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The Effectiveness of Combined Shockwave Therapy and Exercise for Plantar Heel Pain: A Systematic Review Protocol

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ABSTRACT

Review Objective: To synthesize the best available evidence on the effectiveness of interventions that have used a combination of extracorporeal shockwave therapy and any type of exercise to treat plantar heel pain compared to any other treatment intervention.

Introduction: Recent evidence suggests combining shockwave therapy and exercise may be more effective than other treatments for plantar heel pain.

However, no systematic reviews have been conducted on the topic and optimal treatment protocols and clinical recommendations are lacking.

Inclusion criteria: Randomised controlled trials assessing the effectiveness of combined shockwave therapy and exercise for plantar heel pain in adults will be included.

Methods: The authors will search for a wide range of sources to find both published and unpublished studies via EBSCOhost, including, but not limited to, MEDLINE, SPORTDiscus, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), and Allied and Complementary Medicine Database (AMED). Studies published in a language other than English will only be considered if a translation is available. The JBI systematic review methodology will be followed when conducting the review. Data synthesis will be conducted using meta-analysis or narrative synthesis, where appropriate.

Systematic review registration number: CRD42020213286

Keywords: Exercise; Muscle Stretching; Extracorporeal Shockwave Therapy; Resistance training; 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 and meta-analysis to synthesise the available evidence and inform clinical recommendations regarding the combination of ESWT and exercise interventions for treating PHP. This systematic review and meta-analysis will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for systematic reviews of effectiveness and will be conducted in accordance with an a priori protocol, which has been registered in the PROSPERO database (CRD42020213286) [44].

Review question

What is the effectiveness of combined extracorporeal shockwave therapy (ESWT) and exercise interventions compared with other treatments in treating plantar heel pain?

Inclusion Criteria

Participants

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

Interventions

This review will include 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 can include 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 will be permitted.

Comparators

The following comprehensive list of common treatment methods will be included 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.

Trials with two or more arms will be included. The use of active co-interventions such as pain medication (NSAIDs), education, advice, orthotics, insoles and any type of exercise or physical activity will be accepted if used in all arms of the trial.

Outcomes

Primary outcomes will include 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) will be included [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) will be included [48, 49]. Additional secondary outcomes that will be considered for inclusion if available include quality of life measures using validated scales such as the EQ-5D-5L [50].

Types of studies

The review will be restricted to randomized controlled trials (RCTs) in which combined ESWT and exercise formed one arm of the trial. Trials with two or more

arms will be considered for inclusion. The use of active co-interventions such as pain medication (NSAIDs), education, orthotics and exercise will be 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 has identified several potentially eligible RCTs. Therefore, due to the availability of RCTs on this topic, they will be chosen for inclusion over less robust study designs. Any deviation from the standard RCT design such as crossover or cluster designed trials will also be included.

Methods

The systematic review process will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and JBI systematic reviews of effectiveness guidelines [44]. The review has been registered in the PROSPERO database (CRD42020213286).

Search strategy

The search strategy will seek to identify published and unpublished trials utilizing a three-step search strategy. An initial scoping search of Medline will be 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 will then be conducted using the following databases: Medline, CINAHL, AMED, SPORTDiscus, PEDro, Cochrane CENTRAL. The search for unpublished studies will include EThOS Networked Digital Library of Theses and Dissertations and the NICE Guidelines ESWT recommendations. The trial registers to be searched include: ClinicalTrials.gov, UK clinical trials gateway, EU trials registry. Finally, in addition to the comprehensive search, supplementary searches will be undertaken from reviewing bibliographies of articles selected for critical appraisal and related systematic reviews to find those not initially identified. The search strategy will be adapted to each database and be 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 will only be considered if a translation is available as translation services are not available to the authors.

Study selection

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

Assessment of methodological quality

Included studies will be 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 arise between the reviewers will be resolved through discussion or with a third reviewer. The results of critical appraisal will be reported in narrative form, and in a table. The critical appraisal results will be presented in a table and narrative form. All studies meeting inclusion criteria, regardless of their methodological quality, will undergo data extraction and synthesis and be included in the review.

Data extraction

Data will be extracted from papers included in the review using the standardised data extraction tool available on Covidence by two independent reviewers [44]. The data extracted will include 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 that arise between the reviewers will be resolved through discussion or with a third

reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using RevMan software. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard χ^2 and explored using subgroup analyses if possible based on the different quantitative study designs included in this review. Where statistical pooling is not possible due to heterogeneity, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate. Analysis of subgroups or subsets is not planned, although the sources of any heterogeneity detected will be explored using subgroup analyses based on the different quantitative study designs included in the review.

Assessing certainty in the findings

A 'summary of findings' table will be 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 will include heel pain and foot function for the interventions. For each outcome, a ranking of 'high', 'moderate', 'low' or 'very low' will be 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].

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Appendices

Appendix 1: MEDLINE search strategy:

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