

Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis

A meta-analysis of RCTs

Jiale Sun, MD^a, Fuqiang Gao, MD^b, Yanhua Wang, MD^c, Wei Sun, MD^{b,*}, Baoguo Jiang, MD^{c,*}, Zirong Li, MD^b

Abstract

Background: Plantar fasciitis (PF) is the most common reason for heel pain. The efficacy of extracorporeal shock wave therapy (ESWT) as an ideal alternative to conservative treatments and surgery is controversial, and almost all previous articles compared general ESWT with placebo without indicating the kind of shock wave. We undertook a meta-analysis to compare the efficacy of general ESWT, focused shock wave (FSW), and radial shock wave (RSW) with placebo, to assess their effectiveness in chronic PF.

Methods: The PubMed, Medline, EmBase, Web of Science, and Cochrane library databases were searched for studies comparing FSW or RSW therapy with placebo in chronic PF. Clinical outcomes included the odds ratios (ORs) of pain relief, pain reduction, and complications. Relevant data were analyzed using RevMan v5.3.

Results: Nine studies involving 935 patients were included. ESWT had higher improvement rates than the placebo group (OR 2.58, 95% confidence interval [CI] 1.97–3.39, $P < .00001$). ESWT had markedly lower standardized mean difference than placebo, with heterogeneity observed (standardized mean difference 1.01, 95% CI -0.01 to 2.03 , $P = .05$, $I^2 = 96\%$, $P < .00001$). FSW and RSW therapies had greater therapeutic success in pain relief than the placebo group (OR 2.17, 95% CI 1.49–3.16, $P < .0001$; OR 4.63, 95% CI 1.30–16.46, $P = .02$), but significant heterogeneity was observed in RSW therapy versus placebo ($I^2 = 81\%$, $P = .005$).

Conclusion: This meta-analysis suggested that FSW therapy can relieve pain in chronic PF as an ideal alternative option; meanwhile, no firm conclusions of general ESWT and RSW effectiveness can be drawn. Due to variations in the included studies, additional trials are needed to validate these conclusions.

Abbreviations: ESWT = extracorporeal shock wave therapy, FSW = focused shock wave, ORs = odds ratios, PF = plantar fasciitis, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses, RCTs = randomized controlled trials, RSW = radial shock wave, SMD = standardized mean difference.

Keywords: extracorporeal shock wave therapy, heel pain relief, meta-analysis

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^a The Graduate School of Peking Union Medical College, ^b Centre for Osteonecrosis and Joint-Preserving & Reconstruction, Department of Orthopedic Surgery, Beijing Key Laboratory of Arthritic and Rheumatic Diseases, China-Japan Friendship Hospital, National Health and Family Planning Commission of the People's Republic of China, ^c Department of Trauma and Orthopedics, Peking University People's Hospital, Beijing, China.

* Correspondence: Wei Sun, Department of Orthopedics, China-Japan Friendship Hospital, Beijing 100029, China (e-mail: 18901267995@163.com); Baoguo Jiang, Department of Trauma and Orthopedics, Peking University People's Hospital, South Xizhimen Street No. 11, Xicheng District, 100044 Beijing, China (e-mail: jiangbaoguo@vip.sina.com).

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1. Introduction

Plantar fasciitis (PF) is a foot disease, and the most common cause of heel pain, accounting for about 11% to 15% of clinical symptoms requiring treatment.^[1] Although the suffix “-itis” implies an inflammatory condition, mounting evidence indicates that this foot disorder is associated with degenerative changes, and should be appropriately classified as a “fasciosis” or “fasciopathy.”^[1,2] Patients with PF may experience the most serious heel pain with the first few steps in the morning or after a period of rest.^[1,2] The treatment options for relieving PF symptoms include activity modification, plantar fascia stretch, ice massage, night splints, nonsteroidal anti-inflammatory drugs combined with other treatment modalities, local steroid injections, extracorporeal shockwave therapy, and surgery.^[3] Approximately 10% of PF patients cannot be relieved by conservative therapy, whose long course is not satisfactory.^[4] In addition, surgical treatment is considered the last intervention because of serious injury, risks, and postoperative complications.

Extracorporeal shock wave therapy (ESWT) has been widely used as an alternative treatment option for PF for decades due to its noninvasive nature, fast recovery time, and convenience for daily life of patients.^[5,6] The specific mechanisms of ESWT in treating musculoskeletal pain remain unclear; however, multiple studies have shown that it can destroy sensory unmyelinated nerve fibers, and stimulate neovascularization and collagen

synthesis in degenerative tissues.^[7] Recently, both focused shock wave (FSW) and radial shock wave (RSW) therapies were introduced as treatment options for PF. RSW dispersed from the applicator does not concentrate on the tissue compared with FSW.^[8] Several studies have demonstrated the function of ESWT in relieving heel pain. However, there were positive and negative results. Furthermore, some previous meta-analyses compared ESWT and sham or other therapeutic methods, without distinguishing which ESWT type is effective. It is uncertain whether general ESWT, including FSW and RSW therapies, is effective in relieving plantar heel pain. Such debate may be further acknowledged by our meta-analysis combined with previous analysis, aiming at providing useful information on efficacy of ESWT for the treatment of chronic PF.

2. Materials and methods

This meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.^[9] Ethical approval for this study was unnecessary, as a review of existing literature not involving the handling of individual patient data.

2.1. Data sources and study selection

The PubMed, Medline, EmBase, Web of Science, and Cochrane library databases were searched up to July 2016, for comparative studies involving shock wave in the management of pain relief from plantar fasciitis. The search terms were: “extracorporeal shock wave therapy” OR “focused extracorporeal shock wave therapy” OR “radial extracorporeal shock wave therapy” AND “plantar fasciitis” OR “plantar fasciopathy” OR “heel pain.” Then, the articles were searched by abstract and title. Publication language was limited to English. The reference lists of all eligible studies and relevant reviews were manually searched for any additional trials.

2.2. Inclusion criteria

Studies that met the following criteria were included in the current meta-analysis: investigations of patients suffering from heel pain and diagnosed with chronic plantar fasciitis; studies involving the comparison between ESWT without anesthesia and sham therapy as control; randomized controlled trials (RCT).

2.3. Data extraction and quality assessment

Data from the obtained articles were abstracted independently by 3 investigators (J.S., F.G., and W.Y.), including author’s name, year of publication, trial design, total participants and allocation, details of intervention (FSW or RSW, density of shock wave, and time of treatment) and control groups, and trial outcomes and results. Cochrane Risk of Bias Tool was used to assess the quality of clinical trials (Figs. 1 and 2). Discrepancy was resolved by discussing with other investigators and contacting the article’s authors if necessary.

2.4. Statistical analysis

Review Manager Software (Revman v5.3) was used to analyze experimental data from the included trials. Odds ratios (ORs) of successful treatments were assessed for dichotomous data. Heterogeneity among studies was estimated using the I^2 statistics; substantial heterogeneity was reflected by $I^2 > 50\%$. A fixed-effects

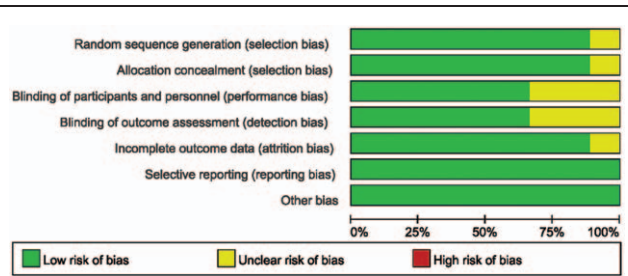


Figure 1. Risk of bias graph.

model was used when $I^2 < 50\%$; otherwise, the random-effects model was adopted. $P < .05$ was considered statistically significant.

3. Results

3.1. Study inclusion

The literature search identified a total of 326 articles, of which 145 were considered to be relevant; 37 clinical RCTs were



Figure 2. Risk of bias summary.

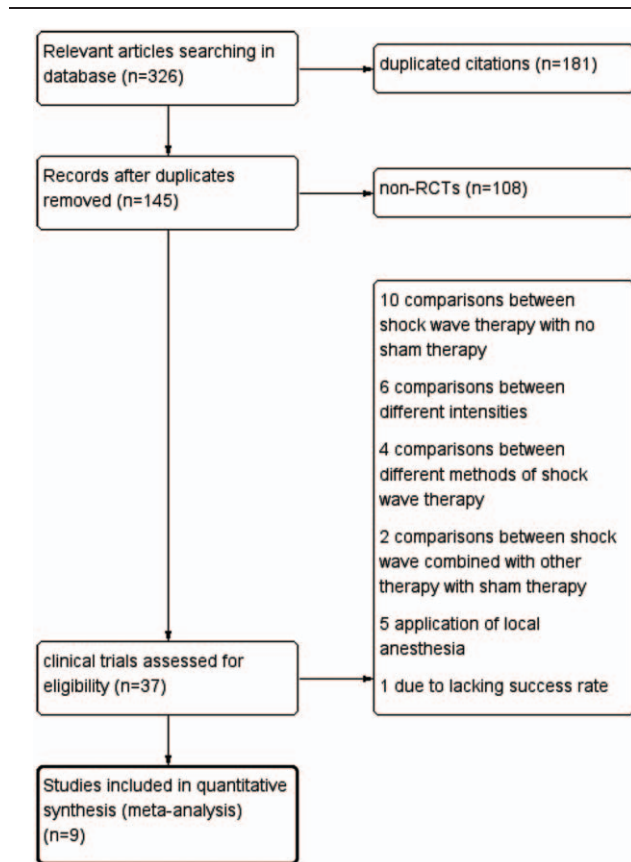


Figure 3. Flow chart of the study selection.

screened. After assessing the abstracts and full text articles, 10 studies were excluded because of comparisons between focused or radial shock wave and other treatments rather than sham therapy;^[10–19] 6 were excluded for comparisons between different intensities,^[20–25] 2 for comparisons between shock wave therapy combined with other therapies and sham therapy,^[26,27] 4 for comparisons between different methods of shock wave therapy,^[28–31] 5 for applying local anesthesia totally,^[5,6,32–34] and 1 for lacking the success rate.^[8] Finally, 9 studies, including 6 reports comparing FSW therapy with a placebo,^[35–40] and 3 comparing RSW,^[41–43] were eligible for data extraction and meta-analysis based on inclusion and exclusion criteria. These articles involved 935 patients (Fig. 3) (Table 1).

3.2. Success or improvement rates

Therapeutic success was defined as a decrease in visual analogue scale (VAS) score from baseline larger than 50% or 60%, or VAS score of less than 4cm after intervention, according to the included studies. In comparison, general ESWT had higher improvement or success rates than placebo as assessed by a fixed-effects model (OR 2.58, 95% confidence interval [CI] 1.97–3.39, $P < .00001$, $I^2 = 38\%$) (Fig. 4). According to the different shock wave types, a subgroup analysis of FSW and RSW therapies was performed. The FSW group involved 474 patients with 244 events, indicating that FSW therapy had greater improvement or success rates than placebo as assessed by a fixed-effects model (OR 2.17, 95% CI 1.49–3.16, $P < .0001$, $I^2 = 0\%$) (Fig. 5). The

RSW therapy group involved 461 patients with 262 events, suggesting that RSW therapy had higher pooled ORs (OR 4.63, 95% CI 1.30–16.46, $P = .02$) than placebo, but significant heterogeneity was observed ($I^2 = 81\%$, $P = .005$) (Fig. 6).

3.3. Reduction in pain scales

Only 4 trials provided adequate information regarding reduction in pain scale with standard error. Of these trials, 3 compared FSW therapy with placebo,^[37–39] whereas 1 comparatively assessed RSW therapy and placebo.^[41] Significant heterogeneity was observed in the comparisons of reduction in pain scale. General ESWT had greater reduction in pain scale than placebo (standardized mean difference [SMD] 1.01, 95% CI –0.01 to 2.03, $P = .05$) (Fig. 7), but 95% CI covered the value of 0, as analyzed by a random-effects model.

3.4. Complications

Seven of 9 included studies described complications of ESWT; there were no serious adverse events, such as hematomas, infections, and abnormal musculoskeletal events, recorded during patient follow-up. A few patients had feelings of discomfort, pain, swelling, and bruise during or after treatment, which may be considered intensity-related adverse events. These findings indicated that ESWT is a safe and effective treatment.

4. Discussion

Unlike previously published meta-analyses that did not distinguish shock wave types, the current meta-analysis pooled comprehensive data on FSW and RSW therapies for chronic PF, and determine whether general ESWT, FSW therapy, and RSW therapy are effective treatments for chronic PF. In addition, few studies have compared the effects of FSW and RSW therapies, respectively, with those of placebo. In this meta-analysis, ESWT and RSW therapy for chronic PF might be more effective than placebo and FSW therapy, as safe alternative options.

General ESWT was shown to be effective and safe in the treatment of chronic PF in a comprehensive comparison of success or improvement rates including both shock wave types with controls. However, Speed et al^[40] and Marks et al^[38] found no significant difference between ESWT and sham therapy. General ESWT was probably more effective, according to the comparisons of pain scale reduction and significant heterogeneity that resulted in a wider range of SMD. Nevertheless, differences were observed in ESWT compared with sham therapy.

The FSW therapy is a traditional alternative option to operation, and was introduced in 1995.^[8] FSW devices generate energy focusing on a small region with the maximum energy level, which can penetrate some centimeters subcutaneously.^[44–46] In the current meta-analysis, significant differences in success or improvement rates were observed in FSW therapy for chronic PF compared with sham therapy, and reduction in pain scale in FSW therapy (SMD 1.29, $I^2 = 87\%$ in random-effects model) (Fig. 8) was higher than in the placebo groups. However, Speed et al^[40] and Marks et al^[38] found no significant difference between FSW and sham therapies.

The RSW therapy is a relatively new method that was introduced in 2001.^[8] Compared with FSW, RSW devices disperse the shock wave at the skin surface and distribute the energy radially into larger treatment tissue areas. Therefore, the

Table 1
Characteristics of the included studies.

Study	Group	Intensity (mJ/mm ²)	Treatment dose	Patients enrolls	Male / female	Mean age (range) (years)	Mean duration of pain (range) (mo)	Follow-up Duration (mo)	Outcome (success criterion)	Success Rates/Improvement Rate	Reduction in pain scale
Gollwitzer et al, 2015 ⁽³⁷⁾	FSW	0.25	2000 pulses × 3 sessions	125	40/84	50.0 ± 11.2 (NA)	>6	3	>60% improvement of VAS in pain from baseline	68/125	-54.5% (6.8%)
Ibrahim et al, 2010 ⁽⁴²⁾	Placebo RSW	0.16	Air-filled standoff 2000 pulses × 2 sessions	121 25	33/88 7/18	47.4 ± 10.6 (NA) 56.6 ± 2.71 (26-87)	>6	3 6	>60% improvement of VAS in pain from baseline	45/121 25/25	-40.3% (7.2%) -93.9% (NA)
Gardesmeier et al, 2008 ⁽⁴¹⁾	placebo RSW	0.16	Heel clasp 2000 pulses × 3 sessions	25 125	11/14 38/87	49.1 ± 2.55 (28-78) 52.4 ± 12.0 (NA)	>6 25.6 ± 26.1	6 3	>60% improvement of VAS in pain from baseline	4/25 75/125	-17.0% (NA) -56.0% (39.3%)
Marks et al, 2008 ⁽³⁸⁾	Placebo FSW	0.16	Placebo hand piece 1500 pulses × 3 sessions	118 16	39/79 7/9	52.0 ± 10.5 (NA) 51.9 ± 11.9 (33-72)	24.9 ± 25.3 35.6 ± 43.2 day	3 6	>50% improvement of VAS in pain from baseline	49/118 9/16	-44.1% (41.8%) -28.25 (26.06)
Gollwitzer et al, 2007 ⁽³⁶⁾	placebo FSW	0.25	Zero energy 2000 pulses × 3 sessions	9 20	4/5 11/9	51.7 ± 14.3 (29-70) 53.9 ± 12.5 (30-72)	21.0 ± 16.4 day 11.3 ± 7.4 (6-28)	6 3	>60% improvement of VAS in pain from baseline	4/9 11/20	-1.78 (44.42) -73.2 (NA)
Malay et al, 2006 ⁽⁴³⁾	Placebo RSW	Air-chambered polyethylene foil NA	A total of 3800 pulses	20 115	4/16 36/79	58.9 ± 10.9 (35-76) 50.8 ± 10.1 (28-75)	12.1 ± 8.0 (6-36) 31.6 ± 36.3 (6-240)	3 3	>50% improvement of VAS in pain from baseline	8/20 48/112	-40.5 (NA) -2.51 (NA)
Rompe et al, 2003 ⁽³⁹⁾	Placebo FSW	Foam-insulated membrane 0.16	2100 pulses × 3 sessions	57 22	21/36 12/10	52.1 ± 11.1 (30-79) 43 (32-59)	26.0 ± 24.4 (6-120) 20 (12-60)	3 6	>50% improvement of VAS in pain from baseline	11/56 12/19	-1.57 (NA) 1.9 (0.9)
Speed et al, 2003 ⁽⁴⁰⁾	Placebo FSW	Sound-reflecting pad 0.12	1500 pulses × 3 sessions	23 46	10/13 20/26	40 (30-61) 51.7 (25-76)	18 (12-72) 16.7 (12-312)	6 3	>50% improvement of VAS in pain from baseline	6/20 17/42	1.0 (1.0) NA
Rompe et al, 1996 ⁽³⁵⁾	Placebo FSW	Minimal energy pulses (0.04) without contacting 0.06	1000 pulses × 3 sessions	42 15	17/25 10/5	52.5 (30-73) 47 (26-61)	13.5 (12-312) 16 (26-61)	3 6week	>50% improvement of VAS in pain from baseline No criterions	10/34 10/15	NA 72.9% (NA)
	Placebo	Keep at a 1 cm distance		15	9/6	51 (31-58)	22 (12-38)	6week		4/15	8.5% (NA)

FSW = focused shock wave, RSW = radial shock wave.

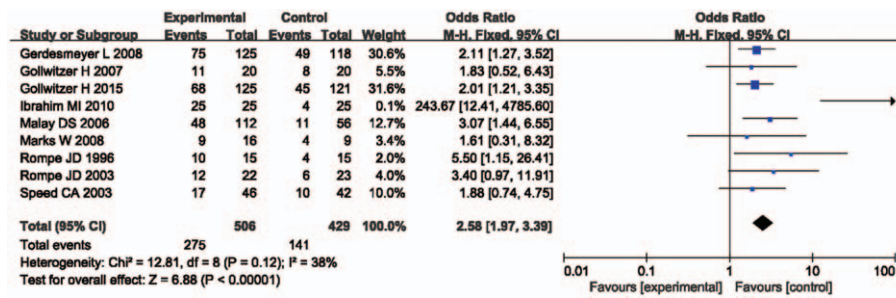


Figure 4. Forest plot of success rate of general ESWT in chronic plantar fasciitis. 95% CI = 95% confidence interval, ESWT = extracorporeal shock wave therapy, fixed = fixed-effects model.

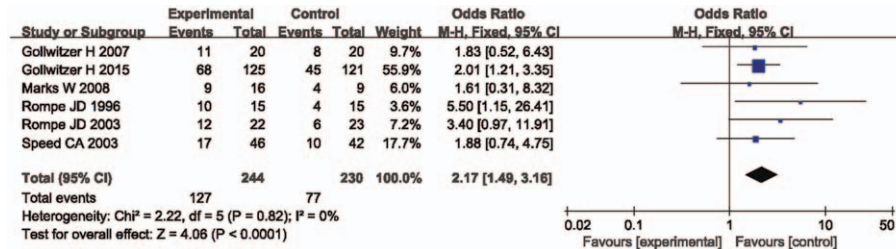


Figure 5. Forest plot of success rate of FSW therapy in chronic plantar fasciitis. 95% CI = 95% confidence interval, FSW = focused shock wave, fixed = fixed-effects model.

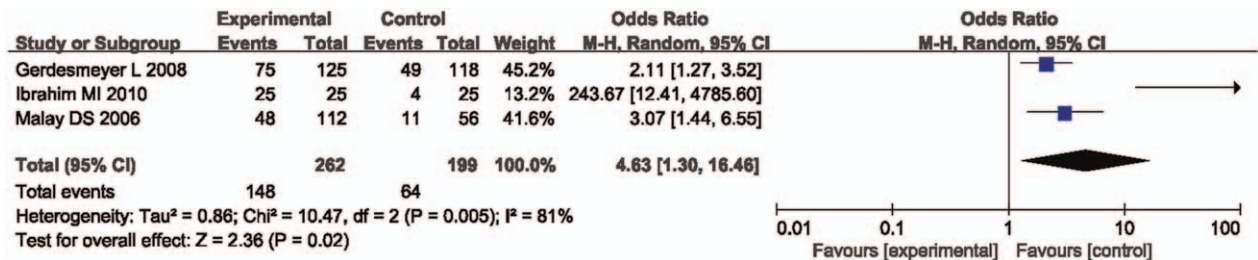


Figure 6. Forest plot of success rate of RSW therapy in chronic plantar fasciitis. 95% CI = 95% confidence interval, random = random-effects model, RSW = radial shock wave.

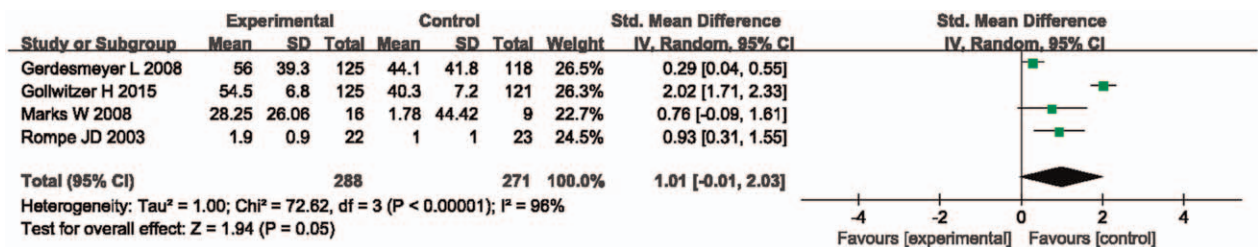


Figure 7. Forest plot of reduction in pain scale of general ESWT. 95% CI = 95% confidence interval, ESWT = extracorporeal shock wave therapy, IV = inverse variance, random = random-effects model, SMD = standard mean difference.

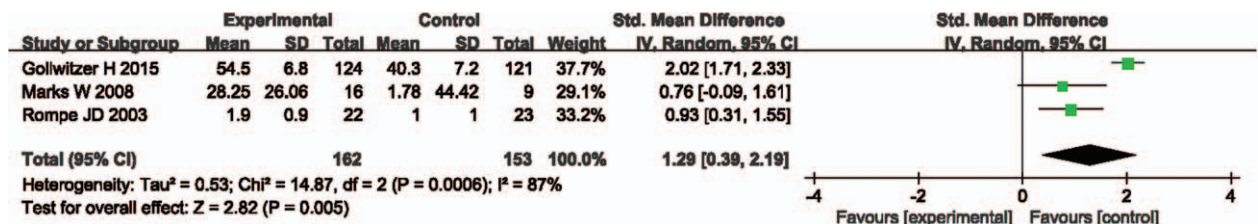


Figure 8. Forest plot of reduction in pain scale of FSW therapy in chronic plantar fasciitis. 95% CI = 95% confidence interval, FSW = focused shock wave, IV = inverse variance, random = random-effects model, SMD = standard mean difference.

radial technique can be used to treat the painful region instead of a point, and an advantage of RSW therapy is extended treatment area.^[8,41,43,47] We found that RSW therapy effectiveness may be due to significant heterogeneity; therefore, no solid conclusions can be drawn, although all included studies demonstrated the effectiveness of RSW therapy in chronic PF.

Most observed heterogeneity appeared to be attributed to clinical practice or trial's methodology. First, in a comprehensive comparison of both shock wave types in reducing pain scale, variations of follow-up time in individual studies may have influenced the results. Gollwitzer et al^[37] trial followed up for 3 months and the other trial for more than 6 months. Excluding Gollwitzer et al's study revealed ESWT efficacy (SMD 0.57, 95% CI 0.12–1.01, $P=.01$) compared with placebo. Secondly, analyzing the success rates of RSW therapy and considering the far better effect in the study by Ibrahim et al,^[42] we concluded that the high difference in participant numbers between the 3 trials evaluating RSW might have influenced the results. However, even excluding the Ibrahim et al's trial, Gerdesmeyer et al^[41] and Malay et al^[43] still showed efficacy for RSW therapy (OR 2.39, 95% CI 1.57–3.65, $P<.0001$) compared with sham therapy. Thirdly, variations in success criteria in each study might have influenced the success rates. Malay et al^[43] considered therapeutic success as a decrease of 50% or more in VAS score from baseline to the third visit, with a VAS score ≤ 4 cm; Gerdesmeyer et al^[41] and Ibrahim et al^[42] defined therapeutic success as a decrease in VAS score from baseline larger than 60%. By excluding Malay et al's study, the efficacy of RSW therapy (OR 18.34, 95% CI 0.14–2413.75) compared with sham therapy remained, but heterogeneity was observed ($I^2=90\%$, $P=.001$). Subgroup analysis based on participant numbers was not carried out due to insufficient data required for further confirmation.

The current meta-analysis included 9 studies not applying local anesthesia to most participations in the RCTs, because according to some literatures, application of local anesthesia would affect the efficacy of shock wave therapy.^[30,48] Some previous meta-analyses did not take this into account. Meta-analyses by Yin et al,^[49] Dizon et al,^[50] and Zhiyun et al^[51] did not exclude studies applying local anesthesia, and more inaccurate results may appear. Furthermore, almost all previous meta-analyses investigated common effectiveness of ESWT in chronic PF, not differentiating the shock wave type, lacking efficacy data about FSW or RSW compared with placebo, respectively. The studies by Yin et al^[49] Aqil et al,^[52] and many other studies compared ESWT (including FSW and RSW therapies) with placebo, which may make it difficult to accurately evaluate the efficacy of general ESWT for chronic PF if the 2 shock wave types have different effectiveness levels.

Numerous studies have evaluated the efficacy of FSW therapy, but yielded inconsistent results. Speed et al^[40] and Marks et al^[38] indicated that FSW has no significant treatment effect in patients, which appeared to be the placebo effect. However, Gollwitzer et al in 2007^[36] and 2015,^[37] respectively, enrolled 40 and 246 patients undergoing treatment with an intensity of 0.25 mJ/mm², and success rates in pain relief were 11/20 and 68/125, respectively, higher than with placebo therapy. In 2003, Rompe et al^[39] enrolled 45 running athletes suffering from chronic PF and demonstrated the beneficial effects of FSW therapy. Therefore, FSW may be considered an effective and noninvasive treatment method. This meta-analysis suggests that FSW therapy should be recommended as remedial treatment after failure of traditional conservative therapy and before operation based on the different included studies.

Moreover, the current meta-analysis compared FSW or RSW therapy with sham therapy, and different indicators to evaluate general ESWT effectiveness; due to significant heterogeneity, RSW therapy may probably have better effectiveness, and no firm conclusions that general ESWT (including FSW and RSW therapies) is effective could be drawn. In addition, we could not determine which shock wave type is more effective. There was only 1 study, the study by Lohrer et al,^[8] comparing focused versus radial extracorporeal shock waves in plantar fasciitis, demonstrating the superiority of FSW therapy over RSW therapy. Due to the limited literature available on FSW versus RSW therapy, whether FSW is more effective than RSW remains to be studied.

This meta-analysis had 4 limitations. First, we included only studies written in English, and some relevant studies in other languages may have been missed. Second, although we estimated the various articles based on inclusion and exclusion criteria, and also Cochrane Risk of Bias Tool, the sample sizes of several included studies were small, and a small proportion of the participants involved used local anesthesia because of unendurable pain rather than routine administration, which limited the statistical power of this meta-analysis. Third, some articles lacked data on functional recovery after shock wave therapy, and we could not estimate this parameter. Therefore, further assessment of comparative efficacy and functional recovery between FSW and RSW therapies is required. Fourth, more multicenter RCTs comparing FSW and RSW therapies are required to further confirm the comparative effectiveness of focused and radial shock wave therapies for treating chronic plantar fasciitis.

5. Conclusions

Focused shock wave therapy appears to be associated with higher success rate and greater pain reduction compared with sham therapy in chronic plantar fasciitis patients. However, due to limitations of the included studies, more large-sample and high-quality clinical trials and systemic reviews are warranted to demonstrate the efficacy of general ESWT (including FSW and RSW therapies) and determine whether RSW therapy is an ideal alternative therapeutic method to conservative treatment and surgery.

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