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The effectiveness of combined extracorporeal shockwave therapy and exercise for plantar heel pain: A systematic review

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ABSTRACT

Background: Plantar heel pain (PHP) is a common musculoskeletal disorder, with both extracorporeal shockwave therapy (ESWT) and specific exercise such as plantar fascia specific stretching shown to be effective treatments. This review aimed to evaluate the effectiveness of combined ESWT and exercise interventions versus other interventions in treating PHP.

Methods: A systematic review of effectiveness was conducted, adhering to the PRISMA guidelines. Five databases were searched for studies published between

January 2000 and March 2020, with 12 studies meeting the inclusion criteria. The Grading of Recommendations Assessment Development and Evaluation (GRADE) framework was used to determine quality of recommendations.

Results: The 12 included studies (n = 861) compared ESWT and stretching with various other treatments. Due to clinical and methodological heterogeneity, pooling of data was not possible, and a narrative synthesis of findings was provided. There was high quality evidence that combined ESWT and stretching interventions are more effective than those using either alone or botulinum toxin injections, and low-quality evidence of superiority versus ultrasound and stretching. There was moderate quality evidence that combined ESWT and stretching is no more effective than corticosteroid injection (CSI), and high quality evidence that the combination is no more effective than blood-derived injection therapies, custom orthotics or low-level laser therapy (LLLT) combined with stretching. There is high quality evidence that the use of topical corticosteroid or laser therapy in combination with ESWT and stretching increases effectiveness compared to ESWT and stretching alone, and moderate quality evidence for the additive effective of dry needling.

Conclusions: Combined ESWT and stretching treatments are effective and may be recommended where they are available and practical to implement. Further high-quality studies with larger sample sizes and longer follow-up durations comparing combined interventions for PHP, including different exercise types such as resistance training are required.

Keywords: Exercise; Muscle Stretching Exercises; Extracorporeal Shockwave Therapy; High-Energy Shock Waves; Fasciitis, Plantar.

Introduction

Recent research on the global burden of disease has highlighted how musculoskeletal disorders are a leading contributor to the global burden of disability and chronic pain [1]. Musculoskeletal disorders have an impact on a broad demographic spectrum of the population, result in extensive expenditure by healthcare systems and are a substantial societal burden [2-4]. However, service-level and health policy responses to this burden have been inadequate, with an integrated research and policy agenda required, including prioritising evidence-based effective treatments [5]. Chronic foot pain constitutes a large proportion of the musculoskeletal disease burden, with Plantar Heel Pain (PHP) causing up to 15% of all foot-related pain complaints and occurring in 10% of the population [6-9]. Symptoms of PHP include sharp heel pain commonly felt in the morning or after prolonged sitting, which can cause an impaired gait pattern and functional limitations [10, 11]. The disorder presents like tendinopathy and results in chronic degeneration of plantar fascia tissues and collagen fibres rather than an acute inflammatory response and may result from excessive weight bearing or biomechanical abnormalities [12, 13]. There are several commonly used clinical treatments for PHP, including exercise therapy, orthotics, corticosteroid injections, non-steroidal anti-inflammatory drugs, taping, manual therapy approaches and platelet rich plasma injections [14-16]. Electrotherapy approaches are also common and include ultrasound, low level laser therapy and extracorporeal shockwave therapy (ESWT) [17, 18]. Of all currently available treatments, ESWT and exercise approaches appear to have the best evidence of long-term effectiveness [19]. Traditionally, plantar fascia specific stretching has been the most evidence-based exercise approach for PHP [20], however in recent years heavy slow resistance training has been shown to be a more effective form of exercise [21]. Other forms of exercise with inconclusive evidence of effectiveness for PHP include isometric exercise [22], intrinsic foot muscle strengthening [23] and kinetic chain strengthening targeting the hip musculature [24].

After first being successfully implemented in urology as a treatment to disintegrate renal calculi, ESWT is now applied to a range of musculoskeletal disorders such as

tendinopathies [25]. For several decades, a significant evidence-base of effectiveness for ESWT has been increasing, particularly for lower limb tendinopathies and PHP [26]. Recalcitrant heel pain that is unresponsive to conservative physiotherapy such as exercise approaches, for three to six months are considered appropriate candidates for ESWT treatment [27]. Several systematic reviews and meta-analyses have concluded there is long-term safety and effectiveness of ESWT compared to placebo or other common PHP treatments, with its use consistently recommended in the literature for PHP [28-32]. In addition, recent evidence suggests that ESWT combined with exercise may be a more effective PHP treatment compared with either of the treatments in isolation [33]. Shockwaves generated by ESWT devices are considered mechanical acoustic energy waves which rapidly create high pressures [34]. This positive high pressure is quickly followed by negative pressure, which returns to ambient values within microseconds [35]. The high pressures generated from shockwaves induce cavitation within human tissue, which involves rapid formation, expansion and forceful collapse of vapor bubbles in liquids due to rapid pressure changes [36]. This cavitation process may stimulate a myriad of biological responses that can activate tissue regeneration effects such as stimulating neovascularisation and collagen synthesis in pathological musculoskeletal tissues [37].

In clinical practice, ESWT is rarely used as monotherapy and is more often combined with exercise, with there being a need for a comparison of polytherapy treatment approaches in future studies [38, 39]. Current research recommends that combined rather than isolated treatments be used in PHP treatment, with ESWT or exercise in isolation having inadequate long-term outcomes [13, 40, 41]. Despite this increasing evidence for ESWT and exercise in PHP treatment, optimal treatment protocols and clinical recommendations are lacking [42]. There is also a dearth of studies investigating a combined approach with a distinct lack of clinical recommendations on combined protocols, despite indications of combined treatment being more optimal than isolated treatments [43]. A search in PROSPERO, The Cochrane Library and in PubMed was performed and identified no systematic reviews comparing the effectiveness of combined ESWT and any type of exercise including stretching or resistance training versus other common treatment methods for PHP. Therefore, the aim of this work is to conduct such a

systematic review to synthesise the available evidence and inform clinical recommendations regarding the combination of ESWT and exercise interventions for treating PHP. This systematic review was conducted in accordance with an a priori protocol, which has been registered in the PROSPERO database (CRD42020213286) [44].

Review question

The specific review question is: What is the effectiveness of combined extracorporeal shockwave therapy (ESWT) and exercise interventions compared with other treatments in treating plantar heel pain based on pain and function?

Inclusion Criteria

Participants

This review considered studies with adult participants aged 18 years old or over, formally diagnosed with PHP. Studies using local anaesthesia were excluded as research has demonstrated that it can diminish ESWT effectiveness [28]. Studies in which participants have the following ESWT contraindications were also excluded: diabetes mellitus, systematic inflammatory disease, previous foot surgery or fractures, malignancy, neurological disorders or pregnancy [45].

Interventions

This review included studies that have investigated the effectiveness of a combined intervention of any type of ESWT and any type of exercise in the treatment of PHP. Exercise types considered included cardiovascular exercise, stretching, strengthening, heavy slow resistance training, plyometric, or combined

exercise interventions. Any healthcare setting including physiotherapy or podiatry clinics and departments, outpatient departments, primary care settings, specialist orthopaedic or surgical clinics, and rehabilitation clinics were considered.

Comparators

The following comprehensive list of common treatment methods were considered as comparators to combined ESWT and exercise:

1. Self-management, education and advice
2. Corticosteroid injection or topical corticosteroid
3. Stem-cell injection therapies
4. Blood derived injection therapies – platelet-rich-plasma or autologous conditioned plasma
5. Radial or focused ESWT (not combined with exercise)
6. Exercise intervention: including any type of single exercise (cardiovascular, stretching, strengthening, plyometric, heavy slow resistance training) or combined exercise approach (not combined with ESWT)
7. Standard/usual care or physiotherapy
8. Ultrasound
9. Low level laser therapy (LLLT) or photo-biomodulation therapy
10. Dry needling
11. Acupuncture
12. Manual/manipulative therapy or massage
13. Custom or standard orthotics, insoles or heel cups
14. Botulinum toxin type A injection
15. Taping, bracing, or splinting
16. Surgery, including endoscopic plantar fasciotomy, open plantar fascia release or radiofrequency ablation
17. Combinations of two or more of treatments 1-16
18. Combined ESWT and exercise further combined with one or more of treatments 1-16.

Outcomes

Primary outcomes included heel pain and foot function. Heel pain evaluated by any validated scale such as the Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), verbal rating scales or Foot Function Index pain subscale (FFI-PS) were considered [46, 47]. Foot function evaluated by any validated scale for PHP such as the Foot Function Index (FFI) or Foot and Ankle Ability Measure (FAAM) were considered as function measures [48, 49]. Additional secondary outcomes that were considered for inclusion if available included quality of life measures using validated scales such as the EQ-5D-5L [50].

Types of studies

The review was restricted to randomized controlled trials (RCTs) in which combined ESWT and exercise formed one arm of the trial. Trials with two or more arms were considered for inclusion. The use of active co-interventions such as pain medication (NSAIDs), education, orthotics and exercise were acceptable if used in all trial arms, to limit confounding [51]. In the hierarchy of evidence, systematic reviews of RCTs offer the highest level of evidence [52]. The strongest inferences can be drawn if the review is well conducted and includes methodologically sound RCTs with consistent results [53]. The authors preliminary work had identified several potentially eligible RCTs. Therefore, due to the availability of RCTs on this topic, they were chosen for inclusion over less robust study designs. Any deviation from the standard RCT design such as crossover or cluster designed trials were also permitted.

Methods

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [44] and was conducted in

accordance with an a priori protocol, which was registered in the PROSPERO database (CRD42020213286).

Search strategy

The search strategy sought to identify published and unpublished trials utilizing a three-step search strategy. An initial scoping search of Medline was conducted (Appendix 1), followed by analysis of text words contained in the title and abstract and article index terms. A comprehensive systematic search using all identified keywords and index terms was conducted using the following databases: Medline, CINAHL, AMED, and SPORTDiscus. The search for unpublished studies included EThOS Networked Digital Library of Theses and Dissertations and the NICE Guidelines ESWT recommendations. The trial registers to searched included: ClinicalTrials.gov, UK clinical trials gateway, EU trials registry. Finally, in addition to the comprehensive search, supplementary searches were undertaken by reviewing bibliographies of articles selected for critical appraisal and related systematic reviews to find those not initially identified. The search strategy was adapted to each database and was limited to the year 2000 onwards. The year 2000 was chosen to ensure seminal work was not missed as research on ESWT for PHP first began around this time. Studies published in a language other than English were only considered if a translation was available as translation services are not available to the authors.

Study selection

All identified citations from the systematic search were uploaded into RefWorks (Proquest LLC), with duplicates removed. Two reviewers independently screened the titles and abstracts of all studies obtained against the identified inclusion criteria. Full-text versions of eligible studies were accessed and reviewed against the inclusion criteria. Studies were removed from the screening process if the information provided did not meet the criteria. The details of studies meeting the criteria were imported in to Covidence [44].

Assessment of methodological quality

Included studies were critically appraised by two independent reviewers at study level for methodological quality in the review using the standardized Cochrane risk of bias tool on Covidence [54]. Any disagreements that arose between the reviewers were resolved through discussion or with a third reviewer. The results of critical appraisal are reported in narrative form, and in a graph. All studies meeting the inclusion criteria, regardless of their methodological quality, underwent data extraction and synthesis and were included in the review. Seven criteria were appraised for RCTs. Item three which pertained to blinding was included but not considered highly relevant in final scoring and grading of recommendations, given that interventions could not be blinded. Therefore, a maximum high-quality score of 6 or 7 could be achieved, with all included studies scoring at least 4/7, which was considered a moderate quality score (figure 2).

Data extraction

Data was extracted from studies included in the review using the standardised data extraction tool available on Covidence by two independent reviewers [44]. The data extracted included specific details relative to the interventions, comparators, populations, study methods and outcomes of significance to the review question which include heel pain and foot function. Any disagreements between the reviewers were resolved through discussion or with a third reviewer.

Data synthesis

Statistical pooling and meta-analysis were not possible due to clinical and methodological heterogeneity; therefore, findings are presented in narrative synthesis. Although some studies used the same outcome measures, no studies used the exact same clinical intervention protocol or comparator with wide variances in intervention protocols, outcome measures and follow-up times.

Assessing certainty of findings and quality of evidence

A summary of findings table was created following The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for assessing the quality of evidence [55]. Evidence from RCTs starts at high quality and the certainty is increased or decreased for several reasons, such as risk of bias [56]. The outcomes reported in the summary of findings table include heel pain and foot function for the interventions. For each outcome, a ranking of 'high', 'moderate', 'low' or 'very low' was assigned to the quality of evidence based on the risk of bias. There is by necessity a considerable amount of subjectivity in each decision as GRADE cannot be implemented mechanically. However, GRADE does provide a reproducible and transparent framework for grading certainty in evidence [57].

Results

Search results and study inclusion

The initial search strategy identified a total of 405 references, which was reduced to 20 studies obtained in full text after screening and removal of duplicates (Figure 1). Reasons for excluding studies obtained in full text included wrong study design such as not being RCTs (three studies), duplication of results (two studies), wrong intervention (two studies), and wrong outcomes (one study). The remaining 12 RCTs underwent quality appraisal and were included in the review.

Methodological quality

Item 3 from the Cochrane risk of bias tool which pertains to blinding was considered not highly relevant as blinding is not possible for ESWT and exercise interventions, therefore the highest RCT score was considered as six or seven, with seven studies achieving this score [33, 40, 42, 58-61]. Three studies scored

five [62-64] and the remaining two scored four [65, 66]. These five studies were unclear about randomization methods and if concealed allocation to treatment groups was used. Two studies did not disclose if outcome assessors were blind to group assignment [65, 66].

Characteristics of included studies

The 12 included RCTs (Table 1) were conducted in a range of countries: Turkey (four), Iran (two), Egypt, Brazil, Germany, Singapore, Canada and Spain. All included studies were conducted within a healthcare setting and there was a total of 861 participants. All participants were diagnosed with PHP, however, there were wide variances in the duration of the condition, ranging from one month [42] to 12 months [33]. All studies investigated the effects of the interventions on heel pain, with ten using VAS scales. The studies also investigated foot function using a variety of outcome measures. Four studies used the full FFI [59, 62, 64, 66] and three used the FFI-PS [33, 40, 42]. No studies used the FAAM or assessed the effects of the interventions on quality of life or used a global rating of change (GRoC) score. The only exercise intervention used in the studies were stretching interventions, with all studies using combined PFSS and gastrocnemius stretching, with only one study not using gastrocnemius stretching and only PFSS [33]. This is despite evidence showing that PFSS is superior to gastrocnemius stretching [20]. No studies used any other type of exercise such as strengthening exercises or resistance training approaches, despite heavy slow resistance training been found to be a more effective exercise treatment than stretching for treating PHP [21]. The studies used a variety of comparator interventions, with some having three or four trial arms comparing multiple combined interventions.

Figure 1: PRISMA study flow diagram

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement*. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed100009

Figure 2: Risk of bias summary

	Risk of bias							Overall
	D1	D2	D3	D4	D5	D6	D7	
Okur et al. 2019								
Bagcier et al. 2020								
Grecco et al. 2013								
Akinoglu et al. 2013								
Cinar et al. 2018								
Rompe et al. 2015								
Ulusoy et al. 2017								
Roca et al. 2016								
Eslamian et al. 2016								
Chew et al. 2013								
Vahdatpour et al. 2018								
Takla et al. 2019								

Study

D1: Random sequence generation (selection bias)
D2: Allocation concealment (selection bias)
D3: Blinding of participants and personnel (performance bias)
D4: Blinding of outcome assessment (detection bias)
D5: Incomplete outcome data (attrition bias)
D6: Selective reporting (reporting bias)
D7: Other bias

Judgement
 High
 Unclear
 Low

Figure 3: Risk of bias graph

Findings

The findings are presented in relation to the primary outcomes of heel pain and foot function from combined ESWT and stretching (PFSS and gastrocnemius) interventions versus other interventions.

Stretching exercise alone

Four studies contained a comparator group involving stretching exercise alone [40, 42, 58, 66]. Chew et al. [58] found clinically and statistically significant VAS pain improvement with combined ESWT and stretching versus stretching at month one (-2 points v -0.75, $P = .017$), three (-3.25 points v 1.0, $P = .022$) and six (-5.5 points v 3.0, $P = .042$). Akinoglu et al. [66] found clinically and statistically significant improvement in FFI in the combined group compared to stretching only ($P < 0.05$). Takla et al. [40] found the combined group was clinically and statistically superior to the stretching only group measured by VAS (7.8 to 1.7 = 48.48% decrease v 7.8 to 8.1 = 3.8% increase) and FFI scores (41.8 to 28.9 =

30.8% decrease v 43.8 to 43.5 = 0.6% increase) at 12 weeks ($P = 0.0001$). Only, Cinar et al. [42] found the combined group not to be superior for reducing pain at 3 weeks, but it was statistically significantly superior at 3 months ($P = .035$). Patients having clinically meaningful FFI-PS improvements were also higher for ESWT (61% v 50%).

ESWT alone

One study compared combined ESWT and PFSS without gastrocnemius stretching with ESWT alone [33]. Two months after baseline, FFI-PS score was clinically and statistically significantly improved for the combined group (-20.1 V -12.2 points) compared with ESWT alone ($P = < 0.001$). Statistically significant but not clinically important differences remained at four and 24 months ($P = < 0.01$).

Ultrasound combined with stretching

Three studies compared combined ESWT and stretching with ultrasound and stretching [63, 65, 66]. Akinoglu et al. [66] found that although both groups had improved FFI-PS scores, the improvements were more clinically meaningful (28.25 V 43.28) in the ultrasound group at one month, which was statistically significant ($P = < 0.05$). Grecco et al. [65] found clinically meaningful but no statistically significant differences between the groups for VAS pain at three (65% v 70% good outcome) and 12 months (85% v 80% good outcome), with good outcome defined as VAS score of 1/10 or less. Ulusoy et al. [63] found ESWT and stretching statistically and clinically significantly superior after one month (success defined as 60% or more VAS improvement) to ultrasound and stretching (65% V 23.5%) for pain measured with VAS ($P = 0.12$).

Autologous conditioned plasma (ACP) injection combined with stretching

One study used a single ACP injection combined with stretching [58]. At month one, three and six, both ACP (-2.0, -3.0, -5.0) and ESWT (-2.0, -3.25, -5.5) combined with stretching was found to be superior to stretching only (-0.75, -1.0, -3.0) in VAS score. These differences were statistically significant at each timepoint for both ESWT ($P = .017, .022, .042$) and ACP ($P = .037, .053, .080$) versus stretching alone. There was no significant difference at each time-point between ACP and ESWT and stretching in VAS scores ($P = .575, .947, .791$).

Single corticosteroid injection combined with stretching

One study found that ESWT and stretching had better scores in VAS and FFI compared to corticosteroid injection and stretching [62]. Although these changes were clinically meaningful, they were not statistically significant [FFI decreased to 19.65 from 60.25 points (67.4% improvement) in ESWT vs 31.50 from 60.25 points (47.7% improvement) in injection group at week 8, ($P = 0.072$)]. Good or excellent results in the opinions of patients were achieved in 55% of ESWT and 30% of corticosteroid injection groups ($P = 0.11$).

Botulinum toxin type A injection combined with stretching

One study compared one session of ESWT with one injection of botulinum toxin type-A (BoNT-A), both combined with stretching [61]. In the ESWT group, the median (and interquartile range) of improvement in the VAS pain, when taking the first steps, was 2 (1–4) points, and in the BoNT-A group the same result was 1 (0–2) points ($p=0.009$). In the ESWT group, the median (and interquartile range) of improvement in the Roles and Maudsley scale was 1 (0–1) points, and in the group of patients that received BoNT-A the same result was 0 (0–1) points ($p=0.006$). In a multivariate analysis use of ESWT was associated with

improvement of pain and function. The combined ESWT and stretching treatment was found superior to BoNT-A.

Custom fabricated orthotics (CFO) combined with stretching

One study compared ESWT versus CFO, with both combined with stretching [59]. Both groups achieved significant clinically important improvements in VAS and FFI scores at 4, 12, 24 and 48 weeks compared with their baseline values. CFO VAS scores over the five time-points (6.6, 5.2, 4.4, 3.9, 4.1) and FFI (82.5, 63.9, 59.3, 55.2, 51.8) were slightly better than ESWT VAS scores (6.3, 5.1, 4.6, 4.4, 4.8) and FFI (78.3, 65.2, 62.8, 62.4, 66.4). However, there was no statistically significant difference between treatments and neither method was superior ($P < 0.001$).

Low level laser therapy (LLLT) combined with stretching

Three studies compared ESWT and stretching with LLLT and [40, 42, 63]. Ulusoy et al. [63] found that although LLLT had a higher clinically meaningful success rate than ESWT for pain and function (70.6% v 65%) there was no statistically significant difference between the groups ($P = .717$) in VAS scores. Takla et al. [40] found that although both groups had statistically significant and clinically meaningful improvements in VAS and FFI scores, ESWT and stretching was significantly superior ($P < 0.0001$). Cinar et al. [42] found that LLLT had statistically significant lower FFI-PS compared to ESWT and stretching at three months ($P = .003$). Patients having clinically meaningful FFI-PS improvements were also higher for LLLT than ESWT (79% V 61%).

ESWT and stretching combined with dry needling

One study investigated the additive effect of dry needling to three sessions of ESWT combined with stretching [64]. In both groups, there were statistically significant improvements in VAS pain, and FFI scores ($p \leq .001$). In intergroup comparison, it was found that VAS scores, and FFI pain subscale scores ($p = .034$) were statistically superior in the combined dry needling group. There was no statistically significant difference between the groups in FFI disability ($p = .081$), and FFI activity limitation subscale ($p = .226$) scores. ESWT, stretching and dry needling combination therapy was superior for pain improvement.

ESWT and stretching combined with topical corticosteroid

One study investigated the additive effect of topical corticosteroid to ESWT and stretching [60]. At one month, VAS pain showed statistically significant improvement in the intervention group, but not at three months ($P = 0.006$). A 50% improvement in VAS scores was considered clinically successful, with 75% (versus 45%) of patients in the intervention group achieving this at one month and 80% (versus 65%) at three months ($P = 0.135$).

ESWT and stretching combined with Photobiomodulation therapy (PBMT)

Both ESWT and PBMT (equivalent to LLLT) combined with stretching were effective in decreasing pain and improving function measured by VAS, and FFI scores compared to stretching and sham PBMT [40]. However, application of PBMT with ESWT and stretching was clinically superior over ESWT and PBMT with stretching alone, in VAS and FFI scores, which was statistically significant ($P < 0.0001$). The study calculated overall VAS and FFI effect sizes of 85.452 (0.68 effect size), and 49.76 (0.56 effect size) for the combined interventions.

Table 1: Characteristics of included studies

Study/ Country	Setting/ context	Participant characterist ics	Groups	Outcomes measured	Description of main results
AKINOGLU B et al. 2017. [66] Turkey	Physical therapy and rehabilitation clinic	Fifty-four (average age = 50 years, range = 39 to 59 years) female patients diagnosed with plantar fasciitis. The inclusion criteria were tenderness on palpation of the heel, presence of pain in the plantar region for at least three months, presence of a calcaneal spur in lateral	1. Radial shockwave therapy (ESWT) treatment once per week for three weeks (3 sessions) and home exercise (including plantar fascia and gastrocnemius stretching) twice a day for four weeks (n=18) 2. Ultrasound treatment twice per week for three weeks (7 sessions) and home exercise (including plantar fascia and gastrocnemius stretching) twice a day for four weeks (n=18) 3. Home exercise (including plantar fascia and gastrocnemius	The patients' pain, and function with the Foot Function Index (FFI), a 10 cm visual analogue scale (VAS) and the American Orthopaedic Foot and Ankle Association (AOFAS) hind foot score. Patients were evaluated before and four weeks after the first treatment.	There was a decrease in FFI values in all groups and these decreases were more prominent in the US group than the other groups ($P < 0.05$). It was observed that the hind foot AOFAS scores increased in all groups, but this increase was less in the control group ($P < 0.05$). Static and dynamic balance increased in all groups ($P < 0.05$). Ankle proprioception sense increased only in the r-ESWT group ($P < 0.05$). All groups and particularly the r-ESWT and US groups symptoms were decreased after treatment. However, FFI parameters were reduced more in the US groups than the other two groups.

		radiographs of the foot, and unilateral PF.	stretching) twice a day for four weeks (n=18)		
CHEW KT et al. 2013. [58] Singapore	Sports medicine centre in a public tertiary care hospital.	Adults aged 18 years or older diagnosed with plantar fasciitis of 4 months or longer duration.	1. Autologous conditioned plasma (ACP) injection (once) and Conventional treatment: daily home exercise program of gastrocnemius and plantar fascia stretching (n=19) 2. Shockwave therapy (ESWT) 2 sessions, 1 week apart and Conventional treatment: daily home exercise program of gastrocnemius and plantar fascia stretching (n=19) 3. Conventional treatment alone: daily home exercise program of gastrocnemius and plantar fascia stretching (n=16)	Outcomes were pain Visual Analog Scale (VAS), American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale, and ultrasound plantar fascia thickness assessed at baseline before treatment and at 1 month, 3 months, and 6 months after treatment.	VAS, AOFAS ankle-hindfoot scale, and plantar fascia thickness improved in all groups. Significant VAS pain score improvements in the ACP group compared with conventional treatment at month 1 ($P = .037$) and for the ESWT group compared with conventional treatment at months 1, 3, and 6 ($P = .017$, $P = .022$, and $P = .042$). The AOFAS ankle-hindfoot scale score improved in the ACP group at months 3 and 6 ($P = .004$ and $P = .013$) and, for the ESWT group, at months 1 and 3 ($P = .011$ and $P = .003$) compared with conventional treatment. Significant improvements in plantar fascia thickness were seen in the ACP group at months 1 and 3 compared with conventional treatments ($P = .015$ and $P = .014$) and at months 3 and 6 compared with the ESWT group ($P = .019$ and $P = .027$). Treatment of plantar fasciitis with ACP or

					ESWT plus conventional treatments resulted in improved pain and functional outcomes compared with conventional treatment alone. There was no significant difference between ACP and ESWT in terms of VAS and AOFAS ankle-hindfoot scale improvements, although the ACP group demonstrated greater reductions in plantar fascia thickness.
CINAR E et al. 2018. [42] Canada	Outpatient physiotherapy department at a multi-centre public hospital.	Adults 18 years or older diagnosed with plantar fasciitis for one month or longer.	1. Radial shockwave therapy (ESWT), once weekly for 3 weeks & Full-length silicone insoles (3 months) & Home exercise including gastrocnemius and plantar fascia stretching (3 weeks) (n=25). 2. Laser therapy (LLLT), three times a week for ten sessions in total & Full-length silicone insoles (3 months) & Home exercise including	Foot Pain measured by the Foot Function Index pain subscale (FFI-p). Functional pain was measured through 12-minute walking test and Numeric Rating Scale for Pain (NRS-p). The scores were recorded at baseline, third week, and third month after the treatment.	There was a significant improvement in pain over the 3 months in all groups on both FFI-p ($P < .001$) and NRS-p ($P < .001$). In NRS-p, LLLT group had significantly lower pain than ESWT ($P = .002$) at the third week and control ($P = .043$) and ESWT ($P = .003$) at third month. In FFI-p total score, ESWT group had higher pain than LLLT ($P = .003$) and control ($P = .035$) groups at third week and LLLT ($P = .010$) group at third month. When LLLT and ESWT were combined with usual care, LLLT was found to be more effective than ESWT in

			gastrocnemius and plantar fascia stretching (3 weeks) (n=24). 3. Control group: Full length silicone insoles (3 months) & Home exercise including gastrocnemius and plantar fascia stretching (3 weeks) (n=17).	Analysis was performed using repeated measures ANOVA.	reducing pain in PF at short-term follow-up.
VAHDATPOUR B et al. 2018. [60] Iran	Physical medicine and rehabilitation clinic based in a hospital	Criteria for inclusion were patients older than 18 years with chronic recalcitrant plantar fasciitis (lasting at least 6 months and refractory to conservative treatment). Only patients with Roles and Maudsley	1. Four sessions at weekly intervals of ESWT combined with topical corticosteroid and home exercise including gastrocnemius and plantar fascia stretching (n=40) 2. Four sessions at weekly intervals of ESWT combined with topical Vaseline (control) and home exercise including gastrocnemius and plantar fascia stretching (n=40)	Pain severity was assessed using visual analogue scale (VAS) at baseline and 1 and 3 months after VAS score recorded as follows: • Heel pain while taking the first steps in the morning (VAS morning) • Heel pain while doing a daily activity (VAS daily). Activity	One month after intervention, VAS morning showed significant improvement in intervention group ($P = 0.006$) and RMS showed better improvement in intervention group ($P = 0.026$). There was no significant difference between the two groups after 3 months in RMS or VAS score. PF thickness was decreased significantly in both groups, but it was not significant between the two groups ($P = 0.292$). This combinational therapy yielded earlier pain reduction and functional improvement than using shock wave alone and topical corticosteroid could enhance the

		score (RMS) of 4 and PF thickness of >4 mm with ultrasonography were enrolled in this study.		limitation due to pain was assessed with the modified RMS 1 and 3 months after intervention.	effectiveness of shockwave in short-term in the treatment of recalcitrant plantar fasciitis.
TAKLA M et al. 2019. [40] Egypt	Private orthopaedic outpatient clinic	Adults aged 18 years or older diagnosed with plantar fasciitis of 6 months or longer in duration who failed previous conservative treatment.	1. Combined ESWT (once weekly for three weeks) with PBMT (three times per week for three weeks) and daily home exercise including gastrocnemius and plantar fascia stretching for three weeks (n=30) 2. ESWT and daily home exercise including gastrocnemius and plantar fascia stretching for three weeks (once weekly for three weeks) (n=30) 3. PBMT (three times per week for three	Outcome measures included pressure pain threshold (PPT), visual analogue scale (VAS), and functional foot index disability subscale (FFI-d) that were collected prior to the first treatment session and at the end of the 3-week treatment period, as well as at a follow-up session, 12 weeks after the	There were statistically significant improvements in post-intervention and follow-up PPT, VAS, and FFI-d values in all treatment groups ($P < 0.0001$). As for the sham-PBMT, no significant difference was found between the pre-, post-intervention and follow-up values ($P > 0.05$). Bonferroni correction test revealed that there was a significant difference between all the four groups in PPT, VAS, and FFI-d values ($P < 0.0001$). All active treatment groups maintained the treatment effect at the 12-week follow-up. Both ESWT and PBMT were effective in increasing PPT values, decreasing pain and increasing functional ability. Additionally, application of PBMT after ESWT was shown to be superior over ESWT and PBMT

			weeks) and daily home exercise including gastrocnemius and plantar fascia stretching for three weeks (n=30) 4. Sham-PBMT and daily home exercise including gastrocnemius and plantar fascia stretching for three weeks (n=30)	final treatment session.	alone, and ESWT was superior over PBMT in terms of reducing pain sensitivity and increasing function.
GRECCO MV et al. 2013. [65] Brazil	Institute of Orthopaedics and Traumatology University hospital	Adults ages 20 years or older diagnosed with plantar fasciitis for 3 months or longer, with plantar fascia thickness greater than 4 mm, as assessed using ultrasonography. The mean	1. Conventional physiotherapy: Ultrasound x ten sessions with home exercise program including plantar fascia and gastrocnemius stretching (n=20) 2. Radial ESWT x 3 sessions at weekly intervals, plantar fascia and gastrocnemius stretching (n=20)	Visual analogue scale (VAS) for morning pain, gait and standing upright; – Fischer's algometer to quantify the painful pressure at the insertion of the plantar fascia in the calcaneus and the middle third of the medial	At the 12-month follow-up, both treatments were effective for improving pain and functional ability among the patients with plantar fasciitis. The improvement with shockwaves was faster.

		age was 49.6±11.8 years (range: 25-68 years), 85% were female, 88% were overweight, 63% were affected bilaterally, and 83% used analgesics regularly.		gastrocnemius; – Use of analgesics before and during the treatment.	
ESLAMIAN F et al. 2016. [62] Iran	Physical medicine and rehabilitation research centre in a university hospital	Adults aged 18 years and older, diagnosed with plantar fasciitis and who did not respond to conservative treatment.	1. Five sessions at 3-day intervals of Radial shockwave therapy (ESWT) and home exercise including gastrocnemius and plantar fascia stretching (n=20) 2. Single Local methylprednisolone injection and home exercise including gastrocnemius and plantar fascia stretching (n=20)	Pain in the morning and during the day based on a visual analogue scale (VAS), functional abilities using the foot function index (FFI), and satisfaction were evaluated before treatment and at 4 and 8 weeks after treatment.	Changes in the VAS in morning and during the day and the FFI throughout the study period were significant in both groups ($P < 0.001$). ESWT group had a higher reduction in VAS in morning and better function in FFI, but these changes were insignificant statistically [FFI decreased to 19.65±21.26 points (67.4% improvement) in ESWT vs 31.50±20.53 points (47.7%) in injection group at week 8, $P=0.072$]. Good or excellent results in the opinions of patients were

					achieved in 55% of ESWT and 30% of corticosteroid injection groups ($P = 0.11$).
ROMPE JD et al. 2015. [33] Germany	Orthopaedic hospital	Adults aged 18 years or older with diagnosed plantar fasciopathy for 12 months or longer in duration.	1. Three sessions at weekly intervals of Shockwave therapy (ESWT) and daily Plantar fascia stretching for 8 weeks ($n=79$) 2. Three sessions at weekly intervals of Shockwave therapy (ESWT) ($n=73$)	Heel pain measured by the pain sub-scale of the validated Foot Function Index (PS-FFI). Patient-relevant outcome measures (SROM) questionnaire.	At two months after baseline, the Foot Function Index sum score showed significantly greater changes for the patients managed with shock-wave therapy plus plantar fascia-specific stretching than those managed with shock-wave therapy alone ($P < 0.001$), as well as individually for item 2 ($P < 0.001$). Twenty-four patients in Group 1 (32%) versus forty-seven patients in Group 2 (59%) were satisfied with the treatment ($P < 0.001$). Significant differences persisted at four months, but not at twenty-four months.
ULUSOY A et al. 2017. [63] Turkey	University physical medicine and rehabilitation department	Adults 18 years or older diagnosed with plantar fasciitis of 6 months or longer in duration that was unresponsive to	1. 5 sessions per week for 3 weeks (15 sessions) of LLLT and home exercise including gastrocnemius and plantar fascia stretching ($n=20$) 2. 5 sessions per week for 3 weeks (15 sessions) of	All patients were assessed using the visual analogue scale (VAS), heel tenderness index (HTI), American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot	Significant improvement was measured using the mean VAS, AOFAS scale, and HTI scores for all 3 groups. The thickness of the plantar fascia had decreased significantly on MRI in all 3 groups. The treatment success rate was 70.6% in the LLLT group, 65% in the ESWT group, and 23.5% in the US group. LLLT and ESWT proved significantly superior

		conservative treatment.	continuous ultrasound (US) and home exercise including gastrocnemius and plantar fascia stretching (n=20) 3. Once weekly for 3 weeks (3 sessions) of ESWT and home exercise including gastrocnemius and plantar fascia stretching (n=20)	scale, Roles–Maudsley score, and MRI before and 1 month after treatment. The primary efficacy success criterion was the percentage of decrease in heel pain of >60% from baseline at 1 month after treatment for 2 of the 3 pain (VAS) measurements.	to US therapy using the primary efficacy criterion ($p = .006$ and $p = .012$, respectively), with no significant difference between the LLLT and ESWT groups ($p > .05$). The treatment of chronic plantar fasciitis with LLLT and ESWT resulted in similar outcomes and both were more successful than US therapy in pain improvement and functional outcomes.
OKUR SC et al. 2019. [59] Turkey	Outpatient physiotherapy clinic	Adults ages 30–60 years with diagnosed with plantar fasciitis.	1. 3 sessions (once weekly) of Radial Shockwave therapy (ESWT) and daily plantar fascia and gastrocnemius stretching for 4 weeks (n=40) 2. Custom fabricated orthotics (CFO) and plantar fascia and gastrocnemius	Visual analogue scale (VAS) was used to evaluate pain in the morning, evening, at rest and while walking. Foot Function Index (FFI) was used to evaluate foot functions, and Foot Health	Both groups achieved significant improvements in evaluation parameters (morning and evening pain) at 4, 12 and 24 weeks compared with their baseline values ($P < 0.001$), and significant improvement observed in the group II continued at 48 weeks ($P < 0.05$); however, there was no significant difference in some parameters in the group I after treatment compared with their baseline values ($P > 0.05$).

			stretching for 4 weeks (n=43)	Status Questionnaire (FHSQ) was used to evaluate foot health.	Neither method was superior in treating plantar fasciitis.
BAGCIER F et al. 2020. [64] Turkey	Physical medicine and rehabilitation outpatient clinic	Adults aged between 18 and 70 years, having symptoms at least for 6 weeks, diagnosed with plantar fasciitis	1. Three sessions at weekly intervals of Shockwave therapy (ESWT) followed by cold application for 15 minutes and home Plantar fascia and gastrocnemius stretching (n=20), 2. Three sessions at weekly intervals of Shockwave therapy (ESWT) followed by dry needling of gastrocnemius muscle and cold application for 15 minutes and home Plantar fascia and gastrocnemius stretching (n=20)	Pain (VAS), Pain (FFI), Function (FFI disability)	In both groups, there were statistically significant improvements in VAS pain, and FFI's pain, disability, and activity limitation subscales scores ($p \leq .001$). In intergroup comparison, it was showed that VAS scores, maximum painless standing time ($p = .002$), maximum painless walking distance ($p \leq .001$), and FFI pain subscale scores ($p = .034$) were statistically superior in the ESWT-DN group. There was not statistically difference between the groups in pressure pain threshold ($p = .132$), FFI disability ($p = .081$), and FFI activity limitation subscale ($p = .226$) scores. ESWT and dry needling combination therapy was superior for pain scores.
ROCA B et al. 2016. [61]	General hospital	Adults older than 15 years; diagnosis of plantar	1. One session of Shockwave therapy (ESWT) and daily Plantar fascia and gastrocnemius	Pain (VAS), Function (VAS activity, RMS)	In the group of patients that received ESWT, the median (and interquartile range) of improvement in the VAS of pain result, when taking the first

Spain		fasciitis made by a physician and symptoms of at least 6-month duration.	stretching (n=37). 2. One injection of Botulinum toxin type A and daily Plantar fascia and gastrocnemius stretching (n=37)		steps, was 2 (1–4) points, and in the group of patients that received BoNT-A the same result was 1 (0–2) points ($p=0.009$). In the group of patients that received ESWT, the median (and interquartile range) of improvement in the Roles and Maudsley scale of pain result was 1 (0–1) points, and in the group of patients that received BoNT-A the same result was 0 (0–1) points ($p=0.006$). In a multivariate analysis use of ESWT and lower weight were associated with improvement of pain with treatment in at least one of the three VAS of pain scales used in the study. ESWT was superior to BoNT-A in the control of pain in patients with PF.
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Abbreviations: BoNT-A: Botulinum toxin type-A; VAS: visual analogue scale; RMS: Roles and Maudsley score; AOFAS: American orthopaedic foot and ankle society scale; FFI: Foot Function Index; ESWT: Extracorporeal shockwave therapy; CFO: Custom fabricated orthotics; LLLT: Low-Level laser therapy; PHP: Plantar heel pain; FHSQ: Foot health status questionnaire; US: Ultrasound.

Discussion

This systematic review investigated the effectiveness of combined ESWT and exercise interventions versus other interventions for pain and function in PHP. The findings suggest that combined ESWT and stretching treatment is superior to using either alone or botulinum toxin injection combined with stretching for improving pain and function in PHP. The combination of ESWT and stretching also appears to be more effective than combining ultrasound with stretching and has similar outcomes to combining LLLT or custom orthotics with stretching. When comparing ESWT and stretching with more invasive injection therapies such as ACP or corticosteroid injection, there was no significant difference between interventions. Combining ESWT and stretching with topical corticosteroid, dry needling or LLLT also led to superior outcomes. The GRADE strength of evidence rating was initially considered high for each of these outcomes, due to having high quality RCT evidence. However, as it pertains to ESWT and stretching being superior to ultrasound, this was downgraded to a 'low' strength of evidence due to potential bias (Table 2). These three studies were all unclear about randomization methods and if concealed allocation to treatment groups was used [63, 65, 66]. Two of these studies also did not disclose if outcome assessors were blind to group assignment [65, 66]. Therefore, these studies could have introduced potential sampling and measurement bias [67]. Both studies were still included in the review as they still maintained an overall moderate score of 4/7 but reduced the strength of the evidence compared to other interventions. Strength of evidence was downgraded from high to moderate for the comparison of ESWT and stretching to corticosteroid injection and the addition of dry needling due to risk of bias regarding unclear randomization methods and use of concealed allocation [62, 64].

Recent systematic reviews have also suggested similar outcomes with ESWT and CSI and ACP injection therapies for PHP [8, 68, 69]. This suggests these invasive injection therapies may be unnecessary if ESWT is available as a treatment option as it is associated with less side effects and a better safety profile [70-72]. Participants were also significantly more satisfied with ESWT vs CSI (55% V 30%) as a PHP treatment in the included study [62]. There was no significant difference

between ESWT and stretching versus CFO and stretching, however CFO or standard orthotics are recommended as an earlier intervention strategy than ESWT [73]. Although systematic reviews have suggested no benefits of standardised orthotics for PHP [74], recent RCTs have shown effectiveness of CFO for PHP [75, 76]. The effectiveness of combined ESWT and stretching was also found to be increased when topical corticosteroid was used prior to ESWT and when LLLT was used following ESWT [40, 60]. This is in keeping with previous studies, as both LLLT and CSI have been shown to be effective for treating PHP, although often not as effective as ESWT [32, 77, 78]. Although LLLT induces tissue regeneration and anti-inflammatory effects like ESWT, it is believed to work by a different mechanism by targeting cell mitochondria [79, 80]. Although CSI has been shown to be effective for short-term pain reduction and reducing inflammation in PHP [81], reported side effects include heel pad atrophy and plantar fascia rupture [82, 83]. Studies in tendinopathy have also found that CSI can reduce effectiveness of exercise interventions and may therefore not be an optimal treatment combination [84, 85].

Although combined PHP treatments can increase intervention effectiveness, they may be impractical and not cost-effective in many clinical settings [42]. Out of all PHP treatments, ESWT may not only be the most effective treatment option to combine with exercise but also the most practical and safest [19]. It is less invasive, has less side effects and has better long-term effectiveness than ACP or CSI injection therapies [29, 32, 86]. It also requires less treatment sessions, with 3 being recommended, compared to LLLT or ultrasound which typically requires 10-15 treatment sessions [87]. All the studies that have used exercise alongside ESWT as an intervention have used stretching interventions including the same PFSS protocol [20]. However, the use of a standardized 12-week heavy slow resistance training (HSRT) program targeting the plantar fascia was found more effective compared to this PFSS protocol for pain (VAS) and function (FFI) in a RCT [21]. A recent RCT found that combining HSRT and PFSS protocols with CSI, was significantly more effective than CSI or the combined exercise program alone for pain and function (VAS and FFI) in PHP [41]. Hip strengthening exercise targeting kinetic chain strength deficits not addressed by heel-raise protocols in isolation have also been found to have positive effects for PHP [24, 88-90].

Currently, no studies have investigated the effects of strengthening exercise combined with ESWT for PHP [23].

Main limitations of included studies

The main limitations of studies included in this review relate to small sample sizes, methodological and clinical heterogeneity in study designs, and the lack of blinding in some studies leading to a risk of bias. Only some studies conducted power calculations for sample sizes [33, 40, 42, 60, 62, 63] resulting in some studies being potentially underpowered to detect true statistically significant differences [58, 59, 61, 64, 65]. One study claimed to have used a power calculation, but details of the sample size obtained from it were omitted [66]. There was a wide variation in intervention protocols. Different types of ESWT were used, with different energy densities, different machines and various numbers of treatment sessions, ranging from two [58] to five [62], with three being most common. All these parameters are known to influence effectiveness of ESWT [91].

There were also wide variations in longest treatment follow-up times, ranging from one month [66] to 24 months [33], with only three studies having a 12-month or longer follow-up [33, 59, 65]. Treatment interventions also varied in length, from three weeks [40, 42, 63] to eight weeks [33]. There were also variances in the participant criteria, such as duration of PHP and diagnostic methods. Duration of PHP ranged from one month [42] to 12 months [33], with three months being the average. This is important as duration of PHP is known to affect outcomes to ESWT [71]. The recommended length of PFSS intervention is eight weeks in order to have physiological effects [20]. Although all studies referred to the same PFSS protocol [20], only one study implemented it with an eight-week intervention [33]. This leads to uncertainty over the true effectiveness of PFSS or its additive effect to ESWT within these studies. Most studies also included gastrocnemius stretching alongside PFSS, which may have influenced outcomes, however the superiority of PFSS over gastrocnemius stretching for PHP has been well documented [21]. Some studies gave exercise instructions and adherence diaries, but these were

poorly reported, raising concerns on exercise adherence [92-94]. Although most studies used VAS scales to measure pain, various outcome measures were used to evaluate foot function. The FFI was the only outcome measure used which has been specifically validated for the PHP population [49], however only four studies used the complete FFI [59, 62, 64, 66].

Limitations of the review

Due to study heterogeneity, statistical pooling and meta-analysis was not possible which limits the conclusions that can be drawn regarding the effectiveness of combined ESWT and exercise interventions versus other interventions in treating PHP [53]. A few non-English articles were excluded which influences the generalizability of findings since treatment methods may differ by country. Half of the included studies (6 of 12) originated from either Turkey or Iran, which influences global generalizability of findings [95]. Although a thorough search for literature was conducted, it is still possible that relevant literature may have been missed, which may have affected the review outcomes [54].

Implications and recommendations for practice and research

The evidence from this systematic review suggests that combined ESWT and stretching interventions are an effective treatment for PHP compared to other treatments. There is high- and low-quality evidence that this combined approach is more effective than either alone or ultrasound. Therefore, clinical recommendations may be made that combined ESWT and stretching should be recommended in favour of either alone or ultrasound. Although there were no significant differences in effectiveness between combined ESWT and stretching with injection therapies (ACP, CSI), ESWT may be recommended over them as they have a better safety profile and less side effects. Topical corticosteroid may be a safer option which has been shown to have an additive short-term effect when combined with ESWT and stretching and may be recommended where available [60, 96]. Although there was no difference between combined ESWT and

stretching and CFO, standard or custom orthotics are consistently recommended alongside or prior to ESWT [97-99].

There are conflicting and mixed findings when ESWT and stretching is compared with LLLT and stretching, with neither method appearing superior. However, ESWT should be considered a more practical and cost-effective method compared to LLLT, as the recommended standardized ESWT protocol requires 3 sessions to be effective, whereas LLLT requires 10-15 sessions [40]. Given that LLLT requires up to 15 sessions and the side effects associated with corticosteroids, a combined ESWT (3 sessions) and stretching protocol may be the most practical, cost-effective, safest and evidence-based conservative treatment currently available for PHP. The review findings support the recommendations from recent PHP reviews that combined rather than single interventions should be recommended for treating PHP [43, 99].

Further large-scale RCTs should be conducted with large sample sizes and robust methods to control for assessor bias, such as ensuring blinding of those assessing outcome measures. Longer-term follow-up times are also required in order to determine long-term effectiveness of combined PHP interventions. Future studies should investigate and compare combined interventions using validated measures, which is reflective of clinical physiotherapy practice, where treatments are often combined [42]. Different types of exercise other than stretching should be combined with ESWT, such as HSRT [13]. Using standardized intervention protocols and validated outcome measures would also allow better translation of findings [38, 100, 101]. Future studies should also emphasise the importance of returning exercise diaries to monitor adherence [13]. Recently, several psychological and nutritional PHP risk factors have been identified, therefore future studies could investigate psychological and nutritional interventions alongside physiotherapy in a biopsychosocial treatment model [102-110].

Table 2: Summary of findings table

Summary of findings:

ESWT and stretching compared to other treatments for Plantar heel pain			
Patient or population: Plantar heel pain			
Setting: Any clinical setting			
Intervention: ESWT and stretching			
Comparison: other treatments			
Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Pain and function in PHP with combined ESWT and stretching versus stretching alone follow up: range 1 months to 6 months	ESWT and stretching statistically significantly superior for improving pain and function	173 (4 RCTs)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus ESWT alone follow up: range 2 months to 24 months	ESWT and stretching statistically significantly superior for improving pain and function	152 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus ultrasound combined with stretching follow up: range 1 months to 12 months	ESWT and stretching statistically significantly superior for improving pain and function	116 (3 RCTs)	⊕⊕○○○ LOW ^a
Pain and function in PHP with combined ESWT and stretching versus ACP injection combined with stretching follow up: 6 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	54 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus corticosteroid injection combined with stretching follow up: 2 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	40 (1 RCT)	⊕⊕⊕○ MODERATE ^b
Pain and function in PHP with combined ESWT and stretching versus LLLT combined with stretching follow up: range 1 months to 3 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	149 (3 RCTs)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus CFO combined with stretching follow up: 11 months	Mixed findings - neither treatment statistically significantly superior for improving pain and function	83 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with combined ESWT and stretching versus botulinum toxin type A injection combined with stretching follow up: 2 months	ESWT and stretching statistically significantly superior for improving pain and function	72 (1 RCT)	⊕⊕⊕⊕ HIGH

Summary of findings:

ESWT and stretching compared to other treatments for Plantar heel pain

Patient or population: Plantar heel pain

Setting: Any clinical setting

Intervention: ESWT and stretching

Comparison: other treatments

Outcomes	Impact	Nº of participants (studies)	Certainty of the evidence (GRADE)
Pain and function in PHP with dry needling combined with ESWT and stretching versus dry needling and stretching follow up: 1 months	Dry needling combined with ESWT and stretching statistically significantly superior for improving pain and function	40 (1 RCT)	⊕⊕⊕○ MODERATE ^b
Pain and function in PHP with topical corticosteroid combined with ESWT and stretching versus ESWT and stretching follow up: 3 months	Topical corticosteroid combined with ESWT and stretching statistically significantly superior for improving pain and function	80 (1 RCT)	⊕⊕⊕⊕ HIGH
Pain and function in PHP with LLLT combined with ESWT and stretching versus ESWT and stretching follow up: 3 months	LLLT combined with ESWT and stretching statistically significantly superior for improving pain and function	60 (1 RCT)	⊕⊕⊕⊕ HIGH

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Unclear randomization methods and if concealed allocation was used. Did not disclose if outcome assessors were blinded to group assignment. Potential sampling and measurement bias.

b. Unclear allocation concealment (potential selection bias)

Conclusion

Plantar heel pain is a very common musculoskeletal disorder, with a significant burden on society, requiring effective evidence-based treatment interventions. This systematic review sought to investigate the effectiveness of combined ESWT and exercise interventions versus other common interventions in improving pain and function in PHP. Twelve RCTs met the inclusion/exclusion criteria (n= 861) with various commonly used comparator interventions. Given the clinical and methodological heterogeneity of included studies, statistical pooling of data for meta-analysis was not possible. Therefore, a narrative synthesis of findings was presented, with quality of evidence assessed by GRADE. There is high quality evidence that combined ESWT and stretching interventions are more effective than those using either alone or BoNT-A injection, with low quality evidence versus ultrasound interventions. There was moderate quality evidence that combined ESWT and stretching is no more effective than corticosteroid injection, and high quality evidence that the combination is no more effective than autologous conditioned plasma injection, custom orthotics or low-level laser therapy combined with stretching. However, ESWT and stretching should be considered as a safer and more practical treatment option than these methods. There was high quality evidence that the use of topical corticosteroid or LLLT in combination with ESWT and stretching increases effectiveness compared to ESWT and stretching alone, and moderate quality evidence for dry needling in combination with ESWT and stretching. The combined treatments for PHP with quality evidence may be recommended where they are available and practical to implement. This review supports recent recommendations in the literature for using combined rather than single treatments for PHP [41, 43, 99]. The combination of ESWT and stretching may be the most practical and effective treatment currently available with high quality evidence. Recently, HSRT has been shown to be superior to stretching, but HSRT or other strengthening exercises have not been investigated either combined with or compared against ESWT as a PHP treatment in RCTs. Further high-quality RCTs with robust methodological design, larger sample sizes and longer follow-up durations comparing combined interventions for PHP are required in order to determine and recommend the most optimal treatment strategy.

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Appendices

Appendix 1: Studies excluded on full text review

1. [111]. Akinoglu B, Kose N. A comparison of the acute effects of radial extracorporeal shockwave therapy, ultrasound therapy, and exercise therapy in plantar fasciitis. J Exerc Rehabil. 2018 Apr 26;14(2):306-12.

Reason for exclusion: Duplication of data

2. [112]. Eun SS, Chachan S, Lee SH. Effectiveness of a double air-cushioned shoe compared with physiotherapy in the treatment of plantar fasciitis. Biomed Res Int. 2020 04/02;2020:9468302.

Reason for exclusion: Wrong study design

3. [113]. Greve JM, Grecco MV, Santos-Silva PR. Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. Clinics (Sao Paulo). 2009;64(2):97-103.

Reason for exclusion: Duplication of data

4. [114]. Krukowska J, Wrona J, Sienkiewicz M, Czernicki J. A comparative analysis of analgesic efficacy of ultrasound and shock wave therapy in the treatment of patients with inflammation of the attachment of the plantar fascia in the course of calcaneal spurs. Arch Orthop Trauma Surg. 2016 Sep;136(9):1289-96.

Reason for exclusion: Wrong intervention

5. [115]. Melegati G, Tornese D, Bandi M, Caserta A. The influence of local steroid injections, body weight and the length of symptoms in the treatment of painful

subcalcaneal spurs with extracorporeal shock wave therapy. Clin Rehabil. 2002 11;16(7):789-94.

Reason for exclusion: Wrong study design

6. [116]. Porter MD, Shadbolt B. Intralesional corticosteroid injection versus extracorporeal shock wave therapy for plantar fasciopathy. Clin J Sport Med. 2005 May;15(3):119-24.

Reason for exclusion: Wrong outcome: did not measure function

7. [90]. Wheeler PC, Tattersall C. Extracorporeal shockwave therapy plus rehabilitation for patients with chronic plantar fasciitis might reduce pain and improve function but still not lead to increased activity: A case-series study with multiple outcome measures. J Foot Ankle Surg. 2018 Mar - Apr;57(2):339-45.

Reason for exclusion: Wrong study design

8. [87]. Uğurlar M, Sönmez MM, Uğurlar ÖY, Adıyeke L, Yıldırım H, Eren OT. Effectiveness of four different treatment modalities in the treatment of chronic plantar fasciitis during a 36-month follow-up period: A randomized controlled trial. J Foot Ankle Surg. 2018 09/20;57(5):913-8.

Reason for exclusion: Wrong intervention

Appendix 2: MEDLINE search strategy:

Full search strategy for Medline (EBSCOhost). Search conducted on 16th March 2020.

Search	Query	Records retrieved
#1	MH extracorporeal shockwave therapy OR KW shock wave therapy OR KW shockwave therapy OR KW shock wave treatment OR KW shockwave* OR KW ESWT	4,025
#2	MH fasciitis, plantar OR KW plantar OR KW heel pain OR KW plantar fasciitis OR KW plantar fasciopathy	14,669
#3	MH exercise OR MH physical therapy modalities OR MH physical therapy specialty OR KW physiotherapy OR KW physical therapy OR KW usual care OR KW standard care OR KW stretching OR KW strengthening OR KW corticosteroid	350,869
#4	#1 AND #2 AND #3	112
	Limited to English language, year 2000 - 2020	

Appendix 3: Search strategy by database

Medline search strategy

(MH extracorporeal shockwave therapy OR TX (shock wave therapy OR shockwave therapy OR shock wave treatment OR shockwave* OR ESWT)) AND (MH fasciitis, plantar OR TX (OR plantar OR heel pain OR plantar fasciitis OR plantar fasciopathy)) AND (MH (exercise OR physical therapy modalities OR physical therapy specialty) OR TX (physiotherapy OR physical therapy OR usual care OR standard care OR stretching OR strengthening OR corticosteroid))

Studies found: 112

CINAHL search strategy

(MH ultrasonics OR TX (extracorporeal shockwave therapy OR shock wave therapy OR shockwave therapy OR shock wave treatment OR shockwave* OR ESWT)) AND (MH plantar fasciitis OR TX (OR plantar OR heel pain OR plantar fasciitis OR plantar fasciopathy)) AND (MH (exercise OR stretching OR physical therapy OR physical therapy practice, research-based) OR TX (physiotherapy OR usual care OR standard care OR strengthening OR corticosteroid))

Studies found: 127

SPORTDiscus search strategy

(MH extracorporeal shock wave therapy OR TX (extracorporeal shockwave therapy OR shock wave therapy OR shockwave therapy OR shock wave treatment OR shockwave* OR ESWT)) AND (MH PLANTAR fasciitis OR TX (OR plantar OR heel pain OR plantar fasciitis OR plantar fasciopathy)) AND (MH (exercise OR stretch (physiology) OR static stretching (physiology) OR physical therapy) OR TX (physiotherapy OR usual care OR standard care OR strengthening OR stretching OR corticosteroid))

Studies found: 147

AMED search strategy

(MH shockwave therapy OR TX (extracorporeal shockwave therapy OR extracorporeal shock wave therapy OR shock wave therapy OR shockwave therapy OR shock wave treatment OR shockwave* OR ESWT)) AND (MH plantar fasciitis OR TX (OR plantar OR heel pain OR plantar fasciitis OR plantar fasciopathy)) AND (MH (exercise OR exercise therapy OR stretching OR physiotherapy physical therapy modalities OR physical therapy specialty OR physical therapy techniques) OR TX (physical therapy OR usual care OR standard care OR strengthening OR stretching OR corticosteroid))

Studies found: 19

Total studies included for screening: 405

Appendix 4: Executive summary

Review title: The effectiveness of combined extracorporeal shockwave therapy and exercise for plantar heel pain: A systematic review.

Objective: This review aimed to evaluate the effectiveness of combined extracorporeal shockwave therapy (ESWT) and exercise interventions versus any other interventions in improving pain and function in plantar heel pain (PHP).

Introduction: PHP is one of the most common musculoskeletal disorders and represents a significant burden, with both ESWT and exercise shown to be effective treatments. Despite the increasing evidence for combining ESWT and specific exercises for PHP, the optimal treatment protocol remains unknown, with clinical recommendations lacking. There are currently no systematic reviews comparing the effectiveness of combined ESWT and exercise versus other treatment methods for PHP. Therefore, the aim of this work was to conduct such a systematic review and make recommendations based on the quality of the evidence.

Inclusion criteria: The review sought to include randomised controlled trials (RCTs) that have investigated the combined effect of ESWT and exercise in the treatment of PHP compared with other interventions. Participants were adults aged 18 years or older and formally diagnosed with PHP. Primary outcomes were heel pain and foot function measured by validated measures such as visual analogue scale (VAS) and the foot function index (FFI).

Methods: A three-step search strategy was employed. Following initial searching of Medline and CINAHL and analysis of text words, seven databases were searched in March 2020. Reference lists of studies included at the critical appraisal stage were hand-searched to identify any additional studies. Studies published in English from 2000 onwards were included. Searching identified 405 studies, with 20 reviewed in full-text, 12 of which met the inclusion criteria. Following title and abstract screening, critical appraisal, and data extraction of included studies were

conducted by the author via tools on Covidence. The Grading of Recommendations Assessment Development and Evaluation (GRADE) framework was used to determine quality of evidence.

Results: The 12 included RCTs were conducted in a range of countries: Turkey (4), Iran (2), Egypt, Brazil, Germany, Singapore, Canada and Spain. All the studies were conducted within a healthcare setting, and there was a total of 861 participants. All studies investigated the effects of the interventions on heel pain and foot function using a variety of validated measures. The studies used a variety of comparator interventions compared to ESWT and exercise, with some having three or four trial arms comparing multiple combined interventions. The only exercise interventions used were plantar fascia specific stretching (PFSS) and gastrocnemius stretching. The highest quality score available was 6-7/7, with seven studies achieving this score, two studies scored five and the remaining two scored four. Pooling of data in a meta-analysis was not possible, and a narrative synthesis of findings was developed. There was high quality evidence that combined ESWT and stretching interventions are more effective than those using either alone or compared to botulinum toxin injection combined with stretching. There was low-quality evidence that the combination is no more effective than ultrasound and stretching interventions. There was moderate quality evidence that combined ESWT and stretching is no more effective than corticosteroid injection (CSI), and high quality evidence that the combination is no more effective than blood-derived injection therapies, custom orthotics or low-level laser therapy (LLLT) combined with stretching. There was high quality evidence that the use of topical corticosteroid or LLLT in combination with ESWT and stretching increases effectiveness compared to ESWT and stretching alone, and moderate quality evidence for dry needling in combination with ESWT and stretching.

Conclusions: Due to consistent high-quality evidence of effectiveness, combined ESWT and stretching treatments may be recommended. The use of additional CSI or LLLT may also be recommended, where they are available and practical to implement. Further high-quality RCTs with larger sample sizes and longer follow-up durations comparing combined interventions for PHP are required in order to determine the optimal treatment strategy. Future studies should also investigate strength exercise combined with or compared against ESWT as a PHP treatment.

Appendix 5: Abbreviations

ACP – Autologous conditioned plasma

BoTN-A – Botulinum toxin type-A

CFO – Custom fabricated orthotics

CSI – Corticosteroid injection

ESWT – Extracorporeal shock wave therapy

FFI – Foot Function Index

FFI-PS – Foot Function Index pain subscale

GRADE - Grading of Recommendations, Assessment, Development and Evaluation

HSRT – Heavy slow resistance training

LLLT – Low-level laser therapy

NHS- National Health Service

NSAIDS – Non-steroidal anti-inflammatory drugs

PBMT – Photo-biomodulation therapy

PFSS – Plantar fascia specific stretching

PHP – Plantar heel pain

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analysis

RCTs - Randomised controlled trials

RMS – Roles and Maudsley score

UK – United Kingdom

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