

**Gollwitzer H, Sacena A, et al. Clinically Relevant Effectiveness of Focused Extracorporeal Shock Wave Therapy in the Treatment of Chronic Plantar Fasciitis: A Randomized, Controlled Multicenter Study. JBJS Am 2015;97:701-8.**

Design: randomized clinical trial

Purpose of study: to estimate the effectiveness of extracorporeal shock wave therapy (ESWT) in the setting of plantar fasciitis

Population/sample size/setting:

- 246 patients (77 men, 169 women, mean age 49) treated for plantar fasciitis at 5 study centers in the United States
- Eligibility criteria were six months with a diagnosis of plantar fasciitis with failure of at least four nonsurgical treatment modalities, including at least two pharmacological and two nonpharmacological modalities
  - o Diagnosis of plantar fasciitis was made by foot and ankle specialists with at least ten years of professional experience
  - o Patients had to have at least 5 points on all three VAS scores (heel pain on taking first steps in the morning, heel pain while doing daily activities, and heel pain while applying a standardized local pressure with a force meter)
  - o A Roles-Maudsley score of fair to poor was also required (excellent R-M score is no pain=1; good scores is occasional discomfort but full movement and activity=2; fair score is discomfort after prolonged activity=3, and poor score indicates pain which limits activity=4)
- Exclusion criteria were active infection or a history of chronic infection, systemic inflammatory disease, neurological or vascular insufficiencies, nerve entrapment, coagulation disturbances, bilateral heel pain in deed of treatment, or pregnancy

Interventions:

- All patients had a minimum washout time of nonsurgical treatments prior to treatment (6 weeks since the last steroid injection, 4 weeks since the last local anesthetic injection, 1 week since the last NSAID drug, 2 days since the last heat, ice, etc)
- Randomization was to either ESWT (n=124) or placebo (n=121), once weekly for 3 weeks
- ESWT was administered with 2000 impulses with 4 impulses/second for a dose of  $0.25 \text{ mJ/mm}^2$  at the most tender point on the affected heel without ultrasound guidance

- Placebo group received sham ESWT with an air-filled standoff that prevented the transmission of shock waves but had an identical handpiece to ensure participant blinding
- The only medication allowed during followup was 2 g of acetaminophen per day for up to 14 days; thereafter, 2 g of acetaminophen per week; no other therapies were allowed

#### Outcomes:

- Primary pain outcome was overall reduction of heel pain, measured by percentage change in VAS composite score 12 weeks after the last intervention, compared with the score at baseline, taken from the 3 VAS pain scores that qualified the patients for entry into the study
- Primary outcome for function was improvement in the mean Roles-Maudsley score at 12 weeks
- Followup was nearly complete, with outcome data available for 98% of the enrolled subjects
- Median composite VAS pain score was reduced by 69.2% in the ESWT group and by 34.5% of the placebo group
- The mean Roles-Maudsley score for the ESWT group was 2.5, which was lower (better) than for the placebo group whose mean score was 2.9
- Treatment was well tolerated; with minor pain during treatment, pain after treatment, and swelling occurring more often in ESWT group (65 adverse events) than in the placebo group (11 adverse events)

#### Authors' conclusions:

- ESWT in weekly interventions without local analgesia is more effective than placebo ESWT in reducing pain and improving function in patients with chronic plantar fasciitis which has not responded to previous pharmacological and nonpharmacological treatments

#### Comments:

- An advantage of the current study is the fairly large sample size and the good retention of patients for outcome measurements
- A blinded investigator used a pressure meter to detect sensitivity at the point of maximal tenderness, which was quantified as the amount of pressure needed to produce a VAS pain of 10 (maximum pain), with an increased pressure tolerance detected as a decrease in pain with followup applications of the same pressure; this could be expected to induce participants to drop out of the study, but this did not occur, and the measurement is not of primary importance

- The statistical analysis plan in the methods called for a nonparametric test (the Mann-Whitney score), analyzed in terms of the probability of a randomly selected ESWT patient having a lower pain score than a randomly selected placebo patient; if this probability is 56%, the effect size is small; if it is 64%, the effect size is medium, and if it is 71%, the effect size is considered small; however, this was not the effect size reported in the outcome results section
- Some secondary measures, which defined “responders” in yes/no terms according to whether they had either 60% pain reduction or had a Roles-Maudsley score of good or excellent, also favored the ESWT group
- Even though there were more frequent reports of pain with ESWT than with placebo, it appears that the pain was not severe enough to lead the patient to request local anesthesia when it was offered as an option
- The dose of 0.25 mJ/mm<sup>2</sup> at the most tender point would be considered “high intensity” ESWT, conventionally set as being greater than 0.2 mJ/mm<sup>2</sup>

Assessment: high quality study for good evidence that high intensity ESWT at a dose of 0.25 mJ/mm<sup>2</sup> is more effective than sham ESWT for improving pain and function in chronic plantar fasciitis which has not responded to both nonpharmacological and pharmacological treatment after 6 months of symptoms