



The Effectiveness of Extracorporeal Shock Wave Therapy for Heel Spur: A Systematic Review and Meta-Analysis

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Abstract

Objective: Conduction a systematic review of randomized controlled trials (RCTs) to assess the effectiveness of extracorporeal shock wave therapy (ESWT) on plantar heel pain.

Methods: The study was designed as a meta-analysis of RCTs identified from the Cochrane Controlled trials register, MEDLINE, EMBASE and CINAHL from January 2000 till December 2016. We included such randomized trials, which evaluated ESWT used to treat plantar heel pain. The trials comparing ESWT with placebo, focused extracorporeal shock wave therapy (FESWT) or orthotics, kinesiotherapy, local cortison injection were considered for the inclusion in the review. Ten RCTs (n=1239) permitted a pooled estimate of the effectiveness based on the collected pain scores using 10 cm visual analogue scale (VAS) for the daily pain.

Results: The estimated total weighted mean difference (WMD) was 0.9 (95% confidence interval 0.1 to 1.8) representing less than 1.0 cm on the VAS. There were evidences of heterogeneity, so we used a random effects model.

Conclusion: A meta-analysis of data from ten RCTs included a total of 1239 patients and reported poor outcomes evaluating ESWT for plantar heel pain. This meta-analysis shows that using of ESWT for plantar heel pain is uncertain in clinical practice. Nevertheless, it suggests that further studies to establish efficacy dose of ESWT for heel pain are needed.

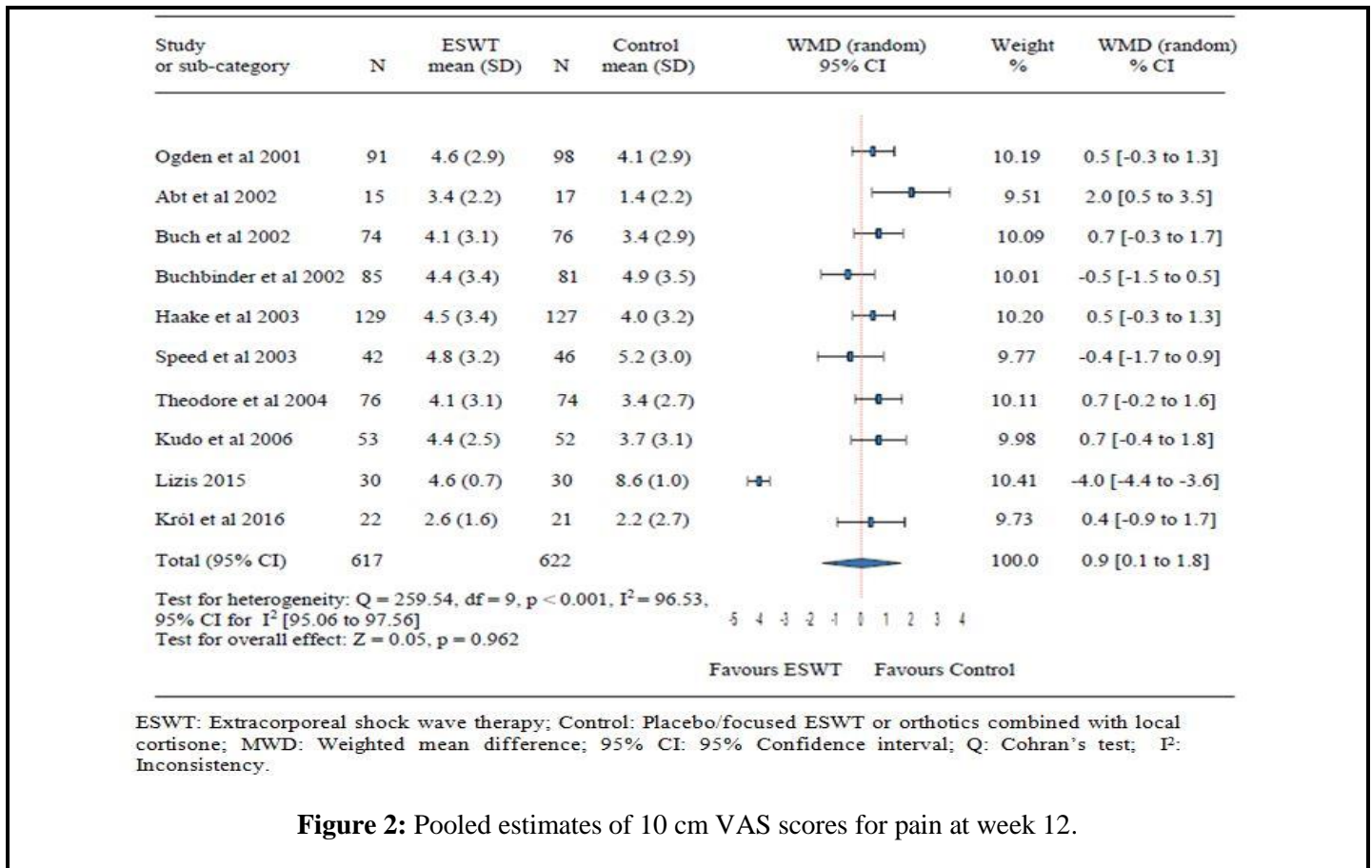
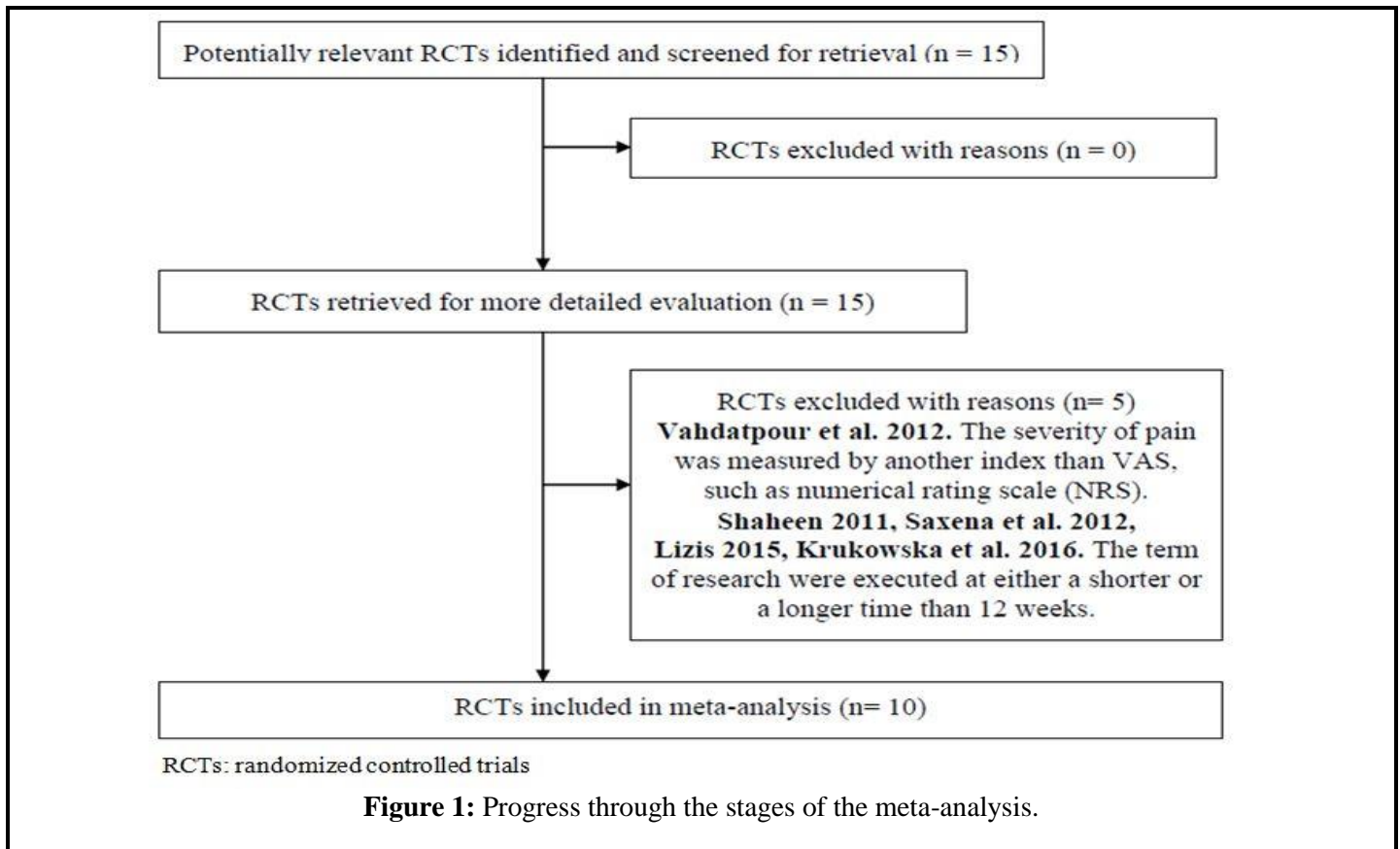
Keywords: Extracorporeal shock wave therapy; Heel spur; Pain; Meta-analysis

Introduction

Heel spur (HS) associated with plantar fasciitis is one of the major causes of disability of adults, which limits their socio-professional activities [1,2]. The treatment of calcaneal spur is primarily conservative, it includes kinesiotherapy [3-6], orthoses [1-9], corticosteroid therapy [10-11], and electrotherapy [12-14], but their efficacy remains controversial.

Extracorporeal shock wave therapy (ESWT) is one the therapeutic approaches of treating HS, however there is

controversy regarding the effectiveness in management of plantar heel pain. RCTs of Buchbinder et al. [15], Haake et al. [16], Speed et al. [17] failed to demonstrate a beneficial effect from the use of ESWT as a treatment for the pain associated with HS. In contrast to these studies, the randomized controlled trials (RCTs) of Cosentino et al. [18], Ogden et al. [19], Vahdatpour et al. [20] provided the evidences to beneficial effects from the use of ESWT as a treatment for the painful heel.



The purpose of this systematic review was to conduct a rigorous evaluation using a quantitative synthesis of evidence from RCTs to make a precise estimate of the effectiveness of ESWT. The aim of this study was to conduct a systematic review and meta-analysis of RCTs

to assess the effectiveness of ESWT on plantar heel pain comparing with a control group treated by placebo, focused extracorporeal shock wave therapy (FESWT) or orthotics, kinesiotherapy, local cortison injection.

Table 1: Baseline characteristics of participants in the respective trials.

Author	Age mean (SD and/or range) years		Duration of pain median/mean (SD and/or range) months		Baseline pain VAS mean (SD)		Female/Male (% female)	
	TG	CG	TG	CG	TG	CG	TG	CG
Ogden et al. 2001	49.6 (20–79)		32.2 (N/a)	35.9 (N/a)	8.1 (N/a)	8.2 (N/a)	112/59 (65.5)	
Abt et al. 2002	56.5 (N/a)	57.4 (N/a)	19.0 (N/a)	19.0 (N/a)	5.7 (N/a)	5.3 (N/a)	11/6 (64.7)	9/6 (60.0)
Buch et al. 2002	50.4 (26–69)	53.0 (31–72)	20.7 (21.1)	24.0 (21.1)	7.7 (1.4)	7.7 (1.5)	61/14 (81.3)	46/26 (63.9)
Buchbinder et al. 2002	52.2 (12.8)	54.2 (12.0)	8.0 (2–138)	10.0 (2–225)	7.3 (2.5)	6.8 (3.2)	46/3 (57.5)	47/3 (58.0)
Haake et al. 2003	53.1 (10.8)	52.9 (10.8)	13.0 (10–24)	13.0 (9–24)	7.8 (2.4)	7.7 (2.3)	98/37 (72.6)	106/30 (77.9)
Speed et al. 2003	51.7 (25–76)	52.5 (30–73)	16.7 (3–72)	13.5 (3–72)	7.4 (2.0)	7.0 (2.0)	26/20 (56.5)	25/17 (59.5)
Theodore et al. 2004	50.0 (26–69)	53.0 (31–72)	22.0 (2–28)	24.1 (1–23)	7.7 (N/a)	7.7 (N/a)	62/14 (81.6)	47/ 27 (63.5)
Kudo et al. 2006	51.1 (10.6)	48.8 (9.8)	31.3 (32.5)	27.1 (23.5)	6.2 (2.0)	6.0 (2.0)	40/18 (68.9)	33/23 (58.9)
Lizis 2015	54.9 (42–59)		15.2 (5.3)		8.5 (0.9)	8.7 (0.9)	N/a	
Król et al. 2016	52.1 (10.8)	53.0 (13.8)	8.9 (8.6)	8.3 (7.0)	8.4 (1.8)	7.9 (1.9)	7/15 (31.8)	11/10 (52.4)

TG: Treatment Group; CG: Control Group; N/a: data not available

Methods

Search strategy

RCTs were identified by searching the following data sources: the Cochrane Controlled trials register, MEDLINE, EMBASE and CINAHL from January 2000 till December 2016. The specific and unified inclusion criteria for meta-analysis were: people diagnosed with unilateral X-ray on the heel spur at the minimum age of 40, and those who had pain under the calcaneal tuber persisting longer than 8 months, the pain measured after daily activity by visual analog scale (VAS), the term of research which was executed at the end of the treatment (week 12). The RCTs of plantar heel pain treatments were considered in the review. The trials comparing ESWT with placebo, different doses of ESWT, focused ESWT (FESWT) as well as

conservative treatment (CT), which included orthotics, kinesiotherapy, local cortison injection were considered. The trials evaluating treatments for plantar heel pain arising from calcaneal fractures, calcaneal tumors, previous surgery for plantar heel pain, or posterior heel pain were excluded. The trials were also excluded when: there was not comparing ESWT with a control group; when severity of pain was assessed by any other manner then VAS; when the term of research was different from that of 12 weeks. Moreover, descriptive articles, literature reviews, case reports, surveys were excluded from the meta-analysis. In this meta-analysis there were evidences of heterogeneity of the interventions, so it was intended to use a random-effects model. Daily plantar heel pain was considered as a primary outcome measure for this meta-analysis, because it is considered to be the most important symptom in people suffering from HS.

Table 2: Characteristics of the included studies.

Author	Device	Interventions	Outcomes	End point
Ogden et al. 2001	Ossatron High Medical Technology	ESWT group: 1500 total Medium energy (0.22 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Abt et al. 2002	Ossatron High Medical Technology	ESWT group: 1000 × 2 Medium Energy (0.08 mJ/m ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Buch et al. 2002	Epos Ultra Dornier Medical Systems	ESWT group: 3800 total Low/medium/high energy (0.03–0.36 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Buchbinder et al. 2002	Epos Ultra Dornier Medical Systems	ESWT group: 2000–2500 × 3 Low/medium/high energy (0.02–0.33 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Haake et al. 2003	Epos Ultra Dornier Medical Systems	ESWT group: 4000 × 3 Medium energy (0.08 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Speed et al. 2003	Sonocur Plus Siemens	ESWT group: 1500 × 3 Low energy (0.06 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Theodore et al. 2004	Epos Ultra Dornier Medical Systems	ESWT group: 3800 total High energy (0.36 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Kudo et al. 2006	Epos Ultra Dornier Medical Systems	ESWT group: 3800 total High energy (0.36–0.64 mJ/mm ²) Control group: Placebo ESWT	Pain intensity: VAS (0-10)	12 weeks
Lizis 2015	BTL-5000 SWT	ESWT group: 8500 total High energy 0.4 mJ/mm ²) Control group: CT (NSAIDs, orthotics, local cortisone injection with 0.5 mL of betamethasone)	Pain intensity: VAS (0-10)	12 weeks
Król et al. 2016	RESWT – Gymna Uniphy's ShockMaster 500 FESWT – Piezowave Richard Wolf GmbH Systems	RESWT group: 4000 totals High energy (0.4 mJ/mm ²) Control group: FESWT (2000 total) High energy (0.4 mJ/mm ²)	Pain intensity: VAS (0-10)	12 weeks

CT: Conservative treatment; RESWT: Radial extracorporeal shock wave therapy; FESWT: Focused extracorporeal shock wave therapy

Results

Selection of trials

In the systematic review we identified 15 studies as RCTs, which evaluated the effectiveness of ESWT comparing with a control treatment for plantar heel pain. Five trials were excluded from the review: in one, the severity of pain was measured by another index than VAS [20]. In four other trials the intervention and the control groups, the term of research was executed at either a shorter or a longer time than 12 weeks [21-24]. Figure 1 shows the progress through the stages of the meta-analysis.

Description of included studies

Ten RCTs were included in this review and they reported data published between 2000–2016 from trials involving 1239 patients [15-17,25-31]. Table 1 presents the details of the baseline pain scores on VAS and demographic variables for the participants from all the ten trials. All of the trials included adult patients only. The duration of pain was 8 months or longer. The baseline pain of the treatment groups as well as the control groups was similar to each other in all the trials.

The trials evaluated different doses of ESWT against either a placebo dose or a control FESWT dose, as well as non-steroidal anti-inflammatory drugs (NSAIDs), orthotics, local cortisone to assess the therapeutic effectiveness of shock wave. The device and doses used for the intervention groups to compare with the control ones are presented in Table 2. The dose of ESWT varied between the trials in both energy levels and the number of impulses administered. In 8 trials the effectiveness of ESWT and placebo on heel pain were compared [15-17, 25-31]. Two trials assessed the effectiveness of ESWT on plantar heel pain comparing with FESWT or orthotics combined with local cortisone injection [29,30].

Quantitative data synthesis

Figure 2 shows the pooled analysis of data from 10 trials which produce a weighted mean difference (WMD) of 0.9, 95% CI 0.1 to 1.8. The overall treatment effect is statistically non-significant ($p=0.962$) with respect to daily pain. All the outcomes were taken at the 12th week. There were the evidences of heterogeneity ($p<0.001$), so a random effects model was used. Six trials identified greater reduction in severity of pain on VAS in the control groups, such as placebo or FESWT then in the ESWT treatment groups, however a non-significant result was observed [16,25-31]. The weight mean difference (WMD) ranged from 0.7 cm, 95% CI -0.2 to 1.6, $p=0.203$ [29] to 0.4 cm, 95% CI -0.9 to 1.7,

$p=0.552$ [31]. Two trials also produced a non-significant result, but a greater reduction of the severity of pain was identified in the ESWT groups compared to the control groups like placebo. The WMD ranged from -0.5 cm, 95% CI -1.5 to 0.5, $p=0.350$ [15] to -0.4cm, 95% CI -1.7 to 0.9, $p=0.546$ [17]. One trial produced significant results, in favor for a control group (placebo), where WMD was 2.0 cm, 95% CI 0.5 to 3.5, $p=0.010$ [26]. The other trial also produced significant results, but in favor for the ESWT group compared to the control group, such as orthotics combined with local cortisone. The WMD was 4.0 cm, 95% CI -4.4 to -3.6, $p < 0.001$ [30].

Adverse events

Five trials did not report any adverse events [17,26-31]. Buchbinder et al. [15] reported adverse events of pain remaining one week. One patient in the ESWT group of the trial reported pain, a sensation of heat and numbness, whilst another one complained on bruising. One patient in the placebo group complained of pain, a burning sensation in the heel and ankle. Hake et al. [16] reported skin reddening, pain and local swelling, complaints of dizziness in each trial group, but less frequently met in a placebo participant. Ogden et al. [25] reported 38 procedure related complications, 18 of which occurred in the ESWT groups. The most common procedure related complications were mild neurological symptoms (numbness, tingling). Theodore et al. [28] reported 31 procedure related complications in the ESWT and 26 in the placebo trials. The most common observed adverse events were pain during the treatment and pain at 3–5 days post-treatment. All these events resolved within a week of the treatment. Kudo et al. [29] reported adverse events in each trial group during the treatment or at the first 3–5 days after the treatment, but there were relatively few of them, and there was no significant difference in the number of side effects reported between the groups at the 12th week. The reported adverse events were primarily anticipated and included ecchymosis, edema, pain, and transient parasthesias, but they were less frequently reported in a placebo participant.

Discussion

The findings from the randomized evaluations of ESWT on plantar heel pain remain controversial and provide in clinical uncertainty about its effectiveness. In this systematic review, we evaluated the effectiveness of ESWT in a meta-analysis and used the pooled data to arrive at more precise conclusions about its application in clinical practice. The meta-analysis from the outcomes of 1239 patients' VAS scores of daily pain

assessed at the 12th week post-intervention indicated that the observed benefit equates were statistically non-significant on a 10 cm VAS. Two trials included in the review reached meaningful reduction in plantar heel pain of 2.0 cm [26] in favor for the control group and 4.0 cm [30] in favor for the ESWT group. One study compared radial ESWT (RESWT) as a treatment, when patients received a total of 4000 shock waves to the heel and plantar sole of the foot, while the control group treated with focused ESWT (FESWT) received a total of 2000 shock waves only to the calcaneal tuber. The therapeutic effect of RESWT and FESWT applied in patients with heel spur showed reduction of the severity of pain, but the between-groups differences were statistically non-significant. Nine trials also used different doses of ESWT and the differences in the use of control interventions and doses. Therefore, it is possible, that the reducing of pain severity depends on the factors, such as doses of ESWT shock waves and their frequency of applied and energy level. So, there probably exists an ESWT dose-response dependent relationships and its analgesic effects, as it is evident from the estimates of the trials included to the meta-analysis. Therefore, we suggest that further studies to establish the most efficacy doses of ESWT for heel pain are needed.

The study has strengths and limitations. The strength of the meta-analysis was, that all of the studies included described appropriate randomization and concealment of allocation. However, none of the included studies met all of the criteria for patient and health care provider blinding. Despite that fact, these flaws could be acceptable because it is impossible to blind the health care providers and it is nearly impossible to blind the patients. Therefore, these unavoidable imperfections could influence the results of the conducted meta-analysis, especially because all of the outcomes were self-reported.

The main limitation was a heterogeneity of the samples in the meta-analysis, therefore the random model was used. Another limitation was a short-term analgesic effect of the ESWT, which was assessed in the study. The limitation of the study was also the fact, that we did not search papers published in other languages besides English.

Conclusion

The meta-analysis of data from ten RCTs included a total of 1239 patients and reported the poor outcomes evaluating ESWT for plantar heel pain. This meta-analysis showed that using of ESWT for plantar heel pain is uncertain in clinical practice. Nevertheless, we

suggest that further studies to establish the most efficacy dose of ESWT for heel pain are needed.

Conflict of Interest

The authors declare that there is no conflict of interest.

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