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Effectiveness of Extracorporeal Shockwave Therapy Combined with Resistance Exercise for the Treatment of Tendinopathy: A Systematic Review and Meta-analysis 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 resistance exercise to treat any tendinopathy compared to any other treatment intervention.

Introduction: Recent evidence suggests combining shockwave therapy and resistance exercise may be more effective than other treatments for tendinopathy. 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 resistance exercise for tendinopathy 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Methods: The authors will search for a wide range of sources to find both published and unpublished studies via EBSCOhost, including, but not limited to, MEDLINE, SPORTDiscus, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), and Allied and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.

Keywords: Exercise; Extracorporeal Shockwave Therapy; Resistance training; High-Energy Shock Waves; Tendinopathy.

INTRODUCTION

Lower and upper limb tendinopathies can cause significant pain and functional limitations for individuals and collectively place a tremendous burden on society through high healthcare costs (Dean et al. 2017). In chronic tendinopathy, tendons experience morphological changes and can present with increased tendon thickness, fibril disorganization, and neovascularization due to angiogenesis caused by repetitive tendon microtrauma, commonly from loading activities such as exercise (Magnusson et al. 2019, Scott et al. 2008). In the general population incidence and prevalence of lower limb tendinopathies has been found to range from 7.0-11.8 and 10.5-16.6 per 1000 people, respectively (Albers et al., 2016; Riel et al., 2019). The prevalence of Achilles and patellar tendinopathy have been reported to be as high as 23 and 45% in runners and elite male volleyball players, respectively (Sprague et al., 2018; Arnold, & Moody, 2018). Tendinopathies are challenging to treat and are considered to have a multifactorial pathogenesis resulting from a range of extrinsic, intrinsic, and psychosocial factors (Steinmann et al., 2020; Mallows et al., 2017; Seitz et al., 2011). A range of common approaches are used in the treatment of tendinopathy including exercise, corticosteroid injections, extracorporeal shockwave therapy (ESWT), laser therapy, ultrasound, platelet-rich plasma injections, topical glyceryl trinitrate, anti-inflammatory medications, manual therapy, surgical intervention, and various forms of resistance training (Challoumas et al. 2019, 2021, Millar et al. 2021, Cardoso et al., 2019). Traditionally, the active treatment of choice for lower limb tendinopathies has been eccentric training, which has been popularised over the last two decades due to a plethora of studies showing a 50-70% chance of clinical improvement following three to six months (Gaida et al. 2011, Malliaras et al. 2013, Murphy et al. 2019). More recently, different types of resistance training have been investigated for lower limb tendinopathies with encouraging findings, such as heavy slow resistance training and isometric training (Lim et al. 2018). Heavy slow resistance training (HSRT) involving both concentric and eccentric strengthening, has been shown to produce positive outcomes for lower limb tendinopathies including Achilles and patellar tendinopathy (Beyer et al., 2015; Kongsgaard et al., 2009).

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 (Korakakis et al. 2018, Mani-Babu et al. 2015). For several decades, a significant evidence-base of effectiveness for ESWT has been increasing, particularly for Achilles, rotator cuff and lateral elbow tendinopathies (Romeo et al. 2014). Several systematic reviews and meta-analyses have concluded there is long-term safety and effectiveness of ESWT compared to placebo or other common tendinopathy treatments, with its use consistently recommended in the literature (Moya et al. 2018, Reilly et al. 2018). In addition, recent evidence suggests that ESWT combined with resistance exercise may be a more effective tendinopathy treatment compared with either of the treatments in isolation, with a need for a comparison of combined treatment approaches in future studies (Burton 2021). Current research recommends that combined rather than isolated treatments be used in tendinopathy treatment, with ESWT or exercise in isolation having inadequate long-term outcomes (Burton 2021). Despite this increasing evidence for ESWT and resistance exercise in tendinopathy treatment, optimal treatment protocols and clinical recommendations are lacking (van der Worp et al. 2013). 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 (Cinar 2020, Burton 2021). Therefore, it is currently unclear how effective the combination is for treating tendinopathies in comparison to other treatments, with no systematic reviews or meta-analysis having been conducted. A search in PROSPERO, The Cochrane Library and in PubMed was performed and identified no systematic reviews comparing the effectiveness of combined ESWT and resistance exercise for tendinopathies. Therefore, the aim of this work is to conduct such a systematic review and if possible meta-analysis to synthesise the available evidence and inform recommendations regarding the optimal combination of ESWT and resistance exercise interventions for treating tendinopathy. This systematic review and meta-analysis will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for systematic reviews of effectiveness (Tufanaru et al., 2020) and will be conducted in accordance with the a priori protocol presented here and registered in the PROSPERO database.

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 (Tufanaru et al., 2020). The review has been registered in the PROSPERO database.

Review question

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

Inclusion Criteria

Participants

This review will consider studies with adult participants aged 18 years old or over, formally diagnosed with a tendinopathy for any time duration. All lower and upper limb tendinopathies will be included, such as gluteal, hamstring, patellar, Achilles, tibialis posterior, rotator cuff and lateral elbow. Any tendon condition characterised by common tendinopathy symptoms, in the absence of a full thickness tendon rupture will be considered for inclusion. A clinician's diagnosis based on verifiable clinical features including pain location and a symptom altering response to palpation or tendon loading with specific tendinopathy tests will be accepted for inclusion.¹ Strategies to rule out other conditions through diagnostic imaging such as ultrasonography or magnetic resonance imaging confirmation of structural change will be permitted. Studies using local anaesthesia will be excluded as research has demonstrated that it can diminish ESWT effectiveness (Lou et al. 2017) 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 (Ibrahim et al. 2017).

Interventions

This review will include studies that have investigated the effectiveness of a combined intervention of any type of ESWT and any type of resistance exercise intervention for treating tendinopathy, versus placebo, control, or any other type of treatment including different types of resistance training. Resistance training can include strengthening exercises, heavy slow resistance training, reactive or plyometric strength training, or combined exercise interventions. Resistance training interventions comprising of concentric, eccentric, isotonic or isometric muscle actions will be considered. Any home or 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

Comparators to HSRT will include placebo, control, or any other type of treatment including the following comprehensive list of common treatment methods:

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 will include pain and function. Pain evaluated by any validated scale for musculoskeletal disorders such as the Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), or verbal rating scales for pain will be included (Boonstra et al., 2008). Tendinopathy-specific patient-reported outcome measures will be included as they have been shown to be superior to more generic tools for some conditions, such as the Victoria Institute of Sport Assessment Achilles questionnaire (VISA-A), Victoria Institute of Sport Assessment Patella questionnaire (VISA-P) and the Patient-Rated Tennis Elbow Evaluation (PRTEE) (Korakakis et al. 2021, Macdermid, & Silbernagel, 2015). In rotator cuff tendinopathy, generic shoulder outcome measures such as the Disabilities of the Arm, Shoulder and Hand (DASH) and disease-specific measures such as the Shoulder Pain and Disability Index (SPADI) have similar outcomes and validity, so will both be included (Littlewood et al., 2016). 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 (Herdman et al., 2011).

Types of studies

The review will be restricted to randomized controlled trials (RCTs) in which combined ESWT, and resistance exercise formed one arm of the trial and was

compared with placebo or any other treatment. 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 variables. In the hierarchy of evidence, systematic reviews of RCTs offer the highest level of evidence (Guyatt et al., 2008). The strongest inferences can be drawn if the review is well conducted and includes methodologically sound RCTs with consistent results (Charrois, 2015). 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.

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, 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 Google Scholar. 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. Databases will be searched from inception to January 1st, 2021. 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 (Tufanaru et al., 2020).

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 (Roque et al., 2020). 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 (Tufanaru et al., 2020). 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 tendinopathy pain and 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 (Balshem et al., 2011). Evidence from RCTs starts at high quality and the certainty is increased or decreased for several reasons, such as risk of bias (Sterne et al., 2016). The outcomes reported in the summary of findings table will include pain and 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 (Mustafa et al. 2013).

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