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BURTON, I., COOPER, K., ALEXANDER, L. and SWINTON, P.A.

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The effectiveness of combined shockwave therapy and plantar fascia stretching interventions in treating plantar heel pain: A systematic review and meta-analysis protocol

Ian Burton1, Kay Cooper1,2,3, Lyndsay Alexander1,2, Paul Alan Swinton*1

1School of Health Sciences, Robert Gordon University, Aberdeen, UK

2The Scottish Centre for Evidence-based, Multi-professional Practice: a Joanna Briggs Institute Centre of Excellence

3NHS Grampian, Aberdeen, UK

Email addresses (in author order): i.burton@rgu.ac.uk; l.a.alexander@rgu.ac.uk; k.cooper@rgu.ac.uk; p.swinton@rgu.ac.uk ;

*Corresponding author: Dr Paul Swinton, School of Health Sciences, Ishbel Gordon Building, Robert Gordon University, Garthdee Road, Aberdeen, AB10 7QE. Email: p.swinton@rgu.ac.uk Tel: +44 (0)1224 263361

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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 plantar fascia specific stretching to treat plantar heel pain compared to any other non-surgical intervention.

Introduction: Recent evidence suggests combining shockwave therapy and plantar fascia stretching 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 plantar stretching for plantar heel pain in adults will be included.

Methods: The authors will search across a wide range of sources to identify both published and unpublished studies via EBSCOhost, including, but not limited to MEDLINE, SPORTDiscus, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), and Allied and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: CRD42020171538

Keywords: Exercise; Muscle Stretching; High-Energy Shock Waves; Fasciitis, Plantar.

Introduction

Musculoskeletal disorders are a leading global cause of disability and pain, which present across a broad spectrum of the population.[1] Collectively, musculoskeletal disorders have a high morbidity and represent a substantial burden to society, with extensive costs incurred by healthcare systems.[2] Musculoskeletal disorders comprise the second highest (21.3%) global volume of years lived with disability and 6.7% of the total global disability-adjusted life years.[3] In the United Kingdom, musculoskeletal disorders account for 25% of all general practitioner consultations, 30% of all years lived with disability, and 8% of total National Health Service expenditure.[4] An important component in responding to the increasing burden of musculoskeletal disorders is the use of evidence-based clinically effective treatments.[5]

Recently, an evidence-base has emerged demonstrating beneficial effects of extracorporeal shockwave therapy (ESWT).[6] After first being introduced in urology to treat kidney stones, ESWT is now applied therapeutically to a broad range of musculoskeletal disorders.[7] Shockwaves are mechanical acoustic energy waves that reach maximum pressure within nanoseconds.[8] This positive high amplitude is quickly followed by negative pressure, returning to ambient values within microseconds.[9] High pressures from shockwaves generate cavitation within human tissue that involves rapid formation, expansion and forceful collapse of vapor bubbles in liquids due to rapid pressure changes.[10] Cavitation has been shown to stimulate a range of biological responses activating tissue regeneration and healing in musculoskeletal disorders.[11] Recent evidence indicates that EWST may be most effective in the treatment of tendinopathies.[12]

Plantar heel pain (PHP) is a common musculoskeletal disorder, affecting up to 10% of the population, and is responsible for 15% of all clinical foot symptoms.[13] Symptoms include heel pain, most commonly experienced in the morning when first walking and functional limitations such as impaired gait.[14] The condition was previously termed 'plantar fasciitis' suggesting an inflammatory cause. However, despite the presence of inflammatory cells, degeneration due to repetitive microtrauma as seen in tendinopathy is considered the main cause of symptoms with 'plantar fasciopathy' considered a more accurate diagnosis.[15] In the absence

of confirmatory degeneration through ultrasonography, the general diagnostic term PHP is preferred to plantar fasciopathy.[16]

Physiotherapy is the consensus first-line management of PHP, with focus on improving mobility, reducing excessive stress on injured tissue and promoting repair.[17] Stretching exercises for the plantar fascia and gastrocnemius are often prescribed alongside education, taping, manual therapy, electrotherapy, orthotics and nonsteroidal anti-inflammatory drugs.[18] Corticosteroid injections, and autologous blood-derived injections such as platelet-rich plasma are also commonly used for treatment.[19] Plantar-fascia specific stretching (PFSS) has been the recommended exercise intervention for PHP for many years and been shown to be effective.[20] However, research has demonstrated that the effectiveness of PFSS is generally limited to the short-term and more effective interventions are warranted to improve long-term outcomes.[21]

Recalcitrant PHP cases that fail to demonstrate responsiveness to physiotherapy for three to six months are considered candidates for ESWT.[22] Several systematic reviews and meta-analyses have concluded on the long-term safety and efficacy of ESWT, recommending its use for PHP.[23-24] In addition, recent evidence suggests combining EWST and stretching exercise may be more effective in treatment of PHP compared with either of the therapies in isolation.[25] Despite this increasing evidence for combining ESWT and exercise, optimal treatment protocols and clinical recommendations are lacking.[26] 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 PFSS versus other non-surgical 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 recommendations regarding the combination of ESWT and PFSS 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 the a priori protocol presented here and registered in the PROSPERO database.[27]

Review question

What is the effectiveness of combined ESWT and PFSS interventions compared to other non-surgical interventions for pain and function in PHP patients?

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 diminished 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 or pregnancy.[29]

Interventions

This review will include studies that have investigated the effectiveness of a combined intervention of ESWT (radial or focused) and PFSS in the treatment of PHP. 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 comparators will be used as each represents commonly used therapies for PHP:

1. Self-management, education and advice
2. Injection therapies – corticosteroid, blood-derived products (orthobiologic)
3. Radial or focused ESWT (not combined with PFSS)
4. Exercise program, including PFSS (not combined with ESWT)
5. Standard care or physiotherapy

6. Other electrotherapy: ultrasound, low level laser therapy (LLLT)
7. Custom or standard orthotics, insoles or heel cups
8. ESWT & PFSS combined with other previously listed treatments.

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.[30-31] Foot function evaluated by any validated scale for PHP such as the Foot Function Index (FFI)[32] or Foot and Ankle Ability Measure (FAAM) will be included.[17] 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 and global rating of change (GRoC) scores.

Types of studies

The review will be restricted to randomized controlled trials (RCTs) in which combined ESWT and PFSS 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.[33] In the hierarchy of evidence, systematic reviews of RCTs offer the highest level of evidence.[34] The strongest inferences can be drawn if the review is well conducted and includes methodologically sound RCTs with consistent results.[35] The authors' preliminary searches have identified more than ten 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.[27] The review has been registered in the PROSPERO database (CRD42020171538).

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 2000 onwards. The year 2000 was chosen to ensure seminal work was not missed as research in this area 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 to the Joanna Briggs Institute's System for the Unified Management, Assessment and Review of Information (JBI SUMARI, The Joanna Briggs Institute, Adelaide, Australia).[27]

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 critical appraisal instrument for RCTs from the Joanna Briggs Institute (JBI SUMARI).[27] 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. Thirteen criteria will be appraised for RCTs therefore, a maximum score of 13. can be achieved. Each criterion will be identified as 'yes', 'no', 'unclear', or 'not applicable'. The critical appraisal results will be presented in a table and narrative form. All studies, 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 from the Joanna Briggs Institute (JBI SUMARI)[27] by two independent reviewers. 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 using pairwise hierarchical models, and all results will be subject to double data entry. Effect sizes will be expressed as standardised mean differences and their sampling variance calculated for pooling in meta-analysis. Given the potential for studies to include multiple outcomes in the same analysis or a single outcome across multiple time points, a three-level hierarchical model will be included to account for within-study covariance. Heterogeneity will be assessed by the between-study variance parameter and explored using subgroup analyses. Data synthesis and analyses

will be performed using the R programming language. If statistical pooling is not possible, 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.[36] Evidence from RCTs starts at high quality and the certainty is increased or decreased for several reasons, such as risk of bias.[37] 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.[38]

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Conflicts of interest

The authors declare no conflict of interest.

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Appendices

Appendix 1: MEDLINE search strategy:

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