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REVIEW ARTICLE (META-ANALYSIS)

Is Extracorporeal Shock Wave Therapy Clinical Efficacy for Relief of Chronic, Recalcitrant Plantar Fasciitis? A Systematic Review and Meta-Analysis of Randomized Placebo or Active-Treatment Controlled Trials

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Abstract

Objective: To assess the efficacy of extracorporeal shockwave therapy (ESWT) and provide clinicians with an evidence base for their clinical decision making.

Data Sources: PubMed, MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and Evidence-Based Medicine Reviews.

Study Selection: All randomized or quasi-randomized controlled trials of ESWT for chronic recalcitrant plantar fasciitis were searched. Searching identified 108 potentially relevant articles; of these, 7 studies with 550 participants met inclusion criteria.

Data Extraction: Number of patients, population, body mass index, duration of symptoms, adverse effects, blinding method, and details of shockwave therapy were extracted.

Data Synthesis: For intervention success rate, ESWT of low intensity was more effective than control treatment of low intensity. For pain relief, the pooled data showed a significant difference between the ESWT and control groups. For function, only low-intensity ESWT was significantly superior over the control treatment.

Conclusions: The efficacy of low-intensity ESWT is worthy of recognition. The short-term pain relief and functional outcomes of this treatment are satisfactory. However, owing to the lack of a long-term follow-up, its long-term efficacy remains unknown.

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Heel pain, occurring in >11% to 15% of adults, is the most prevalent complaint of patients who present to foot and ankle specialists.[1,2] Plantar fasciitis is the most common cause of inferior heel pain in adults,[3,4] which requires professional care. Heel pain has been called by various names, including heel spur syndrome, which lends some importance to the radiographic presence of an inferior calcaneal spur in addition to clinical symptoms. The term plantar fasciitis has also been used for many years in the published literature. It is estimated that >1 million patients seek treatment annually for this condition, two thirds of whom visit their family physician.[5] The etiology of plantar fasciitis is poorly understood and likely multifactorial.[6] This condition is thought to be caused by biomechanical overstress of the calcaneal tuberosity.[7-11] Discussion of its biomechanical etiology usually involves the windlass mechanism and tension of the plantar fascia in both stance and gait.[12] Mechanical overload, irrespective of whether it is the result of biomechanical faults, obesity, or work habits of prolonged standing and running, may contribute to the symptoms.[13,14] Numerous studies have reported this condition to be plantar fasciitis, implying that its etiology is more likely a chronic degenerative process than acute inflammation.[15]

The diagnosis of plantar fasciitis is based on the patient's history and results of physical examination.[16] Patients usually present with plantar heel pain on initiation of weight bearing, particularly in the morning on arising and after periods of rest. The pain tends to decrease after a few minutes and returns as the day proceeds and the amount of time the patient spends on their feet increases; this pain

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usually persists for months or years. Another important characteristic is the location of the pain, usually occurring at the origin of the plantar fascia from the medial tubercle of the calcaneus.[17]

Diagnostic imaging is rarely needed for the initial diagnosis of plantar fasciitis because it may not be helpful; although, it should be considered to rule out other causes of heel pain or to establish the diagnosis of plantar fasciitis when doubts arise. Plain radiographs often reveal a heel spur on the inferior surface of the calcaneus. The presence or absence of heel spurs is not useful in diagnosing plantar fasciitis. Heel spurs are common in asymptomatic individuals and may be an incidental finding. The percentage of asymptomatic individuals in whom heel spurs are present on routine radiographs is about 20%.[18] The results of several studies comparing patients with and without plantar fasciitis showed that patients with thicker heel aponeurosis are associated with plantar fasciitis identified by ultrasonography.[19,20] Bone scans can distinguish between plantar fasciitis and calcaneal stress fracture, and magnetic resonance imaging can show thickening of the plantar fascia.[21] However, these modalities are not routinely used.

Associated significant findings indicate that the risk factors for plantar fasciitis include excessive foot pronation and running, high arch, obesity, high body mass index, tightness of the Achilles' tendon and intrinsic foot muscles, and inappropriate footwear.[17,22-26]

Conservative treatments help alleviate the disabling pain, consisting of rest, shoe inserts, activity modification, oral analgesics, night splints, stretching, and corticosteroid injections.[16,19] If a patient's heel pain lasts $\geq$6 months, it is considered chronic recalcitrant plantar fasciitis.[27] If at least 6 months of conservative treatment is ineffective, extracorporeal shockwave therapy (ESWT) and surgery can be considered.[27] Surgical options for the management of plantar fasciitis resistant to conservative management include endoscopic and open fasciotomy. Operative treatment has shown promising results, but it is associated with morbidities, such as injury of the posterior tibial nerve and its branches, including the medial calcaneal nerve,[2] tarsal instability, swelling of the incision site, immobilization, and potential complications (eg, arch flattening, nerve injury, calcaneal fracture, long recovery time).[28,29]

ESWT has been used for the treatment of recalcitrant heel pain syndrome as an alternative to surgery for decades.[30-34] It is widely used because it enables fast recovery without the necessity of reduced weight bearing or immobilization. The rationale for the use of ESWT for these conditions is based on stimulation of soft tissue healing by local hyperemia, neovascularization, reduction of calcification, inhibition of pain receptors, and denervation to achieve pain relief and persistent healing of chronic processes.[35] A consensus regarding the optimal ESWT intensity is lacking.

Considerable controversy has emerged regarding the use of ESWT for plantar heel pain.[36-40] For chronic recalcitrant plantar fasciitis, only 1 review by Dizon et al[41] has discussed the efficacy of ESWT. However, the study has some limitations (eg, lack of uniformity in certain outcome measures). Therefore, further research is necessary to evaluate this issue.

List of abbreviations:

CI	**confidence interval**
ESWT	**extracorporeal shockwave therapy**
MD	**mean difference**
RCT	**randomized controlled trial**
RM	**Roles and Maudsley**
RR	**risk ratio**
VAS	**visual analog scale**

In general, we found that there were no high-quality studies that had investigated the efficacy of ESWT for chronic recalcitrant plantar fasciitis using comprehensive items, and the existing studies provide no conclusive evidence to support the effectiveness and intensity of ESWT for treating the disease.

The purpose of this meta-analysis was to assess the efficacy of ESWT and provide clinicians with an evidence base for their clinical decision making. Furthermore, the adverse effects that may occur during the use of ESWT were evaluated.

Methods

Search strategy

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations for this meta-analysis.[42] With the assistance of a medical research librarian, we performed serial literature searches for English and non-English articles. The following electronic databases were searched from their inception dates to April 2013: PubMed, MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and Evidence-Based Medicine Reviews. We used Boolean logic with search terms including plantar fasciitis and shockwave therapy. Appendix 1 provides a more detailed account of the search strategy. Because all of the various databases used for this study possessed their own subject headings, each database was searched independently. All human studies that were published in full abstract and text forms were eligible for inclusion, with no restrictions on publication date, language, and status. To reduce the effect of publication bias, conference posters and abstracts were electronically searched through the Conference Papers Index provided by ProQuest, BIOSIS, and SCOPUS. Ongoing clinical trials were identified from the ClinicalTrials.gov website. The references for all located articles, including other systematic reviews, were searched manually for additional relevant articles. We attempted to contact the corresponding authors of the design articles via e-mail to ask if any new results were available.

Inclusion criteria

Types of studies

We included all randomized or quasi-randomized controlled trials of ESWT for chronic recalcitrant plantar fasciitis as defined by the trial investigators, identified by various clinical descriptors. We excluded abstracts and studies for which outcome measures for heel pain could not be separated from the data. For the purpose of our review, studies that lacked reporting of successful treatment standards were also excluded (eg, only stating a decrease of visual analog scale [VAS] scores). In addition, trials that compared different types of shockwave therapy (eg, radio shockwave therapy, focus shockwave therapy) were excluded.

Types of participants

Study participants were restricted to those aged $\geq$18 years. No sex-based restrictions were imposed. We included studies of patients who suffered from chronic plantar fasciitis (for at least 6mo). Further patients included in the study presented with single-site heel pain with local pressure at the origin of the proximal plantar fascia on the medial calcaneal tuberosity. We excluded trials in which specific pathologic changes could be identified (eg, fracture, trauma, vascular disease, inflammation on the involved heels, other specific pain related to neurologic disease).

Table 1 Details of included trials

Study	N	Design	Jadad Score	Treatment	Control	Intensity (mJ/mm^2)	Time for Evaluation (mo)	Success Rate: Experiment Group	Success Rate: Control Group	Pain Evaluation	Definition of Successful
Gerdesmeyer et al[3]	243	DB, RCT	5	ESWT	Placebo	.16	12	77/125	49/118	NR	60% improvement in pain for at least 2/3 of pain measurements
Gollwitzer et al[49]	40	DB, RCT	5	ESWT	Placebo	.25	3	11/20	8/20	NR	60% decrease of VAS
Ibrahim et al[4]	50	DB, RCT	5	ESWT	Placebo	.17	6	25/25	4/25	NR	60% improvement in pain from baseline
Marks et al[33]	25	DB, RCT	4	ESWT	Placebo	.16	6	9/16	4/9	Pain before treatment	50% decrease of VAS
Radwan et al[51]	65	NR, RCT	3	ESWT	EPFR	.22	12	25/34	21/31	Morning pain	50% improvement of AOFAS score
Rompe et al[35]	42	SB, RCT	4	ESWT	Placebo	.16	12	12/20	6/22	First walking in the morning	50% reduction in morning pain
Speed et al[50]	88	DB, RCT	4	ESWT	Placebo	.12	6	19/46	15/42	Pain on initial weight in the morning	50% improvement of morning pain from baseline

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society (clinical rating scale); DB, double blind; EPFR, endoscopic partial plantar fascia release; NR, not reported; SB, single blind.

Types of interventions

Conservative treatments (eg, use of shoe inserts, oral analgesics, night splints, stretching, corticosteroid injections) might provide pain relief in patients with plantar fasciitis. Therefore, studies were considered eligible for inclusion if they were randomized controlled trials (RCTs) or clinical trials that used only 1 intervention as a control compared with ESWT.

Type of outcomes

The primary outcome was the success treatment rate. Our review was more pertinent than other studies with regard to efficacy in managing plantar fasciitis. Therefore, we set the treatment success rate as the primary outcome, which was assessed 12 weeks after intervention. The definition of successful treatments in the studies is shown in table 1.

The secondary outcome was pain relief and functional outcome. Pain relief was measured with the VAS at the short-term follow-up. The VAS is used to record a patient's level of pain and is a reliable and valid instrument for measuring pain intensity.[43] Good feasibility and compliance have also been reported in some studies.[44,45]

Functional outcome was measured using the Roles and Maudsley (RM) score.[46] The RM score was used to evaluate pain in relation with the patient's daily activities. Although the RM score has various shortcomings, it remains widely used in clinical studies. An RM score of 1 represented an excellent quality of life (no symptoms, unlimited walking ability without pain, patient satisfied with the treatment outcome), an RM score of 2 represented a good quality of life (ability to walk for >1 hour without pain, symptoms decreased after treatment, patient satisfied with the treatment outcome), an RM score of 3 represented an acceptable quality of life (inability to walk >1 hour without pain, symptoms somewhat improved and pain more tolerable than before treatment, patient slightly satisfied with the treatment outcome), and an RM score of 4 represented a poor quality of life (inability to walk without severe pain, symptoms not improved or even worsened after treatment, patient not satisfied with the treatment outcome). We considered patients with RM scores of 1 or 2 to have a satisfactory functional outcome. An RM score of 3 or 4 was considered a therapeutic failure. The time periods for evaluating pain relief and RM score were at the last follow-up. The timing of evaluation of included trials and the definition of pain relief are all shown in table 1.

Data extraction and validity assessment

All study characteristics and outcome data were extracted from all included studies independently and in duplicate (M.-C.Y. and M.Y.) on a template adapted from the Cochrane Collaboration. For all studies, we extracted the number of patients, population, body mass index, duration of symptoms, adverse effects, blinding method, and details of shockwave therapy. If certain elements were missing, we contacted the study authors to obtain these data. Publications, missing data, changes in data, median data, and SDs were dealt with using methods from the Cochrane Handbook.[47] Any difference in opinion about eligibility was resolved by consensus. To quantify the level of agreement between reviewers, a kappa statistic was calculated. The kappa statistic is a chance-corrected proportional index with values ranging from 1 (perfect agreement) to −1 (complete disagreement). Results were used only when the kappa statistic was >.75, and disagreements were resolved by discussion or consensus with another 2 authors (W.M. and J.-M.M.) acting as arbiters.

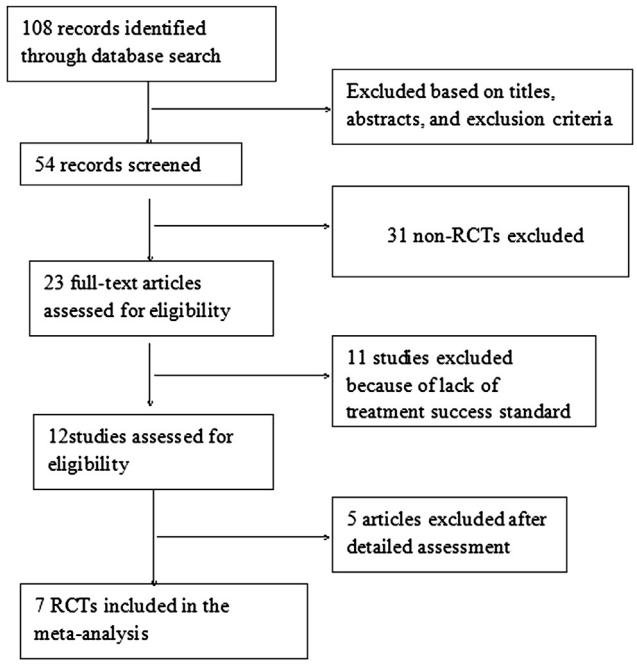

Fig 1 Study selection.

Assessment of methodologic quality and heterogeneity

Two independent reviewers (M.-C.Y. and M.Y.) graded the methodologic quality of all included studies using the Jadad scale (maximum score of 5).[48] This scale allocates a point each for randomization, double-blind design, and description of dropouts. If randomization and double-blind concealment are correct, an additional 2 points are added. Otherwise, 1 point will be deducted for each. A trial with a score ≥ 3 is considered high quality. A trial scoring <3 was regarded as being of poor quality.

This review also assessed the clinical heterogeneity by considering baseline characteristics among all trials (population differences in sex, age, duration of symptoms, outcome). Clinical heterogeneity judgment was used to evaluate whether the trials were similar enough to pool data. The specific parameters of application techniques and details for the location, total energy, follow-up, frequency, and number of treatments were extracted and tabulated.

Assessment of risk bias

Risks of bias of all included trials were also independently assessed by the other 2 reviewers (Y.X. and Q.-X.S.) according to the criteria of the Cochrane Handbook for Systematic Reviews.

Data analysis

Review Manager 5.1.0[a] was used to pool the data. In our review, for categorical data, the success rate and functional outcome were dichotomized into 2 categories (successful improvement or not). We calculated the risk ratio (RR) and 95% confidence interval (CI). Effect size for reported pain relief was defined as a pooled estimate of the mean difference (MD) in the change in score on a 10-point VAS between the ESWT group and control group, that is, the weighted MD of the change between the 2 groups. Variance was calculated from the trial's data with 95% CIs.

For trials reporting changes from baseline values, the mean and SD of the final values were obtained using the following formula,[49] with the correlation between baseline and final values (r baseline, final) assumed to be 0.5: SD2change = SD2baseline + SD2final − 2r baseline, final SDbaseline SDfinal.

We investigated heterogeneity between studies using Cochrane Q statistic and I^2 statistic. The heterogeneity as determined by Cochrane Q statistic was $<.10$ of the chi-square test. If the I^2 value was $>75\%$, we marked it as a considerable level of heterogeneity; otherwise, we considered it to be good homogeneity. This study also assessed clinical heterogeneity. Statistically and clinically homogeneous studies were pooled using a fixed effect model; otherwise, a random effects model was used when the heterogeneity was significant.

Results

Study description

From an initial search yield of 108 articles, 53 potentially relevant articles were identified. After reading the titles and abstracts, 23 studies were identified as RCTs. Among these, 11 lacked a clear definition of successful treatment standards. Two studies

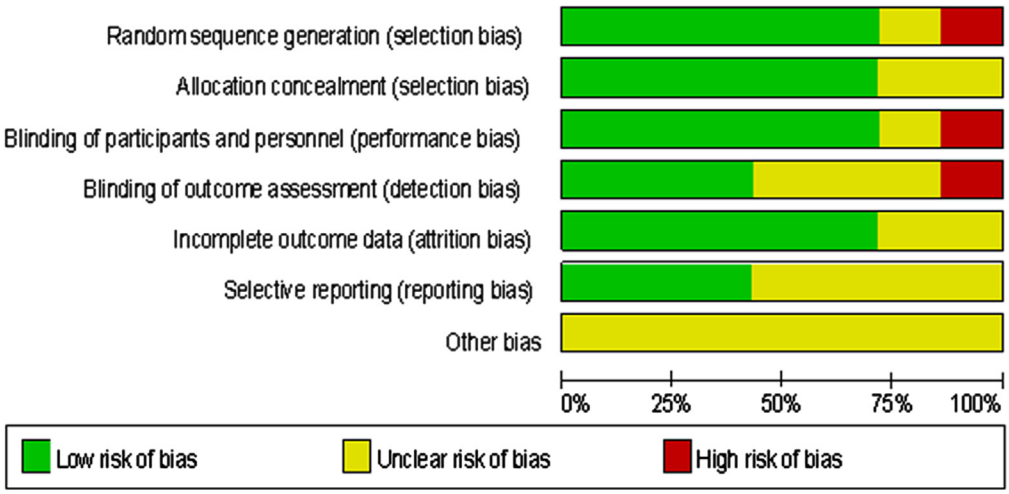

Fig 2 Risk of bias graph: review authors' judgments about each risk of bias item. Values are presented as percentages across all included studies.

compared local ESWT with radial ESWT for the treatment of plantar fasciitis, and 3 studies used a local anesthetic in the ESWT group. After exclusion of these studies, the 7 remaining studies with adequate methodology were incorporated in our systematic review.[3,4,33,35,50,51] These studies included 6 trials that compared ESWT with placebo therapy[3,4,33,35,50,51] and 1 trial of plantar fasciotomy[52] (fig 1). The details of the included trials are shown in table 1.

Methodologic quality

All included trials mentioned randomization, 5 of which described the method of randomization and concealment of allocation in detail, with appropriate and feasible methods. In addition, 5 trials mentioned double blinding, and 1 trial mentioned single blinding in their methodologic design. We also evaluated all included studies as recommended by the Cochrane Handbook 5.0. Figures 2 and 3 show the results of our judgment about each included trial's methodologic quality.

Intervention success rate

All 7 included trials (N≥550) reported a treatment success rate. According to the different intensity levels, we used a subgroup analysis. The treatment intensity of ESWT was divided into 2 levels: low intensity (energy <0.20mJ/mm^2) and high intensity (energy >0.2mJ/mm^2).

For the low-intensity group, the number of events in each trial ranged from 25 to 243. The pooled data showed that in terms of the overall success rate, ESWT was more effective than control treatment using the fixed effect model (5 trials; n=448; pooled RR=1.69; 95% CI, 1.37−2.07; P<.001) (fig 4).

For the high-intensity group, the number of events in each trial ranged from 40 to 65. The pooled data showed that there was no significant difference in the overall success rate between the ESWT and control groups using the fixed effect model (2 trials; n=105; pooled RR=1.16; 95% CI, .86−1.56; P=.32) (fig 5).

Intervention for pain relief

Four trials (n=210) reported a decrease in the VAS to evaluate pain relief outcomes. We evaluated the outcome at the last follow-up, and the number of events in each trial ranged from 25 to 78.

For pain relief in the low-intensity group, the pooled data showed that there was a significant difference between the ESWT and control groups using the fixed effect model (n=145; pooled MD=1.51; 95% CI, .77−2.26; P<.001) (fig 6).

For the high-intensity group, 1 trial also showed that the ESWT group had superior pain relief relative to the control group (n=65; pooled MD=1.4; 95% CI, .57−2.23; P=.001) (fig 7).

Intervention for function

Five trials (n=423) reported RM scores as an indicator of function/disability outcomes, and the number of events in each trial ranged from 40 to 243.

Three trials that reported the therapeutic success rate used RM scores categorized as excellent and good (n=348; pooled RR=1.38; 95% CI, 1.12−1.71; P=.003). In the subgroup analysis of short-term function using the RM score, only low-intensity ESWT was significantly superior over the control treatment.

High-intensity ESWT was more effective than placebo (RR=1.33; 95% CI, .94−1.9; P=.11) (fig 8).

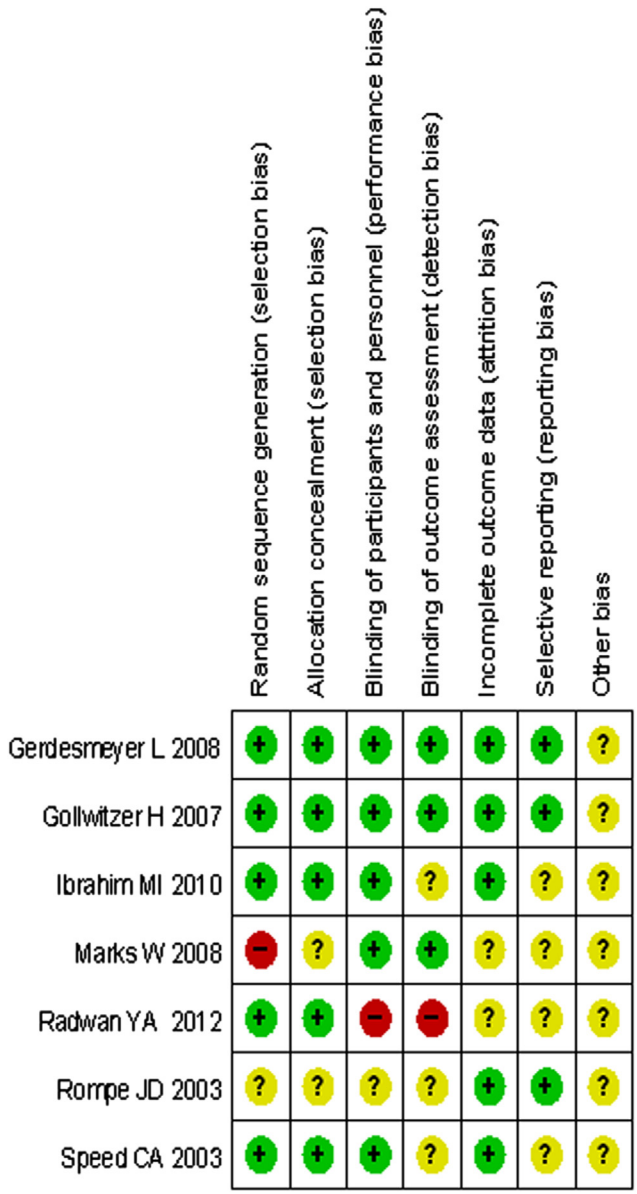

Fig 3 Risk of bias summary: review authors' judgments about each risk of bias items for each included study. Abbreviations: +, yes; −, no; ?, unsure.

A subgroup analysis of low-intensity ESWT also showed greater improvement than controls (RR=1.41; 95% CI, 1.08−1.82; P=.01).

Safety of ESWT

Adverse event-related outcomes were reported in 2 of the 7 included trials. One trial reported no serious device-related adverse events in both groups, which had no influence on outcomes. No severe adverse events occurred regarding tendon rupture.[3] One trial reported that 1 participant used concomitant analgesic therapy during the study period, and none of the active ESWT patients used concomitant analgesia.

Funnel plot analysis

The resultant funnel plot was unsymmetrical. The symmetry of a funnel plot may be impacted not only by publication bias but also

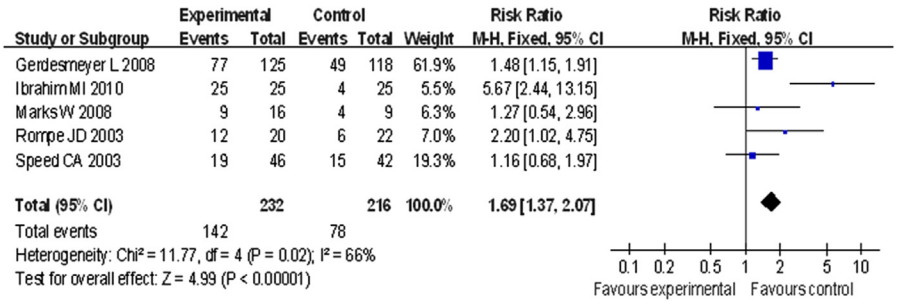

Fig 4 ESWT versus control treatment on a success rate of low intensity.

by trial and effect size. The funnel plot showed that there was a lack of small studies with a relatively small effect size.

Discussion

Summary of the main findings

We used 5 levels of evidence to assess whether treatment was beneficial: strong evidence (consistent findings in several high-quality RCTs), moderate evidence (findings from 1 high-quality RCT or consistent findings in several low-quality trials), limited evidence (1 low-quality RCT), unclear evidence (inconsistent or contradictory results in several randomized trials), and no evidence (no studies identified).

The results of the present review showed strong statistical evidence for the efficacy of ESWT in the treatment of chronic, recalcitrant plantar fasciitis over a midterm follow-up period. Short-term follow-up refers to outcomes that are measured closest to 4 weeks after randomization. Intermediate follow-up refers to measures taken at least 6 months after treatment. Long-term follow-up refers to measures taken close to 2 years after treatment. Therefore, we define our follow-up period as midterm.[53] Categorical data of the overall success rate significantly favored ESWT over control treatment. Further, for chronic pain, we recorded an average reduction in VAS scores across all included trials, which is a clinically important change.

We studied the relevant clinical outcomes, including success rate, pain relief, and function. To assess the treatment success rate, 6 trials set the degree of improvement in the VAS as a success standard, but with a different focus (eg, pain in the morning, pain during the first step). Three VAS scores (ie, pain when taking the first steps in the morning, pain while performing daily activities, heel pain while applying a standardized local pressure) were analyzed in all trials. One study considered the treatment successful with the improvement of American Orthopaedic Foot and Ankle Society (clinical rating scale) scores by >50%. Such nonuniform evaluation criteria may cause bias during evaluation. According to our findings, the between-group difference of the ESWT and control groups was not statistically significant in 4 trials. In a subgroup analysis, there appears to be a significant effect with low-intensity ESWT in patients with chronic, recalcitrant plantar fasciitis.

For pain relief and improvement, some trials select the terminal value to evaluate the VAS; however, this measure only reflects the pain status after intervention. These studies evaluate pain relief, but they cannot reflect the role of intervention in the healing process. Therefore, we compared the value of ESWT for pain relief before and after treatment. This study indicated that both the high-intensity and low-intensity ESWT groups show acceptable results. Moreover, the low-intensity group was somehow superior to the high-intensity group in pain relief.

For function outcome, ESWT was significantly superior over the control treatment. We acknowledged that using some functional assessment scales was more clinically useful than reporting success rates of pain reduction. The RM score has not been validated for foot disorders and has various shortcomings (eg, self-assess system), but it has been used extensively in similar studies and was assessed to allow comparison of the results with other investigations. Therefore, we hope to build a better scoring system to evaluate the clinical outcome of chronic plantar fasciitis.

Some of the literature included in other similar systematic reviews use both ESWT and local anesthetics, thereby decreasing the validity of the results and resulting in evaluation bias. Therefore, our study included trials with patients who had plantar fasciitis for >6 months, with clear standards of efficacy, and used ESWT alone in the experimental group.

Intensity assessment is crucial for analysis of ESWT study outcomes and is considered a major aspect of negative outcomes and adverse effects. To date, no study, to our knowledge, has successfully achieved an intensity that was in the recommended range of previous reports. The direct relation between positive outcomes of trials with excess ESWT intensity for the appropriate condition has been reported in edema and soft-tissue disorder.

Several other crucial aspects of ESWT treatment should be taken into consideration for further analysis (eg, total energy,

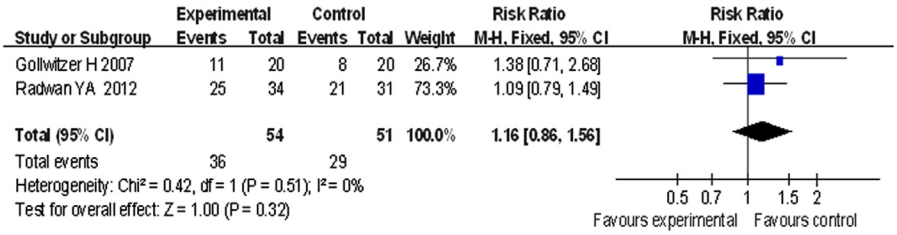

Fig 5 ESWT versus control treatment on a success rate of high intensity.

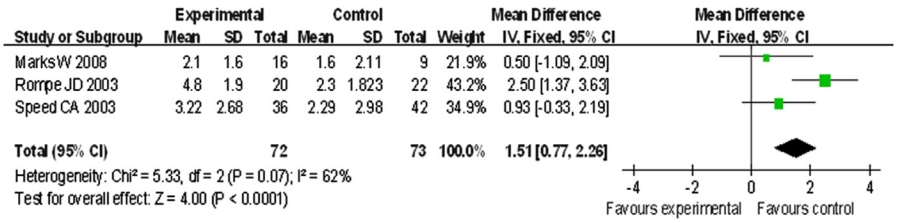

Fig 6 ESWT versus control treatment on pain relief of low intensity.

frequency of intervention, other related parameters). Unfortunately, many key pieces of information were incompletely reported in the studies that we reviewed. Our analysis only suggests that low-intensity ESWT was superior to high-intensity treatment. These results contradict those of the systematic review conducted by Dizon et al.[41] We are unable to provide further optimal and practical information for clinicians in this regard. In our future clinical work, we will make an effort to conduct a multicenter, pragmatic RCT in a sufficiently powered and proper study to test the intervention of ESWT, with pain intensity, pain relief, and functional improvement as outcome measures, to establish a stronger clinical treatment guideline and undertake extensive analysis in exploring important variables that could affect clinical management. The results of these studies will provide clinicians with an evidence base for clinical decision making.

In addition, the follow-up period of all the included trials were relatively short, with the longest being 1 year; therefore, the long-term efficacy remains unknown. How long will the effects of ESWT last? Relevant related information was also unreported. Therefore, we failed to draw a conclusion about these 2 questions. The number of clinical trials comparing ESWT with other therapies is small, causing a lack of further understanding of the efficacy of ESWT.

Moreover, we faced some difficulty regarding clinical heterogeneity in this review. Many levels of heterogeneity were noted (eg, different machines, parameters, intensity used). However, the most difficult challenge we faced was the lack of uniformity in a certain diagnosis and treatment success criteria. Many apparently disparate diagnostic terms are applied to patients presenting with heel pain. Diagnosis of plantar fasciitis is based on the patient's history and results of a physical examination. There are no obvious abnormalities on radiographic tests (eg, radiograph, computed tomography, magnetic resonance imaging). Most of the trials only assessed the degree of improvement in VAS scores. Further, an accurate scale that more reliably and feasibly evaluates the outcomes of plantar fasciitis patients is lacking. The RM scale is a widely used self-assessment scale, which has many shortcomings in various aspects. RM scores will be affected by the patient's subjective factors, and it lacks an objective, quantifiable statement of the disease before and after treatment (eg, foot range of motion, imaging). This is likely the main reason for the lack of uniform criteria for judging the clinical efficacy.

Strengths of this review

Our study should be considered in the context of several notable strengths. First, this review is the first, to our knowledge, to investigate the efficacy of ESWT for chronic, recalcitrant plantar fasciitis with clear success standards and represents the most comprehensive study of pain relief, functional outcome, intensity, and adverse effects to date. Second, we aimed to investigate the efficacy of ESWT for chronic, recalcitrant plantar fasciitis and judged whether the difference was clinically important. With this objective in mind, we conducted a systematic literature search to guarantee the comprehensiveness of the trials included. These trials provided a large number of patients, and this review has adequate statistical power to analyze and explore the treatment effects of ESWT, despite the exclusion of numerous clinical trials because of a lack of clearly defined treatment success standards. A previous similar systematic review assessed the effectiveness of ESWT in chronic plantar fasciitis. However, the trials included patients with no clear description of symptom duration. This review makes up this deficiency because all included patients had symptoms lasting for >6 months. Third, our results are robust and consistent as shown by our risk bias and subgroup analyses.

Study limitations

The present results should also be considered in the context of some limitations. First, some trials were included in previous reviews. Bias can be introduced in different ways during the process of locating and selecting studies for inclusion. This review only included 7 clinical trials, with a relatively small sample size. A systematic review of small trials has been shown to be potentially unreliable in some fields (eg, surgery, medicine),[54,55] which cannot be ignored. We did not include any observational studies in which evidence may suggest an association between ESWT and chronic plantar fasciitis because these trials are beyond the scope of our systematic review. Although we used a detailed search strategy, we still cannot be sure that all relevant trials were found. Selecting, publishing, and reporting are other major causes of bias that should be considered.[56] All of these factors may increase bias. Further, although, overall, the quality of the studies included in the review was satisfactory, this review included some trials without high-quality methodology. Inclusion of these trials could affect the robustness of our results.[57] To improve the trial design quality and level of performance, future trials should follow the guidelines for

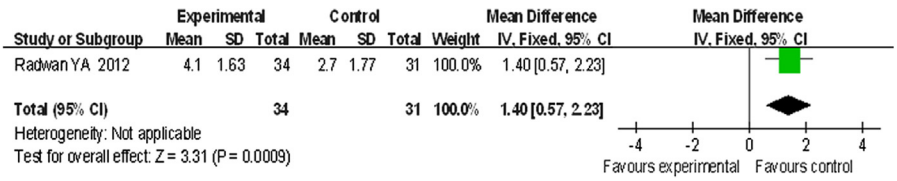

Fig 7 ESWT versus control treatment on pain relief of high intensity.

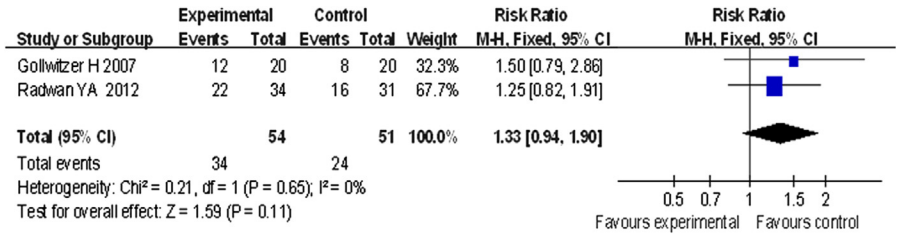

Fig 8 ESWT versus control treatment on function.

reporting clinical trials (eg, Consolidated Standards of Reporting Trials statement,[58,59] which is widely used to improve the reporting of RCTs). Finally, we were unable to assess the interactions between physical exercise, oral analgesics, corticosteroid injections, and other conservative interventions and the treatment effects of ESWT because trials reporting these factors used widely differing units or methods, and we could not calculate a summary evaluation. Despite these limitations, this review still used an appropriate approach to provide sufficient clinical treatment evidence.

Conclusions

This meta-analysis provides substantive clinical evidence for clinicians in the treatment of chronic, recalcitrant plantar fasciitis. The results show that the efficacy of low-intensity ESWT is worthy of recognition. The short-term pain relief and functional outcomes of this treatment are satisfactory. However, owing to the lack of a long-term follow-up, its long-term efficacy remains unknown.

Supplier

a. The Nordic Cochrane Centre, The Cochrane Collaboration. Available at: http://tech.cochrane.org/revman/about-revman-5.

Keywords

Rehabilitation

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Appendix 1 PubMed and MEDLINE Database Search Strategy

1 trial [Title]
2 randomly [Title/Abstract]
3 clinical trials [MeSH Major Topic]
4 placebo [Title/Abstract]
5 randomized [Title/Abstract]
6 randomized controlled trial [Publication Type]
7 controlled clinical trial [Publication Type]
8 OR/#1-#7
9 animals [mh] not humans [mh]
10 # 8 not # 9
11 heel pain
12 plantar fasciitis
13 calcaneodynia
14 plantar heel pain
15 plantar fasciopathy
16 OR/#11-15
17 shock wave therapy
18 radio shock wave therapy
19 focus shock wave therapy
20 extracorporeal shock wave therapy
21 shock wave
22 OR/#17-21
23 #10 and #16 and #22

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