Evidence-Based Practice Group
Answers to Clinical Questions

Extracorporeal Shock Wave Therapy in Treating Calcific Supraspinatus Tendinopathy – Update 2024

A Rapid Systematic Review

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Date	March 2024

WorkSafeBC

About this report

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Published: March 2024

About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

Suggested citation

WorkSafeBC Evidence-Based Practice Group, Martin CW. Extracorporeal Shock Wave Therapy in Treating Calcific Supraspinatus Tendinopathy. Richmond, BC: WorkSafeBC Evidence-Based Practice Group; March 2024.

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Background

- In 2010 the Evidence-Based Practice Group (EBPG) was asked to investigate whether there was any evidence on the efficacy/effectiveness of extracorporeal shock wave therapy (ESWT) in treating calcific supraspinatus tendinopathy.

Objectives

- This review is undertaken to update our latest report from 2010 and to determine whether the evidence on the efficacy/effectiveness of ESWT in treating calcific supraspinatus tendinopathy and other calcific tendinopathies of the rotator cuff has changed since then.

Methods

- A systematic literature search was undertaken on January 22, 2024.
- The search was done on commercial medical literature databases, including EBM Reviews - ACP Journal Club (1991 to December 2023), EBM Reviews - Cochrane Central Register of Controlled Trials (December 2023), EBM Reviews - Cochrane Database of Systematic Reviews (2005 to January 17, 2024), EBM Reviews - Database of Abstracts of Reviews of Effects (1st Quarter 2016), EBM Reviews - Health Technology Assessment (4th Quarter 2016), Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily (1946 to January 19, 2024) that are available through Ovid platform. We repeated the same search approach using EMBASE.
- The search strategy employed the same keywords from the EBPG 2010 review and several additional ones. These were combined using the Boolean operators 'AND' and 'OR'.
- The keywords employed were:
  (((extracorporeal **OR** extra-corporeal) **AND** (shockwave **OR** shock wave) **AND** therapy)) **OR** (extracorporeal shockwave therapy) **OR** ESWT)))
  AND
  (((supraspinatus **OR** rotator cuff OR rotator-cuff) **AND** (calcific **OR** calcinosis **OR** calcification) **AND** (tendinitis **OR** tendinosis **OR** tendinopathy)))
- No limitations, such as on the date or language of publication was implemented initially during these searches.
- Predetermined inclusion/exclusion criteria:
  Studies were included if they:
  - were published in peer-reviewed journals.
  - investigated the efficacy/effectiveness of extracorporeal shock wave therapy (ESWT) in treating calcific supraspinatus tendinopathy or other calcific tendinopathies of the rotator cuff.
  - compared ESWT with placebo/sham or other interventions (e.g., supervised exercises, transcutaneous electrical nerve stimulation (TENS), ultrasound-guided dry needling, percutaneous lavage), or compared different types and dosages of ESWT for calcific supraspinatus tendinopathy and other tendinopathies of rotator cuff, or if was a single study should have used a control group and randomization.
  - were RCTs or systematic reviews/meta-analyses of more than five primary comparative studies, each of which included at least 10 study subjects.
  - included response rate measured by level of change of calcification from baseline, complete resorption of the calcification, incomplete resorption, and symptom reduction (e.g., improvement in pain and range of motion (ROM) scores), time to response, tolerability of ESWT as the primary outcomes of the study.

Studies were excluded if they:

- were animal studies
- included children, adolescents, the elderly, pregnant patients, or other special patient groups.
- studied ESWT only for non-calcific supraspinatus tendinopathy.
- had no comparison groups.
- had comparison groups that included co-interventions.
- were published in the formats of conference abstracts/posters, editorials, opinion/position papers, reprints in other journals, proposals, trial registry entries narrative reviews, qualitative interviews, trial registrations, pilot studies, proof-of-concept studies, posthoc analyses, anchor-based analyses, open-label studies, case studies, case series, other observational studies, and uncontrolled trials.

Results

Search results:

- In total, 163 publications were identified (142 from the Ovid platform and 21 from the EMBASE platform).
- Citations from both platforms were combined.
- In total 49 duplicates were removed.
- From both platforms, in total 114 citations were retained.
- Some of the citations met the exclusion criteria based on more than one criterion and were excluded with the first criterion they met.
- Four [1,2,3,4] of 114 were written in languages different than English, which we did not have resources to review and were discarded.
- The remaining citations were 110.
- Thirty-six [1,2,3,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,2829,30,31,32,33,34,35,36,37] of the 110 were published before 2010 and were discarded.
- Out of 74 remaining citations, three [5,38,39] were duplicate publications of the same article in different journals and were discarded.
- The number of the selected citations for abstract review was 71.
- After the abstract review, based on the predetermined inclusion/exclusion criteria in total 53 were discarded. Some of them met multiple exclusion criteria and were discarded at the first criteria they met.
- Out of these discarded publications, six were narrative reviews [40,41,42,43,44,45] and fourteen were plans for future studies (proposals, clinical trial records). [46,47,48,49,50,51,52,53,54,55,56,57,58,59] One was a pilot study, [60] two were bibliographic records, [61,62] three were commentaries, [63,64,65] one was a book chapter, [66] one was a bibliometric analysis, [67] and one was an abstract only publication. ([68])
- Seven of the studies were not relevant, because they focused on other populations, not on patients with calcific tendinopathies of the rotator cuff. [69,70,71,72,73,74,75] Another ten were also discarded due to the interventions they studied (e.g., kinesio taping, nutritional supplements, manual therapy, US-guided percutaneous irrigation, needling). [76,77,78,79,80,81,82,83,84,85] Two studies were not relevant as one was focusing on ESWT treatment protocols [86] and the other one was on two types of questionnaires used in measuring the effect of high-energy ESWT and ultrasound-guided needling in rotator cuff calcific tendinitis. [87] Two were observational studies [88, 89] and seven were comparative studies with no control groups. [90,91,92,93,94,95,96]
- There were four RCTs [97,98,99,100] and fourteen systematic reviews with or without meta-analysis. [101,102,103,104,105,106,107,108,109,110,111,112,113,114]
- We collected full text articles for the RCTs and systematic reviews/meta-analyses.

- After full text article reviews, all fourteen [101,102,103, 104,105,106,107, 108, 109, 110, 111, 112, 113, 114] of the systematic reviews/meta-analyses were selected to be appraised. We also appraised the RCT by Fatima [99] as it was not an RCT included in the selected and appraised systematic review/meta-analyses.
- The evidence level was determined using the WorkSafeBC — Evidence-Based Practice Group levels of evidence (Appendix 1).
- The systematic review and meta-analysis by Al-Abbad et al. (2020) [101] explored the effects of extracorporeal shockwave therapy (SWT) on a wide range of musculoskeletal disorders (e.g., rotator cuff calcifying tendinitis, plantar fasciitis, osteonecrosis of the femoral head, fracture nonunion, lateral epicondylitis, knee osteoarthritis, Achilles tendinopathy, post-traumatic myositis ossificans). Their outcome of interest was the changes in imaging studies after SWT application (e.g., MRI, ultrasonography, CT, DEXA or plain radiography). In total, they included 63 studies. Data for effect size pooling was available for only 27 of them. The effect sizes reflected pre- to post-imaging changes. The authors performed meta-analyses and meta-regression on 11 of the 23 studies on rotator cuff calcific tendinitis (21 used focused SWT, two used radial SWT). SWT delivered shocks and energy flux density varied widely across studies, as well as the number of SWT sessions. Several studies used anesthesia or imaging guidance, while others did not. The outcomes reported also varied across studies, e.g., change in size of calcium deposit, number of participants demonstrating total calcification resorption, and reduction or fragmentation of the calcium deposit. Several studies reported a reduction in size of the calcium deposit. The authors found that the size of the baseline calcium deposit was the only covariate to explain the variance in SWT effect, hence, making it a potential predictor for the response to SWT ($p=0.002$). In reducing the calcium deposit size, SWT worked better (although not significantly) than placebo. But when compared to ultrasound-guided needling (UGN) SWT's effect was significantly less. Regarding total calcium resorption, SWT worked significantly better than placebo. However, when compared to UGN, the needling was significantly better. To assess risk of bias in primary studies, the authors used Cochrane risk of bias tool (RCTs) and the MINOR tool (non-RCT studies) and found that the mean score was 60% for RCTs and 74% for non-RCT studies. Using Kappa coefficient, overall agreement between two assessors was moderate ($k = 0.53$). Due to limited selection, timing, and reporting of imaging modalities (e.g., accuracy of imaging measurements) and related outcomes, and a relatively high risk of bias in primary studies, the authors were not able to draw solid conclusions with this systematic review. Based on the EBPG Levels of Evidence chart (Appendix-1), this review is considered Level-1. However, when appraised using the AMSTAR-2 checklist [115] there were areas that could have been performed better (e.g., providing a list of excluded studies).
- Angileri et al. [102] reviewed randomized controlled trials that compared outcomes and complications of nonoperative and operative interventions for chronic calcific tendinitis of the rotator cuff. They aimed to offer evidence-based treatment guidelines for the management of chronic calcific tendinitis. They identified 503 studies from three databases (EMBASE, MEDLINE and PubMed). After the full text review stage, the authors selected 27 primary studies (all RCTs). Nine of these used ESWT. Four out of nine were published after 2010, and three [77,97,100] were captured in our search as well. We did not capture the RCT by Tornese (2011) [116] as it was not on efficacy/effectiveness of ESWT. The authors used the Cochrane risk of bias assessment for 27 of the included studies, and reported low risk, moderately low risk or unclear risk for different domains across the studies. In addition, the authors stated that only four of the RCTs included a sham/control group, and the remaining only compared various interventions, techniques, or treatment combinations. After a series of meta-analysis on different intervention/outcomes (effect sizes were listed as mean differences) the authors

reported their main findings. Both ESWT and ultrasonography-guided needling (UGN), as well as operative treatment led to clinical improvements in both pain and functional outcomes in patients with calcific tendinitis of the rotator cuff. In terms of the studies on ESWT and UGN, the authors pointed to the heterogeneity in administration techniques (e.g., energy level, frequency and type of treatment application, session duration). They stated that compared to ESWT, UGN was better in terms of pain reduction, shoulder function, and complete resolution of the calcific deposit. Improvement in functional outcomes was larger with operative treatment compared to nonoperative interventions, but no directly comparable studies were available to test for statistical significance. Hence, the authors called for future studies directly comparing operative and nonoperative interventions. They also referred to the significant heterogeneity across treatment applications, especially in non-operative approaches (e.g., dosage, various treatment combinations, differences in follow-up, and postoperative rehabilitation).

- Arirachakaran et al. [114] assessed minimally invasive treatment methods (ESWT, barbotage, and subacromial corticosteroid injection (SAI)) for calcific tendinitis by comparing relevant clinical outcomes using different measurement methods. For example, visual analog score (VAS), Constant–Murley Score (CMS), Disabilities of the Arm, Shoulder and Hand (DASH), Western Ontario Rotator Cuff index (WORC), University of California Los Angeles scale (UCLA)), and complete resorption rate and adverse effects (pain during treatment, soreness, local subcutaneous hematomas and small petechial hemorrhages). They combined direct and indirect evidence in a network meta-analysis. Medline and Scopus databases were searched for RCTs and quasi-experimental design studies using a list of keywords. The seven papers (all but one (Kim-2014) were publications before 2010) were selected based on predetermined inclusion/exclusion criteria and were assessed for biases using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The authors checked for publication bias and reported none. Five studies used CMS and five studies used VAS score for pain. Size of calcium deposit was reported by four, and adverse effects were reported by seven studies. During the analysis the authors used unstandardized mean difference (UMD) for continuous and relative risk (RR) for dichotomous outcomes. If heterogeneity was present, they estimated UMD using a random-effects model; if not, they used a fixed-effects model. When using network meta-analysis for indirect comparisons they applied a mixed effect model (i.e., treatment as a fixed effect, the study variable as a random effect). The authors defined the network meta-analysis as a method that "'borrows' treatment information from other studies and increases the total sample size" and detect treatment effects that could not be detected otherwise. In terms of limitations of their network meta-analysis, the authors stated that 85.7%of the studies did not explain randomization sequence generation/allocation concealment (e.g., selection bias or confounding issues). There was unexplained heterogeneity in the pooled results. The authors reported their findings as "combined US-guided needling and subacromial corticosteroid injection significantly decreased shoulder pain VAS, improved CMS score and decreased the size of calcium deposits, while also lowering risks of adverse event when compared to barbotage plus ESWT, ESWT and subacromial corticosteroid injection; therefore, the evidence points to UGPL as being the treatment of choice for nonsurgical options of treatment in calcific tendinitis of the shoulder."
- The purpose of the systematic review by Bannuru et al. [103] was to assess the benefits and harms of ESWT in rotator cuff tendinitis by comparing ESWT to placebo and other treatment modalities, also by comparing different ESWT energy level applications. In addition, they were interested in subgroup analysis in calcific and non-calcific tendinitis. After the literature search using pre-determined keywords, in five databases (MEDLINE, the Cochrane Central Register of Controlled Trials, EMBASE, Web of Science, and Google

Scholar) 376 articles were located. Applying their inclusion/exclusion criteria, and eliminating the articles which were not suitable, a final selection included 28 articles of which 20 compared ESWT with placebo and eight compared ESWT with other treatment modalities. Sixteen studies were on calcific and four were on non-calcific tendinitis. The ESWT energy levels varied across studies. Outcomes studied were pain, function, and resolution of calcifications. In general, the quality of primary studies was low (6 trials with proper double-blinding, and only 3 high-quality RCTs). Due to high heterogeneity and bias in primary studies, a meta-analysis was not undertaken. Eight trials on calcific tendinitis compared high-energy ESWT (energy flux density (EFD) ≥0.28 mJ/mm2) with low-energy ESWT. The authors found that high-energy ESWT was more beneficial over low-energy ESWT (e.g., in improving shoulder function and pain, and resolving shoulder calcium deposits). The studies comparing ESWT with other treatment modalities found that ESWT was as effective as exercise or radiation therapy, and more effective than transcutaneous electric nerve stimulation (TENS). Several studies suggested that calcific tendinitis treatment could be augmented with needling, focusing on calcium deposits using fluoroscopy, and hyperextended internal rotation position of the shoulder. The authors concluded that high-energy ESWT (≥0.28 mJ/mm2) was more effective than low-energy level ESWT in reducing pain and increasing function in chronic calcific tendinitis of the shoulder, and a complete resolution of calcification was also possible. However, they also stated that the application, dosage, and efficacy of ESWT were not still clear, and RCTs on the topic showed conflicting results.

- To explore the effectiveness of ESWT in patients with rotator cuff tendinopathy, Fatima et al. [104] conducted a systematic review and meta-analysis. They identified 265 publications through their comprehensive review of the databases PubMed, PEDro, and Cochrane Central Register of Controlled Trials (CENTRAL) that were published in 2000-2019 period. Additionally, they used sources like the clinical trial registry, Open Assess, thesis dissertations and journals. Twenty-five articles were reviewed as full text, and 11 met the inclusion criteria. Two of these did not have extractable data. Hence, nine studies were included for the meta-analysis. They used Physiotherapy Evidence Database (PEDro) scoring for quality assessment and found four studies to be high and five studies to be fair quality. The authors stated that most of the included studies reported ESWT to be an alternative method to surgical intervention for tendinopathies with calcified deposits. But they also acknowledged the heterogeneity across studies in terms of study design, location, outcome measure and delivery method. The authors concluded that they were not able to find a consensus on the efficacy of ESWT compared to classical rehabilitation methods for patients with rotator cuff tendinopathy. However, there was limitations of this systematic review as high heterogeneity was a major issue. As a result, no forest plot with a summary estimate of the pooled results were provided. Studies had small sample sizes (less than 100) except for one study, and one of the included studies was a pilot study only.
- To study the effectiveness of conservative interventions (alone or as a combination) on shoulder conditions (i.e., shoulder impingement syndrome, rotator cuff-associated disorders, adhesive capsulitis, and nonspecific shoulder pain) Hawk et al. [105] undertook a systematic review of the relevant RCTs and systematic reviews/meta-analyses. They used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline during the study selection. The quality assessment of each study was conducted using the Scottish Intercollegiate Guidelines Network (SIGN) checklist. The conservative nondrug, nonsurgical interventions included manual therapy, physiotherapy, kinesiotaping, low-level laser therapy (LLLT), pulsed electromagnetic field (PEMF) therapy, and extracorporeal shockwave therapy (ESWT). The comparison groups were active treatments, placebos/shams, wait list, and no treatment. The authors were interested in only pain and function/disability outcomes. They screened 77 full-text

articles and 25 systematic reviews and 44 RCTs were selected. Strength of evidence was considered high if the results from at least two low risk-of-bias studies were consistent. For rotator cuff calcific tendinitis, the authors selected five systematic reviews on ESWT and two of them included a meta-analysis. The systematic review by Louwerens et al. (2014) was rated as high quality and the other four were rated as acceptable quality studies. The systematic reviews on other rotator cuff-associated disorders (not calcific tendinitis) included two studies comparing ESWT with sham, both of which found significant improvement overtime, but only one had a comparative group. Out of 44 RCTs the authors found three that studied ESWT for rotator cuff-associated disorders. These were listed as acceptable and high quality RCTs. One of them was on chronic, primary long-head bicipital tenosynovitis, one was comparing positioning for ESWT (internal or neutral), and the other one was comparing radial ESWT with sham in patients with chronic rotator cuff tendinitis. The authors reported that in general, the studies on nondrug, nonsurgical treatment of shoulder conditions were low to moderate quality and did not present outcome data for the long term. They concluded that out of all conservative interventions studied LLLT was the only one that was supported with moderate evidence to be used for all four of the shoulder conditions studied.

- Huisstede et al. [106] studied the effectiveness of ESWT as a treatment for calcific and non-calcific rotator cuff tendinosis which go with shoulder impingement symptoms. The search for relevant RCTs and systematic reviews was undertaken on Cochrane Library, PubMed, Embase, Pedro and Cinahl, and after applying inclusion/exclusion criteria 17 RCTs were selected for the study. These included studies on both calcific and non-calcific tendinosis, and as well as on low-, medium- and high-energy extracorporeal shockwaves (<0.11 mJ/mm2, between 0.12 and 0.28 mJ/mm2, and >0.28 mJ/mm2, respectively). The quality assessment of the studies was undertaken using the criteria developed by Furlan et al. (2008). If the response was "yes" to ≥50% of the 12 questions, the study was accepted as 'high-quality'. When the 17 RCTs were reviewed, the evidence synthesis had the highest score (level of evidence: strong) if the effectiveness was consistently positive (significant findings) within multiple high-quality RCTs. If the significantly positive findings were within one low-quality RCT only, the level of evidence was considered to be limited. There was also moderate evidence, conflicting or no evidence, and no RCTs categories as well. The authors reported on two RCTs (one high and one low quality) that used high-energy ESWT for calcific tendinopathy of the shoulder. They reported that there was moderate evidence for effectiveness of ESWT when compared with placebo in the short-term, mid-term, and long-term. One low-quality RCT that was included studied high-ESWT versus no treatment, and high-ESWT for one versus two sessions; both revealed limited evidence. The authors included two RCTs that compared high-energy versus low-energy ESWT and concluded that there was strong evidence supporting that high-energy ESWT was more effective for shoulder impingement syndrome in the short-term. The evidence was moderate for mid-term and long-term. Included were RCTs comparing high-energy ESWT versus medium-energy ESWT, high-energy ESWT: focus calcific deposit versus focus tuberculum majus, high-energy ESWT versus high-energy ESWT plus needling, high-energy ESWT versus transcutaneous electrical nerve stimulation (TENS), low-energy ESWT versus no treatment, low-energy ESWT: point of tenderness by palpation versus computer-assisted. There was one RCT comparing radial shock wave therapy (RSWT) to placebo for rotator-cuff tendinosis. There was moderate evidence for the effectiveness in favour of RSWT the short- and mid-term. There were seven RCTs included on the use of ESWT for non-calcific tendinosis. The authors reported no evidence of effectiveness of ESWT when used for this condition. The overall conclusion of the authors was that there was evidence for effectiveness of high-energy ESWT for calcific RC-tendinosis, but not for its effectiveness for non-calcific tendinosis.

- Ioppolo et al. published a systematic review with meta-analysis in 2013. [107] They studied the clinical improvement and resorption of calcifications in calcific tendinitis of the shoulder six months after ESTW application. They were interested in improvement in pain and functional outcomes, as well as in the resorption of calcifications. They searched MEDLINE, Embase, CINAHL, Ovid database, Physiotherapy Evidence Database (PEDro), and the Cochrane Library for RCTs and the quality assessment was undertaken using Physiotherapy Evidence Database (PEDro) scale. The authors selected six studies that had a follow-up after six months, of which four had comparison groups and a meta-analysis was undertaken. The other two RCTs presented a descriptive analysis. The outcome of interest was the radiologic rate of resorption of calcific deposits at 6 months' follow-up. According to the results from the studies with meta-analyses the authors reported that ESWT was more effective than no treatment or placebo for the outcomes of partial and total resorption. Using the fixed effects model the pooled total resorption ratio was 27.19 (95% confidence interval [CI], 7.20 – 102.67) and pooled partial resorption ratio was 16.22 (95% CI, 3.33 – 79.01). The two descriptive studies highlighted that high-energy ESWT achieved a better response compared to low-energy ESWT. The authors noted that the general quality of the selected RCTs were low, as only two of the studies used intention-to-treat analysis and provided the size of the treatment effects. The authors also underlined the need for standardization of the ESWT parameters such as energy flux density (EFD), number of sessions and impulses.
- The systematic review/meta-analysis by Lee et al. [108] explored whether ESWT would be an effective treatment for chronic calcific tendinitis of the shoulder by improving pain and functional symptoms at least six months after the ESWT application. The authors were also interested in studying whether there was a dose-response relationship in effectiveness of ESWT. They searched the databases Cochrane Controlled Trials Register, MEDLINE, CINAHL, PUBMED, EMBASE, SPORTSDiscus and PEDro. The authors selected nine RCTs to be included in the review. Methodologic quality was assessed using the PEDro scale. Six RCTs scored seven or more when the total score was kept as 10 (they skipped one item of the PEDro scale). The strength of the evidence was reported using the matrix from the National Health and Medical Research Council. The key components evaluated were consistency of findings, clinical effect, and relevance to the target population. They did not use the last dimension of the matrix which was 'applicability' of evidence. The authors found that reporting of variance for 'patient mean age' and 'duration of symptoms' was not consistent across the included studies. The majority of the studies applied ESWT directly at the site of calcification, and the dosage, energy levels, and impulses of the shock wave applied varied. In addition to the lack of consistency in intervention parameters, there was heterogeneity in studied outcome measures. Moreover, the number of treatment sessions and the interval between each session varied across studies. As a result, the authors did not undertake a meta-analysis. They focused on the pain and functional outcomes and did not explore other outcomes that were occasionally presented such as patients' subjective satisfaction or radiologic investigations. Based on their qualitative review the authors concluded that ESWT was effective and had minimal side effects in improving pain and function for patients with rotator cuff calcific tendinitis in the midterm (after six months and up to one year) (moderate –level B– overall evidence). They recommended that in the cases where patients do not respond to classical conservative treatments, before moving to surgery, ESWT could be offered. Since the quantitative data was not suitable, the authors were not able to run a dose-response analysis.
- The systematic review and meta-analysis by Louwerens et al. [109] focused on minimally invasive therapies (e.g., ESWT, radial SWT, transcutaneous electronic nerve stimulation (TENS), and ultrasound-guided percutaneous needling, laser therapy, and ultrasound therapy) for the management of chronic calcific tendinopathy of the rotator cuff. They

explored the short-term and mid-term effectiveness of these therapies. The primary outcome of interest was shoulder function and secondary outcomes of interest were pain and change in the size of the calcific deposits. With regards to ESWT, since there is no universal agreement on the thresholds for high-energy and low-energy ESWT, the authors chose energy flux density (EFD) of <0.20 mJ/mm2 as low-energy and >0.20 mJ/mm2 as high-energy ESWT. The authors used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines when conducting this review. The literature search was done using Medline, Cochrane Database of Systematic Reviews, Cochrane Clinical Trial Register, PEDro, CINAHL, and Embase. Methodological quality of the selected RCTs, quasi-randomized controlled (qRCT), and controlled clinical trials (CCT) was evaluated using six criteria (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias) recommended by the Cochrane Review Group. The authors used Grades of Recommendation Assessment, Development and Evaluation (GRADE) for the overall quality of evidence for each outcome. In total, 20 studies were reviewed. Different functional outcomes were quantitatively evaluated including the data on three and six months after the treatment. For most of the outcomes, there was only one study. When the analysis for ESWT was considered, the effect size for five studies comparing high ESWT versus low ESWT was 7.02. Three studies compared high ESWT vs placebo/sham treatment for function at 3 months and the effect size was 17.14. Low ESWT vs placebo/sham treatment was compared in two studies and displayed a 5.94 effect size. High-energy ESWT and ultrasound-guided needling combined was more effective than high-energy ESWT alone with an effect size of 9.50, and ESWT focused on calcific deposit vs greater tubercle had a 31.51 effect size, ESWT focused on calcific deposit vs point of maximum pain had an effect size of 12.72. Studies focusing on outcomes at six months after the treatment also found various effect sizes (e.g., the effect size for high ESWT vs placebo/sham treatment from three studies was 22.75). All these ESTW-related effect sizes pointed to moderate-quality evidence, overall. The other minimally invasive therapies displayed variable-quality GRADE evidence.

- Following their systematic review/meta-analysis in 2014, in 2016 Louwerens et al. [110] undertook a systematic review specifically on ESWT, ultrasound-guided needling, and arthroscopic surgery in the management of chronic calcific rotator cuff tendinopathy. The authors used the PRISMA Guidelines and searched Medline, Embase, CINAHL, Cochrane, PEDro, and SPORTDiscus databases. Out of 942 citations (of which 466 were duplicates) 22 papers were selected for the review based on the predetermined inclusion/exclusion criteria. Eleven of the selected studies were RCTs, one was a prospective non-RCT, six were prospective cohort studies, and four were retrospective cohort studies. The two reviewers were not blinded when evaluating the articles. The methodological quality of each study was assessed using the Coleman Methodology Scoring system (scores between 0 and 100). The Coleman score for studies ranged from 61 to 94, with a mean score of 77.1. Outcomes of interest were pain, shoulder function, and calcific resorption following the treatment. At this time, the authors defined high-energy ESWT as EFD >0.20 mJ/mm2 and included only studies that used high-energy ESWT. The quantitative analysis included a comparison of the baseline outcome of interest scores with the scores in the follow-up period (e.g., 6 months 1 year 2 years, >2 years >5 years). Outcome measures included Constant-Murley Scale score (CMS), Disabilities of the Arm, Shoulder and Hand (DASH) score, Shoulder Pain and Disability Index (SPADI), Simple Shoulder Test (SST), University of California, Los Angeles (UCLA) score, Western Ontario Rotator Cuff (WORC) index, American Shoulder and Elbow Surgeons (ASES) score. The most utilized outcome measure for shoulder function was the Constant Murley Scale (CMS), as well as the measurements of resorption/change in the size of calcifications. The authors explained the techniques of each treatment methods (i.e., ESWT, ultrasound-guided

needling, arthroscopic surgery) highlighting pros and cons for each and concluded that all three treatments resulted in good to excellent clinical outcomes for calcific tendinopathy of the shoulder, especially for the long term. However, they pointed out that the pooling of the results for a meta-analysis was not possible due to the heterogeneity in the treatment protocols and the methodologic quality of the included studies. They stated that only the studies on ESWT offered Level-1 evidence, whereas the studies on ultrasound-guided needling and arthroscopic surgery had Level-4 evidence. The authors also pointed to the debate on whether good clinical results and resorption of the calcifications with these three treatments were in fact due to the natural course of the calcific tendinopathies.

- Simpson et al. [111] conducted a systematic review of non-surgical interventions for calcific tendinopathy of the rotator cuff in adult patients. Five interventions were identified through the searches, i.e., ESWT, ultrasound-guided percutaneous intervention, pulsed ultrasound, acetic acid iontophoresis, and transcutaneous electrical nerve stimulation. Besides single, uni-modal non-surgical interventions (placebo/sham trials) bi-modal ones (inter-modality comparisons) were also considered to reflect common clinical practice. In addition, studies comparing different parameters (dose, duration, frequency, techniques) within the same treatment modality (intra-modality comparisons) were also included. The searches were undertaken using Medline, EMBASE, CINAHL, Cochrane Register of Clinical Trials, PEDro, and SPORTDiscus databases to find relevant RCTs. Outcomes of interest were the short- (0-12 weeks), medium- (13-52 weeks), and long-term (≥ 1 year) pain, shoulder function, and change in calcific morphology related to the rotator cuff calcific tendinopathy. Due to the heterogeneity of outcome measures used across studies, a meta-analysis was not attempted. In total, 2085 citations were identified, and 18 studies were selected for the review. However, based on the domain-based (random sequence generation, allocation concealment, effective blinding, and whether outcomes were pre-specified, analyzed, and reported appropriately) Cochrane tool for evaluating RCTs, all carried a high risk of bias. For methodological quality, other aspects such as sample size, co-interventions and compliance, and validity or generalizability were also evaluated. A meta-analysis was not performed because of the heterogeneity in treatments, dosages, frequencies, and outcomes in the primary studies. When findings were consistent across multiple high-quality RCTs the authors categorized the level of evidence as 'strong'. When findings from one high-quality RCT and one (or more) low-quality RCTs, or across multiple low-quality RCTs were consistent the level of evidence was categorized as 'moderate'. When findings were from only one RCT (of high or low quality) or were inconsistent across multiple RCTs, the level of evidence was categorized as 'limited' or 'conflicting'. With regards to ESWT, the authors reported that there was moderate evidence in favour of high-energy ESWT compared to low-energy ESWT for pain and function in the follow-up periods of three months and six months. Also, when compared to placebo ESWT displayed improved function up to 6 months follow-up. In reducing pain and changing calcific morphology (in a positive way), the evidence that ultrasound-guided percutaneous intervention worked better than the medium/high-energy ESWT over a one-year period was moderate. Due to high heterogeneity across studies and concerns about the methodological quality of many, the authors were not able to generate recommendations. They reported that even if high-energy ESWT seemed to be the most effective non-surgical modality compared to placebo in treating calcific rotator cuff tendinopathy in the first six months, there was no strong evidence in favour of any of the treatment modalities studied.
- Another systematic review was undertaken by Speed et al. [112] to explore the effectiveness of two types of shock wave therapies, focused extracorporeal shockwave therapy (F-ESWT) and radial pulse therapy (RPT), in treating various soft tissue

musculoskeletal conditions. The authors focused on the literature from 1980 to 2012. All studies were included unless they met any of the exclusion criteria (uncontrolled studies and those which did not have an appropriate sham treatment control, those with methodological shortcomings, such as lack of formal randomization process, differing baseline characteristics of study and control groups, mixed study populations, unblinded study subjects, inappropriate statistical analysis or lacking explanations, unvalidated outcome measures, follow-up issues, and total sample size <40). The musculoskeletal conditions included were plantar fasciitis, Achilles tendinopathies, calcific tendinopathy of the rotator cuff, non-calcific rotator cuff tendinosis, and lateral epicondylitis. There seems to be confusion with the numbers of the included studies. The authors have stated different numbers in different sections of the review (e.g., 26 studies in the 'results' section, 24 in the flow chart, and 23 in the abstract). The US Preventative Tasks Force Classification was used to determine the levels of evidence. Based on these selected studies, the authors reported the evidence on both F-ESWT and RPT to be safe and beneficial in a number of soft tissue musculoskeletal conditions. Out of five studies related to rotator cuff tendinopathies three were on calcific tendinopathy and used focused ESWT. Two were single-blind RCTs applying high-energy ESWT, and one was a multi-center study testing high-energy and low-energy ESWTs vs sham. The authors stated that there was level 1 evidence of effectiveness for midterm (at least 6 months) focused ESWT. The effect was more pronounced for high-energy ESWT in improving shoulder function and pain for patients with chronic calcific tendinopathy. However, the authors highlighted some limitations in the ESWT research area. For example, the practice of combining several outcome measures into one measure (composite scores), small sample sizes usually with no power calculations provided, increased chances of bias due to industry research sponsorship, as well as disproportionally higher availability/access for studies with positive results. On a positive note, the authors highlighted the safety record of the ESWT applications.

- A Cochrane systematic review was undertaken by Surace et al. in 2020. [113] They studied the efficacy of ESWT for rotator cuff disorders with or without calcification. The search was done using Ovid MEDLINE, Ovid Embase, CENTRAL, ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform (ICTRP) to locate RCTs and controlled clinical trials (CCTs) comparing ESWT to other interventions. Based on the predetermined criteria 32 trials were included, of which 25 included patients with a calcific rotator cuff disease, five included patients with no calcification and the remaining two had both calcific and non-calcific rotator cuff disease patients. The primary comparison was ESWT compared to placebo (12 trials) at three-month follow-up. In eleven trials high-energy was compared to low-energy ESWT. Other comparisons included ESWT vs ultrasound-guided glucocorticoid needling, ultrasound-guided hyaluronic acid injection, transcutaneous electric nerve stimulation (TENS), and no treatment or exercise. Certainty of evidence was assessed using GRADE. The authors reported that the risk of bias was high in included studies (e.g., selection, performance, detection, and selective reporting biases). The pain-related outcomes were pain relief (% 8), and mean pain of 2.2 in the ESWT group and 3 in the placebo group (0 to 10 scale, higher scores pointing to more pain). The function-related outcome was improved by 8%, mean function was at 74 points in the ESWT group and 66 in the placebo group (0 to 100 scale, with higher scores meaning better function). Participant reported success was expressed by 15% more of the participants in the treatment group, (41% in ESWT and 26% in the placebo group), but quality of life was not measured in any of the trials. Withdrawal or adverse event rates were not different in ESWT and placebo groups, but there was uncertainty due to the small sample sizes of the primary studies. In terms of between-group differences in patients with and without calcific deposits, the authors did not find any difference with regard to pain and function outcomes. The authors

concluded that there was low-certainty to moderate-certainty evidence to support the limited clinical benefits of ESWT, and its safety was uncertain. There was a wide clinical diversity and heterogeneity in treatment protocols, which might have led to an underestimation of potential benefits. The authors suggested that standard dose and treatment protocols should be agreed on before further research on the topic and a designated core set of outcomes would help synthesize the evidence.

- The only RCT we located which was not part of the systematic reviews/meta-analyses included in this review was by Fatima et al. [99] They recruited 42 patients in total who were affected by rotator cuff calcific tendinopathy (21 in treatment and 21 control groups). The control group received routine physical therapy (RPT) and the treatment group received both ESWT and RPT. High-energy ESWT was applied (2000 shockwaves of 0.32 mJ/mm2 per treatment) in two sessions per week for six weeks. The authors had baseline inclusion criteria (age 30 to 65, pain and limited range of motion (ROM) pain in shoulder, symptoms lasting for three months, positive Neer's impingement test, calcific changes (types A and B, >10 mm) in the rotator cuff through ultrasound). For the random allocation of patients to the treatment and control groups, they used a computer-generated randomization method. Both the assessor and statistician were blinded, but the physiotherapist was not. Pain intensity (the numeric pain rating scale (NPRS)), shoulder functional ability (Constant-Murley score (CMS)), calcific changes (ultrasonography), and quality of life (Western Ontario rotator cuff index (WORC)) were assessed. Two patients dropped out and 40 patients completed the trial. The authors reported that there was a significant reduction in pain intensity, size of calcific deposits, functional activity, and quality of life in both treatment and control groups. There were statistically significant differences reported for NPRS and CMS at different time points compared to baseline values. The authors referred to the limitations of their study (e.g., small sample size and generalizability issues, short follow-up period of 12 weeks, and lack of more detailed/repeated measurements). However, they concluded that the shockwave therapy was superior to routine physiotherapy in their follow-up period of 12 weeks.

Summary

- The preferred treatment for calcific tendinopathy of the rotator cuff is a topic of debate.
- Most of the studies are comparing ESWT with placebo/sham. And there is a lack of studies with high-level evidence comparing ESWT with other treatment modalities.
- There is a large heterogeneity across studies regarding treatment protocols (e.g., follow-up period, type (focused or radial) and intensity (energy flux density (EFD) of shockwaves, dosage (high- vs low-energy), number of sessions and interval between, if used details of analgesia and cointerventions).
- Due to this heterogeneity across study protocols a number of studies might have applied subtherapeutic doses and potentially might have underestimated the likely benefits of ESWT.
- Since most of the studies comparing ESWT low to high energy doses found that higher doses provided better outcomes, a 'dose dependency' is considered for ESWT.
- In several systematic reviews a quantitative synthesis with a meta-analysis was not possible because of the heterogeneity in treatment protocols, different outcome measures used, and inadequate reporting details of the primary studies.
- With the current low-to-moderate-level evidence for its effectiveness, ESWT can be used as an alternative before surgery when conservative treatments (e.g., nonsteroidal anti-inflammatory drugs, steroidal injections, and physiotherapy) fail to relieve symptoms of the calcified rotator cuff tendinopathy in patients suffering from significant pain and functional limitations.

- Currently, there are few ESWT studies with a follow-up period beyond one year.
- As a minimally invasive therapy, the cost of ESWT is higher than conservative treatment modalities, and slightly lower than arthroscopic surgery.
- It is claimed that there are few clinically important benefits of ESWT and there is uncertainty about its safety.
- With regards to the chronic symptomatic calcium deposits, there is a chance that occasionally they can spontaneously heal within a few weeks without any treatment application.
- In conclusion, according to our review, the current evidence level for the effectiveness of ESWT is moderate. In the future, to ensure higher quality research studies with clearly defined study populations, presenting reliable control groups (e.g., placebo/sham controls), with larger sample sizes to ensure adequate statistical power, using validated outcome measures, with better methodologic design using standardized treatment protocols (e.g., standard dosage, energy flux density) and with longer follow-up periods with minimum loss to follow-up, and presenting results with effect sizes (for a greater insight for the clinician) are required.

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Appendix 1

WorkSafeBC — Evidence-Based Practice Group levels of evidence (adapted from 1-6)

1	Experimental, randomized controlled trial (RCT), systematic review RTCs with or without meta-analysis.
2	Evidence from controlled trials without randomization (quasi-experimental studies) or systematic reviews of observational studies.
3	Evidence from cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees based on scientific evidence.

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Appendix 2

Flow Chart