
Design: randomized clinical trial

Study question: Is platelet-rich plasma injection an effective intervention for chronic plantar fasciitis?

Population/sample size/setting:

- 40 patients (17 men, 23 women, mean age 55) treated for a diagnosis of plantar fasciitis in Nantucket, MA
- Chronic plantar fasciitis defined as at least 4 months of heel pain despite a trial of rest, physical therapy for 6 weeks, silicone heel lifts for at least 4 weeks, cam walker bracing or cast immobilization for at least 4 weeks, night splinting for at least 4 weeks, and NSAIDS
- All patients screened with plain x-rays and MRI to confirm the diagnosis of plantar fasciitis

Interventions:

- Randomization was into two groups: steroid injection (n=20) or platelet rich plasma (PRP, n=20)
  - Steroid group had a single ultrasound-guided injection of 40 mg of Depo-Medrol
  - PRP group had a blood draw of 27 ml spun for 12 minutes at 2400 RPM; a 3cc PRP isolate was injected with ultrasound guidance
- After the injection both groups were placed onto a cam walker boot for 2 weeks and instructed to follow a home eccentric exercise and calf stretching program
  - NSAIDS were not allowed for the 2 weeks after injection and were discouraged throughout the study

Outcomes:

- Followup was done at 3, 6, 12, and 24 months after treatment
- Baseline BMI was similar between groups
- American Orthopedic Foot and Ankle Society (AOFAS) hindfoot scoring was done by a blinded observer immediately prior to the injection and repeated at each followup visit
  - AOFAS score allocates 40 points for pain, 50 points for function, and 10 points for alignment, with 100 points being the best score
- In the steroid group, the baseline AOFAS score was 52, which increased to 81 at 3 months but returned to near baseline levels of 58 at 12 months
In the PRP group, the baseline AOFAS score was 37, which increased to 95 at 3 months and was 94 at 12 months

Authors’ conclusions:

- Steroid injection provides temporary relief from the symptoms and functional consequences of plantar fasciitis, but PRP provides lasting relief
- The study was single blind, which is its primary flaw

Comments:

- The study need not have been single blind, and there is no reason the patients could not have been blinded to their intervention group; this has been done in other studies of PRP when the non-PRP group had the same amount of blood drawn prior to the injection being evaluated
- Even the single blinding was done using the AOFAS score, 60% of which is based on self-report and 40% is based on measurements done by the observer
- There is no description of the randomization method or how the randomization sequence was generated, and no indication of allocation concealment
- There is only a single author, who is a consultant for the platelet-concentrating system used in the study
- The diagnosis was arrived at by an undetermined method; imaging was used to “confirm” the diagnosis, but it is primarily a clinical diagnosis and the way that patients qualified for the study is not clear
- The finding that the PRP group did better than the steroid group could be due to a detrimental effect of steroid rather than a therapeutic effect of PRP

Assessment: Inadequate for evidence of PRP effectiveness