Low-energy extracorporeal shock wave therapy: a critical analysis of the evidence for effectiveness in the treatment of plantar fasciitis

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CRD summary
This poorly conducted and reported review concluded that there is only limited evidence to suggest that extracorporeal shock wave therapy is effective for the treatment of plantar fasciitis in the general population, and that further research is necessary. The conclusions should be interpreted with caution due to limitations with the review, especially in relation to the inclusion criteria and literature search.

Authors' objectives
To determine the effectiveness of low-energy extracorporeal shock wave therapy (ESWT) for conservative treatment of plantar fasciitis.

Searching
MEDLINE and CINAHL were searched from inception to February 2005; the search terms were reported. The references of the retrieved articles were also checked for additional papers.

Study selection

Study designs of evaluations included in the review
The authors did not state what study designs were eligible for inclusion in the review. Only studies which the authors considered to have satisfactory study designs and methodologies were included. All of the included studies were randomised controlled trials (RCTs). The duration of the studies ranged from 12 weeks to 5 years.

Specific interventions included in the review
Studies in which low-energy ESWT was used as the primary intervention were eligible for inclusion. The energy density of the shock wave ranged from 0.02 to 0.33 mJ/mm² (increased to highest tolerable level in one trial), with the number of impulses received during treatment varying between 1,000 and 4,000. Most of the included studies delivered ESWT at three weekly applications; in one study ESWT was delivered at three biweekly applications and in another three monthly applications. ESWT was applied at the heel spur, the greatest thickening of plantar fascia, or the most tender area of plantar fascia.

Participants included in the review
Studies including participants with a clinical diagnosis of plantar fasciitis were eligible for inclusion. Most of the included trials were conducted in general patient populations; one trial included only non-elite long-distance runners. The mean age of the participants ranged from 40 to 54.2 years, and the mean duration of symptoms or pain ranged from 8 to 18 months.

Outcomes assessed in the review
No inclusion criteria relating to the outcomes were specified, although some studies appear to have been excluded because of the outcome measures reported. A variety of outcomes were assessed: pain (resting, night, morning, pressure, activity and start up); weight-bearing capability; walking capability; walking time; adverse effects; overall symptom relief, patient satisfaction, and walking ability (modified Roles and Maudsley score); quality of life (SF-36); disability (Problem Elicitation Technique); ankle or foot symptoms and characteristics, function, alignment and range of motion (American Orthopedic Foot and Ankle Society’s Ankle-Hindfoot Scale); Maryland foot score; and success of blinding.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.
Assessment of study quality
The authors stated that a modified version of a data extraction and critical appraisal form was used to evaluate the quality of each study, but they did not provide explicit details of the criteria used. The authors did not state how the validity assessment was performed.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The results of each study were discussed; there was no attempt to synthesise them.

How were differences between studies investigated?
Differences between the studies in terms of study design, intervention, outcomes and aspects of study quality were highlighted within individual descriptions of the included studies.

Results of the review
Six RCTs (n=700) were included in the review. The sample sizes ranged from 30 to 271.

Five of the included studies were randomised controlled, double-blind trials. The other study was a randomised single-blind crossover study.

General population (5 RCTs).
Three of the 5 studies comparing ESWT with placebo in the general population did not demonstrate any statistically significant between-group differences on any outcome measure. Two studies showed a positive effect of ESWT compared with placebo. One crossover study (n=30) showed significantly improved subjective pain scores (p<0.05), weight-bearing capability (p<0.05) and walking capability (p<0.0005) in the treatment group at 6 weeks. After crossover, the initial placebo group reported a similar improvement to the treatment group. One RCT (n=100) showed that significantly more individuals reported experiencing good-to-excellent results at 6 months compared with control (p<0.001), and less requirement for subsequent surgical treatment (p=0.0001).

Long-distance runners (1 RCT, n=45).
The ESWT group reported a significant improvement (of at least 50%) in pain on first walking in the morning at 6 and 12 months (p=0.0004 and p=0.0051, respectively), compared with placebo. A significant improvement on the Ankle-Hindfoot Scale compared with placebo was also shown at the 6- and 12-month follow-ups (p=0.0025 and p=0.0211, respectively).

Authors’ conclusions
At present, only limited evidence exists to suggest that ESWT is effective for the treatment of plantar fasciitis in the general population. Further research is necessary.

CRD commentary
The review question was clear but selection criteria were only reported in terms of the intervention and participants. The authors stated that only studies fulfilling certain methodological criteria were included, but it was unclear what these criteria were. Studies were also excluded for providing unsatisfactory outcome data but, again, it was unclear what form of outcome data was required for inclusion. Two electronic databases were searched for relevant papers and no attempt to locate unpublished material was made, which may suggest a risk of publication bias. The authors did not
state whether their search was restricted by language. Without details of the study selection, data abstraction and quality assessment processes it is difficult to assess whether error or bias may have been introduced during the review process. Although the quality of the included studies was assessed, the authors did not report the results of this assessment.

The authors made no attempt to synthesise the results and simply presented a summary of each of the included studies. Although a narrative synthesis might have been appropriate given the clinical heterogeneity between the included studies, further attempts to synthesise the results would have greatly improved this review. The authors’ cautious conclusion reflects the limited evidence base but should be interpreted with caution given the problems associated with the selection criteria, literature searches and lack of detail on review methods.

**Implications of the review for practice and research**
Practice: The authors stated that traditional conservative treatment of plantar fasciitis should be attempted before considering more invasive procedures, such as ESWT.

Research: The authors stated that there is a need for further controlled, long-term studies using validated outcome measures. In particular, evaluations comparing the efficacy of different methods of generating shock waves and variations in the applied energy of these different methods should be conducted.

**Bibliographic details**

**Indexing Status**
Subject indexing assigned by CRD

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**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.