

The Effectiveness of High-Energy Shockwave Therapy in Patients with Plantar Fasciopathy

A Systematic Review of Randomised Controlled Trials

I. Janssen Pt ^{1,2}

¹ Rehabilitation Centre Blixembosch, Eindhoven, the Netherlands

² Clinical Health Sciences, Physiotherapy sciences, University of Utrecht, Utrecht, the
Netherlands

Corresponding address:

Postbus 1355, 5602 BJ Eindhoven, The Netherlands

E-mail: I.Janssen2@students.uu.nl

English abstract

Background: Plantar fasciopathy is characterised by pain and tenderness under the medial tubercle of the calcaneus under weight bearing. Shock wave therapy is increasingly used in this diagnosis, however limited scientific evidence supports its use. The primary aim is to systematically review the effectiveness of high-energy shockwave therapy on pain in patients with chronic plantar fasciopathy.

Methods: Electronic databases (Cochrane Controlled trials register, MEDLINE / EMBASE, PubMed, PEDro and CINAHL) were systematically searched from inception until the 31st of March 2010. Only randomised controlled trials, comparing high-energy shock wave therapy with placebo therapy, were eligible for inclusion. Two independent reviewers assessed the methodological quality of the included studies using the Physiotherapy Evidence Database (PEDro) scale. A best evidence synthesis was applied for qualitative analysis on three outcome measures: 'morning pain', 'activity-related pain' and 'pressure pain'.

Results: Seven randomised controlled trials, with a total of 1195 patients, were included. Methodological quality of the individual studies ranged from 6 to 9 points on the PEDro scale. Best evidence synthesis showed limited evidence regarding the effectiveness of high-energy shockwave therapy on 'morning pain' and 'pressure pain' at 12 weeks after intervention. No evidence was found regarding the effectiveness of high-energy shockwave therapy on 'activity-related pain' in patients with chronic plantar fasciopathy.

Conclusion: Although the results are not completely unequivocal, in the majority of the studies a positive effect was found of high-energy shockwave therapy on pain in patients with plantar fasciopathy. Based on the available literature, it is not entirely clear what factors are responsible for a positive effect of high-energy shockwave therapy. Therefore, further research is needed.

Keywords: plantar fasciopathy, plantar fasciitis, heel pain, high-energy shockwave therapy, pain.

Dutch abstract

Achtergrond: 'Plantar fasciopathy' wordt gekenmerkt door pijn bij belasting van het mediale tuberculum van de calcaneus. Shockwave therapie wordt steeds vaker gebruikt bij deze diagnose, maar er is weinig wetenschappelijk bewijs voor de toepassing ervan. Het belangrijkste doel is het systematisch reviewen van de effectiviteit van high-energy shockwave therapie op pijn bij patiënten met chronische 'plantar fasciopathy'.

Methode: De elektronische databases van Cochrane Controlled Trials Register, MEDLINE / EMBASE, PubMed, PEDro en CINAHL werden systematisch doorzocht van aanvang tot 31 maart 2010. Alleen randomised controlled trials, waarbij 'high-energy shockwave therapy' werd vergeleken met placebo therapie, kwamen in aanmerking voor inclusie. De methodologische kwaliteit van de studies werd beoordeeld door twee onafhankelijke reviewers met behulp van de Physiotherapy Evidence Database (PEDro) schaal. Een best evidence synthese werd toegepast voor de kwalitatieve analyse van drie uitkomstmaten: 'morgen pijn', 'activiteiten-gerelateerde pijn' en 'druk pijn'.

Resultaten: Zeven randomised controlled trials, met een totaal van 1195 patiënten werden geïnccludeerd. De methodologische kwaliteit van de afzonderlijke studies varieerde van 6 tot 9 punten op de PEDro schaal. De best evidence synthese toonde gering bewijs met betrekking tot de effectiviteit van high-energy shockwave therapie op 'morgen pijn' en 'druk pijn' 12 weken na de interventie. Er werd geen bewijs gevonden voor de effectiviteit van 'high-energy shockwave therapy' op activiteiten-gerelateerde pijn bij patiënten met chronische 'plantar fasciopathy'.

Conclusie: Hoewel de resultaten niet geheel eenduidig zijn, wordt in het merendeel van de studies een positief effect gevonden van 'high-energy shockwave therapy' op pijn bij chronische 'plantar fasciopathy'. Op basis van de beschikbare literatuur is nog niet geheel duidelijk welke factoren verantwoordelijk zijn voor een positief effect van 'high-energy shockwave therapy'. Daarom is nader onderzoek nodig.

Trefwoorden: plantar fasciopathy, plantar fasciitis, hielpijn, high-energy shockwave therapy, pijn.

Background

Plantar fasciopathy (PF) is associated with a painful plantar fascia, which spans between the medial calcaneal tubercle and the proximal phalanges of the toes ¹. The diagnosis PF is made on clinical findings and typical symptoms are pain and tenderness on weight bearing, which characteristically gets worse during the first few steps in the morning ². The prevalence of PF has not been studied ³, but it is estimated that PF affects 10% of the general population at some time during life time ⁴.

The aetiology of PF, with or without soft tissue ossification (heel spur), is not completely understood, and is probably multifactorial ¹. Reduced ankle dorsiflexion, obesity, and work-related weight bearing appear to be risk factors ⁵. Histopathological examination of affected plantar fascia revealed the absence of inflammatory cells. New insights indicate that chronic complaints of collagenous tissue, like the plantar fascia, may be susceptible to failed healing process leading to degenerative alterations which is in agreement with the lack of inflammatory cells ⁶. However, acute overuse of the fascia may superpose a reactive inflammation even in chronic pathology ⁶.

Many conservative treatments have been used to treat PF with variable success, including: stretching exercises, taping, shoe inserts, cortisone injections, physical therapy, and night splints ⁷. The role of these treatments should be considered in the light of the self-limiting nature of PF, with 80% of patients experiencing resolution within 12-24 months, regardless of management ^{1, 8}. Four years after occurrence of PF, 20% of the patients is still not free of symptoms ⁹. A surgical approach is one of the options for patients that suffer from this condition for a long time. Reports of the results of these surgical treatments, including endoscopic and open fasciotomy, have generally been favourable ¹⁰. Unfortunately, complications with surgical intervention, particularly swelling, pain and the inability to walk, are not uncommon ¹¹.

With the desire for a less invasive approach, shock wave therapy (SWT) has emerged as an alternative treatment for chronic PF ¹². Although its exact mechanism of action remains unknown, the rationale of this treatment is the stimulation of soft tissue healing, reduction of calcification, inhibition of pain receptors or denervation to achieve pain relief ¹³. Nevertheless, the scientific effectiveness of SWT remains inconclusive: in some trials SWT has been reported to be an effective treatment in patients with PF; in others it was no more effective than placebo. A possible explanation of the conflicting results in clinical trials is the heterogeneity of the SWT application within the individual studies.

The difference in the amount of energy delivered is one of the multiple variables that make comparing clinical trials difficult ¹⁴. The energy density of shock wave therapy can be subdivided into high-energy SWT (HESWT) and low energy SWT (LESWT). In this systematic review, SWT was defined as high-energy SWT if the positive energy flux density (unit: mJ/mm²) was 0.2 mJ/mm² or more, according to Rompe et al. ¹. Until now, no systematic review is available about the effectiveness of high-energy ESWT on PF. Therefore, the primary aim is to systematically review the effectiveness of HESWT on pain in patients with chronic PF.

Methods

Search strategy

To identify relevant studies, a search was performed in six electronic databases (MEDLINE / EMBASE, PubMed, CINAHL, Cochrane Central Register of Controlled Trials and PEDro) from inception to March 31st 2010. The search strategy (Table 1) was first developed for PubMed, to be adapted later to search other databases. Combinations of Medical Subject Headings (MeSH) and keywords were used. Additionally, reference lists of all included studies were screened and key author searches were applied to identify additionally relevant studies. To improve reliability of the search strategy, the search was done by the author (IJ) and checked by a second reviewer (MG). Further details on the search strategy are described in Appendix 1.

Table 1. Specific search strategy used to identify relevant articles

Search number	Search Term	Hits
# 1	Plantar fasciitis	638
# 2	Plantar heel pain	403
# 3	Plantar fasciopathy	9
# 4	Calcaneal spur	219
# 5	Heel spur	181
# 6	Heel spur syndrome	661
# 7	<i>#1 OR #2 OR #3 OR #4 OR #5 OR #6</i>	<i>918</i>
# 8	Shock wave	5.830
# 9	Shockwave	1.266
# 10	Shock wave therapy	7.418
# 11	Shockwave therapy	1.169
# 12	Shock wave treatment	4.869
# 13	Lithotripsy	9.170
# 14	ESWT	254
# 15	<i>#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14</i>	<i>11.113</i>
# 16	Placebo	137.752
# 17	Sham therapy	37.828
# 18	<i>#16 OR #17</i>	<i>145.288</i>
# 19	<i>Randomised controlled trial</i>	<i>346.023</i>
# 20	<i>#7 AND #15 AND #18 AND #19</i>	<i>19</i>

Study selection

The first stage of the study selection, screening title and abstract, was accomplished by the author (IJ). In the second stage, two reviewers (IJ and MG) screened the full-text of all

potential relevant articles to determine whether the article met the inclusion criteria. Disagreement between the two reviewers in any stage was resolved by discussion until consensus was reached or, where necessary, a third person (FH) made the final decision. Only full reports written in English, Dutch or German and meeting the following inclusion criteria (based on design, population, intervention and control group and outcome measures) were selected.

Design

Systematic reviews of randomized controlled trials (RCTs) are considered to constitute the best single source of information about the effectiveness of health care interventions¹⁵. Therefore, only RCTs were included in this systematic review.

Population

Studies including male or female adults (between the age of 18 and 80) with chronic plantar fasciopathy (PF), diagnosed on clinical examination, were eligible for inclusion. At baseline, patients had to have a painful heel for > 3 months. Pain had to be located at the origin of the plantar fascia from the medial tubercle of the calcaneus. Studies that examined patients with PF, who had previous surgery for PF or (drug) treatment within 2 weeks of the intervention, were excluded.

Intervention and control group

Studies in which high-energy shockwave therapy (HESWT) was used as the primary intervention, and compared with a placebo-control group, were eligible for inclusion. Studies comparing HESWT with other treatments, or SWT therapy with a different energy density were excluded.

Outcome measures

Studies focussed on pain as primary outcome measure. Pain had to be measured with the Visual Analogue Scale (VAS). The VAS is a global observational rating scale to evaluate pain, and its use is accepted in both research and clinical settings¹⁶. The VAS is comprised of a single straight 100 mm line. The extremes of the line denote the limits of the pain experience from 'no pain' to 'worst possible pain'. The individual performing the assessment marks the score by making a perpendicular line through the VAS. The distance from the end denoting 'no pain' to the subject's mark indicates the amount of pain. Its strengths are considered to be its ease of use, good reliability and validity, low costs, and metric measure that enables parametric testing.

Data-extraction and management

Data were extracted by the author (IJ) and checked by a second reviewer (MG) through a self-made extraction form (Appendix 2). Disagreements between the two reviewers were resolved by discussion until consensus was reached or, where necessary, a third person (FH) made the final decision.

Assessment of methodological quality

Two reviewers (IJ and MG) independently assessed the methodological quality of the included RCTs, according to the 10-point Physiotherapy Evidence Base Database (PEDro) scale (Appendix 3). The PEDro scale is based on the Delphy list developed by Verhagen et al.¹⁷ and assesses quality criteria related to internal, statistical and external validity. Each item is scored as 'yes' or 'no', resulting in a total score of the positive rated items from 0 to 10.

According to Van Peppen et al.¹⁸ PEDro scores of 4 points or higher were classified as 'high quality', whereas studies with 3 points or lower were classified as 'low quality'. PEDro scores were not used as inclusion/exclusion criteria, but rather as a basis for data-analysis and to discuss the strengths and weaknesses of studies.

The PEDro scale has shown moderate levels of interrater reliability (intraclass correlation coefficient (ICC) 0.54, 95% confidence interval (CI) 0.39 to 0.71)¹⁹. To improve the reliability of the scale, any disagreement between the reviewers was resolved by discussion with an independent reviewer (FH) until consensus was reached. Inter-observer agreement was calculated through Cohen's Kappa (K) after the initial screening.

Data-analysis

To summarize the evidence about the effectiveness of HESWT on pain in patients with PF, a Best Evidence Synthesis (BES) was performed, based on the criteria of Van Tulder et al.²⁰ and adjusted by Steultjens et al.²¹. In the BES, the results of each individual study were combined and adjusted for methodological quality based on the PEDro scale. Overall ratings were then classified according to 5 levels of evidence: (1) strong evidence, (2) moderate evidence, (3) limited evidence and (4) indicative findings, and (5) no or conflicting evidence (Appendix 4).

Results

Results search strategy and study selection

The results of the search strategy are presented in figure 1. The literature search of databases resulted in 27 potentially relevant articles, after removing duplicates. After screening on title and abstract, 19 articles were considered for review. Another 12 articles were excluded after the full text was read. The main reason for exclusion was the intervention: 10 studies did not focus on high-energy shockwave therapy as described in the eligibility criteria^{13, 22-31}. One study was excluded because of the design (no RCT)³¹, and one study was not available in full-text³². In the end 7 studies were included in this systematic review³³⁻³⁹.

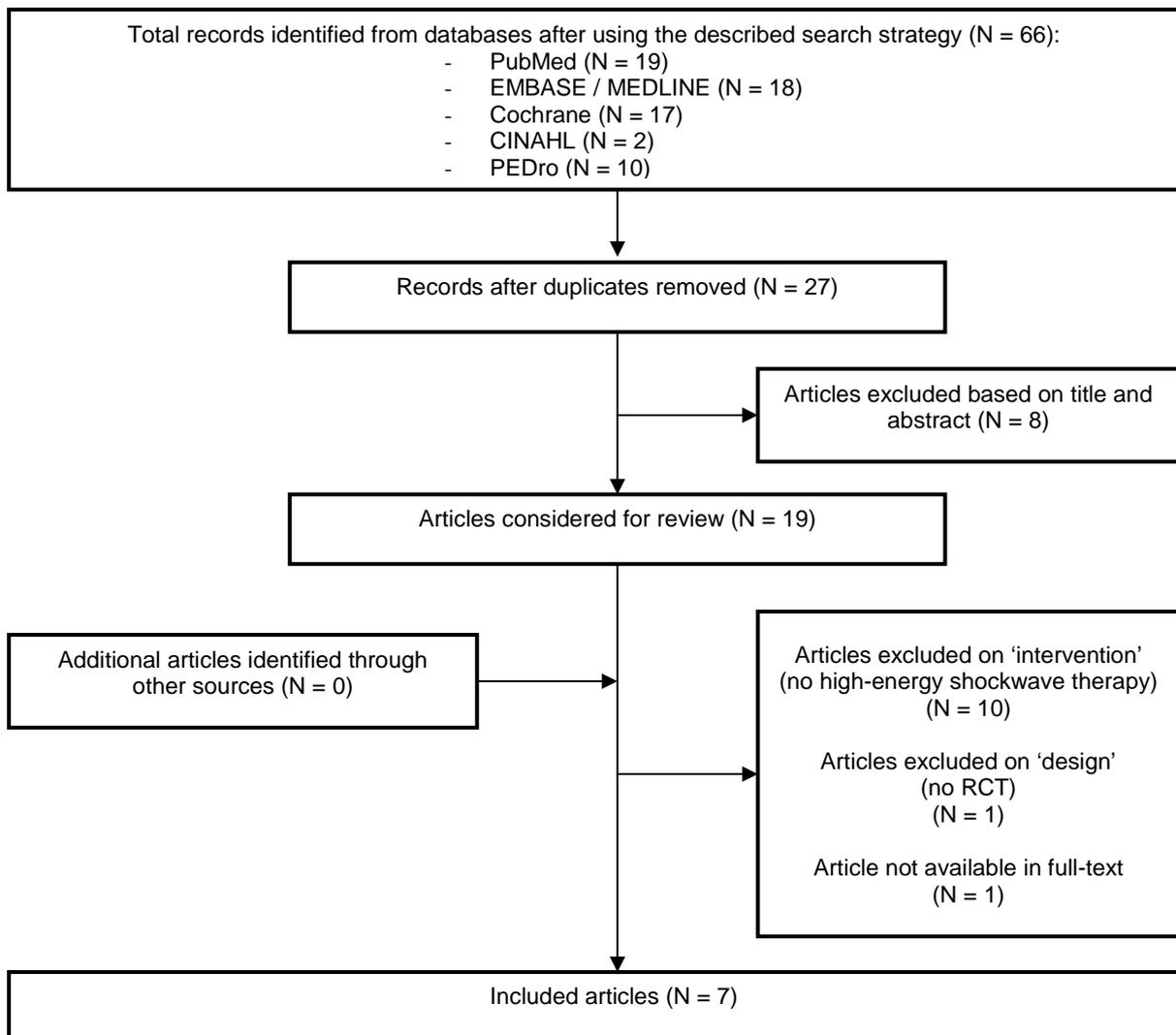


Figure 1. Flow chart of the articles during the study selection.

Results data-extraction

Design

Seven randomised controlled trials (RCTs) were included in this systematic review³³⁻³⁸, with publication dates ranging from 2001 to 2008.

Population

The number of included participants with PF ranged from 40 to 293 per RCT. The total number of included participants was 1195 and predominantly consisted of woman (65.5%). The mean age of the participants ranged from 48.6 to 56.5 years. The mean body weight ranged from 183 to 184 pounds, and the mean duration of symptoms or pain ranged from 10 to 33.5 months. Further details are described in Table 2. In all included RCTs, baseline characteristics were similar for the intervention and the control group.

Table 2. Baseline characteristics of participants in each individual RCT.

Author	N (I/C)	Gender	Age (years)	Body weight (pounds)	Duration of pain (months)
Ogden et al. ³⁷	260 (130/130)	Male: 89 (34%) Female: 171	Mean: 49,6 Range: 20-79	Mean: N/A Range: N/A	Mean: 33,5 Range: 6-216
Buchbinder et al. ³³	166 (81/85)	Male: 70 (42%) Female: 96	Mean: 53 Range: N/A	Mean: 183 Range: N/A	Mean: 10 Range: 3-245
Theodore et al. ³⁹	150 (76/74)	Male: 41 (27%) Female: 109	Mean: 51,5 Range: 26-72	Mean: 183 Range: 115-294	Mean: 23 Range: 6-120
Ogden et al. ³⁸	293 (148/145)	Male: 99 (34%) Female: 194	Mean: 48,6 Range: 19-79	Mean: N/A Range: N/A	Mean: N/A Range: N/A
Kudo et al. ³⁵	114 (58/56)	Male: 41 (36%) Female: 73	Mean: 50 Range: N/A	Mean: 183,5 Range: N/A	Mean: 29,2 Range: N/A
Malay et al. ³⁶	172 (115/57)	Male: 57 (33%) Female: 115	Mean: 51 Range: 28-79	Mean: 184 Range: 112-290	Mean: 29 Range: 6-240
Gollwitzer et al. ³⁴	40 (20/20)	Male: 15 (37%) Female: 25	Mean: 56,5 Range: 30-76	Mean: N/A Range: N/A*	Mean: 11,7 Range: 6-36

Abbreviation: N/A = data not available, N = number of participants, I = intervention group, C = control group.

* Body Mass Index ranged from 20-39 with a mean of 27,6 kg/m²

Intervention and control group

In all studies high-energy shockwave therapy (HESWT) was used as the primary intervention. The energy density of the shock wave ranged from 0.22 to 0.36 mJ/mm², with the number of impulses received during treatment varying between 1500 and 3800. Different shockwave devices were used. Further details are described in Table 3. In all studies HESWT was applied at the most tender area of plantar fascia, in either 1 or 3 treatments. In 5 studies, both the intervention group and control group received local anaesthesia before

treatment. In 2 of those studies, local anaesthesia was different for the intervention and the placebo group. In 6 studies, the procedure of application in the placebo group was identical to the treatment group, only shockwaves were blocked. Only in the study of Buchbinder et al.³³ a minor total dose of 6.0 mJ/mm² was given to the placebo group.

Table 3. Details about the intervention and placebo.

Author	Device	Nr. of shockwaves (energy density)	Nr. of treatments	Local anaesthesia	Follow-up (weeks)
Ogden et al. ³⁷	Ossatron High Med Technology	1500 (0.22mJ/mm ²)	One	Yes*	4, 8 and 12
Buchbinder et al. ³³	Epos Ultra Dornier Medical Systems	2500 (0.33mJ/mm ²)	Three	No	6 and 12
Theodore et al. ³⁹	Epos Ultra Dornier Medical Systems	3800 (0.36mJ/mm ²)	One	Yes	6, 12 and 26
Ogden et al. ³⁸	Ossatron High Med Technology	1500 (0.22mJ/mm ²)	One	Yes *	12 and 52
Kudo et al. ³⁵	Epos Ultra Dornier Medical Systems	3500 (0.36mJ/mm ²)	One	Yes	1, 6 and 12
Malay et al. ³⁶	Orthospec System	3800 (0.36mJ/mm ²)	One	No	4, 8 and 12
Gollwitzer et al. ³⁴	Duolith SD1 System	2000 (0.25mJ/mm ²)	Three	Yes	6 and 12

* Local anaesthesia not the same in intervention and control-group.

Outcome measures

Most commonly reported outcome measures in the included studies were 'morning pain', 'pressure pain' and 'activity-related pain' (Table 4). 'Morning pain' (pain on first rising, first step pain or start up pain) is universally reported by patients complaining of plantar heel pain and it is also strongly diagnostic for PF¹. Therefore, this systematic review primarily focuses on 'morning pain'. Secondary outcome measures are 'pressure pain' and 'activity-related pain'.

Table 4. Outcome measures reported in the included studies.

Author	Morning pain (VAS)	Activity-related pain (VAS)	Pressure pain (VAS)
Ogden et al. ³⁷	-	-	-
Buchbinder et al. ³³	P = 0.92	P = 0.68	-
Theodore et al. ³⁹	P = 0.0149*	-	-
Ogden et al. ³⁸	P = 0.014*	P = 0.059	P = 0.002*
Kudo et al. ³⁵	P = 0.0124*	P = 0.0524	P = 0.0027*
Malay et al. ³⁶	-	-	P = 0.045*
Gollwitzer et al. ³⁴	P = 0.0659 (1-sided)	P = 0.0469 (1-sided)	P = 0.0472 (1-sided)

*Statistical significant difference between intervention and control group.
Abbreviation: VAS = Visual Analogue Scale.

Results methodological quality assessment

The methodological quality of the included RCTs, according to the PEDro scale, is described in Table 5. Initially there was disagreement between the 2 independent reviewers on 4 of the 77 items scored, resulting in a Cohen's Kappa of 0.850. After discussion, there was agreement on all items. According to Van Peppen¹⁸, all 7 included studies are considered high-quality RCTs, with a methodological quality ranging from 6 to 9 out of 10 points. Due to the nature of the interventions, the criterium 'therapist blinded' could not be scored. Therefore, a score of nine points might be considered as the best score possible in this kind of intervention study.

Table 5. Methodological quality according to the PEDro-scale.

Author	Item PEDro	1*	2	3	4	5	6	7	8	9	10	11	Total	Quality
Ogden et al. ³⁷		Y	Y	N	Y	Y	N	Y	Y	N	Y	N	6/10	'High'
Buchbinder et al. ³³		Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9/10	'High'
Theodore et al. ³⁹		Y	Y	N	Y	Y	N	Y	Y	N	Y	Y	7/10	'High'
Ogden et al. ³⁸		Y	Y	Y	Y	Y	N	Y	Y	N	Y	N	7/10	'High'
Kudo et al. ³⁵		Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9/10	'High'
Malay et al. ³⁶		Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	8/10	'High'
Gollwitzer et al. ³⁴		Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9/10	'High'

* This item is not used to calculate the total PEDro score.
Abbreviation: Y=yes, N=no.

Best evidence synthesis

Primary outcome measure

Morning pain (VAS)

Five studies^{33-35, 38, 39} (n=763) reported morning pain at 12 weeks after intervention as most important outcome measure. Ogden et al.³⁸, Kudo et al.³⁵, and Theodore et al.³⁹ all reported a statistical significant difference between intervention and control group in morning pain at 12 weeks (respectively p=0.014, p=0.0124 and p=0.0149). Buchbinder et al.³³ and Gollwitzer et al.³⁴ both reported no statistical significant difference between both groups (respectively p=0.92 and p=0.0659(1-sided)). All studies named above, are 'high-quality' studies, according to the PEDro scale. Using a best evidence synthesis, there is conflicting evidence regarding the effectiveness of HESWT in morning pain at 12 weeks after intervention in patients with PF.

Secondary outcome measures

Activity-related pain (VAS)

Activity-related pain at 12 weeks after intervention was measured in 4 studies^{33-35, 38} (n=613). Kudo et al.³⁵, Ogden et al.³⁸, Gollwitzer et al.³⁴ and Buchbinder et al.³³ all reported no statistical significant difference in pain during normal daily activities between intervention and control group (respectively p=0.0524, p=0.059, p=0.0469(1-sided) and p=0.68). All studies named above, are 'high-quality' studies, according to the PEDro scale. Using a best evidence synthesis, there is no or insufficient evidence regarding the effectiveness of HESWT on activity-related pain at 12 weeks after intervention in patients with PF.

Pressure pain (VAS)

Pressure pain outcomes (from either a manual application or an electronic device) at 12 weeks after intervention were measured in 4 studies^{34-36, 38} (n=619). Kudo et al.³⁵, Malay et al.³⁶ and Ogden et al.³⁸ reported a statistical significant difference on pressure pain between intervention and control group (respectively p=0.0027, p=0.045 and p=0.002). Gollwitzer et al. reported no statistical significant difference between both groups on pressure pain (p=0.0472, 1-sided). All studies named above, are 'high-quality' studies, according to the PEDro scale. Using a best evidence synthesis, there is conflicting evidence that HESWT is effective on pressure pain at 12 weeks after intervention in patients with PF.

Discussion

Study objective

The primary aim was to systematically review the effectiveness of high-energy shockwave therapy (HESWT) on pain in patients with chronic plantar fasciopathy (PF). After a systematic search and study selection, 7 randomised controlled trials were included in this review. All 7 RCTs were of high methodological quality, according to the PEDro scale. Therefore, all 7 studies were treated equally in the best-evidence syntheses (BES). The conclusion regarding the BES, based on the results and the methodological quality of the individual studies are as follows:

- 1) There is conflicting evidence regarding the effectiveness of HESWT on 'morning pain' and 'pressure pain' at 12 weeks after intervention in patients with PF.
- 2) There is no evidence regarding the effectiveness of HESWT on 'activity-related pain' at 12 weeks after intervention in patients with PF.

Interpretation of the results

Although shockwave therapy is increasingly used in clinical practice and success rates are promising, scientific evidence on the effectiveness of HESWT remains inconclusive, also in this systematic review. However, abovementioned conclusions should be interpreted with caution for a number of reasons.

First of all, the definition of high-energy shockwave therapy which in the current review was chosen at an energy flux density of ≥ 0.22 mJ/mm² is debatable. Shockwaves have previously been defined as low energy (~ 0.08 mJ/mm²), medium energy (~ 0.28 mJ/mm²) and high-energy (~ 0.60 mJ/mm²)³⁴. According to the last definition, the current review included studies assessing the effectiveness of medium-energy shockwave therapy.

Secondly, research in the field of shockwave therapy and tendinopathies is still hampered by the fact that the exact working mechanism of SWT has not been elucidated so far. Controversy exists about the different shockwave devices used, the different energy levels applied, the dissimilar methods of localisation, whether using local anaesthesia, the various numbers of shockwaves per treatment and the different numbers of treatments^{1, 40, 41}. Also the exact pathophysiology of plantar fasciopathy remains unknown. The lack of knowledge about both the working mechanism of SWT and the pathophysiology of plantar fasciopathy may have negatively influenced the outcome of the studies and makes comparisons between studies difficult.

Thirdly, in all included studies except for Buchbinder et al.³³, improvements on pain were reported in favour of the intervention group, but not always statistically significant (Table 4)^{33-35,38}. Buchbinder et al. suggests that the small shock wave dose delivered to the placebo group in her study could explain the failure to detect a difference in benefit between the intervention and the control group³³. Gollwitzer et al.³⁴ suggests that the use of local anaesthesia in the trial conducted by Buchbinder et al. resulted in failure to demonstrate the superiority of SWT compared with placebo. The authors of Gollwitzer et al. reported that the use of local anaesthesia might inhibit direct analgesic effects, like modification of the release of pain mediators, hyperstimulation, and the gate-control mechanism³⁴.

Fourthly, in both 'morning pain' and 'pressure pain' in our current review, more individual studies found statistically significant results in favour of the intervention^{35,36,38,39}, then otherwise^{33,34}. Unfortunately, the levels of evidence in the best-evidence synthesis (BES), according to van Tulder et al.²⁰ and adjusted by Steultjens et al.²¹, are not explicit enough, to be able to distinguish between conflicting results with more studies in favour of the intervention group, and conflicting results with less studies in favour of the intervention group.

Although the best-evidence synthesis as applied in the current systematic review shows conflicting evidence about the effectiveness of high-energy shockwave therapy, the third and fourth reason mentioned above indicate that more evidence is in favour of the intervention than otherwise. All studies, except for Buchbinder et al. show favourable results regarding shockwave therapy. Therefore, we have to conclude that the best-evidence synthesis in the current review gives a distorted view and is therefore unsuitable. According to our own classification, we would like to re-formulate the abovementioned conclusions:

- 1) There is limited evidence regarding the effectiveness of HESWT on 'morning pain' at 12 weeks after intervention in patients with PF (with 3 high-quality RCTs statistically significant in favour of the intervention, 1 high-quality RCT not statistically significant in favour of the intervention and 1 high-quality RCT not in favour of the intervention).
- 2) There is limited evidence regarding the effectiveness of HESWT on 'pressure pain' at 12 weeks after intervention in patients with PF (with 3 high-quality RCTs statistically significant in favour of the intervention and 1 high-quality RCT not statistically significant in favour of the intervention).
- 3) There is no evidence regarding the effectiveness of HESWT on 'activity-related pain' at 12 weeks after intervention in patients with PF (with 4 high-quality RCTs non statistical significant in favour of the intervention).

Comparison with other research

Our findings of a lack of benefit of HESWT are consistent with the findings of the systematic review of Burton et al.⁴² about the effectiveness of low-energy shockwave therapy. The authors reported limited evidence supporting the use of low-energy ESWT as a therapeutic modality for treating plantar fasciopathy. This indicated that high-energy shockwave therapy does not seem to be in favour of low-energy shockwave therapy or vice versa. These findings are also consistent with the RCT of Schofer et al.⁴³ about the effectiveness of high-energy versus low-energy shockwave therapy in rotator cuff tendinopathy. The authors reported no statistically significant differences between high-energy and low-energy shockwave therapy. Gollwitzer et al.³⁴ reported that, more than the choice between low- and high energy, the total energy density seem to influence the final outcome.

Adverse effects

Although the known adverse local effects of SWT include subcutaneous haematoma, skin erosion, swelling, petechial haemorrhage and pain/paresthesia³⁴, no serious sight effects were observed in any of the included studies. Therefore, shockwave therapy should be considered a safe tool in the treatment of chronic plantar fasciopathy.

Advantages of shockwave therapy

Shockwave therapy is a non-invasive technology without the obvious potential complications associated with surgery and it has limited recovery time. Moreover, shockwave therapy demonstrates a success rate comparable to surgery and even to other conventional therapies for plantar fasciopathy¹¹.

Strengths and limitations

The strength of this review lies in its rigorous methods, which include systematic search en study selection, thorough grading of evidence and systematic appraisal of methodological quality of the individual studies. Also, a few limitations concerning this systematic review need to be considered. First of al, methods of identifying publication bias were not conducted. Secondly, we only focused on outcome measures 12 weeks after intervention, because follow-ups at 12 weeks were mostly reported. Treatment effects directly after intervention or long-term effects were not taken along. These limitations, limit the precision of the results of this systematic review.

Recommendations for further research

First of all, fundamental research is needed to completely understand the mechanisms of action of shockwave therapy, so that standardised treatment protocols can be developed. Secondly, RCTs in large patient groups, with sufficient follow-up time, using adequate standardised treatment protocols are necessary to assess the true value of shockwave therapy for plantar fasciopathy.

Conclusion

Although the results are not completely unequivocal, in the majority of the studies a positive effect was found of high-energy shockwave therapy on pain in patients with plantar fasciopathy. Based on the available literature, it is not entirely clear what factors are responsible for a positive effect of high-energy shockwave therapy. Therefore, further research is needed.

Acknowledgements

A special thank you to Maarten Gijssel (MG), Fred Hartgens and Marco van Brussel for their contribution to this systematic review.

Literature

1. Rompe JD, Furia J, Weil L, Maffulli N. Shock wave therapy for chronic plantar fasciopathy. *Br Med Bull.* 2007;81-82:183-208.
2. Cole C, Seto C, Gazewood J. Plantar fasciitis: Evidence-based review of diagnosis and therapy. *Am Fam Physician.* 2005;72:2237-2242.
3. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: A national study of medical doctors. *Foot Ankle Int.* 2004;25:303-310.
4. DeMaio M, Paine R, Mangine RE, Drez D, Jr. Plantar fasciitis. *Orthopedics.* 1993;16:1153-1163.
5. Riddle DL, Pulisic M, Pidcoe P, Johnson RE. Risk factors for plantar fasciitis: A matched case-control study. *J Bone Joint Surg Am.* 2003;85-A:872-877.
6. Cook JL, Purdam CR. Is tendon pathology a continuum? A pathology model to explain the clinical presentation of load-induced tendinopathy. *Br J Sports Med.* 2009;43:409-416.
7. Crawford F, Thomson CE. Interventions for treating plantar heel pain. *Cochrane Database Syst Rev.* 2010;(1):CD000416.
8. Buchbinder R. Clinical practice. plantar fasciitis. *N Engl J Med.* 2004;350:2159-2166.
9. Wolgin M, Cook C, Graham C, Mauldin D. Conservative treatment of plantar heel pain: Long-term follow-up. *Foot Ankle Int.* 1994;15:97-102.
10. Boyle RA, Slater GL. Endoscopic plantar fascia release: A case series. *Foot Ankle Int.* 2003;24:176-179.
11. Davies MS, Weiss GA, Saxby TS. Plantar fasciitis: How successful is surgical intervention? *Foot Ankle Int.* 1999;20:803-807.

12. Wang CJ. An overview of shock wave therapy in musculoskeletal disorders. *Chang Gung Med J*. 2003;26:220-232.
13. Rompe JD, Kullmer K, Riehle HM, et al. Effectiveness of low-energy extracorporeal shock waves for chronic plantar fasciitis. *Foot and Ankle Surgery*. 1996;2:215-221.
14. Sems A, Dimeff R, Iannotti JP. Extracorporeal shock wave therapy in the treatment of chronic tendinopathies. *J Am Acad Orthop Surg*. 2006;14:195-204.
15. Centre for Evidence-Based Medicine. Oxford Centre for Evidence-Based Medicine. Available at www.cebm.net. Accessed at april 17, 2010. .
16. van Dijk M, Koot HM, Saad HH, Tibboel D, Passchier J. Observational visual analog scale in pediatric pain assessment: Useful tool or good riddance? *Clin J Pain*. 2002;18:310-316.
17. Verhagen AP, de Vet HC, de Bie RA, et al. The delphi list: A criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by delphi consensus. *J Clin Epidemiol*. 1998;51:1235-1241.
18. Van Peppen RP, Kwakkel G, Wood-Dauphinee S, Hendriks HJ, Van der Wees PJ, Dekker J. The impact of physical therapy on functional outcomes after stroke: What's the evidence? *Clin Rehabil*. 2004;18:833-862.
19. Sherrington C, Herbert RD, Maher CG, Moseley AM. PEDro. A database of randomized trials and systematic reviews in physiotherapy. *Man Ther*. 2000;5:223-226.
20. van Tulder MW, Cherkin DC, Berman B, Lao L, Koes BW. The effectiveness of acupuncture in the management of acute and chronic low back pain. A systematic review within the framework of the cochrane collaboration back review group. *Spine (Phila Pa 1976)*. 1999;24:1113-1123.
21. Steultjens EM, Dekker J, Bouter LM, van de Nes JC, Cup EH, van den Ende CH. Occupational therapy for stroke patients: A systematic review. *Stroke*. 2003;34:676-687.

22. Abt T, Hopfenmuller W, Mellerowicz H. Shock wave therapy for recalcitrant plantar fasciitis with heel spur: A prospective randomized placebo-controlled double-blind study. *Z Orthop Ihre Grenzgeb.* 2002;140:548-554.
23. Dogramaci Y, Kalaci A, Emir A, Yanat AN, Gokce A. Intracorporeal pneumatic shock application for the treatment of chronic plantar fasciitis: A randomized, double blind prospective clinical trial. *Arch Orthop Trauma Surg.* 2010;130:541-546.
24. Gerdesmeyer L, Frey C, Vester J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: Results of a confirmatory randomized placebo-controlled multicenter study. *Am J Sports Med.* 2008;36:2100-2109.
25. Haake M, Buch M, Schoellner C, et al. Extracorporeal shock wave therapy for plantar fasciitis: Randomised controlled multicentre trial. *BMJ.* 2003;327:75.
26. Marks W, Jackiewicz A, Witkowski Z, Kot J, Deja W, Lasek J. Extracorporeal shock-wave therapy (ESWT) with a new-generation pneumatic device in the treatment of heel pain. A double blind randomised controlled trial. *Acta Orthop Belg.* 2008;74:98-101.
27. Mehra A, Zaman T, Jenkin AI. The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis. *Surgeon.* 2003;1:290-292.
28. Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. *Am J Sports Med.* 2003;31:268-275.
29. Rompe JD, Schoellner C, Nafe B. Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis. *J Bone Joint Surg Am.* 2002;84-A:335-341.
30. Speed CA, Nichols D, Wies J, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. *J Orthop Res.* 2003;21:937-940.
31. Waddington G. Extracorporeal shock wave therapy no better than placebo in the treatment of plantar fasciitis. *Aust J Physiother.* 2003;49:69.

32. Lee GP, Ogden JA, Cross GL. Effect of extracorporeal shock waves on calcaneal bone spurs. *Foot Ankle Int.* 2003;24:927-930.
33. Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabakaran V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: A randomized controlled trial. *JAMA.* 2002;288:1364-1372.
34. Gollwitzer H, Diehl P, von Korff A, Rahlfs VW, Gerdesmeyer L. Extracorporeal shock wave therapy for chronic painful heel syndrome: A prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. *J Foot Ankle Surg.* 2007;46:348-357.
35. Kudo P, Dainty K, Clarfield M, Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shockwave therapy (ESWT) device: A north american confirmatory study. *J Orthop Res.* 2006;24:115-123.
36. Malay DS, Pressman MM, Assili A, et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: Results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. *J Foot Ankle Surg.* 2006;45:196-210.
37. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop Relat Res.* 2001;(387):47-59.
38. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. *J Bone Joint Surg Am.* 2004;86-A:2216-2228.
39. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. *Foot Ankle Int.* 2004;25:290-297.
40. Rompe JD, Meurer A, Nafe B, Hofmann A, Gerdesmeyer L. Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis. *J Orthop Res.* 2005;23:931-941.
41. van Leeuwen MT, Zwerver J, van den Akker-Scheek I. Extracorporeal shockwave therapy for patellar tendinopathy: A review of the literature. *Br J Sports Med.* 2009;43:163-168.

42. Burton A, Overend TJ. Low-energy extracorporeal shock wave therapy: A critical analysis of the evidence for effectiveness in the treatment of plantar fasciitis. *Physical Therapy Reviews*. 2005;10:152-162.

43. Schofer MD, Hinrichs F, Peterlein CD, Arendt M, Schmitt J. High- versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy: A prospective, randomised, controlled study. *Acta Orthop Belg*. 2009;75:452-458.