Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial.

Malay DS, Pressman MM, Assili A, Kline JT, York S, Buren B, Heyman ER, Borowsky P, Lemay C.

Abstract

Extracorporeal shockwave therapy (ESWT) has demonstrated efficacy in the treatment of recalcitrant proximal plantar fasciitis.

Objective

The objective of this investigation was to compare the outcomes of participants treated with a new ESWT device with those treated with placebo.

Methods

A total of 172 volunteer participants were randomized in a 2:1 active-to-placebo ratio in this prospective, double-blind, multicenter trial conducted between October 2003 and December 2004. ESWT (n = 115) or placebo control (n = 57) was administered on a single occasion without local or systemic anesthesia or sedation, after which follow-up was undertaken.

Results

The primary outcomes were the blind assessor's objective, and the participant's subjective assessments of heel pain during the first 3 months of follow-up. Participants were also followed up to 1 year to identify any adverse outcomes that may have been related to the shockwave device. On the visual analog scale, the blind assessor's objective assessment of heel pain displayed a mean reduction of 2.51 in the shockwave group and 1.57 in the placebo group; this difference was statistically significant (P = .045). On the visual analog scale, the participant's self-assessment of heel pain displayed a mean reduction of 3.39 in the shockwave group and 1.78 in the placebo group; this difference was statistically significant (P < .001). No serious adverse events were observed at any time.

Conclusions

It was concluded that ESWT was both efficacious and safe for participants with chronic proximal plantar fasciitis that had been unresponsive to exhaustive conservative treatment. J Foot Ankle Surg. 2006 Jul-Aug;45(4):196-210.