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Meta-analysis of high-energy extracorporeal shock wave therapy in recalcitrant plantar fasciitis

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Summary

INTRODUCTION: Randomised controlled trials (RCTs) have reported conflicting results on whether extracorporeal shock wave therapy alleviates the pain of recalcitrant plantar fasciitis patients. We focused on high-energy extracorporeal shock wave therapy (HESWT) and aimed to assess the effectiveness and feasibility of HESWT versus placebo in the treatment of recalcitrant plantar fasciitis.

PATIENTS AND METHODS: We reviewed all RCTs comparing HESWT and placebo from PubMed, EMBASE, Cochrane Central Register of Controlled Trials and also the reference lists of articles. We used a fixed-effects model or a random model depending on heterogeneity and estimated the odds radio (OR) and 95% confidence interval (95% CI). Study quality was assessed using the Jadad scale.

RESULTS: Five placebo-controlled and double-blinded clinical trials including 716 patients were included. Overall, the quality of the trials was good, and a test for heterogeneity confirmed the presence of little heterogeneity ($p = 0.31$, $I^2 = 16\%$). The pooled OR from the five trials was estimated to be 2.25 (95% CI, 1.66–3.06; $p < 0.00001$) at 12 weeks after active treatment.

CONCLUSION: The results of the meta-analysis provide strong evidence that HESWT was effective in the treatment of recalcitrant plantar fasciitis when compared with placebo. We recommend HESWT as a remedial measure after failure of traditional conservative treatment and ahead of surgical intervention.

Introduction

Plantar fasciitis is the most common cause of inferior heel pain, and about 10% of people develop this disease throughout their lifetime. The aetiology of plantar fasciitis is not clearly understood, but several risk factors such as bone spurs, pronated foot type, obesity, limb-length discrepancy and work-related weight-bearing appear to increase the risk of plantar fasciitis [1–3]. Histological findings show that "plantar fasciitis" is a chronic degenerative process rather than an acute inflammatory change [4].

Plantar fasciitis is regarded as a self-limiting disease, and over 90% of patients will be cured within 6 months with nonoperative treatment [5]. Conservative treatment includes: physical treatment such as low dye strapping, therapeutic orthotic insoles, orthotic devices, night splints, Achilles and plantar fascia stretching; pharmacotherapy such as oral inflammatory medication, cortisone injections and botulinum toxin injections [6]. The American College of Foot and Ankle Surgeons (ACFAS) heel pain committee recommend that patients should have chronic symptoms and undergo conservative treatment for at least 6 months prior to considering extracorporeal shock wave therapy (ESWT) or surgical treatment [7].

ESWT is a derivative of lithotripsy. The use of ESWT for the treatment of plantar fasciitis evolved in Europe. ESWT received first FDA-approval for the treatment of plantar fasciitis in 2000. Methods of shockwave generation include electrohydraulic, electromagnetic, piezoelectric or radial. Low-energy ESWT (LESWT) was considered to be flux application <0.2 mJ/mm^2 and high-energy ESWT (HESWT) was flux application >0.2 mJ/mm^2; high-energy flux application may require local or regional anaesthesia when not well tolerated. Chow compared the effectiveness of a "fixed" energy density and "maximum tolerable" energy density of ESWT in the treatment of RPF, and the results showed that ESWT with a maximum tolerable energy density was more effective in terms of relieving pain and restoring functional activity [8]. It is generally understood that enough energy should be delivered to induce a therapeutic response, and that LESWT needs repeated treatments to achieve a therapeutic dose and is more expensive than HESWT.

We performed this meta-analysis focusing on HESWT in order to produce a firm evidence base for clinical decision-making. Strong evidence is needed to guide clinical decisions and to provide the best therapeutic schedule for the patients.

Methods

Data sources and study selection

We reviewed all RCTs comparing ESWT and placebo from PubMed, EMBASE and the Cochrane Central Register of Controlled Trials up to the end of December 2013, as well as the reference lists of the articles, and contacted the original author if necessary. We also searched unpublished

RCTs to minimise publication bias. The keywords included "shock waves" or "ultrasonic therapy" concatenated with "plantar fasciitis" or "plantar fasciopathy" or " heel spur syndrome". Assessment of eligibility of studies and extraction of data from study reports were preceded by two independent reviews, and any dispute was resolved by the third reviewer. Title and abstract were reviewed first and if they met our inclusion criteria, the full article was obtained.
All research was screened for eligibility into the study using the inclusion and exclusion criteria listed in table 1.

Data extraction

All identified studies were reviewed in full text and abstracted data independently and in parallel by two authors (Li ZY, Jin Tao). The following data were extracted: the author and year of publication, method of randomisation, method of blinding, method of allocation concealment, withdrawals and dropouts inclusion criteria; exclusion criteria, HESWT applied; patients enrolled and loss to follow up, follow up period and also clinical success on VAS. Disagreements were resolved through discussion.

Validity assessment

Reviewers Li ZH and Jin Tao evaluated the quality of all included trials in accordance with the Jadad score [9]; allocation concealment was included in this quality score. This widely used scale evaluates the reporting of studies with respect to the method of randomisation, adequacy of blinding and appropriate description of withdrawals. Allocation concealment was assessed as a supplement. Controversy was also resolved by discussion.

Statistical methods

Five RCTs were included in this study and thus the sample size was too small for a funnel plot to detect publication bias. Q-statistic was used to investigate the degree of variation between trials, a p-value >0.1 was interpreted as homogeneity. The I^2-statistical test was further used as a measure of heterogeneity, I^2 <30% was considered as mild heterogeneity, I^2 >50% was considered notable heterogeneity, and a value of I^2 between the two values was considered as moderate heterogeneity. Since in our study I^2 was equal to 0.31, a fixed-effects model was used to pool estimates.
All data analyses were performed using Revman 5.0.

Results

Literature search and study characteristics

We identified 21 RCTs comparing ESWT with placebo in the treatment of plantar fasciitis from the initial search. After full text review, eleven trials were excluded because the energy of ESWT was <0.2 mJ/mm^2; Cosentino [10] employed energy densities varying from 0.03 to 0.4 mJ/mm^2 in the active group and was excluded; Buchbinder [11] compared ESWT with energy varying from 0.02 to 0.33 mJ/mm^2 with a small dose of ESWT as placebo and was also excluded; Hammer [12] and Chow [8] performed nonblinded and single-blind RCTs, respectively, which were excluded; Wang [13, 14] performed a RCT with a long follow-up, which was excluded. Ultimately, five trials (table 2) met all inclusion criteria and were included in the final meta-analysis (fig. 1).
Inclusion criteria and exclusion criteria were generally similar among the five trials. However, three trials applied

Table 1: Inclusion criteria and exclusion criteria.

	Inclusion criteria	Exclusion criteria
Participants	Adults over the age of 18 years; recalcitrant plantar fasciitis（plantar fasciitis over 6 months; unsuccessful conservative treatment including at least one pharmacological therapy and two nonpharmacological therapies; Baseline pain ≥5 points on VAS.	Any other treatment used for the duration of the study.
Intervention	ESWT with energy >0.2 mJ/mm^2	ESWT with energy ≤0.2 mJ/mm^2
Comparison	Placebo treatment without energy transmit to treatment site	Low dose of ESWT or other conservative treatment
Outcome	Clinical success on VAS	Lack of reporting clinical success on VAS score
Study	RCT with double blind	No blinding or single blind

VAS, visual analog scale. Clinical success on VAS: 50% decrease from baseline and a VAS score ≤4 cm or >60% improvement from baseline on the visual analog scale

Table 2: Characteristics of included trials.

Study	HESWT applied	Patients enrolled (completed), N (n)	Follow-up	Outcome (Clinical success)	Result
Ogden et al. [21], 2004	Single treatments 1,500 shockwaves 0.22 mj/mm^2	293 (285)	12 weeks	50% decrease from baseline and a VAS score ≤4 cm	Significant difference
Theodore et al. [16], 2004	Single treatments 3,800 shockwaves 0.36 mJ/mm^2	150 (146)	12 weeks	>60% improvement from baseline on the visual analogue scale	Significant difference
Kudo et al. [26], 2006	Single treatments 3,800 shockwaves 0.36 mJ/mm^2	114（105）	12 weeks	>60% improvement from baseline on the visual analogue scale	Significant difference
Malay et al. [27], 2006	Single treatments 3,800 shockwaves High energy" Level 7"	172 (152)	12 weeks	50% decrease from baseline and a VAS score ≤4 cm	Significant difference
Gollwitzer et al. [28], 2007	3 treatments 2,000 shockwaves 0.25 mJ/mm^2	40 (40)	12 weeks	>60% improvement from baseline on the visual analogue scale	Not significant

3,800 shockwaves with similar energy density in a single treatment while the other two applied different energy densities or different treatment times. All five trials reported 12 weeks of follow-up with assessment of clinical success on a visual analogue scale (VAS). Two criteria for clinical success were used (table 2): in the 10-point VAS, either over 60% improvement from baseline or over 50% improvement and a VAS score ≤4 cm. Four trials showed significant differences in the outcome and one nonsignificant outcome after 12 weeks follow-up.

Validity assessment

The results of quality scoring are shown in table 3, and all five trials met the criteria for high quality.

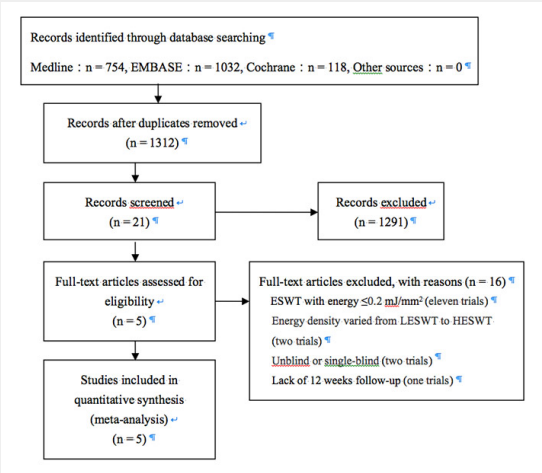

Figure 1

Flow-chart.

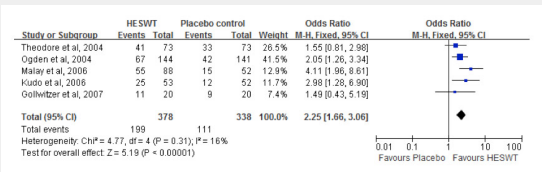

Figure 2

Forest plot of the five studies.

Quantitative data synthesis

From our pooled analysis of five studies with 716 patients, clinical success varied from 46.5% to 62.5% in the active group and 28.8% to 45.2% in the placebo group. A Forest plot illustrating the ORs of the individual trials and the pooled data are shown in figure 2. The Forest plot revealed obvious overlapping confidence intervals, indicating homogeneity between these trials. Formal testing for heterogeneity confirmed the presence of little heterogeneity ($p = 0.31$, $I^2 = 16\%$), and a fixed-effects model was used to pool estimates. Therefore, conclusions from this analysis are crediblebecause of the high quality of the inclusion trials and homogeneity among these trials. Meta-analysis of the five studies indicated a significant curative effect of HESWT in the treatment of recalcitrant plantar fasciitis, the pooled OR from the five trials was estimated at 2.25 (95% CI 1.66–3.06; $p < 0.00001$).

Sensitivity and subgroup analysis

Table 4 shows the results of the sensitivity and subgroup analyses. We performed sensitivity analyses for the fixed-effects model versus a random-effects model by dislodging one study in turn. The fixed effects model and random-effects model had similar results, and the overall risk estimates do not show obvious change by any of the studies, with OR value ranging from 1.98 (95% CI 1.41–2.78) to 2.5 (95% CI 1.77–3.55).

Discussion

Up to 90% of patients with PF will be cured within 6 months with conservative treatment. For the remaining 10%, with what was regarded as recalcitrant plantar fasciitis (RPF), the dispute is as to whether one should take HESWT or progress to surgery. The results of this meta-analysis provide strong evidence that HESWT is effective in the treatment of recalcitrant plantar fasciitis compared with placebo. According to our meta-analysis, 46.5% to 62.5% RPF patients achieved clinical success with HESWT after 12 weeks follow-up. Ogden [15] performed retreatment for the failure patients, and found that at 3 months, 22 of the 42 patients who received a second active treatment attained success. Actually, the effect of shockwave therapy seemed cumulative and time-dependent. Theodore [16] reported 94% success at 12 months follow-

Table 3: Validity assessment.

	Ogden et al. 2004	Theodore et al. 2004	Kudo et al. 2006	Malay et al. 2006	Gollwitzer et al. 2007
Study described as randomised?	Yes	Yes	Yes	Yes	Yes
If randomised, is the method described and appropriate?	Yes	Not clear	Yes	Yes	Yes
Study described as double blind?	Yes	Yes	Yes	Yes	Yes
If double blind, is the method described and appropriate?	Yes	Yes	Yes	Yes	Yes
Appropriate description of withdrawals and dropouts?	Yes	Yes	Yes	Yes	Yes
Study described as allocation concealment	Yes	Yes	Yes	Yes	Yes
If allocation concealment, is the method described and appropriate?	Yes	Not clear	Yes	Yes	Yes
Total score	7 points	5 points	7 points	7 points	7 points

up while Wang reported 82.7% excellent or good pain and function scores at 60 to 72 months.

Subjective reports of pain as the primary outcome usually exhibit a large placebo effect and it seems typical in our included studies that success rates vary from 28.8% to 45.2% in the placebo group. However, in the nonblinded or single-blinded RCTs, the placebo group reported minimal improvement in pain scores, as compared with blinded studies [17, 18]. This large placebo effect demonstrates the effectiveness of the blinding technique, so nonblinded or single-blinded RCTs were excluded from our meta-analysis. There are two possible explanations for the relatively high success rates of placebo group: the self-limiting character of this disease or the placebo curative effect [19]. Partial PF patients take a turn for the better without any kind of special treatment; however, RPF patients do not experience any improvement when no intervention is applied [20]. For the placebo group, the recurrence rate was 38.1%–55% versus 3%–11% for the shockwave group [14, 21]. All of these suggest that the placebo treatment effect may play the main role in the high success rates in the placebo group. The unalloyed treatment effect and the associated placebo effect are not distinguishable and mingle to produce the clinical effect [22].

Compared with traditional treatment, HESWT is no more effective but more expensive [23, 24], but in contrast to surgery, HESWT is noninvasive, well-tolerated and a relatively inexpensive treatment. Patients return to daily life and most jobs within a short time. The main adverse events with HESWT for RPF included erythema, swelling of the local region and pain during treatment. The patients recover in several days after the treatment [16, 21].

However, many orthopaedists recommend surgery as a remedial measure after the failure of conservative treatment. The main reason is the conflicting results reported by different kinds of randomised controlled trials (RCTs) and the lack of homogeneity between these RCTs, which makes it unfeasible to combine these results in a meta-analysis and very difficult to make the final decision.

Meta-analysis of all the studies with ESWT compared with placebo is not feasible because significant heterogeneity between the studies precluded pooled analyses [25]. Heterogeneity between these studies is related to differences in study design, the method of shockwave generation (electrohydraulic, electromagnetic, piezoelectric or radial), the amount of shockwave energy delivered, the use of anaesthesia and sedation and the outcome measure. We included only high quality studies and focused on the HESWT in order to reduce the heterogeneity. As we mention above, satisfactory homogeneity between these trials make the conclusion of this meta-analysis stable and credible.

From all of our analysis above, we can conclude that HESWT is an effective treatment for RPF. We recommend HESWT as a remedial measure after failure of traditional conservative treatment and before of surgical intervention. RCTs will still be needed to compare the curative effect of HESWT with surgery in the treatment of recalcitrant plantar fasciitis.

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Table 4: Sensitivity and subgroup analysis.

	No. of studies	Group; no.		Pheterogeneity	I^2(%)	OR [95% CI]
		HESWT	Placebo			
Analysis model						
Fixed effects model	5	(119) 378	(111) 338	0.31	16	2.25 [1.66, 3.06]
Random effects model	5	(119) 378	(111) 338	0.31	16	2.26 [1.60, 3.21]
HESWT applied times						
Single treatments	4	(188) 358	(102) 318	0.23	31	2.31 [1.69, 3.18]
Triple treatments	1	(11) 20	(9) 20	Null	Null	1.49 [0.43, 5.19]
Flux application						
>0.3 mJ/mm^2	2	(66) 126	45 (125)	0.23	30	1.99 [1.19, 3.32]
<0.3 mJ/mm^2	2	(78) 164	51 (161)	0.64	0	1.97 [1.25, 3.10]
Outcome						
>50% decrease and VAS score <=4 cm	2	(122) 232	(57) 193	0.12	58	2.54 [1.70, 3.81]
>60% decrease from baseline	3	(77) 146	(54) 145	0.45	0	1.91 [1.19, 3.06]

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Figures (large format)

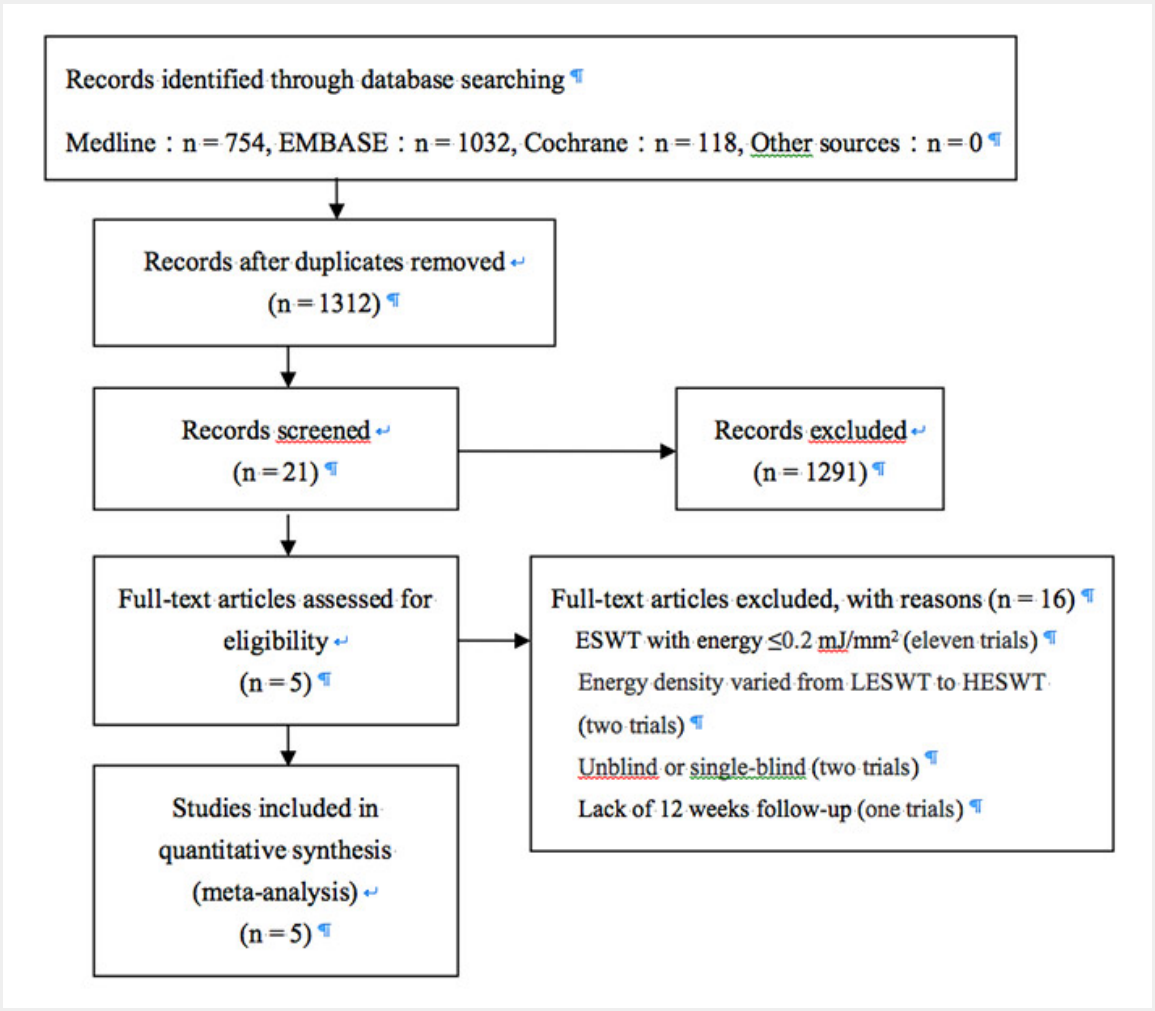

Figure 1

Flow-chart.

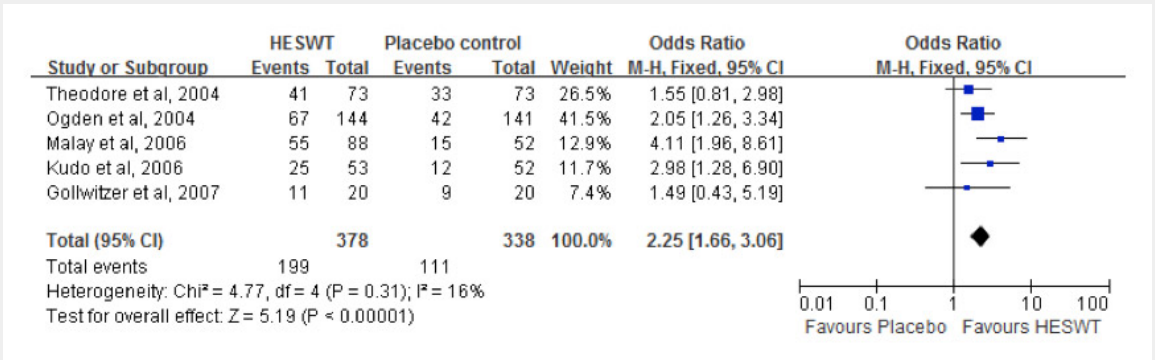

Figure 2

Forest plot of the five studies.