

Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial

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Abstract

Background: Extracorporeal shock wave therapy (ESWT) is an increasingly popular therapeutic approach in the management of a number of tendinopathies. Benefit has been shown in calcific tendinitis of the rotator cuff, but evidence for its use in non-calcific disorders is limited.

Aims: To perform a double blind randomised controlled trial of moderate dose shock wave therapy in plantar fasciitis.

Methods: Adults with plantar fasciitis for at least 3 months were randomised to receive either active treatment (0.12 mJ/mm²) or sham therapy, monthly for 3 months. Pain in the day, nocturnal pain and morning start-up pain were assessed at baseline, before each treatment and 1 and 3 months after completion of therapy.

Results: Eighty-eight subjects participated and no differences existed between the groups at baseline. At 3 months, 37% of the subjects in the ESWT group and 24% in the sham group showed a positive response (50% improvement from baseline) with respect to pain. Positive responses in night pain occurred in 41% and 31% in the ESWT and sham groups, respectively. Positive responses in start-up pain occurred in 37% and 36% in the ESWT and sham groups, respectively. Both groups showed significant improvement over the course of the study, but no statistically significant difference existed between the groups with respect to the changes were seen in any of the outcome measures over the 6-month period.

Conclusions: There appears to be no treatment effect of moderate dose ESWT in subjects with plantar fasciitis. Efficacy may be highly dependent upon machine types and treatment protocols. Further research is needed to develop evidence based recommendation for the use ESWT in musculoskeletal complaints.

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Introduction

Extracorporeal shock waves are focussed, single pressure pulses of microsecond duration and represent one of the most effective approaches to the treatment of renal calculi. More recently extracorporeal shock wave therapy (ESWT) has been used in the treatment of a number of musculoskeletal conditions, including insertional disorders such as plantar fasciitis, at doses of 10–20% of those used in lithotripsy of renal calculi [3,7,11,13,14,16,19]. The rationale for such an approach is the stimulation of soft tissue healing, reduction of calcification, inhibition of pain receptors, or denervation

to achieve pain relief [3,5,7,8,11,13,19], although the true effects have not been established and doses and regimes can vary. Despite the increasing popularity of this treatment modality, there remains a lack of randomised controlled trials in specific musculoskeletal conditions. We report the results of a double blind randomised controlled trial of moderate dose ESWT in the management of plantar fasciitis.

Methods

Adult subjects with a clinical diagnosis of plantar fasciitis were recruited in the out-patient clinic after assessment by a rheumatologist (CAS). Permission for the study was obtained from the Local Medical Ethics Committee and informed consent was obtained by all subjects prior to participation.

Inclusion criteria were: adults over the age of 18 years with unilateral plantar heel pain for at least 3 months. All subjects had point tenderness at or near the medial calcaneal insertion of the plantar fascia.

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Exclusion criteria were: additional foot or ankle pathology including instability, arthritis, diffuse heel pad tenderness or a local dermatological problem, generalised polyarthritis, neurological abnormalities, anticoagulant therapy, treatment to the affected foot within previous six weeks, pregnancy, diabetes, connective tissue or infectious disease, vasculitis or malignancy.

Subjects were assessed prior to treatment by a blinded observer. All subjects completed 100 mm visual analogue scales for foot pain during the day and at night in the preceding 24 h. All assessments were repeated prior to each treatment and 1 and 4 months after completion of therapy (i.e. 3 and 6 months from baseline). Each subject also completed a 100 mm visual analogue score for pain on initial weight bearing first thing in the morning (start-up pain).

All treatments were applied using a Sonocur Plus Unit (Siemens), which generates mechanical shock waves using an electromagnetic generator. The shock waves are delivered through a treatment head which must be inflated to allow focussing and tissue penetration. Subjects were randomised using randomisation tables to receive either local ESWT (1500 pulses at 0.12 mJ/mm²) or sham treatment, based on that used by others, where the treatment head was deflated, no coupling gel was applied and standard contact with the skin was avoided [16,18]. The machine makes a noise with every shock wave delivered and, in order to enhance the sham design, minimal energy pulses (0.04 mJ/mm²) were generated, but without contact with the site of interest [12,16,18]. No local anaesthesia was used. We used two parameters to focus the treatment upon the target area [18]. Firstly, ultrasonographic localisation of the region of interest was performed. Secondly, the focus was altered according to the site of maximum reproduction of local pain by the subject at initiation of treatment.

All subjects received three ESWT or sham treatments at monthly intervals. No other treatments were permitted during the study period. The primary end point was taken as 3 months from baseline (1 month after completion of treatment). Data was analysed on an intention to treat basis and a positive response was taken as a 50% improvement from baseline at 3 months. Groups were compared with respect to those who had a positive response using Fisher's exact test. Paired non-parametric *t*-tests were used to evaluate the within group change in each of the outcome measures over the study period. A result was considered to be statistically significant if the observed significance level (*p* value) was <0.05.

Results

The characteristics of the eighty-eight subjects who participated are detailed in Table 1. No significant difference existed between the groups at baseline.

Twelve subjects (4 in the ESWT group and 8 in the sham group) did not complete the study. Three of the subjects in the ESWT group withdrew after 1 treatment

Table 2

Subjects with 50% improvement from baseline at 3 months

Group	ESWT	Sham	Fishers exact test
Pain	17 (37%)	10 (24%)	$P = 0.248$; RR = 0.827 (95%CI 0.626–1.093)
Night pain	19 (31%)	13 (31%)	$P = 0.378$; RR = 0.850 (95%CI 0.620–1.166)
Start-up pain	19 (31%)	15 (36%)	$P = 0.664$; RR = 0.913 (95%CI 0.656–1.271)

and one after 2 treatments due to the following: significant improvement (1) inability to tolerate the therapy (1) difficulties with transport (1) and reasons unknown (1). In the sham group, five subjects withdrew after 1 treatment and three after 2 treatments. Reasons given were: no improvement (1), difficulties with transport (2) and reasons unknown (5). One adverse event was reported, which involved syncope with active ESWT due to pain, leading to withdrawal from the study.

At 3 months, 17 (37%) of the subjects in the ESWT group and 10 (24%) of the subjects in the sham group showed a positive response (50% improvement from baseline) with respect to pain. Positive responses in night pain occurred in 19 (41%) and 13 (31%) in the ESWT and sham groups, respectively. Positive responses in start-up pain occurred in 19 (37%) and 15 (36%) in the ESWT and sham groups, respectively (Table 2).

Both groups showed significant improvement over the course of the study, which was maintained at the 6 month follow up assessment. No significant difference existed between the groups with respect to the changes seen in any of the outcome measures over the 6-month period.

Discussion

Plantar fasciitis is a common and often disabling complaint and although there are a vast number of treatment options available, they can be ineffective and some are associated with risks [2]. For example plantar fascial rupture has been reported after steroid injection [2] and surgical measures can be associated with prolonged healing and altered biomechanics of the foot. Perhaps for these reasons, ESWT has quickly been proposed as a therapeutic option in the treatment of a variety of musculoskeletal complaints. In 1996 over 66,000 treatments of ESWT were administered for musculoskeletal complaints in Germany, where the therapy was developed. Since then ESWT has become increasingly popular world wide, illustrated by recent FDA approval for the use of ESWT for plantar fasciitis in the USA [9].

This approval was related to a double-blind multi-centre randomised trial of ESWT in 260 subjects with

Table 1
Baseline characteristics of subjects in each group

Demographic details	Treatment <i>n</i> = 46	Placebo <i>n</i> = 42
Male/female	20/26	17/25
Mean age (range) (years)	51.7 (25–76)	52.5 (30–73)
Mean duration (range) (months)	16.7 (12–312)	13.5 (12–312)
Affected foot (left/right)	16/30	14/28
<i>Previous treatments</i>		
Analgesics	21	20
NSAIDs	31	20
Injections (no. of subjects)	17	16
Physiotherapy	4	13
Change in footwear	30	28
Insoles	37	36

chronic plantar fasciitis, which, like our study, indicated improvement in both active treatment and placebo in relation to some measures, a superior outcome being noted with the ESWT. This study differed from ours in several respects, including the treatment protocol, which involved a single dose of ESWT at a higher energy level ($>0.18 \text{ mJ/mm}^2$), generated using an electrohydraulic generator. Treatment does not appear to have been focussed and the heel was continually manipulated by the treating physician during the treatment session. The placebo involved a styrofoam block without coupling gel. Local anaesthetic was used, although this differed between treatment and placebo groups. Data was not analysed on an intention to treat basis [13]. Outcome measures also differed from our study. Ogden et al. used investigator rated pain on pressure using a dolorimeter, subject estimation of the time and distance of pain free walking, estimation of the use of analgesics and, as with our study, rating of start-up pain were also measured. Treatment success with respect to start-up pain was noted in 59.7% of the ESWT group and in 48.2% of the placebo group. Pain free activity improved similarly in both groups and investigator rated pain 62.2% versus 43% in the ESWT and placebo groups respectively.

The use of investigator-rated dolorimetry is a relatively novel outcome measure in studies of local soft tissue injuries. Measurement of different outcomes provides different and complementary information and all have a role to play in the evaluation of a treatment. We utilised standard subject-rated visual analogue scales, since patient-based outcome measures are considered to be the priority in the evaluation of the effects of an intervention [20,21]. Arguably, measurement of night pain may have been less useful in this condition.

In another study, Rompe et al. performed a prospective single-blind randomised controlled study of low dose ESWT in chronic planar fasciitis [16]. Thirty patients were randomised to blindly receive three treatments at weekly intervals of either 1000 impulses of low energy (0.06 mJ/mm^2) shock waves or sham therapy, involving no contact with skin and the absence of gel. All patients had had symptoms for at least 12 months but the placebo group had a longer mean duration of symptoms (22 months compared to 16 months). A significant improvement in pain and function was noted

only in the ESWT group at 3 months follow up, but six subjects withdrew and data was not analysed on an intention to treat basis (Table 3).

The differences between different studies in the apparent efficacy of ESWT in plantar fasciitis may be related to a number of factors, including differences in study populations, heterogeneity of treatment parameters such as shock wave intensity, focal energy, geometry of the shock wave focus, different placebos and different machine design. Different machines may well have dissimilar effects and notably while the intensity of treatment delivered by some machines (e.g. that used in the study by Ogden et al.), necessitates the use of local anaesthetic, others (such as the machine used in our study) do not. Use of different outcome measures can also prevent direct comparisons between studies.

The results of our study indicate that moderate dose ESWT delivered using an electromagnetic generator has no significant benefit over placebo. The improvement shown with the placebo may explain the significant improvements noted by others in uncontrolled studies [6,7,17]. It is not unreasonable that such a placebo effect can be noted, since pain, the cardinal symptom of musculoskeletal disorders, is the feature most responsive to a placebo effect [15]. However, other factors can lead to false impressions of a placebo effect, most importantly regression to the mean and two special forms of this, spontaneous improvement and fluctuation of symptoms [10]. We did not include an untreated control group in our study. However, Rompe et al. monitored 30 patients with plantar fasciitis of a group with similar duration of symptoms, for 3 weeks prior to ESWT and noted no significant change in pain, night pain nor in start-up pain over this period [16]. In addition, other clinical studies of similar populations where these outcome measures have been used did not note regression to the mean, nor spontaneous improvement or significant fluctuation of symptoms [2,16]. Nevertheless, although this implies a placebo effect of ESWT as used in our study a further study with an untreated control group would be necessary to be certain.

The form of sham therapy we used was carefully devised to ensure that no energy was delivered to the region of interest. Elements utilised by Rompe et al. [16] were included but with additional measures to ensure

Table 3
Pain in affected heel on 100 mm VAS (mean (SD; range))

	Baseline	1 month	2 months	3 months	6 months
ESWT	73.6 (20.1; 23–100)	62.5 (23.3; 3–99) ^a	51.6 (29.8; 2–100) ^b	41.4 (27.5; 0–97) ^b	34.7 (33.4; 0–95) ^b
Sham	70.0 (20.1; 9–98)	63.7 (21.8; 15–99) ^c	48.1 (32; 0–100) ^b	47.1 (31.5; 0–100) ^b	29 (30; 0–84) ^b

Non-parametric *t*-tests, compared with baseline value.

^a $p < 0.01$.

^b $p < 0.001$.

^c $p < 0.05$.

this was a true sham therapy. The combination of features used make it highly unlikely to have resulted in any treatment being delivered to the patient [12,18].

There is no consensus on appropriate ESWT doses and treatment parameters remain empirical. An emphasis was placed upon the use of a feasible regime with minimal side effects. For this reason a moderate dose regime using an electromagnetic generator was chosen, which avoided the need for administration of local anaesthetic or significant post treatment rest.

In order to identify any significant side effects of treatment we used a wide dosage interval in comparison to those used by others in multiple treatment regimes (commonly 1 week) [3,7]. Although the technique is widely reported to be safe, there is a potential for haemorrhage and local soft tissue damage through cavitation [4]. This appears to be more likely with the high doses that were avoided in our study [4]. Significant adverse effects were not noted, in agreement with the experience of others [1,6,11,14,16,17].

Conclusions

This study indicates that this regime of moderate dose ESWT has no significant treatment effect in patients with chronic plantar fasciitis compared to placebo. The improvement shown with placebo may be simply improvement in symptoms or a true placebo effect. Our findings may explain the significant improvements noted by others in uncontrolled studies. Efficacy may be highly dependent upon hardware, treatment protocols and the specific condition being treated. These issues warrant further research in order to develop evidence based recommendation for the use ESWT in musculoskeletal complaints.

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