Effects of shockwave therapy on pain and disability in individuals with rotator cuff tendinopathy: a systematic review protocol

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ABSTRACT

Objective: The objective of this study is to systematically review randomized controlled trials comparing the effect of shockwave therapy with other forms of interventions on pain and disability in individuals with rotator cuff tendinopathy.

Introduction: Shoulder pain is a common musculoskeletal complaint in which rotator cuff tendons are usually affected. Shockwave therapy is a novel conservative treatment option for rotator cuff–related shoulder pain. A systematic review in 2004 reported conflicting results on the effectiveness of shockwave therapy in treating chronic rotator cuff tendonitis, whereby it is effective for calcific rotator cuff tendonitis but not for non-calcific ones. Hence, it is timely to review this topic with the addition of results from studies published since 2004.

Inclusion criteria: This review will consider randomized controlled trials that have evaluated shockwave therapy delivered via radial or focused extracorporeal means in individuals with rotator cuff tendinopathy without restrictions of race, gender, and age. Studies comparing individuals receiving shockwave therapy of varying dosages will be excluded in this review.

Methods: A three-step search strategy will be used to locate studies published in English from databases. No search restrictions were applied regarding the year of publication. Study selection, assessment of methodological quality, and data extraction will be conducted by two independent reviewers. Data will be pooled in statistical meta-analysis, where possible. A funnel plot will be generated to detect any potential publication bias. The quality of the evidence will be analyzed using the Grading of Recommendations, Assessment, Development and Evaluation approach.

Systematic review registration number: PROSPERO CRD42020160166.

Keywords rotator cuff; shockwave therapy; shoulder; tendinopathy

JBI Evid Synth 2021; 19(0):1–6.

Introduction

Shoulder pain is a common musculoskeletal complaint with reported prevalence in the world ranging from 7% to 27% among adults.1 It is the third-most-common musculoskeletal presentation in primary care.2 The chronicity and recurrence rate of shoulder pain is common. Approximately 40% of patients return to see their general practitioner within a year.3 At least 14% of patients had to continue with physician follow-up even after three years from the initial onset of pain.4 Shoulder pain is associated with long-term disability as many patients with shoulder pain have recurrent complaints after 12 to 18 months.5 Furthermore, shoulder pain was shown to have a marked impact on an individual’s perception of quality of life that is comparable to the effects of conditions such as congestive heart failure, myocardial infarction, and clinical depression.6

The rotator cuff tendons and associated structures around the subacromial space are thought to be the main causes of shoulder pain.2,7 However, there is currently no consistency in the labeling of shoulder pain conditions due to the limited ability to accurately differentiate between these structures.3,4,8 A more generic diagnostic term has been suggested:

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The authors declare no conflict of interest.
DOI: 10.11124/JBIES-20-00169
rotator cuff tendinopathy or rotator cuff–related shoulder pain. These are overarching clinical terms that include several conditions, such as rotator cuff tendinosis, subacromial pain syndrome, and subacromial impingement syndrome.9

The main objectives of the treatment of rotator cuff tendinopathy are to reduce pain and restore functional ability of the shoulder. Conservative treatments include analgesics,10 corticosteroid injections,11 non-steroidal anti-inflammatory drugs (NSAIDs),12 electrotherapy modalities,13 acupuncture,14 topical glyceryl trinitrate,15 manual therapy, and therapeutic exercises.16 These treatments may be used in conjunction or sequentially. In the event that patients fail to respond to these treatments, surgery would be considered.17 Due to the large variety of treatments available for rotator cuff tendinopathy, there is a need to determine the treatment efficacy based on current evidence to allow better clinical decisions to be made. Available evidence supports the use of analgesics, corticosteroid injections, and NSAIDs for short-term reduction in pain levels for patients with rotator cuff tendinopathy.10-12 High-quality evidence supports the use of manual therapy and exercise in improving the function of patients with rotator cuff tendinopathy, whereas there is only low-quality evidence that supports the use of topical glyceryl trinitrate, acupuncture, electrotherapy modalities, and surgery for the management of rotator cuff tendinopathy.13-17

Shockwave therapy is a non-invasive treatment that involves passing shock waves through the skin to the affected area. These high energy sound waves dissipate mechanical energy at the interface of two substances with different acoustic impedance.18 They are produced by an electrical energy generator that has an electroacoustic conversion mechanism and a focusing device.19 Shockwave therapy was first introduced into clinical practice as a treatment for nephrolithiasis in 1980, but over the last two decades it has also been used to treat various musculoskeletal disorders.20 Although the exact treatment mechanism of shockwave therapy is not well understood, it has been suggested that the repeated microtrauma can stimulate positive effects on the neovascularization of the tendon and blood supply to the tissue, thereby promoting tissue regeneration.21 It has also been theorized that shockwave therapy has a beneficial effect on promoting calcium reabsorption in calcific tendinitis.22 As shockwave is a type of sound wave that can spread through soft tissues with little energy loss, it can cause the vibration of tissue molecules and improves the effect of cavitation and fragmentation of calcium deposits, which speeds up the calcium breakdown process.23 Furthermore, shockwave therapy is speculated to reduce pain through hyperstimulation of nociceptors (gate control theory of pain transmission), changing pain receptor neurotransmission, and by increasing local pain inhibiting substances.24

In a previous systematic review published in 2004, Harniman et al.25 reported moderate evidence that shockwave therapy is effective in treating chronic calcific rotator cuff tendinitis. However, it also reported moderate evidence that shockwave therapy is not effective for treating chronic non-calcific rotator cuff tendinitis. Therefore, the effectiveness of shockwave therapy in rotator cuff tendinopathy remains unclear. In recent years, there has been an increasing number of research activities and journal publications on the effectiveness of shockwave therapy in shoulder-related musculoskeletal conditions. This systematic review aims to review all relevant studies published until the present and update the current evidence base relating to the effectiveness of shockwave therapy on pain and disability in individuals with rotator cuff tendinopathy and the differences compared to other forms of intervention.

Review question
What is the effectiveness of shockwave therapy (Intervention) when compared to other forms of interventions (Comparator) on pain and disability (Outcomes) in individuals with rotator cuff tendinopathy (Participants)?

Inclusion criteria
Participants
This review will include trials with participants described as having rotator cuff tendinopathy (subacromial pain syndrome or subacromial impingement syndrome; rotator cuff tendinosis or tendinitis; subscapularis, infraspinatus or supraspinatus tendinitis; subacromial bursitis or rotator cuff tears) without restrictions of race, gender, and age. This review will exclude studies that included participants with local or generalized arthritis, a history of significant injury, systemic inflammatory conditions, pregnancy, infections, tumors, or neurologic conditions.
**Intervention**
This review will consider studies that evaluate shock-wave therapy delivered via radial or focused extracorporeal means. Studies comparing individuals receiving shockwave therapy of varying dosages will be excluded in this review.

**Comparator**
The intervention will be compared with other forms of intervention, for example, medications, ultrasound therapy, surgery, and exercises delivered to another group of individuals of similar shoulder condition.

**Outcomes**
This review will consider studies that include the following outcomes: pre- and post-intervention pain intensity scores and disability scores. Pain intensity scores will be measured by any pain measurement tools, such as the Visual Analog Scale or the Numeric Rating Scale. Disability scores will be measured by questionnaires such as the Disabilities of the Arm, Shoulder and Hand (DASH), 36-Item Short Form Health Survey, Shoulder Pain And Disability Index (SPADI), Shoulder Disability Questionnaire (SDQ), Health Assessment Questionnaire (HAQ).

**Types of studies**
This review will only consider studies that were randomized controlled trials. Studies of different research designs such as quasi-randomized controlled trials, non-randomized clinical trials, cohort studies, case-control studies, case reports, case series, and non-clinical studies will be excluded.

**Methods**
The proposed systematic review will be conducted in accordance with JBI methodology and the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines.26,27

**Search strategy**
The search strategy aims to find both published and unpublished studies. In keeping with JBI methodology for systematic reviews, a three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by an analysis of text words contained in the title and abstract of relevant articles, and of the index terms used to describe these articles. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all included studies will be screened for additional studies. Only studies published in English will be included in this review. The search will be conducted from the date of database inception until the present. The full search strategy is detailed in Appendix I.

**Information sources**
The following electronic databases will be searched: MEDLINE (PubMed), CINAHL (EBSCO), Embase (Ovid), Physiotherapy Evidence Database (PEDro), Cochrane Library (Cochrane Reviews, Cochrane Central Register of Controlled Trials), Google Scholar, and ProQuest.

**Study selection**
Following the search, all identified citations will be entered into EndNote X9.3.2 (Clarivate Analytics, PA, USA). The references will be added to Covidence (Veritas Health Innovations, Melbourne, Australia). References will be screened by the Covidence software for duplicates, which will be removed after initial screening. The remaining titles and abstracts will then be screened by two independent reviewers (HHRL and JJW) for assessment against the inclusion criteria for the review. Next, the selected articles will undergo full-text screening by the same two reviewers. Disagreements will be resolved through discussion with a third reviewer (ZYT), and reasons for exclusion recorded. Illustrations of the selections process will be done using a PRISMA flowchart in the final systematic review.28

**Assessment of methodological quality**
Eligible studies will be critically appraised by two independent reviewers (HHRL and JJW) using the standardized JBI critical appraisal checklist tool for randomized controlled trials. The following information will be extracted: first author, published year, location, study design and methods, interventions, outcomes, and any other reporting information. A third reviewer (ZYT) will resolve any disagreements if divergences occur between the two reviewers. Methodological quality will be evaluated for the population domain, allocation of treatment, blinding, and statistical analyses. The risk of bias will also be evaluated across the studies.
**Data extraction**

Data will be extracted from studies included in the review by two independent reviewers (HHRL and JJW) using the Covidence software and standardized JBI data extraction tool. Information on participant characteristics such as: age, gender, duration of symptoms, details of intervention (frequency and duration of treatment), and pre- and post-outcome measures (pain and disability) will be extracted from each included study. Any disagreements that arise between the two reviewers (HHRL and JJW) will be resolved through discussion or with the third reviewer (ZYT). The extracted data will be presented in a table in the results section of the systematic review.

**Data synthesis**

Reliability analyses of inter-rater agreement will be performed using IBM SPSS Statistics 25 (Armonk, NY: IBM Corp). Inter-rater reliability will be reported for the total quality score with Kappa statistics. Meta-analytical analyses will be performed for the pooled results, where possible, using RevMan 5.3 (Copenhagen: The Nordic Cochrane Centre, Cochrane). To account for any possible differing outcome scales used among studies, standardized mean differences for pain and disability scores will be calculated with 95% confidence intervals. Tests of heterogeneity will be assessed statistically using the standard $\chi^2$ and I² tests. Fixed effects or random effects will be used as appropriate where possible.29 Where there is sufficient data, subgroup analyses will be performed to stratify and group the comparator form of intervention against shockwave therapy depending on the degree and complexity of the intervention used in the control arm. If possible, sensitivity analyses will be conducted to test the robustness of the pooled results. Where statistical pooling is not possible, the findings will be presented in narrative form, including tables and figures to aid in data presentation, where appropriate. To detect potential publication bias, a funnel plot will be generated using RevMan 5.3 if there are more than 10 included studies. In addition, statistical tests for funnel plot asymmetry (Egger test, Begg test, Harbord test) will be performed, where appropriate.

**Assessing certainty in the findings**

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for grading the certainty of evidence will be followed and a Summary of Findings (SoF) will be created using GRADEpro software (McMaster University, ON, Canada). The SoF will present the following information where appropriate: absolute risks for experiment and control; estimates of relative risk; and a ranking of evidence quality based on the directness, heterogeneity, risk of bias, precision, and risk of publication bias of the review results. The pre- and post-intervention pain and disability scoring outcomes will be reported in the SoF.

**Acknowledgments**

Goh Boon Kwang, the Head of the Department of Allied Health, for his support. The physiotherapy team for their assistance in the development of the protocol.

**References**


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20. Vitali M, Peretti G, Mangiavini L, Caschera G. The treatment with extracorporeal shock wave therapy in some of most frequently musculoskeletal pathologies. Orthopaedic Proceed 2006;88-B(SUPP_III), 423-.
Appendix I: Search strategy


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