ultrasound guided and unguided steroid injections show a sustained benefit at 6 and 12 weeks compared to a placebo injection
- Ultrasound guidance did not appear to make a difference in outcome, perhaps due to the diffusion of the steroid in the vicinity of the injection site; precise placement of the needle may not be critically important to success
- A single injection of 20 mg of methylprednisolone acetate is beneficial for pain that has not responded to 8 weeks of conservative treatment

Comments:

- Most threats to internal validity appear to have been controlled; the syringes were masked with tape to preserve blinding of physicians and patients, and the randomization sequence was done in a way to preserve allocation concealment
- These results contrast with those of other investigators (Crawford 1999 and McMillan 2012), who found short term effectiveness of steroid injection but not past one month
- There may be differences in the placement of the steroid, or the dose and form of the steroid, which, in addition to the play of chance, could account for the contrasts in duration of reported effectiveness of the steroid injections
- Pain VAS, fascial thickness, and an index for heel tenderness were the reported outcomes; a functional outcome is lacking
- The text alludes to supplementary material in the online version of the article, but a link to that supplementary data yields no results; the journal has been contacted regarding this issue
- No instruction was given regarding plantar stretching exercises, which are likely to be beneficial and which could have improved the outcomes in the placebo group

Assessment: High quality study for evidence that an injection of 20 mg of methylprednisolone acetate, with or without ultrasound guidance, may be more effective than a placebo injection in reducing heel pain up to 12 weeks in patients with plantar fasciitis, but functional outcomes are uncertain

References: