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Shock wave therapy for rotator cuff disease with or without calcification (Review)

Surace SJ, Deitch J, Johnston RV, Buchbinder R

Surace SJ, Deitch J, Johnston RV, Buchbinder R.
Shock wave therapy for rotator cuff disease with or without calcification.
Cochrane Database of Systematic Reviews 2020, Issue 3. Art. No.: CD008962.
DOI: 10.1002/14651858.CD008962.pub2.

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[Intervention Review]

Shock wave therapy for rotator cuff disease with or without calcification

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Editorial group: Cochrane Musculoskeletal Group.
Publication status and date: New, published in Issue 3, 2020.

Citation: Surace SJ, Deitch J, Johnston RV, Buchbinder R. Shock wave therapy for rotator cuff disease with or without calcification. *Cochrane Database of Systematic Reviews* 2020, Issue 3. Art. No.: CD008962. DOI: 10.1002/14651858.CD008962.pub2.

ABSTRACT

Background

Shock wave therapy has seen widespread use since the 1990s to treat various musculoskeletal disorders including rotator cuff disease, but evidence of its efficacy remains equivocal.

Objectives

To determine the benefits and harms of shock wave therapy for rotator cuff disease, with or without calcification, and to establish its usefulness in the context of other available treatment options.

Search methods

We searched Ovid MEDLINE, Ovid Embase, CENTRAL, ClinicalTrials.gov and the WHO ICTRP up to November 2019, with no restrictions on language. We reviewed the reference lists of retrieved trials to identify potentially relevant trials.

Selection criteria

We included randomised controlled trials (RCTs) and controlled clinical trials (CCTs) that used quasi-randomised methods to allocate participants, investigating participants with rotator cuff disease with or without calcific deposits. We included trials of comparisons of extracorporeal or radial shock wave therapy versus any other intervention. Major outcomes were pain relief greater than 30%, mean pain score, function, patient-reported global assessment of treatment success, quality of life, number of participants experiencing adverse events and number of withdrawals due to adverse events.

Data collection and analysis

Two review authors independently selected studies for inclusion, extracted data and assessed the certainty of evidence using GRADE. The primary comparison was shock wave therapy compared to placebo.

Main results

Thirty-two trials (2281 participants) met our inclusion criteria. Most trials (25) included participants with rotator cuff disease and calcific deposits, five trials included participants with rotator cuff disease and no calcific deposits, and two trials included a mixed population of participants with and without calcific deposits.

Twelve trials compared shock wave therapy to placebo, 11 trials compared high-dose shock wave therapy (0.2 mJ/mm^2 to 0.4 mJ/mm^2 and above) to low-dose shock wave therapy. Single trials compared shock wave therapy to ultrasound-guided glucocorticoid needling, ultrasound-guided hyaluronic acid injection, transcutaneous electric nerve stimulation (TENS), no treatment or exercise; dual session

shock wave therapy to single session therapy; and different delivery methods of shock wave therapy. Our main comparison was shock wave therapy versus placebo and results are reported for the 3 month follow up.

All trials were susceptible to bias; including selection (74%), performance (62%), detection (62%), and selective reporting (45%) biases.

No trial measured participant-reported pain relief of 30%. However, in one trial (74 participants), at 3 months follow up, 14/34 participants reported pain relief of 50% or greater with shock wave therapy compared with 15/40 with placebo (risk ratio (RR) 1.10, 95% confidence interval (CI) 0.62 to 1.94); low-quality evidence (downgraded for bias and imprecision). Mean pain (0 to 10 scale, higher scores indicate more pain) was 3.02 points in the placebo group and 0.78 points better (0.17 better to 1.4 better; clinically important change was 1.5 points) with shock wave therapy (9 trials, 608 participants), moderate-quality evidence (downgraded for bias). Mean function (scale 0 to 100, higher scores indicate better function) was 66 points with placebo and 7.9 points better (1.6 better to 14 better, clinically important difference 10 points) with shock wave therapy (9 trials, 612 participants), moderate-quality evidence (downgraded for bias). Participant-reported success was reported by 58/150 people in shock wave therapy group compared with 35/137 people in placebo group (RR 1.59, 95% CI 0.87 to 2.91; 6 trials, 287 participants), low-quality evidence (downgraded for bias and imprecision). None of the trials measured quality of life.

Withdrawal rate or adverse event rates may not differ between extracorporeal shock wave therapy and placebo, but we are uncertain due to the small number of events. There were 11/34 withdrawals in the extracorporeal shock wave therapy group compared with 13/40 withdrawals in the placebo group (RR 0.75, 95% CI 0.43 to 1.31; 7 trials, 581 participants) low-quality evidence (downgraded for bias and imprecision); and 41/156 adverse events with extracorporeal shock wave therapy compared with 10/139 adverse events in the placebo group (RR 3.61, 95% CI 2.00 to 6.52; 5 trials, 295 participants) low-quality evidence (downgraded for bias and imprecision).

Subgroup analyses indicated that there were no between-group differences in pain and function outcomes in participants who did or did not have calcific deposits in the rotator cuff.

Authors' conclusions

Based upon the currently available low- to moderate-certainty evidence, there were very few clinically important benefits of shock wave therapy, and uncertainty regarding its safety. Wide clinical diversity and varying treatment protocols means that we do not know whether or not some trials tested subtherapeutic doses, possibly underestimating any potential benefits.

Further trials of extracorporeal shock wave therapy for rotator cuff disease should be based upon a strong rationale and consideration of whether or not they would alter the conclusions of this review. A standard dose and treatment protocol should be decided upon before further research is conducted. Development of a core set of outcomes for trials of rotator cuff disease and other shoulder disorders would also facilitate our ability to synthesise the evidence.

PLAIN LANGUAGE SUMMARY

Shock wave therapy for rotator cuff disease with or without calcification

Background

Rotator cuff disease is the most common cause of shoulder pain, especially at night and when lifting the arm above the head. Calcium deposits may form on the tendons in the shoulder joint.

Shock wave therapy passes sound or shock waves through the skin to the affected area, and may break up calcium deposits. There is currently no standard dose or treatment regimen.

Review question

In people with rotator cuff disease with or without calcific deposits, what are the benefits and harms of shock wave therapy compared to placebo (pretend) or other available treatments?

Study characteristics

We included 32 trials (2281 participants), published up to November 2019.

Twelve trials compared shock wave therapy to placebo. Eleven trials compared high- and low-dose shock wave therapy, although dosages varied across trials. Single trials compared shock wave therapy to other treatments including ultrasound-guided glucocorticoid needling, transcutaneous electric nerve stimulation (TENS), exercise, or no treatment; or different regimens of shock wave therapy.

Overall, 61% of participants were women, the average age was 52 years, and the average duration of the condition was 33 months. Two trials were funded by manufacturers of shock wave machines.

Key results for the primary comparison, shock wave therapy versus placebo

Participant-reported pain relief of 50% or greater (one trial):

• four more people out of 100 reported pain relief of 50% or more (ranging from 19 fewer to 26 more).

42 out of 100 people reported pain relief of 50% or greater with shock wave therapy compared with 38 out of 100 with placebo.

Pain (higher scores mean more pain) (nine trials):

• Improved pain by 8% (ranging from 2% better to 14% better) or 0.78 points better (ranging from 0.17 better to 1.4 better) on a 0- to 10-point scale.

People who had shock wave therapy rated their pain as 2.2 points and people who had placebo rated their pain as 3 points.

Function (ability to use the shoulder; higher scores meanbetter function) (nine trials):

• Improved by 8% (ranging from 1.6% to 14%) or 8 points better (ranging from 1.6 better to 14 better) on a 0- to 100-point scale.

People who had shock wave therapy rated their function as 74 points and people who had placebo rated their function as 66 points.

Participant-reported success (six trials):

• 15% (ranging from 3% fewer to 49% more) more people reported their treatment a success.

41 out of 100 people reported treatment success with shock wave therapy and 26 out of 100 people reported treatment success with placebo.

Withdrawals due to side effects (seven trials):

• 3% fewer (ranging from 6% fewer to 3% more) people withdrew from treatment due to side effects.

8 out of 100 people withdrew from treatment with shock wave therapy and 10 out of 100 people withdrew from the placebo group.

Side effects (five trials):

• 19% more people reported side effects (ranging from 7% more to 40% more):

26 out of 100 people had a side effect with shock wave therapy and seven out of 100 people had a side effect with placebo.

Certainty of the evidence

In people with rotator cuff disease, moderate-certainty evidence (downgraded due to bias) shows that shock wave therapy probably does not improve pain and function compared with placebo, and low-certainty evidence (downgraded due to bias and lack of accuracy) shows there may be no improvement in those with a pain reduction of 50% or more and participant-reported success. We are uncertain if withdrawals or side effects differed between groups due to small number of events. It did not appear to matter if participants had calcific deposits or not. We are uncertain if higher doses of shock wave therapy have benefits with more side effects compared with lower doses, as there was only low- or very low-certainty evidence available, and we cannot recommend a particular treatment dose.

Side effects included treatment-related pain, bruising and bleeding although these were generally minor and short-lived. Rare and serious side effects, including loss of blood supply and bone death, while possible, were not reported.

Summary of findings for the main comparison. Shock wave therapy versus placebo for rotator cuff disease with or without calcification

Shock wave therapy for rotator cuff disease with or without calcification at 3 months

Patient or population: rotator cuff disease with or without calcification
Setting: outpatient clinic
Intervention: shock wave therapy
Comparison: placebo therapy

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with shock wave therapy				
Pain relief > 50%[a] Follow-up: 3 months	375 per 1000	413 per 1000 (232 to 728)	**RR 1.10** (0.62 to 1.94)	74 (1 study)	⊕⊕⊖⊖ **Low**[b,c]	Shockwave therapy may provide no improvement in the number of participants with a pain reduction of 50% or more. Absolute change 4% more had relief (19% fewer to 26% more); relative change 10% more had relief (38% fewer to 94% more); NNTB: NA[d]
Pain Multiple scales[e] translated to VAS 0–10 (10 was severe pain)[f] Follow-up: 3 months	Mean pain in the control group was **3.02 points**[g]	Mean pain in the intervention group was **0.78 points better** (0.17 better to 1.4 better)	**SMD −0.49** (95% CI −0.88 to −0.11)	608 (9 studies)	⊕⊕⊕⊖ **Moderate**[h]	Shockwave therapy probably results in little or no clinically important improvement in pain. Mean pain did not appear to differ in participants with and without calcification: test for subgroup differences: $Chi^2 = 0.25$, df = 1 (P = 0.62), $I^2 = 0\%$ Absolute change 8% better (2% to 14% better); relative change 14% better (3% better to 25% better);[i] NNTB: 4 (95% CI 2 to 34)[d]
Function Multiple scales[e] translated to Constant 0–100 scale (100 was best function)f	Mean function in the control group was **66 points**[g]	Mean function in the intervention group was **7.9 points better** (1.6 better to 14 better)	**SMD 0.62** (95% CI 0.13 to 1.11)	612 (9 studies)	⊕⊕⊕⊖ **Moderate**[j]	Shockwave therapy probably results in little or no clinically important improvement in function. Mean function did not appear to differ in participants with and without calcification: test for subgroup differences: $Chi^2 = 1.00$, df = 1 (P = 0.32), $I^2 = 0.1\%$ Absolute change: 8% better (1.6% to 14% better); relative change 12% better (3% to 22% better);[i] NNTB: 3 (95% CI 2 to 18)[d]

Follow-up: 3 months						
Participant-reported success Follow-up: end of studies	255 per 1000	406 per 1000 (222 to 743)	**RR 1.59** (0.87 to 2.91)	287 (6 studies)	⊕⊕⊖⊖ **Low**[b,c]	Shockwave therapy may provide no improvement in the number of participants reporting treatment success. Absolute change 15% more had success (3% fewer to 49% more); relative change 59% more (13% fewer to 191% more); NNTB: NA[d]
Quality of life	—	—	—	—	—	Not measured
Number of participant withdrawals due to adverse events or treatment intolerance	103 per 1000	77 per 1000 (44 to 135)	**RR 0.75** (0.43 to 1.31)	581 (7 studies)	⊕⊕⊖⊖ **Low**[b,c]	We are uncertain if shockwave therapy increases withdrawal rates. Absolute change 3% less events (6% less to 3% more); relative change 25% less (57% less to 31% more); NNTH: NA[d]
Number of participants experiencing any adverse event Follow-up: 12 months	72 per 1000	260 per 1000 (144 to 469)	**RR 3.61** (2.00 to 6.52)	295 (5 studies)	⊕⊕⊖⊖ **Low**[b,c]	We are uncertain if shockwave therapy increases adverse events. Absolute difference: 19% more events (7% more to 40% more); relative change: 261% more (100% more to 552% more); NNTH: NA[d]

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: confidence interval; **NA:** not applicable; **NNTB:** number needed to treat for an additional beneficial outcome; **RR:** risk ratio; **SMD:** standardised mean difference; **VAS:** Visual Analogue Scale.

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]The a priori outcome was pain relief 30% or greater, which was not reported in any studies; thus we reported pain relief 50% or greater.
[b] Downgraded one level due to study limitations (including risk of selection, detection, attrition, and reporting bias).
[c]Downgraded one level for imprecision due to wide confidence intervals, or small number of participants or small number of events.

[d]Number needed to treat for an additional beneficial outcome (NNTB), or an additional harmful outcome (NNTH) not applicable (n/a) when result is not statistically significant. NNTB or NNTH for dichotomous outcomes calculated using Cates NNT calculator (www.nntonline.net/visualrx/). NNTB or NNTH for continuous outcomes calculated using Wells Calculator (CMSG editorial office), with an assumed minimal clinical important difference for pain of 1.5 points on 0 to 10 VAS, and for function of 10 points on 0 to 100 Constant score.

[e]Pain scores: VAS 0 to 10, VAS 0 to 100, Constant Score 0 to 15 (also called Constant score); function scores: Constant-Murley 0 to 100, Shoulder Pain And Disability Index 0 to 100.

[f]Translated from SMD and 95% CIs to 0 to 10 VAS for pain and 0 to 100 Constant scale for function by multiplying the SMD by the standard deviation (SD) at baseline in the placebo group from Gerdesmeyer 2003 (values were mean (SD) VAS pain 5.6 (1.6), and mean Constant score (SD) 64.2 (12.8).

[g]Control group mean (SD) values at 3 months' follow-up from Gerdesmeyer 2003: values were 3.8 (2.3) on 0 to 10 VAS pain; 74 (15.5) on 0 to 100 Constant function score.

[h] Downgraded one level due to study limitations (including risk of selection, detection, and attrition bias). Although this outcome had a high I^2 (80%), the outcome was not downgraded for inconsistency. This high I^2 was due to one outlier,Hsu 2008 and removing this outlier removes the statistical heterogeneity (I^2 = 0%) and does not change the direction of the effect

[i]Relative changes calculated as absolute change (mean difference) divided by mean at baseline in the control group from Gerdesmeyer 2003 (values were 5.6 on 0 to 10 point VAS pain; 64.2 on 0 to 100 Constant score).

[j]Downgraded one level due to study limitations (including risk of selection, detection, and attrition bias), and one level due to inconsistency (I^2 = 91%). Removing the potential extreme outlier reported in Hsu 2008 still left considerable heterogeneity (I^2 = 72%), additional removal of another, less extreme outlier (Cosentino 2003) resulted in I^2 = 38%. As we could explain the heterogeneity, we did not downgrade the certainty further.

BACKGROUND

Description of the condition

Shoulder disorders are common, with a reported prevalence ranging from 7% to 26% in adults (Luime 2004). Shoulder problems account for 1.3% of all general practice encounters in Australia (Britt 2016), and up to 14% of all referrals to physiotherapists in the UK (May 2003). Shoulder pain persists or recurs in 40% of people within one year after their first visit to a primary care physician (van der Windt 1996), and has a substantial impact upon quality of life (MacDermid 2004; Taylor 2005).

Rotator cuff disease is the most common cause of shoulder pain seen by physicians (Ostor 2005), and is estimated to occur in up to 50% of people aged 75 years or over (Urwin 1998). The incidence is expected to rise with the ageing of the population (Gomoll 2004). A wide range of pathophysiological conditions are included under the umbrella term of 'rotator cuff disease', including rotator cuff tendonitis or tendinopathy, supraspinatus, infraspinatus or subscapularis tendonitis, subacromial bursitis, and partial and complete rotator cuff tears. There is no uniformity in how these conditions are labelled and defined (Green 1998; Lewis 2009). Among published controlled trials for rotator cuff disease, the definition most commonly used is based on clinical features and includes the presence of positive impingement signs including a painful arc and pain with resisted movements or normal passive range of movement (ROM) (Green 1998).

The pathophysiology of rotator cuff disease has traditionally been viewed as a continuum that ranges from impingement syndrome to partial- and full-thickness rotator cuff tears (Neer 1983). While it is commonly believed that intrinsic degeneration of the rotator cuff tendons together with repetitive microtrauma contribute to its development (Ogata 1990), it is probably multifactorial, and many conflicting theories have been presented (Lewis 2007). Based on magnetic resonance imaging (MRI) scans, asymptomatic partial and full-thickness rotator cuff tears have been demonstrated in 4% of people aged less than 40 years and in more than 50% of people aged more than 60 years (Sher 1995). It is currently not known how many asymptomatic rotator cuff tears will subsequently become symptomatic. For example, one study of people aged 50 to 80 years who presented with unilateral shoulder pain and had the contralateral shoulder examined by ultrasound suggested that 50% of asymptomatic rotator cuff tears become symptomatic within five years (Yamaguchi 2001). Another study in asymptomatic young elite athletes aged 18 to 38 years participating in sports involving the shoulder, none of the eight athletes with partial or full-thickness tears found on MRI had developed symptoms five years later (Connor 2003).

The diagnosis of rotator cuff disease in primary care is predominantly made by history and physical examination. People may present with impingement-type symptoms, pain at night and at rest, and painful movement, with or without features of a torn rotator cuff tendon such as painful weakness and atrophy. The diagnostic utility of various physical examination tests is limited (Hegedus 2008); however, rotator cuff disease is usually distinguishable from adhesive capsulitis by the lack of global restriction of movement. Imaging techniques are also limited in their usefulness for diagnosis. X-rays may exclude other causes of shoulder pain such as glenohumeral osteoarthritis, calcific tendinitis indicated by the presence of calcific deposits situated just proximal to the rotator cuff insertion in the setting of acute onset of pain, or an acromial spur that might impinge on the rotator cuff. Elevation of the humeral head, together with narrowing of the subacromial space, might indicate the presence of a large rotator cuff tear (Weiner 1970). Imaging modalities such as ultrasound and MRI are able to detect full thickness rotator cuff tears but have less accuracy for detection of partial-thickness tears (Dinnes 2003; Lewis 2007).

Description of the intervention

The objectives of treatment of symptomatic rotator cuff disease are to relieve pain and restore movement and function of the shoulder. Conservative treatments include corticosteroid injections (Buchbinder 2003), analgesics (Paoloni 2005), non-steroidal anti-inflammatories (NSAIDs) (Green 1999), and physical modalities including exercise (Page 2016a; Page 2016b). Topical glyceryl trinitrate has also been proposed as a treatment (Cumpston 2009). These treatments may be used in combination or sequentially. Surgery (decompression with or without rotator cuff repair) is usually reserved for people who do not respond to non-operative treatment (Karjalainen 2019a; Karjalainen 2019b).

Shock wave therapy can be either extracorporeal or radial. Extracorporeal shock wave therapy (ESWT) is a non-invasive treatment that involves passing sound waves (or shock waves) through the skin to the affected area, sometimes used with ultrasound-guided positioning of the device. Shock waves are single pulsed acoustic or sonic waves, which dissipate mechanical energy at the interface of two substances with different acoustic impedance (Loew 1997). They are produced by generators of an electrical energy source and require an electroacoustic conversion mechanism and a focusing device (Ueberle 1997). Three types of systems can be distinguished based upon the sound source: electrohydraulic, electromagnetic and piezoelectric systems. Various doses appear to be used, with no apparent consensus on the minimum therapeutic dose. The definition that will be used throughout this review was defined by Cacchio 2006 as low-energy shock waves: less than 0.1 mJ/mm^2 and high-energy shock waves: 0.2 mJ/mm^2 to 0.4 mJ/mm^2).

Radial shock wave therapy (RSWT) is generated through the acceleration of a projectile inside the handpiece of the treatment device and then transmitted radially from the tip of the applicator to the target zone. Radial shock waves show a lower peak pressure and a considerably longer rise time than extracorporeal shock waves. In RSWT, the focal point is not centred on a target zone, as occurs in ESWT, but on the tip of the applicator (Cacchio 2006).

ESWT has been used since the 1990s to treat various musculoskeletal disorders, but evidence of its efficacy remains equivocal, with trials and reviews reporting conflicting results and there is no known standard dose and treatment protocol. Evidence from one Cochrane systematic review indicated that ESWT did not improve pain and function in lateral elbow pain (Buchbinder 2005; Buchbinder 2006), while another Cochrane Review reported that the evidence for heel pain was equivocal (Crawford 2003). In terms of safety, adverse effects that have been described include local erythema and pain although these are generally minor and short-lived and no serious adverse effects have been reported.

How the intervention might work

The mechanism of action of ESWT on damaged tendons is not understood. Possible mechanisms have been proposed including overstimulation of pain nerve fibre endings producing an analgesic effect (Melzack 1975; Rompe 1996), or disruption of the tendon tissue by the physical effects of the sound waves (or radial shock wave) resulting in induction of a healing process of the tendon (Loew 1997).

Why it is important to do this review

Despite widespread use of shock wave therapy, evidence of its effectiveness for rotator cuff disease is equivocal. Several systematic reviews have been published (Bannuru 2014; Ioppolo 2013; Vavken 2009; Verstraelen 2014). Three reviews only considered participants with calcific rotator cuff tendinitis (Ioppolo 2013; Vavken 2009; Verstraelen 2014). Vavken 2009 included 14 trials (995 participants) published up to 2008 and concluded that high-dose ESWT was effective for calcific tendinitis but noted that the conclusions were susceptible to bias. They did not separate placebo from other treatments in their pooled comparative analyses. Ioppolo 2013 included six trials published between 1992 and 2011 and reported that ESWT increased shoulder function, reduced pain and was effective in dissolving calcifications. Verstraelen 2014 included five trials (359 participants) that compared low- to high-energy shock wave therapy for calcific tendinitis and reported that high-energy shock waves resulted in greater benefits with respect to function and resorption of the calcific deposits at three months compared with low-energy shock waves. Bannuru 2014 included 28 trials (1745 participants) investigating different energy levels of ESWT for people with both calcific or non-calcific rotator cuff tendinitis. They were unable to perform any meta-analyses due to clinical heterogeneity but concluded that high-energy ESWT was only of benefit for improving pain and function in chronic calcific shoulder tendinitis. An updated high-quality systematic review is needed to synthesise all the available data up to the present day.

OBJECTIVES

To determine the benefits and harms of shock wave therapy for rotator cuff disease, with or without calcification, and to establish its usefulness in the context of other available treatment options.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) that used quasi-randomised methods to allocate participants, for example by date of birth, hospital record number or alternation. We included trials published in any language.

Types of participants

We included trials with participants described as having rotator cuff disease (rotator cuff tendonitis or tendinopathy, supraspinatus, infraspinatus or subscapularis tendonitis, subacromial bursitis or rotator cuff tears) with or without calcific deposits. We also planned to include studies of multiple soft tissue diseases and pain due to tendonitis in different parts of the body provided that the rotator cuff disease results were presented separately, or greater than 90% of participants in the study had rotator cuff disease, but we did not identify any such studies. We excluded RCTs that included participants with a history of significant injury or systemic inflammatory conditions such as rheumatoid arthritis.

Types of interventions

We included all randomised controlled comparisons of shock wave therapy (ESWT or RSWT) versus placebo, or another treatment, or of varying types and dosages of ESWT. Trials that included co-interventions were eligible for inclusion provided co-interventions were given to both experimental and control groups.

Types of outcome measures

There is considerable variation in the outcome measures reported in clinical trials of interventions for pain. For the purpose of this systematic review, we aimed to include clinically important changes in pain, as recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT). Reductions in pain intensity of 30% or greater reflect moderate clinically important differences and 50% or greater reflect substantial clinically important differences, and it is recommended that the proportion of patients who respond with these degrees of pain relief be reported (Dworkin 2008).

Continuous outcome measures in pain trials (such as mean change on a 100 mm Visual Analogue Scale (VAS)) may not follow a Gaussian distribution. Often, a bimodal distribution is seen instead, where patients tend to report either very good or very poor pain relief (Moore 2010). This creates difficulty in interpreting mean changes in continuous pain measures. For this reason, a dichotomous outcome measure (the proportion of participants reporting 30% or greater pain relief) is likely to be more clinically relevant and was the main outcome measure of benefit in this review. However, it is recognised that it has been the practice in most trials of interventions for chronic pain to report continuous measures and, therefore, the mean pain score or mean change in pain score were also included as major outcomes.

The pain state at the end of a clinical trial of an analgesic intervention, in contrast to measures of pain improvement, has also been recommended as a clinically relevant dichotomous outcome measure and was included as a secondary efficacy measure in this review (Moore 2010). A global rating of treatment satisfaction, such as the Patient Global Impression of Change scale (PGIC), which provides an outcome measure that integrates pain relief, changes in function and adverse effects, into a single, interpretable measure, is also recommended by IMMPACT, and was included as a major outcome (Dworkin 2008).

Major outcomes

We presented the major outcomes below in the 'Summary of findings' tables.

- Participant-reported pain relief of 30% or greater.
- Mean pain score, or mean change in pain score on VAS or Numerical Rating Scale (NRS) or categorical rating scale (in that order of preference).
- Disability or function. Where trialists reported outcome data for more than one function scale, we extracted data on the scale that was highest on the following an a priori consensus-based list:

- Shoulder Pain And Disability Index (SPADI);
- Shoulder Disability Questionnaire (SDQ);
- Constant score;
- Disabilities of the Arm, Shoulder and Hand (DASH);
- Health Assessment Questionnaire (HAQ);
- any other function scale.

- Composite endpoints measuring 'success' of treatment such as participants feeling no further symptoms.
- Quality of life.
- Number of participant withdrawals, for example, due to adverse events or intolerance to treatment.
- Number of participants experiencing any adverse event.

Minor outcomes

- Proportion of participants achieving pain score below 30/100 mm on VAS.
- ROM active preferred over passive measures: shoulder abduction, flexion, external rotation and internal rotation (measured in degrees or other; e.g. hand-behind-back distance in centimetres).
- For participants with calcification, the effect of ESWT on the size of the calcification.
- For participants with calcific deposits, the number of participants with complete or partial resolution (defined or not) of calcific deposits.

We extracted outcome measures assessing benefits of treatment (e.g. pain, function, success, quality of life) at the time points:

- up to six weeks;
- greater than six weeks to three months (this was the primary time point);
- greater than three months to up to six months;
- greater than six months to 12 months;
- greater than 12 months.

If data were available in a trial at multiple time points within each of the above periods (e.g. at four, five and six weeks), we only extracted data at the latest possible time point of each period. We extracted adverse events, calcification resolution and treatment success at the end of the trial.

Search methods for identification of studies

Electronic searches

We searched the following electronic databases, unrestricted by date or language, on 11 November 2019:

- the Cochrane Central Register of Controlled Trials (CENTRAL, via the Cochrane Library);
- MEDLINE (Ovid);
- Embase (Ovid);
- ClinicalTrials.gov;
- World Health Organization (WHO) International Clinical Trials Registry Platform.

For the database searches, we combined search terms and text words describing rotator cuff disease and ESWT for the CENTRAL search (Appendix 1), and with validated methodological filters designed to identify CCTs for the MEDLINE database (Appendix 2) (Lefebvre 2011), and the Embase database (Appendix 3). We searched ClinicalTrials.gov (Appendix 4) and the WHO International Clinical Trials Registry Platform (www.who.int/trialsearch/Default.aspx) (Appendix 5) for ongoing trials.

Searching other resources

We checked reference lists of all included articles for additional references.

Data collection and analysis

Selection of studies

Two review authors (SJS, JD) independently selected the trials to be included in the review and retrieved all articles selected by at least one of the review authors for further examination. The review authors were not blinded to the journal or authors. A third review author (RJ) resolved disagreement about inclusion or exclusion of individual studies.

Data extraction and management

Two review authors (SJS, JD) independently extracted data using a standard data extraction form developed for this review. The authors resolved any discrepancies through discussion or adjudication by a third author (RJ or RB), until we reached consensus. We pilot tested the data extraction form and modified it accordingly before use. In addition to items for assessing risk of bias and numerical outcome data, we extracted the following data.

- Trial characteristics, including type (e.g. parallel or cross-over), country, source of funding and trial registration status (with registration number recorded if available).
- Participant characteristics, including age, sex, duration of symptoms and inclusion/exclusion criteria.
- Intervention characteristics, including description of modality used, dose of treatment, method of administration, frequency of administration and use of co-interventions.
- Outcomes reported, including measurement instrument used and timing of outcome assessment.

Two review authors (SJS, JD) each independently compiled half of the comparisons and entered outcome data into Review Manager 5 (Review Manager 2014). The two review authors (SJS, JD) then independently checked the other author's work to ensure all data were accurate.

For a particular systematic review outcome there may be a multiplicity of results available in the trial reports (e.g. multiple scales, time points and analyses). To prevent selective inclusion of data based on the results (Page 2015), we used the following a priori defined decision rules to select data from trials.

- Where trialists reported both final values and change from baseline values for the same outcome, we extracted final values.
- Where trialists reported both unadjusted and adjusted values for the same outcome, we extracted unadjusted values.
- Where trialists reported data analysed based on the intention-to-treat (ITT) sample and another sample (e.g. per-protocol, as-treated), we extracted ITT-analysed data.
- For cross-over RCTs, we extracted data from the first period only.

Where trials did not include a measure of overall pain but included one or more other measures of pain, for the purpose of combining data for the primary analysis of overall pain, we combined overall pain with other types of pain in the following hierarchy:

- overall or unspecified pain;
- pain at rest;
- pain with activity;
- daytime pain;
- night-time pain.

Where trials included more than one measure of disability or function, we extracted data from the one function scale that was highest on the following a priori defined list:

- SPADI;
- SDQ;
- Constant score;
- DASH;
- HAQ;
- any other function scale.

Where trials included more than one measure of treatment success, we extracted data from the one function scale that was highest on the following a priori defined list:

- participant-defined measures of success, such as asking participants if treatment was successful;
- trialist-defined measures of success, such as a 30-point increase on the Constant Score.

For ROM, we only extracted active ROM (abduction or flexion) measured in number of degrees.

Assessment of risk of bias in included studies

Three review authors (SJS, JD, RJ) independently assessed the risk of bias of each included study. The authors resolved any discrepancies through discussion or adjudication by a fourth author (RB), until consensus was reached.

We assessed the following methodological domains, as recommended by Cochrane (Higgins 2011a):

- sequence generation (to determine if the method of generating the randomisation sequence was adequate, such as random-number tables, computer-generated random numbers, minimisation, coin tossing, shuffling of cards and drawing of lots);
- allocation sequence concealment (to determine if adequate methods were used to conceal allocation, such as central randomisation and sequentially numbered, sealed, opaque envelopes);
- blinding of participants and personnel;
- blinding of outcome assessors: we considered blinding of assessors of self-reported subjective outcomes (pain, function, success, quality of life) separately from assessors of more objective outcomes (such as calcification and adverse events);
- incomplete outcome data;
- selective outcome reporting;
- other potential threats to validity including baseline imbalance, unit of analysis issues, inappropriate or unequal application of co-interventions across treatment groups.

Measures of treatment effect

When possible, we based analyses on ITT data (outcomes provided for every randomised participant) from the individual trials. For each trial, we presented outcome data as point estimates with mean and standard deviation (SD) for continuous outcomes and risk ratios (RRs) with corresponding 95% confidence interval (CI) for dichotomous outcomes. Where possible, for continuous outcomes, we extracted end of treatment scores, rather than change from baseline scores.

For continuous data, we presented results as mean differences (MD), if possible. When studies used different scales to measure the same conceptual outcome (e.g. disability), we calculated standardised mean differences (SMD), with corresponding 95% CI. SMD was back-translated to a typical scale (e.g. 0 to 10 for pain) by multiplying the SMD by a typical among-person SD (e.g. the SD of the control group at baseline from the most representative trial) (Schünemann 2011a). For ESWT versus placebo, we converted pain (Analysis 1.2) to a 0- to 10-point VAS score using the SD reported at baseline in the placebo group from Gerdesmeyer 2003 (mean (SD): 5.1 (1.6)). For ESWT versus placebo, we converted function (Analysis 1.3) to a 0- to 100-point Constant scale using the SD reported at baseline in the placebo group from Gerdesmeyer 2003 (mean (SD): 64.2 (12.8)). For high-dose versus low-dose ESWT, we converted pain (Analysis 8.1) to a 0- to 10-point VAS score using the SD reported at baseline in the placebo group from Gerdesmeyer 2003 (mean (SD): 5.1 (1.6)). For high-dose versus low-dose ESWT, we converted function (Analysis 8.2) to a 0- to 100-point Constant scale using the SD reported at baseline in the placebo group from Gerdesmeyer 2003 (mean (SD): 64.2 (12.8)).

In the 'Comments' column of the 'Summary of findings' table, we reported the absolute percent difference and the relative percent change from baseline.

For dichotomous outcomes, we calculated the absolute risk difference using the risk difference statistic in Review Manager 5 (Review Manager 2014), and the result expressed as a percentage. For continuous outcomes, we calculated the absolute benefit as the improvement in the intervention group minus the improvement in the control group (MD), in the original units, and expressed as a percentage.

We calculated the relative percent change for dichotomous data as the RR – 1 and expressed as a percentage. For continuous outcomes, we calculated the relative difference as the absolute benefit divided by the baseline mean of the control group, expressed as a percentage.

Unit of analysis issues

Where a single trial reported multiple trial arms, we included only the relevant arms. For the comparison, ESWT versus placebo, if two different energy doses of shock wave therapy and a placebo or control arm were included in a three arm trial (Gerdesmeyer 2003; Peters 2004), we chose the lower dose shock wave therapy as the shock wave arm and compared this to placebo to avoid the data for that study population being over-represented in the meta-analysis. The rationale for choosing the lower dose was to reduce clinical

heterogeneity within the meta-analysis, as the lower dose seemed closer to the dose used in the active treatment group of the two arm trials, and there did not appear to be consensus for a definition of a clinical therapeutic dose.

Two trials treated two shoulders in a single participant without adjusting their analysis for the lack of independence (Pan 2003; Pleiner 2004). We reported this as a potential source of additional bias and assessed the impact of including these trials in a sensitivity analysis. When the data for these studies was extracted, the number of shoulders was taken as the population for the study.

If we had identified cross-over trials, we planned to extract data from the first phase of the trial to avoid potential carry over effects. If we had identified cluster-randomised trials that did not adjust for potential unit of analysis issues, we would note this and assess the effect of including studies with potential unit of analysis issues in a sensitivity analysis.

Dealing with missing data

Where data were missing or incomplete, we sought further information from the study authors.

In cases where participants were missing from the reported results, we assumed the missing values to have a poor outcome. For dichotomous outcomes that measured adverse events (e.g. number of withdrawals due to adverse events), we calculated the withdrawal rate using the number of participants who received treatment as the denominator (worst-case analysis). For dichotomous outcomes that measured benefits (e.g. proportion of participants with 30% or more reduction in pain), we calculated the worst-case analysis using the number of randomised participants as the denominator. For continuous outcomes (e.g. pain), we calculated the MD or SMD based on the number of participants analysed at the time point. If the number of participants analysed were not presented for each time point, we used the number of randomised participants in each group at baseline.

Where possible, we computed missing SDs from other statistics such as standard errors, CIs or P values, according to the methods recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). If SDs could not be calculated, they were imputed (e.g. from other studies in the meta-analysis (Higgins 2011c).

Assessment of heterogeneity

We assessed clinical heterogeneity by determining whether the characteristics of participants, interventions, outcome measures and timing of outcome measurement were similar across trials. We assessed statistical heterogeneity using the Chi^2 statistic and the I^2 statistic (Higgins 2002). We interpreted the I^2 statistic using the following as an approximate guide.

- 0% to 40% may not be important heterogeneity.
- 30% to 60% may represent moderate heterogeneity.
- 50% to 90% may represent substantial heterogeneity.
- 75% to 100% may represent considerable heterogeneity (Deeks 2011).

Assessment of reporting biases

To determine whether reporting bias was present, we determined whether the protocol of the RCT was published before recruitment of participants of the study was started. For studies published after 1 July 2005, we screened the WHO International Clinical Trials Registry Platform (apps.who.int/trialssearch). We evaluated whether selective reporting of outcomes was present (outcome reporting bias).

We compared the fixed-effect estimate against the random-effects model to assess the possible presence of small-sample bias in the published literature (i.e. in which the intervention effect is more beneficial in smaller studies). In the presence of small-sample bias, the random-effects estimate of the intervention is more beneficial than the fixed-effect estimate (Sterne 2011).

The potential for small-study effects in the main outcomes of the review were further explored using funnel plots if at least 10 studies were included in a meta-analysis for the main efficacy outcome.

Data synthesis

For clinically similar studies that used a common comparator, we pooled outcomes in a meta-analysis using the random-effects model as a default, and performed a sensitivity analysis with the fixed-effect model.

'Summary of findings' table

We created a 'Summary of findings' table using the following outcomes: pain relief greater than 50% (the a priori outcome was pain relief of 30% or greater, which none of the studies reported so we reported pain relief greater than 50%), mean pain score, function, participant-reported success, quality of life, number of participant withdrawals due to adverse events or treatment intolerance, and number of participants experiencing any adverse event. We selected three months as the primary time point (for the outcomes assessing benefits of treatment) and placebo as the main comparator.

All review authors independently assessed the certainty of the evidence. We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence as it related to the studies which contribute data to the meta-analyses for the prespecified outcomes. We used methods and recommendations described in Section 8.5, Section 8.7, Chapter 11 and Section 13.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a; Reeves 2011; Schünemann 2011b) using GRADEpro software (GRADEpro GDT 2015). We justified all decisions to downgrade the certainty of the studies using footnotes and made comments to aid the reader's understanding of the review where necessary.

Subgroup analysis and investigation of heterogeneity

We planned to carry out the following subgroup analyses:

- those with and without calcification.

We used the following outcomes in subgroup analyses, for the main comparison (ESWT versus placebo):

- pain;

- function.

Sensitivity analysis

We performed the following sensitivity analyses for the main comparator (ESWT vs placebo), for the outcomes pain and function:

- adequate allocation concealment (selection bias);
- participant blinding (detection bias).

We removed the trials that reported inadequate or unclear allocation concealment and lack of participant blinding from the meta-analysis of pain and function for the main comparison (ESWT versus placebo), at the primary time point (three months) to assess the effect of potential selection and detection biases on the overall treatment effect.

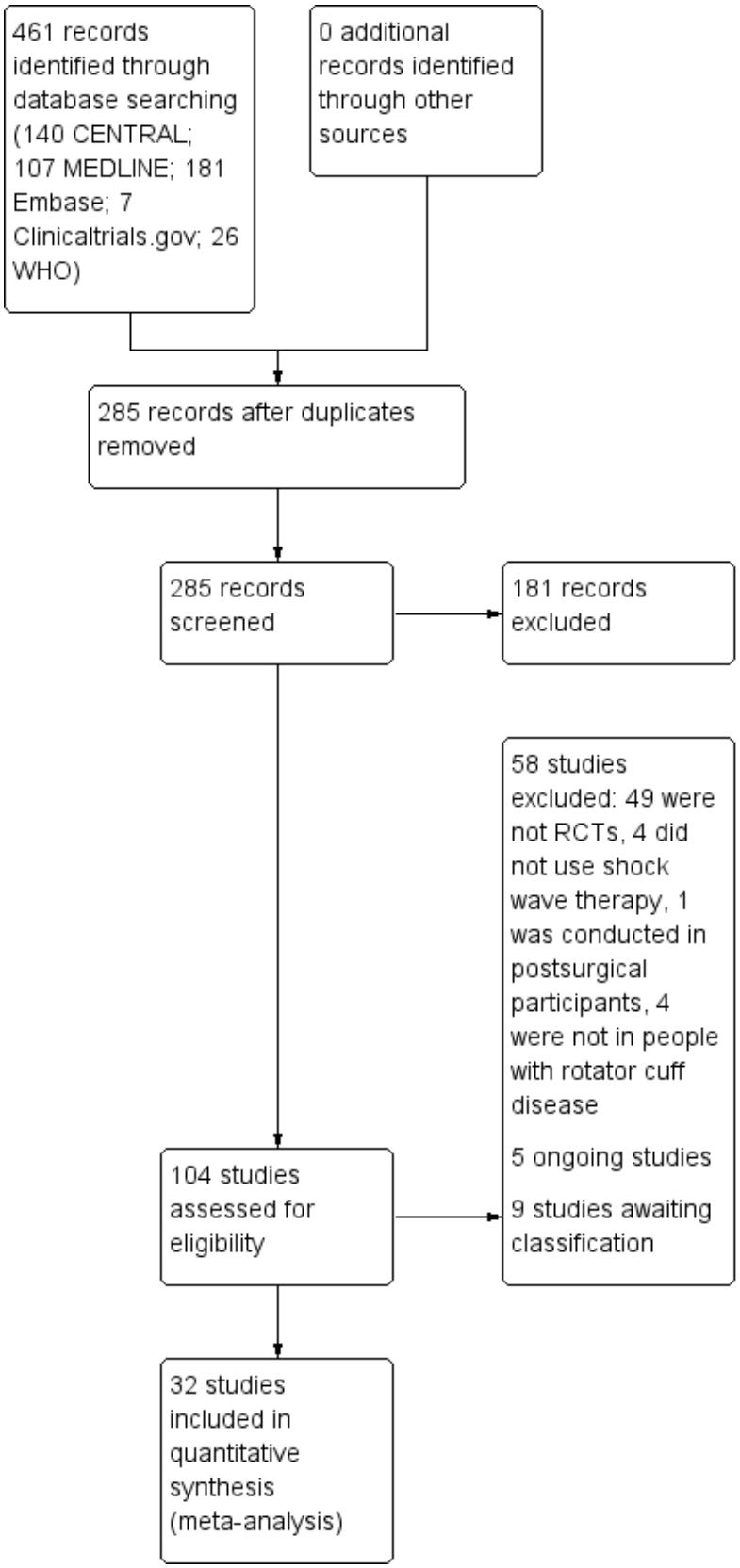
RESULTS

Description of studies

Results of the search

The database searches conducted up to 11 November 2019 resulted in retrieval of 461 records. After removal of duplicates, 285 unique records remained. After screening the abstracts, we retrieved 104 unique studies for full-text screening, out of which we excluded 58 studies (see Characteristics of excluded studies table). We selected 32 trials for inclusion (Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Duymaz 2019; Engebretsen 2009; Farr 2011; Frizziero 2017; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Ioppolo 2012; Kim 2014; Kolk 2013; Kvalvaag 2017; Li 2017; Loew 1999; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009; Speed 2002; Tornese 2011; Characteristics of included studies table). Nine additional trials are awaiting classification, as they could not be translated (Berner 2004; Diehl 2011; Gross 2002; Loew 1995; Mao 2003; Paternostro-Sluga 2004; Rompe 1997a; Rompe 1997b; Seil 1999; Characteristics of studies awaiting classification table). We identified five ongoing trials in clinical trials registries (ChiCTR1900022932; NCT02677103; NCT03779919; NTR7093; PACTR201910650013453; Characteristics of ongoing studies table). Figure 1 shows the flow diagram of the study selection process.

Figure 1. Study flow diagram.



Included studies

A full description of all included trials is provided in the Characteristics of included studies table. We contacted authors of 24 trials to request information about study design, participants, interventions and outcomes of the trial; information required to complete the risk of bias assessments; or missing data for unreported or partially reported outcomes (Albert 2007; Cacchio 2006; Cosentino 2003; Engebretsen 2009; Farr 2011; Frizziero 2017; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Ioppolo 2012; Kim 2014; Kolk 2013; Loew 1999; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti-Aschraf 2005; Sabeti 2007; Tornese 2011). We received replies from five trialists (Engebretsen 2009; Frizziero 2017; Galasso 2012; Kolk 2013; Sabeti 2007).

Study design and setting

All studies were parallel-group RCTs. Twenty-eight trials included two intervention arms, three trials included three intervention arms (Peters 2004; Gerdesmeyer 2003; Melegati 2000), and one trial included four intervention arms (Loew 1999).

Trials were set in Italy (Cacchio 2006; Cosentino 2003; Frizziero 2017; Galasso 2012; Ioppolo 2012; Melegati 2000; Tornese 2011), Germany (Haake 2002; Loew 1999; Perlick 2003; Peters 2004; Rompe 1998; Schmitt 2001; Schofer 2009), Austria (Farr 2011; Pleiner 2004; Sabeti 2007; Sabeti-Aschraf 2005), Germany and Austria (Gerdesmeyer 2003), Norway (Engebretsen 2009; Kvalvaag 2017), the Netherlands (De Boer 2017; Kolk 2013); UK (Hearnden 2009; Speed 2002), China (Hsu 2008; Li 2017), France (Albert 2007), Taiwan (Pan 2003), Spain (Del Castillo-Gonzales 2016), Turkey (Duymaz 2019), and South Korea (Kim 2014).

Two studies were funded by manufacturers of shock wave machines (Galasso 2012; Kolk 2013), seven studies were funded by grants from research foundations or universities (Albert 2007; Del Castillo-Gonzales 2016; Engebretsen 2009; Gerdesmeyer 2003; Ioppolo 2012; Kvalvaag 2017; Li 2017), three studies were provided with the shock wave machines (Albert 2007; Gerdesmeyer 2003; Pleiner 2004), nine studies explicitly reported they received no funding (Cacchio 2006; Duymaz 2019; Hearnden 2009; Kim 2014; Loew 1999; Pan 2003; Schmitt 2001; Speed 2002; Tornese 2011), while 13 studies did not report either way (Cosentino 2003; De Boer 2017; Farr 2011; Frizziero 2017; Haake 2002; Hsu 2008; Melegati 2000; Perlick 2003; Peters 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Schofer 2009).

Participant characteristics

The 32 trials included 2281 participants, and the number of participants per trial ranged from 20 to 243. Of the 16 studies that reported mean age of the overall cohort, the mean age of participants ranged from 48 years to 56.2 years. Of the seven studies that reported the mean duration of symptoms of the overall cohort, the mean duration of symptoms ranged from 7.1 to 60 months. Of the 30 studies that reported population gender numbers, 61% of participants were female.

Inclusion criteria or definitions of the included conditions (or both) varied between trials. Ten trials specified calcific or calcifying tendonitis or tendinopathy without specifying the involved tendons (Albert 2007; Cacchio 2006; Duymaz 2019; Farr 2011; Gerdesmeyer 2003; Haake 2002; Hsu 2008; Pan 2003; Sabeti-Aschraf 2005; Tornese 2011); 11 trials specified the presence of symptoms such as pain (De Boer 2017; Del Castillo-Gonzales 2016; Duymaz 2019; Frizziero 2017; Haake 2002; Hsu 2008; Kvalvaag 2017; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti-Aschraf 2005), four trials specified supraspinatus or infraspinatus calcification (Cosentino 2003; Hearnden 2009; Kim 2014; Sabeti 2007), two trials specified non-calcific tendonitis of the supraspinatus tendon (Schmitt 2001; Schofer 2009), two trials specified non-calcific tendonitis of any part of the rotator cuff (Galasso 2012; Speed 2002), four trials specified calcific deposits without tendonitis (De Boer 2017; Del Castillo-Gonzales 2016; Ioppolo 2012; Kim 2014), two trials specified subacromial shoulder pain (Engebretsen 2009; Kvalvaag 2017), two trials included shoulder pain without a specified location (Loew 1999; Perlick 2003), one trial specified subacromial impingement syndrome (Melegati 2000), and two trials specified chronic tendonitis (Kolk 2013; Li 2017). Twenty trials included radiographic imaging as part of their definition for the condition (Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Frizziero 2017; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Ioppolo 2012; Kim 2014; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Speed 2002; Tornese 2011).

Twenty-three trials only included participants with calcific tendinitis (Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Duymaz 2019; Farr 2011; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Ioppolo 2012; Kim 2014; Kvalvaag 2017; Loew 1999; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Tornese 2011), seven trials only included participants without calcific deposits (Frizziero 2017; Galasso 2012; Li 2017; Melegati 2000; Schmitt 2001; Schofer 2009; Speed 2002), and two trials included participants with or without calcific deposits (Engebretsen 2009; Kolk 2013). Only Kolk 2013 reported data for participants with and without calcific deposits separately.

Interventions

A detailed description of the interventions delivered in each trial is summarised in the Characteristics of included studies table and a summary of the shock wave technique and comparison tested in each trial is presented in Table 1. Shock wave treatments were very heterogeneous across trials and varied in the machines used to generate the shock waves, number and size of energy pulses, and the number of treatment sessions (one to six sessions varying from seven to 16 days apart).

Twelve trials compared ESWT to a placebo control (Cosentino 2003; Galasso 2012; Gerdesmeyer 2003; Hearnden 2009; Hsu 2008; Kolk 2013; Kvalvaag 2017; Li 2017; Peters 2004; Pleiner 2004; Schmitt 2001; Speed 2002). The trials the placebo control variably. Six trials used negligible or 0 mJ/mm^2 energy density (Cosentino 2003; Hearnden 2009; Hsu 2008; Kolk 2013; Peters 2004; Speed 2002), four trials physically blocked or dampened the shock waves (Gerdesmeyer 2003; Li 2017; Pleiner 2004; Schmitt 2001), one trial disconnected the shock wave device in the placebo group (Galasso 2012), and one trial did not clearly describe the sham procedure (Kvalvaag 2017).

Ten trials compared high-dose to low-dose ESWT (Albert 2007; Farr 2011; Gerdesmeyer 2003; Ioppolo 2012; Loew 1999; Perlick 2003; Peters 2004; Rompe 1998; Sabeti 2007; Schofer 2009), and one

trial compared high-dose to low-dose RSWT (Cacchio 2006). Trials differed in their definition of high and low dose (Table 1).

One trial compared ESWT directed to the calcific deposit versus directed to the origin of the supraspinatus tendon (Haake 2002); one trial compared ESWT with the arm hyperextended versus with the arm in a neutral position (Tornese 2011); one trial compared fluoroscopic-guided ultrasound targeted to the calcific deposit versus the shock waves directed to the area of maximum tenderness (Sabeti-Aschraf 2005); one trial compared shock wave therapy plus physiotherapy to physiotherapy alone (Duymaz 2019); and one trial compared two versus one session of ESWT (Loew 1999).

Four trials compared ESWT to ultrasound-guided needling (De Boer 2017; Del Castillo-Gonzales 2016; Frizziero 2017; Kim 2014); one trial compared shock wave therapy to TENS (Pan 2003); ESWT to no treatment (Loew 1999); and combination of ESWT and exercise to exercise alone or advice alone (Melegati 2000). One trial compared RSWT to supervised exercise (Engebretsen 2009).

Outcomes

Of the major outcomes, no trial measured participant-reported pain relief of 30% or greater or quality of life. However, one study reported participant-reported pain relief of 50% or greater (Speed 2002); thus, we report this outcome as a major outcome.

Twenty-nine trials measured pain (mean or mean change), with most using a 0- to 10-point VAS with 10 indicating the worst pain. Of these, five partially reported the pain outcome (Cosentino 2003; Frizziero 2017; Hearnden 2009; Kim 2014; Speed 2002). Three trials did not measure the pain outcome (Loew 1999; Melegati 2000; Rompe 1998).

Thirty trials measured function, with the Constant score being the most commonly used. Of these, four trials partially reported the function outcome (Hearnden 2009; Kim 2014; Perlick 2003; Rompe 1998). Two trials did not measure function (Del Castillo-Gonzales 2016; Peters 2004).

Fourteen trials measured treatment success using a variety of methods (Albert 2007; Cacchio 2006; De Boer 2017; Del Castillo-Gonzales 2016; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Loew 1999; Peters 2004; Sabeti 2007; Schmitt 2001; Speed 2002).

Eight trials measured withdrawals due to adverse events (Engebretsen 2009; Gerdesmeyer 2003; Kolk 2013; Kvalvaag 2017; Li 2017; Peters 2004; Pleiner 2004; Speed 2002). Twenty-seven trials measured adverse events (Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Engebretsen 2009; Farr 2011; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Ioppolo 2012; Kolk 2013; Kvalvaag 2017; Li 2017; Loew 1999; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009; Speed 2005), and of these one partially reported the adverse event outcome (Hearnden 2009). Five trials did not measure adverse events (Duymaz 2019; Frizziero 2017; Kim 2014; Melegati 2000; Tornese 2011)

We contacted authors of all trials who did not fully report outcomes to request missing data, and received missing data from two authors (Engebretsen 2009; Frizziero 2017). In two studies, it was possible to use alternate scores or extrapolation to extract the data for review (Kolk 2013; Sabeti 2007).

Of the minor outcomes, one trial measured pain below 30/100 on a VAS (Haake 2002), three trials measured active ROM (Cacchio 2006 measured active flexion; Duymaz 2019 measured flexion, extension, abduction and external rotation; and Engebretsen 2009 measured active abduction). Twenty-one trials measured calcification size (mean size, mean change in size or disappearance/resolution of calcification) (Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Farr 2011; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Ioppolo 2012; Kim 2014; Loew 1999; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Tornese 2011).

Excluded studies

A full description of all excluded trials is provided in the Characteristics of excluded studies table. Of the 58 full-text articles excluded, 49 were not RCTs (Adamietz 2003; Astore 2003; Avancini-Dobrovic 2011; Barnsley 2001; Boxberg 1996; Buch 1999; Buselli 2010; Bytomski 2006; Charrin 2001; Cheing 2003; Cosentino 2004; Costa 2002; Cyteval 2003; Friedberg 2010; Garcia Marti 2004; Hayes 2005; Jakobeit 2002; Labek 1999; Lee 2011; Lippincott 2010; Loew 1995; Lorbach 2008; Magosch 2003; Maier 2000; Mangone 2010; Manske 2004; Meier 2000; Moretti 2005; Mundy 2004; Noel 1999; Notarnicola 2011; Pigozzi 2000; Rebuzzi 2008; Rees 2009; Rompe 1995; Rompe 2000; Rompe 2001; Rompe 2003; Sabeti-Aschraf 2004; Sarrat 2004; Seil 2006; Sistermann 1998; Speed 2005; Spindler 1998; Steinacker 2001; Thigpen 2010; Wang 2001; Wang 2003; Wiley 2002), four studies did not investigate shock wave therapy (Bringmann 2001; Krasny 2005; Polimeni 2003; Saggini 2010), four studies investigated conditions other than rotator cuff disease (Ali 2016; Chow 2007; Liu 2012; Njawaya 2018), and one study included postsurgical participants (Kim 2012).

Studies awaiting classification

Nine trials are awaiting classification, subject to translation into English (Berner 2004; Diehl 2011; Gross 2002; Loew 1995; Mao 2003; Paternostro-Sluga 2004; Rompe 1997a; Rompe 1997b; Seil 1999; Characteristics of studies awaiting classification table).

Ongoing studies

At the time of publication of this review, there were five ongoing studies that did not have study results available at the time of submission of this review (ChiCTR1900022932; NCT02677103; NCT03779919; NTR7093; PACTR201910650013453). A description of these trials is provided in the Characteristics of ongoing studies table.

Risk of bias in included studies

All trials were susceptible to bias. Overall, 24/32 (75%) trials were susceptible to selection bias, 20 (62%) trials at risk of performance bias, 20 (62%) trials at risk of detection bias and 14 (45%) trials at risk of selective reporting bias (Figure 2).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

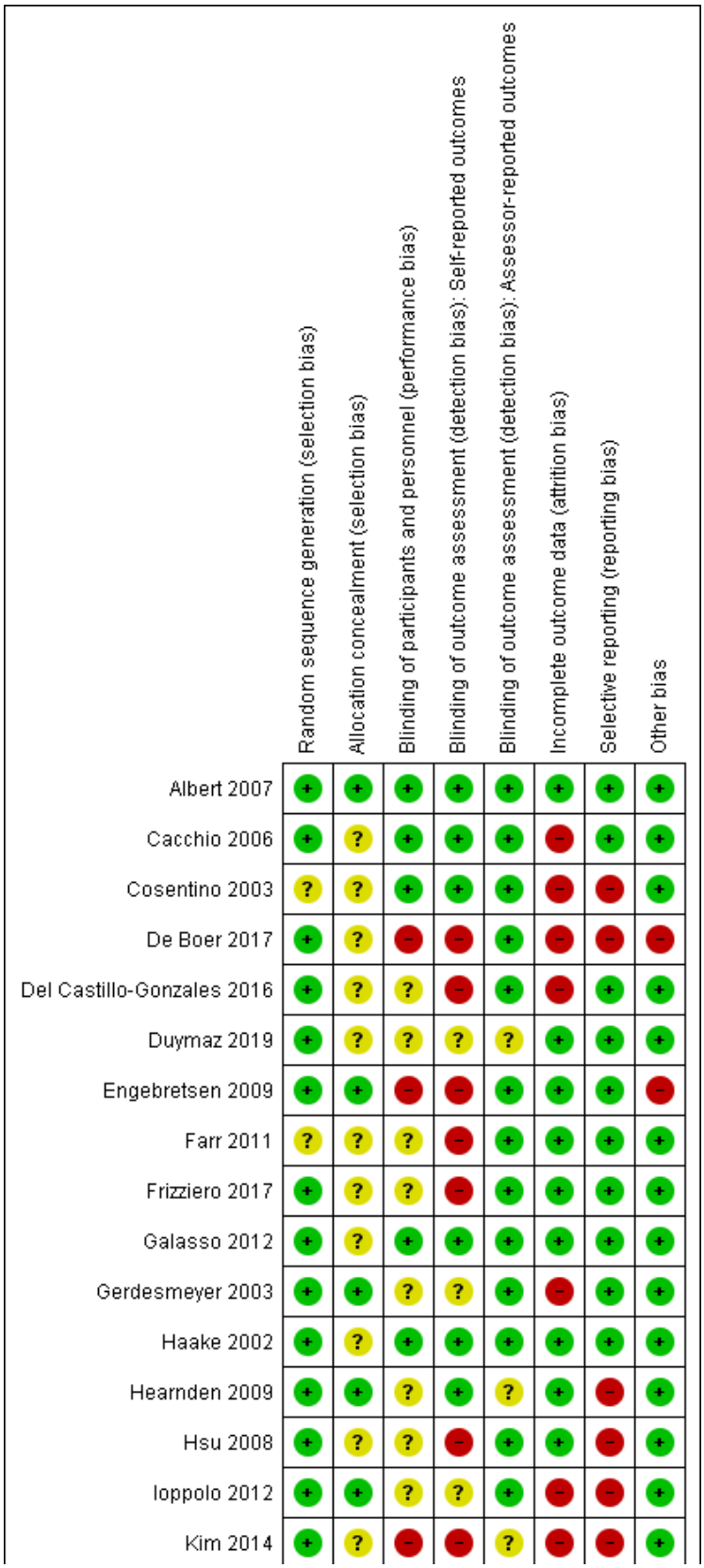
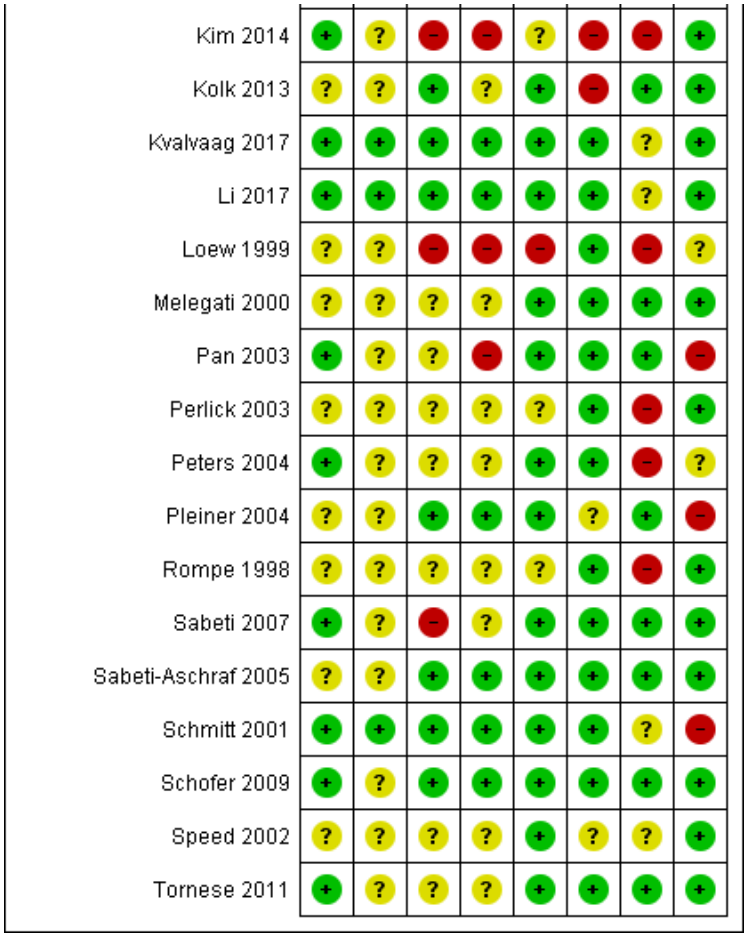


Figure 2. (Continued)



Allocation

Only eight (26%) trials used appropriate methods to both generate and conceal their allocation sequence, and so were rated at low risk of selection bias (Albert 2007; Engebretsen 2009; Gerdesmeyer 2003; Hearnden 2009; Ioppolo 2012; Kvalvaag 2017; Li 2017; Schmitt 2001).

Ten (32%) trials did not clearly report their method of sequence generation (Cosentino 2003; Farr 2011; Kolk 2013; Loew 1999; Melegati 2000; Perlick 2003; Pleiner 2004; Rompe 1998; Sabeti-Aschraf 2005; Speed 2002), and 24 (75%) trials did not adequately report their method of allocation concealment (Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Duymaz 2019; Farr 2011; Frizziero 2017; Galasso 2012; Haake 2002; Hsu 2008; Kim 2014; Kolk 2013; Loew 1999; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Schofer 2009; Speed 2002; Tornese 2011). Therefore, the risk of selection bias in these trials was unclear.

Blinding

We judged 12 (38%) trials at low risk of performance bias because participants and personnel were likely successfully blinded (Albert 2007; Cacchio 2006; Cosentino 2003; Galasso 2012; Haake 2002; Kolk 2013; Kvalvaag 2017; Li 2017; Pleiner 2004; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009). We judged five (15%) trials at high risk of performance bias as participants or personnel were not successfully blinded to treatment groups (De Boer 2017; Engebretsen 2009; Kim 2014; Loew 1999; Sabeti 2007).

In the remaining 15 trials (50%) the risk of performance bias was unclear as it was not clearly reported if personnel or participants, or both, were blinded (Del Castillo-Gonzales 2016; Duymaz 2019; Farr 2011; Frizziero 2017; Gerdesmeyer 2003; Hearnden 2009; Hsu 2008; Ioppolo 2012; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Rompe 1998; Speed 2002; Tornese 2011).

Twelve (38%) trials were at low risk of detection bias in self-reported outcomes because participants were probably successfully blinded to treatment (Albert 2007; Cacchio 2006; Cosentino 2003; Galasso 2012; Haake 2002; Hearnden 2009; Kvalvaag 2017; Li 2017; Pleiner 2004; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009).

We judged 11 (32%) trials at unclear risk of detection bias due to lack of reporting of blinding methods (Duymaz 2019; Gerdesmeyer 2003; Ioppolo 2012; Kolk 2013; Melegati 2000; Perlick 2003; Peters 2004; Rompe 1998; Sabeti 2007; Speed 2002; Tornese 2011). We judged nine (29%) trials at high risk of detection bias as participants were either not blinded or likely guessed their treatment group due to the differing nature of the treatment groups (De Boer 2017; Del Castillo-Gonzales 2016; Engebretsen 2009; Farr 2011; Frizziero 2017; Hsu 2008; Kim 2014; Loew 1999; Pan 2003).

Twenty-seven trials included assessor-rated outcomes (calcification size, ROM). There was a low risk of detection bias for these outcomes in 26 (84%) trials, as assessors were adequately blinded (Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Engebretsen 2009; Farr 2011; Frizziero 2017; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Hsu 2008; Ioppolo 2012; Kolk 2013; Kvalvaag 2017; Li 2017; Melegati 2000; Pan 2003; Peters 2004; Pleiner 2004; Sabeti 2007; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009; Speed 2002; Tornese 2011). Outcome assessors were not blinded in one (3%) study, which was judged at high risk of detection bias (Loew 1999). It was unclear if assessors were blinded in five (15%) trials (Duymaz 2019; Hearnden 2009; Kim 2014; Perlick 2003; Rompe 1998).

Incomplete outcome data

We rated 22 (68%) trials at low risk of attrition bias because they had no dropouts or the losses to follow-up, exclusions or attrition was sufficiently small that it was unlikely to have biased the results (Albert 2007; Duymaz 2019; Engebretsen 2009; Farr 2011; Frizziero 2017; Galasso 2012; Haake 2002; Hearnden 2009; Hsu 2008; Kvalvaag 2017; Li 2017; Loew 1999; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009; Tornese 2011). In eight (26%) trials there was differential dropout across groups or reasons for drop out were related to treatment (e.g. no effect in placebo group) and thus we rated these trials as high risk of attrition bias (Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Gerdesmeyer 2003; Ioppolo 2012; Kim 2014; Kolk 2013). The remaining two (6.4%) trials did not clearly report the amount of incomplete outcome data or reasons for incomplete outcome data so the risk of attrition bias was unclear (Pleiner 2004; Speed 2002).

Selective reporting

We rated 18 (56%) trials at low risk of selective reporting bias (Albert 2007; Cacchio 2006; Del Castillo-Gonzales 2016; Duymaz 2019; Engebretsen 2009; Farr 2011; Frizziero 2017; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Kolk 2013; Melegati 2000; Pan 2003; Pleiner 2004; Sabeti 2007; Sabeti-Aschraf 2005; Schofer 2009; Tornese 2011). One trial reported all outcomes listed in the study protocol (Galasso 2012). One trial measured several outcomes which were not specified in the ClinicalTrials.gov registry but were added to the publication (e.g. function, active ROM, work status) (Engebretsen 2009). For the other 15 trials, while there was no published study protocol, results were reported for all outcomes measured (as stated in the methods) and included all major outcomes (except for quality of life, which no trial measured) sufficient for us to judge these as having a probable low risk of selective reporting bias (Albert 2007; Cacchio 2006; Del Castillo-Gonzales 2016; Farr 2011; Frizziero 2017; Gerdesmeyer 2003; Haake 2002; Kolk 2013; Melegati 2000; Pan 2003; Pleiner 2004; Sabeti 2007; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009; Tornese 2011).

We rated four (13%) trials at unclear risk of selective reporting bias due to incomplete reporting of outcomes (Kvalvaag 2017; Li 2017; Schmitt 2001; Speed 2005). One study reported changes from baseline at the follow-up (Li 2017). The trial protocol for Kvalvaag 2017 stated that return to work and health-related quality of life were measured as secondary outcomes, but these outcomes were not reported in the results paper. Another trial had a significant number of unexplained dropouts without clear reporting of the number of participants who completed outcome measurements (Speed 2002). In one trial an outcome (treatment success) was possibly added post-hoc (Schmitt 2001).

We rated 10 (32%) trials at high risk of selective reporting bias, as data were missing for one or more outcomes listed as measured in the methods (Cosentino 2003; De Boer 2017; Hearnden 2009; Loew 1999), or measures of variance were not reported for one or more outcomes (Hsu 2008; Ioppolo 2012; Kim 2014; Perlick 2003; Peters 2004; Rompe 1998).

Other potential sources of bias

Five (16%) trials were at high risk of other bias (De Boer 2017; Engebretsen 2009; Pan 2003; Pleiner 2004; Schmitt 2001). Two trials were at high risk of unit of analysis bias as trialists in both cases did not adjust for the non-independence between groups due to bilateral treatment (Pan 2003; Pleiner 2004). One trial showed a high risk of bias as it was terminated prematurely because of higher pain in the shock wave group (De Boer 2017). Another trial was at high risk of bias because of imbalance between groups in the number of additional treatments received outside of the trial setting, which may have biased the results in favour of the radial extracorporeal shock wave therapy group (rESWT) (Engebretsen 2009). In another trial, 40% of participants were not satisfied with the allocated treatment and were unmasked and informed of their treatment group, and participants in the placebo group were offered shock wave therapy (Schmitt 2001). The remaining 26 (84%) trials were rated as being free from other potential sources of bias.

Effects of interventions

See: **Summary of findings for the main comparison** Shock wave therapy versus placebo for rotator cuff disease with or without calcification

Shock wave therapy versus placebo

Twelve studies assessed shock wave therapy (using ESWT) compared to placebo (Cosentino 2003; Galasso 2012; Gerdesmeyer 2003; Hearnden 2009; Hsu 2008; Kolk 2013; Kvalvaag 2017; Li 2017; Peters 2004; Pleiner 2004; Schmitt 2001; Speed 2002).

Major outcomes

Participant-reported pain relief of 30% or greater

The studies did not report pain relief of 30% or greater but did report pain relief of 50% or greater, which we report below.

Participant-reported pain relief of 50% or greater

One study reported participant-reported pain relief of 50% or greater at three months' follow-up (Speed 2002). Speed 2002 reported that 14/34 participants in the ESWT group and 15/40 participants in the placebo group reported 50% or greater improvement in pain relief, a difference that was not statistically different, but of some uncertainty as it is based on low-certainty evidence (RR 1.10, 95% CI 0.62 to 1.94; 74 participants), or in absolute terms, 4% more had pain relief (19% fewer to 26% more), and a relative change of 10% (38% fewer to 94% more) (Summary of findings for the main comparison).

Mean pain

Six trials reported pain at zero to six weeks measured on two scales, a VAS score (Hsu 2008; Li 2017; Pleiner 2004; Schmitt 2001; Speed 2002) and Constant score (Galasso 2012). There was a small

statistically significant but clinically uncertain reduction in pain with ESWT compared to placebo at six weeks' follow-up (SMD −0.75, 95% CI −1.33 to −0.17; I^2 = 81%; 304 participants; Analysis 1.2). Based on an SD of 1.6 (Gerdesmeyer 2003), this was equivalent to a mean reduction of 1.2 points (95% CI −2.13 to −0.27) on a 0- to 10-point VAS score, where 1.5 points is considered a clinically important difference in pain. Hsu 2008 found a large benefit in favour of shock wave therapy, which appears to be the main contributor to the large heterogeneity; removing data from Hsu 2008 removes the statistical heterogeneity (I^2 = 0%) without changing the direction of the effect (SMD −0.41, 95% CI −0.66 to −0.16; I^2 = 0%); this was equivalent to a pain reduction of 0.66 (95% CI −1.06 to −0.26 on a 0- to 10-point scale).

Nine trials reported pain at six weeks to three months on two scales, a VAS score (Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Kvalvaag 2017; Li 2017; Pleiner 2004; Schmitt 2001; Speed 2002) and Constant score (Galasso 2012). Low-certainty evidence indicated a clinically unimportant reduction in pain with shock wave therapy compared to placebo (SMD −0.49, 95% CI −0.88 to −0.11; I^2 = 80%; 608 participants; Analysis 1.2). Based on an SD of 1.6 (Gerdesmeyer 2003), this translated to a mean improvement of 0.78 points (95% CI −1.4 to −0.17) on a 0- to 10-point scale; or 7.8% improvement in pain (95% CI 2% to 14%), relative improvement of 14% (95% CI 3% to 25%) and number need to treat for an additional beneficial outcome (NNTB) of 4 (95% CI 2 to 34) (Summary of findings for the main comparison).

The high heterogeneity was due to the large outlier reported in Hsu 2008; removing these data removed most heterogeneity (SMD −0.36, 95% CI −0.59 to −0.13; I^2 = 18%) (equivalent to a mean reduction of 0.58 points, 95% CI −0.94 to −0.21 on a 0 to 10 scale).

Five trials reported pain at three to six months using a 0- to 10-point VAS score (higher score indicating more pain) (Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Kvalvaag 2017; Speed 2002). There was no evidence of a between-group difference in pain (MD -1.53, 95% CI -3.49 to 0.43) I^2 = 90%; 419 participants; Analysis 1.2).

Three trials reported pain at six to 12 months using a 0- to 10-point VAS score (higher score indicating more pain) (Gerdesmeyer 2003; Hsu 2008; Pleiner 2004). There was no evidence of a between-group difference in pain (MD −2.42, 95% CI −5.79 to 0.95; I^2 = 95%; 155 participants; Analysis 1.2). The high heterogeneity was due to the large outlier reported in Hsu 2008; removing these data removed all heterogeneity (MD −0.75, 95% CI −1.62 to 0.13; I^2 = 0%).

For the subgroup analysis comparing outcomes for participants with and without calcification, we pooled six-week to three-month data from five studies of people with calcific deposits (Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Kvalvaag 2017; Pleiner 2004; 256 participants) and five studies of people without calcific deposits (Galasso 2012; Kolk 2013; Li 2017; Schmitt 2001; Speed 2002; 253 participants). Subgroups did not appear to differ with respect to mean pain (with calcific deposits: SMD −0.59, 95% CI −1.33 to 0.14; 256 participants; without calcific deposits: SMD −0.39, 95% CI −0.70 to −0.09; 253 participants; test for subgroup differences: Chi^2 = 0.25, df = 1 (P = 0.62), I^2 = 0% despite the 'without calcification' group achieving statistical significance; Analysis 1.11).

In the sensitivity analyses for pain at six weeks to three months, removing studies at risk of selection bias or detection bias did not alter the findings substantially.

Removal of five studies with possible selection bias (Galasso 2012; Hsu 2008; Kolk 2013; Pleiner 2004; Speed 2002) changed the effect size from SMD −0.66 (95% CI −1.14 to −0.18; I^2 = 81%; 8 studies, 465 participants) to SMD −0.49 (95% CI −0.76 to −0.21; I^2 = 0%; 2 studies, 210 participants).

Removal of five studies with possible detection bias (Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Pleiner 2004; Speed 2002) changed the effect size from SMD −0.66 (95% CI −1.14 to −0.18; I^2 = 81%; 8 studies, 465 participants) to SMD −0.61 (95% CI −0.94 to −0.27; I^2 = 0%; 3 studies, 142 participants).

Function

Ten trials reported mean function using the Constant score (lower score is worse) (Cosentino 2003; Galasso 2012; Gerdesmeyer 2003; Hearnden 2009; Hsu 2008; Kolk 2013; Kvalvaag 2017; Li 2017; Pleiner 2004; Schmitt 2001), and one trial used the SPADI score (lower score is better) (Speed 2002). We changed the direction of the SPADI scores to 0 to 100 score with a higher score indicating better function.

Seven trials reported function at zero to six weeks (Cosentino 2003; Galasso 2012; Hsu 2008; Li 2017; Pleiner 2004; Schmitt 2001; Speed 2002). There was a statistically significant improvement in function when comparing ESWT to placebo at six weeks' follow-up (SMD 0.79, 95% CI 0.30 to 1.28; I^2 = 79%; 374 participants; Analysis 1.3). Using the SD of 12.8 from Gerdesmeyer 2003, this is equivalent to a mean increase of 10.11 points (95% CI 3.84 to 16.38) on a 0- to 100-point scale. The clinical importance of this improvement was uncertain as the 95% CIs included both a clinically important (greater than 10-point) increase and clinically unimportant (less than 10 points) change.

Nine trials reported function at six weeks to three months (Galasso 2012; Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Kvalvaag 2017; Li 2017; Pleiner 2004; Schmitt 2001; Speed 2002). Based on low-certainty evidence, there was a statistically significant improvement of uncertain clinical importance in function when comparing ESWT to placebo at three months' follow-up (SMD 0.62, 95% CI 0.13 to 1.11; I^2 = 88%; 612 participants; Analysis 1.3). Using the SD of 12.8 from Gerdesmeyer 2003, this translated to a mean increase of 7.93 points (95% CI 1.66 to 14.2) on a 0- to 100-point scale, an absolute improvement of 8% (95% CI 1.6% to 14%), relative improvement of 12% (95% CI 3% to 22%), or NNTB of 3 (95% CI 2 to 18) (Summary of findings for the main comparison). Removal of the extreme outlier reported in Hsu 2008 reduced heterogeneity to a moderate level (I^2 = 47%), and removed any clinical significance from the results (SMD 0.26, 95% CI −0.00 to 0.52; I^2 = 56%), translating to a mean improvement of 3.33 points on a 0- to 100-point scale (95% CI 0.00 to 6.65).

Seven trials reported function at three to six months (Cosentino 2003; Gerdesmeyer 2003; Hearnden 2009; Hsu 2008; Kolk 2013; Kvalvaag 2017; Speed 2002). There was a statistically significant but clinically unimportant improvement in function favouring the ESWT group (SMD 0.91, 95% CI 0.24 to 1.57; I^2 = 91%; 471 participants; Analysis 1.3). Using the SD of 12.8 from Gerdesmeyer 2003, this translated to a mean increase on the Constant scale of 11.65 points (95% CI 3.07 to 20.1).

Three trials reported function at six to 12 months (Gerdesmeyer 2003; Hsu 2008; Pleiner 2004). There was no evidence of a between-group difference in function measured using the Constant score

(MD 15.18, 95% CI −2.55 to 32.91; I^2 = 94%; 155 participants). The significant heterogeneity was largely due to Hsu 2008; removal of these more extreme data reduced the heterogeneity to a likely unimportant level, without changing the direction of the effect (MD 6.51, 95% CI −0.07 to 13.10; I^2 = 20%).

For the subgroup analysis comparing outcomes for participants with and without calcification, we pooled six week to three month data from five trials that included people with calcific deposits (Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Kvalvaag 2017; Pleiner 2004) and five trials including people without calcific deposits (Galasso 2012; Kolk 2013; Li 2017; Schmitt 2001; Speed 2002). Subgroups did not appear to differ with respect to mean function (with calcific deposits: SMD 0.84, 95% CI −0.20 to 1.89; 260 participants; without calcific deposits: SMD 0.29, 95% CI −0.04 to 0.61; 253 participants; test for subgroup differences: Chi^2 = 1.00, df = 1 (P = 0.32), I^2 = 0.1%; Analysis 1.12).

In the sensitivity analyses for function at six weeks to three months, removing studies at risk of selection bias or detection bias did not alter the effect size dramatically.

Removal of five studies with possible selection bias (Galasso 2012; Hsu 2008; Kolk 2013; Pleiner 2004; Speed 2002) changed the effect size and eliminated the slight between-group statistical difference from SMD 0.74 (95% CI 0.18 to 1.31; I^2 = 88%; 8 studies, 469 participants) to SMD 0.38 (95% CI 0.11 to 0.66; I^2 = 0%; 3 studies, 210 participants) at six weeks to three months.

Removal of five studies with possible detection bias (Gerdesmeyer 2003; Hsu 2008; Kolk 2013; Pleiner 2004; Speed 2002) changed the effect size and eliminated the slight between-group statistical difference from SMD 0.74 (95% CI 0.18 to 1.31; I^2 = 88%; 8 studies, 469 participants) to SMD 0.48 (95% CI −0.02 to 0.97; I^2 = 45%; 3 studies, 142 participants) at six weeks to three months.

Participant-reported success

Six trials reported treatment success (Galasso 2012; Gerdesmeyer 2003; Hearnden 2009; Peters 2004; Schmitt 2001; Speed 2002). Low-certainty evidence indicated there may be no statistical difference in the number reporting success: 255 per 1000 participants reported success with placebo and 405 per 1000 reported success with shock wave therapy (RR 1.59, 95% CI 0.87 to 2.91; I^2 = 53%; 287 participants; Analysis 1.4), or 15% more (3% fewer to 49% more) participants had success with shock wave therapy, a relative increase of 59% (13% fewer to 191% more) (Summary of findings for the main comparison).

Quality of life

None of the trials reported quality of life.

Number of participant withdrawals

Withdrawals specifically due to adverse events were not well reported across studies. Three trials reported that there were no withdrawals for any reasons (Galasso 2012; Peters 2004; Schmitt 2001; 167 participants), while only one study explicitly reported a withdrawal due to an adverse event, namely, a single participant withdrew due to intolerance of the shock wave therapy (Speed 2002). Kvalvaag 2017 reported that four participants withdrew from each group with two discontinuing intervention in the shock wave group and three discontinuing intervention in the placebo group due to an adverse event. Cosentino 2003 reported that 23/35 participants dropped out from the placebo group at six months' follow-up, without reporting the reasons, and also did not explicitly report if any participants dropped out from the shock wave group. Therefore, we could not include data from this study in the analysis.

For withdrawals due to adverse events or treatment intolerance, seven trials provided low-certainty evidence (Gerdesmeyer 2003;Kolk 2013; Kvalvaag 2017; Li 2017; Peters 2004; Pleiner 2004; Speed 2002). There was no between-group difference in withdrawals, 103 per 1000 withdrawals in the placebo group compared with 77 per 1000 in the shock wave therapy group (RR 0.75, 95% CI 0.43 to 1.31; I^2 =0%; 581 participants; Analysis 1.5), an absolute difference of 3% less events (6% less to 3% more), or a relative change of 25% less (57% less to 31% more) (Summary of findings for the main comparison). One participant in the shock wave group withdrew due to intolerance of the therapy, while other 10 participants who withdrew from active treatment offered no reason. From the placebo group, one participant withdrew due to deteriorating symptoms and a further 12 did not complete treatment but offered no reason for withdrawing.

Number of participants experiencing any adverse event

Several trials reported adverse events incompletely. Cosentino 2003 and Pleiner 2004 explicitly reported that there were zero adverse events in either treatment group, although Cosentino 2003 also reported that there was transient treatment pain associated with shock wave therapy without reporting the number of people who had the event. Hsu 2008 reported transient treatment-associated pain treated with ice and paracetamol, but did not report the number of participants with the event. Hearnden 2009 reported bruising in 7/11 (62%) participants in the shock wave group, but did not report if participants in the placebo group had any adverse events. Thus treatment-related pain from these three studies could not be included in the meta-analysis.

Five trials provided data on the number of participants per treatment group with adverse events for a meta-analysis (Galasso 2012; Gerdesmeyer 2003; Hsu 2008; Peters 2004; Speed 2002). Low-certainty evidence indicated no between-group difference in the proportion of people with adverse events, 72 per 1000 in the placebo group compared with 260 per 1000 in the shock wave therapy group (RR 3.61, 95% CI 2.00 to 6.52; 295 participants; Analysis 1.7), an absolute change of 19% more adverse events with shock wave therapy (7% more to 40% more), or a relative change of 261% more (100% more to 552% more) (Summary of findings for the main comparison).

The type of adverse events included: pain associated with shock wave therapy or placebo treatment (Cosentino 2003; Galasso 2012; Gerdesmeyer 2003; Hsu 2008; Peters 2004; Speed 2002); localised redness, bleeding or bruising (Gerdesmeyer 2003; Hearnden 2009; Hsu 2008; Peters 2004); and increased shoulder pain following treatment (Peters 2004).

Minor outcomes

Proportion of participants achieving pain score below 30/100 mm on Visual Analogue Scale

None of the trials reported proportion of participants achieving pain score below 30/100 mm on VAS.

Range of movement

None of the trials reported ROM.

Calcification size: number with complete resolution

Four trials reported number of participants with complete resolution of calcium deposits (Cosentino 2003; Hsu 2008; Peters 2004; Pleiner 2004; 218 participants). Peters 2004 (59 participants) reported that no participants in either treatment group had complete resolution of deposits and was not included in the analysis. Based on the other three trials, there was a statistically significant increase in the number of calcium deposits which completely resolved with ESWT compared to placebo although this is of uncertain clinical importance (RR 4.78, 95% CI 1.31 to 17.39; 159 participants; Table 2; Analysis 1.8).

Calcification size: number with partial resolution

Four trials reported the number of participants with partial resolution of calcium deposits (Cosentino 2003; Hsu 2008; Peters 2004; Pleiner 2004: 218 participants). Peters 2004 (59 participants) reported that no participants in either treatment group had partial resolution of deposits and was not included in the analysis. Based upon the other three trials, there was no statistically significant difference in the number of calcium deposits which partially resolved in the ESWT group compared to the placebo group (RR 3.41, 95% CI 0.95 to 12.23; 159 participants; Table 2; Analysis 1.9).

Calcification size: mean or change in mean calcification size

One trial reported mean calcification width at six weeks to three months (Gerdesmeyer 2003). Mean change in size was 56.3 mm in the treatment group compared with 30.3 mm in the placebo group, which was not statistically different (MD −26.00, 95% CI −85.77 to 33.77; 88 participants; Table 2; Analysis 1.10).

One trial reported mean change in calcification size at three to six months (Gerdesmeyer 2003; 46 participants). Mean change was −77.7 mm in the treatment group and −41 mm in the placebo group, which was not statistically different (MD −36.70, 95% CI −94.86 to 21.46; 87 participants; Table 2; Analysis 1.10).

Two trials reported mean calcification width at six to 12 months (Gerdesmeyer 2003; Hsu 2008). Mean change was 5.5 mm in the ESWT group and 9.8 mm in the placebo group, which was not statistically significantly different (MD −21.76, 95% CI −60.99 to 17.46; I^2 = 86%; 122 participants; Table 2; Analysis 1.10).

Shock wave therapy versus no treatment

One study compared shock wave therapy versus no treatment (Loew 1999).

Major outcomes

Function

There was no between-group difference in function (Constant score) at three months (mean function: 51.6 in the shock wave group and 47.8 in the no treatment group; MD 3.80, 95% CI −6.33 to 13.93; 40 participants; Analysis 2.1).

Participant-reported success

At the end of the trial, there was no between-group difference in the number of participants who reported that the treatment was successful (6/20 participants in the shock wave group versus 1/20 participants in the no treatment group; RR 6.00, 95% CI 0.79 to 45.42; Analysis 2.2).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, mean pain, participant-reported success, quality of life, number of participant withdrawals and number of participants experiencing any adverse event.

Minor outcomes

Number of participants with complete resolution of calcific deposits

At the end of the trial, there were no between-group differences in the number of participants who had achieved complete resolution of calcific deposits (4/20 participants in the shock wave group versus 2/20 participants in the no treatment group; RR 2.00, 95% CI 0.41 to 9.71; Analysis 2.3).

Other minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM or effect of ESWT on the size of the calcification.

Shock wave therapy versus ultrasound-guided needling with glucocorticoid

One study assessed ESWT versus ultrasound-guided needling with glucocorticoid (Kim 2014).

Major outcomes

Mean pain

The study incompletely reported mean pain (no measures of variance), therefore, we could not extract or substantiate these data. The authors reported a greater improvement in pain and function with ultrasound-guided needling than with shock wave therapy.

Function

The study incompletely reported function (no measures of variance), therefore, we could not extract or substantiate these data. The authors reported a greater improvement in pain and function with ultrasound-guided needling than with shock wave therapy.

Other major outcomes

The study did not report participant reported pain relief of 30% or greater, participant-reported success, quality of life, number of withdrawals due to adverse events and number of participants experiencing any adverse event.

Minor outcomes

Calcification size: mean calcification width

Mean calcification width decreased in both groups but the difference favoured glucocorticoid needling (mean calcification size was 5.6 mm in the shock wave group versus 0.45 mm in the glucocorticoid needling group; MD 5.15, 95% CI 4.84 to 5.46; 54 participants; Analysis 3.1). This difference is of uncertain clinical importance.

Calcification size: number with complete resolution

Complete resolution of calcific deposits occurred less frequently in the shock wave therapy group (12/29 participants in the shock wave group versus 18/25 participants in the glucocorticoid needling group; RR 0.57, 95% CI 0.35 to 0.95; Analysis 3.2). This difference is of uncertain clinical importance.

Calcification size: number with partial resolution

There was no between-group difference in the number of participants who had partial resolution of calcific deposits (5/29 participants in the shock wave group versus 3/25 participants in the needling group; RR 1.44, 95% CI 0.38 to 5.42; Analysis 3.3).

Other minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS and ROM.

Radial shock wave therapy versus ultrasound-guided needling with glucocorticoids

One study assessed RSWT versus ultrasound-guided needling with glucocorticoids (De Boer 2017).

Major outcomes

Pain

At six weeks to three months, there was a statistically significant and clinically important increase in mean pain (NRS 0 to 10, higher score indicating greater pain) in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (MD 1.60, 95% CI 0.13 to 3.07; 25 participants; Analysis 4.1).

At 12 months and greater, there was no statistically significant or clinically important change in mean pain (NRS 0 to 10, higher score indicating greater pain) in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (MD 0.20, 95% CI −2.05 to 2.45; 19 participants; Analysis 4.1).

Function

At six weeks to three months, there was no statistically significant or clinically important change in mean function (Constant score 0 to 100, higher score indicating better function or Oxford score, 12 to 60 with a higher score indicating better function) in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (Constant score: MD −11.70, 95% CI −24.79 to 1.39; 25 participants; Analysis 4.2; Oxford score: MD −2.30; 95% CI −9.30 to 4.70; 25 participants; Analysis 4.3).

At 12 months and greater, there was no statistically significant or clinically important change in mean function (Oxford score, 12 to 60, higher score indicating better function) in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (MD −4.10, 95% CI −15.74 to 7.54; 19 participants; Analysis 4.3).

Participant-reported success

At the end of the trial, there was no difference in treatment success (proportion of participants with no complaints) in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (4/9 participants with RSWT versus 4/10 participants with ultrasound-guided needling with glucocorticoids; RR 1.11, 95% CI 0.39 to 3.19; Analysis 4.4).

Number of participants experiencing any adverse event

At the end of the trial, there was no difference in the proportion of participants with adverse events in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (5/14 participants with RSWT versus 1/11 participants with ultrasound-guided needling with glucocorticoids; RR 3.93, 95% CI 0.53 to 28.93; Analysis 4.5).

Other major outcomes

The trial did not report participant-reported pain relief of 30% or greater and quality of life. There were no withdrawals listed due to adverse events.

Minor outcomes

Calcification size

At the end of the trial, there was no difference in the calcification size (number with complete resolution) in participants who received RSWT compared to participants who underwent ultrasound-guided needling with glucocorticoids (1/14 participants with RSWT versus 5/11 participants with ultrasound-guided needling with glucocorticoids; RR 0.16, 95% CI 0.02 to 1.16; Analysis 4.6).

Radial shock wave therapy versus supervised exercise

One study assessed rESWT versus supervised exercises (Engebretsen 2009).

Major outcomes

Pain

There was no between-group differences in mean pain (Likert 0 to 9, 9 indicating severe pain) at any time point (six weeks: 2.9 with shock wave versus 2.6 with supervised exercises; MD 0.30, 95% CI −0.53 to 1.13; 90 participants; six weeks to three months: 2.9 with shock wave versus 2.5 with supervised exercises; MD 0.40, 95% CI −0.36 to 1.16; 102 participants; three to six months: 2.7 with shock wave versus 2.5 with supervised exercises; MD 0.20, 95% CI −0.56 to 0.96; 100 participants; one year: 2.6 with shock wave versus 2.1 with supervised exercises; MD 0.50, 95% CI −0.20 to 1.2; 97 participants; Analysis 5.1).

Function

There was no between-group differences in mean function (SPADI 0 to 100, 100 indicating worst function) at any time point (six weeks: 33.5 with shock wave versus 25.8 with supervised exercises; MD 7.70, 95% CI −1.57 to 16.97; 90 participants; six weeks to three months: 36.1 with shock wave versus 27.0 with supervised exercises; MD 9.10, 95% CI −1.13 to 19.33; 102 participants; three to six months: 29.2 with shock wave versus 24.5 with supervised exercises; MD 4.70, 95% CI −5.39 to 14.79; 100 participants; 12 months: 27.9 with shock wave versus 24.0 with supervised exercises; MD 3.90, 95% CI −6.08 to 13.88; 97 participants; Analysis 5.2).

Number of participant withdrawals

There was no between-group difference in withdrawals due to adverse events, but the event rates were too low to be certain (2/52 participants with shock wave versus 1/50 participants with supervised exercise; (RR 3.00, 95% CI 0.32 to 27.91; 104 participants; one study; Analysis 5.3). Withdrawal of one participant from the supervised exercise group was due to increased pain and stiffness consistent with adhesive capsulitis and the two withdrawals from the shock wave group were due to aggravation of pain.

Number of participants experiencing any adverse event

Adverse events included frozen shoulder (two in the exercise group, one in the shock wave group); polymyalgia rheumatica (one in the exercise group); depression (one in the shock wave group); aggravation of pain (two in the shock wave group, crossed over to exercise), and one participant from shock wave group had surgery (unreported if this was due to an adverse event or inefficacy; we have included this as an adverse event). Total adverse events did not differ statistically between groups (5/52 participants with shock wave versus 3/50 participants with supervised exercise (RR 1.60, 95% CI 0.40 to 6.36; Analysis 5.4).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, participant-reported success and quality of life.

Minor outcomes

Range of movement

There was no between-group difference in mean active abduction (measured in degrees, data supplied by the trial authors) at any time point (six weeks to three months: 167.65 degrees with shock wave versus 169.6 degrees with supervised exercise group; MD −1.95 degrees, 95% CI −10.50 to 6.60; three to six months: 154.78 degrees with shock wave versus 166.6 degrees with supervised exercise; MD −11.82 degrees, 95% CI −25.37 to 1.73; Analysis 5.5). Data were not reported at one year.

Other minor outcomes

The trial did not report proportion of participants achieving pain score below 30/100 mm on a VAS, size of the calcification and number of participants with complete or partial resolution.

Shock wave therapy plus exercise and advice versus exercise and advice alone

One study assessed ESWT plus a supervised exercise programme (called kinesitherapy) and advice versus kinesitherapy and advice alone (Melegati 2000).

Major outcomes

Function

At six to 12 months, there was a statistically significant but clinically unimportant improvement in function in the shock wave plus exercise and advice group compared to the exercise and advice control group (Constant score: 74.5 with shock wave plus exercise and advice versus 65.15 with exercise and advice control; MD 9.35, 95% CI 4.98 to 13.72; 60 participants; Analysis 13.1).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, mean pain, participant-reported success of treatment, quality of life, number of participant withdrawals and number of participants experiencing any adverse event.

Minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM, effect of ESWT on the size of the calcification and number of participants with complete or partial resolution.

Shock wave therapy versus transcutaneous electrical nerve stimulation

One study compared ESWT to TENS (Pan 2003).

Major outcomes

Pain

At six weeks, the MD in pain (measured by 0- to 10-point VAS, higher score indicating more pain) favoured shock wave therapy but the CIs indicated that this may or may not be of clinical importance (pain improvement: 3 points with shock wave therapy versus 1.1 points with TENS; MD −1.90, 95% CI −2.98 to −0.82; 62 participants; Analysis 7.1). At three months, there was a clinically important difference in pain in favour of shock wave therapy (−4.08 points with ESWT versus −1.74 points with TENS; MD −2.34, 95% CI −3.53 to −1.15; 62 participants; Analysis 7.1).

Function

At six weeks, the MD in function (measured by Constant score) favoured shock wave therapy but the CIs indicated that this may or may not be of clinical importance (mean function improvement: 24.12 points with shock wave versus 9.59 points with TENS; MD 14.53, 95% CI 8.70 to 20.36; 62 participants; Analysis 7.2). At three months, there was a clinically important difference in function favouring shock wave therapy (mean function improvement: 28.31 points with shock wave versus 11.86 points with TENS; MD 16.45, 95% CI 9.86 to 23.04; 62 participants; Analysis 7.2).

Number of participant withdrawals

There was only one withdrawal due to severe pain from the TENS group. It was not clearly reported if the pain was due to the TENS treatment (or due to the shoulder disorder). The difference between groups was not statistically significant, but there were too few events to be conclusive (0/33 participants with shock wave versus 1/29 participants with TENS; RR 0.29, 95% CI 0.01 to 6.95; Analysis 7.3).

Number of participants experiencing any adverse event

Reported adverse events included soreness due to the shock wave therapy (five participants) or pain, possibly due to TENS (one participant), anxiety resulting in heart palpitations in the shock wave group (one participant). No haematomas or paraesthesia were reported. There were no statistical differences between the number of participants who experienced an adverse event, but there were too few events to be certain (6/33 participants with shock wave versus 1/29 with TENS; RR 5.27, 95% CI 0.67 to 41.00; Analysis 7.4).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, participant-reported success and quality of life were not reported.

Minor outcomes

Calcification size: mean calcification width

At six weeks, there was a greater reduction in mean width of calcific deposits in the shock wave therapy group (mean change: –3.16 mm with shock wave versus –0.75 mm with TENS; MD –2.41, 95% CI –3.94 to –0.88; 62 participants; Analysis 7.5). This is of unknown clinical relevance.

At six weeks to three months, there was a greater reduction in mean width of calcific deposits in the shock wave therapy group (mean change: –4.39 mm with shock wave versus –1.65 mm with TENS; MD –2.74, 95% CI –4.39 to –1.09; 62 participants; Analysis 7.5). This is of unknown clinical relevance.

Other minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM and complete or partial resolution of calcification.

Comparisons of different parameters of shock wave therapy

High-dose versus low-dose shock wave therapy

Eleven studies compared high-dose to low-dose shock wave therapy (Albert 2007; Cacchio 2006; Farr 2011; Gerdesmeyer 2003; Ioppolo 2012; Loew 1999; Perlick 2003; Peters 2004; Rompe 1998; Sabeti 2007; Schofer 2009).

Major outcomes

Participant reported pain relief of 30% or greater

None of the trials reported participant reported pain relief of 30% of greater.

Pain

Two trials reported pain at six weeks (Cacchio 2006; Farr 2011). There was a slight improvement in pain that favoured high-dose shock wave therapy (mean pain on a 0- to 10-point VAS, 10 indicating most pain: 2 points with high-dose versus 5 points with low-dose; SMD -1.73, 95% CI -3.94 to 0.48; 117 participants; I^2 = 95%; Analysis 8.1). Although the 95% CIs included both a clinically important and a clinically unimportant pain reduction (assuming a clinically important difference is 1.5 points), the clinical significance of this improvement may be unimportant. The high heterogeneity was largely driven by Cacchio 2006, who reported a large improvement with high-dose therapy.

Six trials reported pain at three months (Albert 2007; Farr 2011; Gerdesmeyer 2003; Ioppolo 2012; Sabeti 2007; Schofer 2009). There was no statistical between-group difference in pain (SMD –0.26, 95% CI –0.67 to 0.16; I^2 = 70%; 326 participants; Analysis 8.1). Based on an SD of 1.9 (Gerdesmeyer 2003), this translates to a mean reduction in pain of 0.49 points (95% CI –1.27 to 0.31) on a 0- to 10-point scale.

Four trials reported pain at three to six months (Cacchio 2006; Gerdesmeyer 2003; Ioppolo 2012; Perlick 2003). There was a slight, possibly clinically unimportant, improvement in pain favouring the high-dose group (SMD –1.66, 95% CI –2.98 to –0.33; I^2 = 96%; 326 participants; Analysis 8.1). Based on an SD of 1.9 (Gerdesmeyer 2003), this translates to a mean reduction of 3.15 points (95% CI –5.66 to –0.63) on a 0- to 10-point scale, the 95% CIs include both a clinically important and a clinically unimportant pain reduction. The heterogeneity was driven by the more extreme improvements reported in Cacchio 2006 and Ioppolo 2012; removing their data reduced heterogeneity to zero (SMD –0.47, 95% CI –0.77 to –0.17).

Three trials reported pain at six to 12 months (Gerdesmeyer 2003; Perlick 2003; Schofer 2009). There was no between-group difference in pain (SMD –0.60, 95% CI –1.39 to 0.18, I^2 = 85%; 196 participants; Analysis 8.1). Based on a SD of 1.9 (Gerdesmeyer 2003), this translated to a mean reduction of 1.14 points (95% CI –2.64 to 0.34) on a 0- to 10-point scale.

Function

Two trials reported function at six weeks (Cacchio 2006; Farr 2011). While there were no between-group differences (SMD 3.71, 95% CI –3.71 to 11.14; I^2 = 99%; 117 participants; Analysis 8.2), the heterogeneity meant the pooled effect size was uninterpretable. Cacchio 2006 found a large benefit favouring high-dose therapy while Farr 2011 found no between-group difference.

Seven trials reported function at three months (Albert 2007; Farr 2011; Gerdesmeyer 2003; Ioppolo 2012; Loew 1999; Sabeti 2007; Schofer 2009). There was a clinically unimportant benefit favouring high-dose therapy (SMD 0.31, 95% CI 0.08 to 0.53; I^2 = 11%; 366 participants; Analysis 8.2). Based on an SD of 12.8 (Gerdesmeyer 2003), this translated to a mean increase of 4.0 points (95% CI 1.02 to 6.78) on a 0- to 100-point scale. Assuming an minimal clinically important difference of 10 points, this benefit was not clinically significant.

Five trials reported function at six months (Cacchio 2006; Gerdesmeyer 2003; Ioppolo 2012; Perlick 2003; Rompe 1998). The analysis favoured the high-dose ESWT group, although there was significant heterogeneity (SMD 2.29, 95% CI 1.05 to 3.52; I^2 = 96%; 409 participants; Analysis 8.2). Based on an SD of 12.8 (Gerdesmeyer 2003), this translated to a mean increase of 29.31 points (95% CI 13.44 to 45.06) on a 0- to 100-point Constant scale. Heterogeneity was reduced but still substantial with removal of the more outlying study (I^2 = 79%; Cacchio 2006) (SMD 1.36, 95% CI 0.81 to 1.91; equivalent to a mean increase of 17.4 points, 95% CI 10.4 to 24.4, on a 0- to 100-point function scale).

Three trials reported function at 12 months using the Constant score (Gerdesmeyer 2003; Perlick 2003; Schofer 2009). The MD favoured the high-dose group but the CIs indicated that this may or may not be of clinical importance (MD 12.47, 95% CI 6.91 to 18.03; I^2 = 0%; 196 participants); Analysis 8.2).

Participant-reported success

Six trials reported participant-reported success at the end of the trial (Albert 2007; Cacchio 2006; Gerdesmeyer 2003; Loew 1999; Peters 2004; Rompe 1998). There was a clinically important increase in the proportion of successful treatments in the high-dose compared with the low-dose ESWT group (174/221 participants with high dose versus 61/229 participants with low dose; RR 2.74, 95% CI 1.58 to 4.77; I^2 = 80%; 450 participants; Analysis 8.3). However, the large effect and the high heterogeneity was

driven largely by Cacchio 2006 who reported no success with low-dose therapy, and Peters 2004 who reported that 31/31 (100%) participants had success in the high-dose group compared to only 4/30 (13%) in the low-dose group. Removal of these two studies with outlying results modified the effect size to a more moderate increase in success rate and eliminated statistical heterogeneity (RR 1.96, 95% CI 1.57 to 2.45; I^2 = 0%).

Number of participant withdrawals

Cacchio 2006 reported that no participants withdrew from the study due to adverse events. No other studies reported if there were any withdrawals.

Number of participants experiencing any adverse event

Five trials reported adverse events (Albert 2007; Cacchio 2006; Perlick 2003; Peters 2004; Schofer 2009). A sixth trial reported that haematomas occurred in participants in the high-dose group, without reporting the number of participants who had the event, so data from this study could not be included in the analysis (Loew 1999). More participants reported adverse events in the high-dose shock wave group (89/175 participants with high dose versus 23/173 participants with low dose; (RR 3.51, 95% CI 1.53 to 8.03; I^2 = 17%; 351 participants; Analysis 8.5).

Adverse events included bruising or skin lesions with high-dose treatment (Albert 2007; Cacchio 2006; Loew 1999; Perlick 2003; Peters 2004); increased shoulder pain following treatment (Perlick 2003; Peters 2004; Schofer 2009); and acute subacromial bursitis possibly associated with shock wave penetration (Perlick 2003).

One participant in the low-dose group of one trial reported a panic attack (Albert 2007).

Minor outcomes

Proportion of participants achieving pain score below 30/100 mm on Visual Analogue Scale

None of the trials reported the proportion of participants achieving pain score below 30/100 mm on VAS.

Range of movement

One trial reported ROM (Cacchio 2006).

At six weeks, active flexion was much greater in the high-dose shock wave group (134 degrees with high dose versus 85.00 degrees with low dose; MD 49.35, 95% CI 37.39 to 61.31; 90 participants; Analysis 8.6).

At six months, active flexion favoured the high-dose group (152.00 degrees with high dose versus 90 degrees with low dose; MD 62.00, 95% CI 50.59 to 73.41; 90 participants; Analysis 8.6).

Calcification size: number with complete resolution

Five trials reported the number of participants with complete resolution of calcium deposits at the end of the trial (Loew 1999; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998). More participants in the high-dose shock wave therapy group had complete resolution (73/172 (42%) participants with high dose versus 20/166 (12%) participants with low dose; (RR 2.91, 95% CI 1.04 to 8.15; I^2 = 72%; 281 participants; Analysis 8.7).

Calcification size: number with partial resolution

Two trials reported number of participants with partial resolution of calcium deposits at the end of the trial (Perlick 2003; Rompe 1998). There was no between-group differences in partial resolution (29/90 participants with high dose versus 26/90 participants with low dose; RR 1.13, 95% CI 0.73 to 1.75; I^2 = 0%; Analysis 8.8).

Calcification size: mean calcification width

Three trials reported mean change in calcification size at six months (Cacchio 2006; Gerdesmeyer 2003; Ioppolo 2012). There was a greater reduction in the high-dose therapy group (MD –24.19, 95% CI –44.83 to –3.55; I^2 = 31%; 229 participants; Analysis 8.9).

One trial reported mean change in calcification size at 12 months (Gerdesmeyer 2003). There was a greater reduction in the high-dose group (MD –70.70, 95% CI –141.05 to –0.35; 79 participants; Analysis 8.9).

Calcification size: greater than 80% reduction of calcified surface on anteroposterior view

One trial reported proportion of participants with greater than 80% reduction of calcified surface on anteroposterior view at the end of the trial (Albert 2007). There was no evidence of a difference (6/40 participants with high dose versus 2/40 participants with low dose; RR 3.00, 95% CI 0.64 to 13.98; 80 participants; Analysis 8.10).

Two versus one treatment session of shock wave therapy

One small trial (40 participants) compared one versus two treatment sessions of ESWT (Loew 1999), and reported only function, treatment success and adverse events. Findings were uncertain given that the evidence was very-low certainty due to the small number of participants and potential for selection, performance, detection and selective reporting bias.

Major outcomes

Function

There was no evidence of a difference in function at three months (mean function using Constant score 0 to 100, 0 indicating worst function: 68.5 (SD 13.1) with two sessions versus 63.7 (SD 14.6) with one session (MD 4.80, 95% CI -3.80 to 13.40; one study, 40 participants; Analysis 9.1).

Participant-reported success

There was no evidence of a difference in treatment success (proportion of participants satisfied with the treatment) (14/20 participants with two sessions versus 12/20 participants with one session (RR 1.17, 95% CI 0.74 to 1.85; one study, 40 participants; Analysis 9.2).

Number of participants experiencing any adverse event

Loew 1999 reported that haematomas occurred in participants in the two-session group, without reporting the number of participants who had the event, so these data could not be included in an analysis.

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, pain, quality of life, withdrawals due to adverse events and the number of people with adverse events.

Minor outcomes

Proportion with resolution of calcification

There was no evidence of a difference in the number of participants with resolution of calcifications (12/20 participants with two sessions versus 11/20 participants with one session (RR 1.09, 95% CI 0.64 to 1.86; 40 participants one study; Analysis 9.3).

Other minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM and size of the calcification.

Shock wave therapy directed to the calcific deposits or to the supraspinatus origin

One study compared calcification-focused ESWT with supraspinatus origin-focused ESWT (Haake 2002).

Major outcomes

Participant reported pain relief of 30% or greater

The trial did not report participant-reported pain relief of 30% or greater.

Pain

There was no statistically significant difference in pain when comparing calcification-focused ESWT with supraspinatus origin-focused ESWT at three months' follow-up (mean pain at rest, visual NRS 0 to 11, 11 indicating worst pain: 3.21 with calcification-focused ESWT versus 4.74 with supraspinatus origin-focused ESWT; MD −1.53, 95% CI −3.24 to 0.18; 47 participants; Analysis 10.1).

There was a statistically significant but clinically unimportant decrease in pain when comparing calcification-focused ESWT with supraspinatus origin-focused ESWT at 12 months' follow-up (mean pain at rest, visual NRS 0 to 11, 11 indicating worst pain: 1.48 with calcification-focused ESWT versus 3.75 with supraspinatus origin-focused ESWT; MD −2.27, 95% CI −3.49 to −1.05; 49 participants; Analysis 10.1).

Function

There was a statistically significant and clinically important increase in function when comparing calcification-focused ESWT with supraspinatus origin-focused ESWT at six weeks to three months' follow-up (mean function using Constant score 0 to 100, 1000 indicating best function: 104.59 with calcification-focused ESWT versus 73.08 with supraspinatus origin-focused ESWT; MD 31.51, 95% CI 16.33 to 46.69; 47 participants; Analysis 10.2).

There was a statistically significant and clinically important increase in function when comparing calcification-focused ESWT with supraspinatus origin-focused ESWT at 12 months' follow-up (mean function using Constant score 0 to 100, 100 indicating best function: 116.24 with calcification-focused ESWT versus 83.51 with supraspinatus origin-focused ESWT; MD 32.73, 95% CI 20.40 to 45.06; 49 participants; Analysis 10.2).

Participant-reported success

Haake 2002 measured treatment success by the proportion of participants satisfied with the treatment. There was a statistically significant but clinically unimportant increase in success rate in the calcification-focused ESWT group compared with the supraspinatus origin-focused ESWT group (25/25 participants with calcification-focused ESWT versus 10/24 participants with supraspinatus origin-focused ESWT; RR 2.34, 95% CI 1.47 to 3.71; Analysis 10.3).

Quality of life

The trial did not report quality of life.

Number of participant withdrawals

The trial did not report number of participant withdrawals.

Number of participants experiencing any adverse event

Haake 2002 reported that no participants experienced adverse events during the study. These data could not be analysed in this review.

Minor outcomes

Calcification size: number with complete resolution

There was a statistically significant increase of uncertain clinical significance in the number with complete resolution in the calcification-focused ESWT group compared with supraspinatus origin-focused ESWT group at the end of the trial (14/24 participants with calcification-focused ESWT group versus 8/22 participants with supraspinatus origin-focused ESWT (RR 1.60, 95% CI 0.84 to 3.07; 46 participants; one study; Analysis 10.4).

Other minor outcomes

The trial did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM and calcification width.

Palpation-guided versus image-guided shock wave therapy

One study compared palpation-guided ESWT to image-guided ESWT (Sabeti-Aschraf 2005).

Major outcomes

Pain

There was a statistically significant and clinically important difference in improvement in pain favouring the image-guided ESWT at three months (mean pain using a 0- to 100-point VAS, 100 indicating most pain: 18.21 with image-guided ESWT versus 33.36 with palpation-guided ESWT; MD −15.15, 95% CI −26.62 to −3.68; 50 participants; Analysis 11.1).

Function

There was no between-group difference in function at three months (mean Constant score: 79.48 with image-guided ESWT versus 73.00 with palpation-guided ESWT; MD 6.48, 95% CI −2.22 to 15.18; 50 participants; Analysis 11.2).

Number of participants experiencing any adverse event

There were no adverse events reported.

Other major outcomes

The trial did not report participant-reported pain relief of 30% or greater, participant-reported success, quality of life and withdrawals due to adverse events.

Minor outcomes

Calcific deposits: number with complete resolution

There was no difference in the number of participants who had complete resolution of calcific deposits at the end of the trial (6/25 participants with image-guided ESWT versus 1/25 participants with palpation-guided ESWT; RR 6.00, 95% CI 0.78 to 46.29; Analysis 11.3).

Calcification size: number with partial resolution

There was no difference in the number of participants who had partial resolution of calcific deposits at the end of the trial (7/25 participants with image-guided ESWT versus 5/25 participants with palpation-guided ESWT; RR 1.40, 95% CI 0.51 to 3.82; Analysis 11.4).

Other minor outcomes

The trial did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM and mean calcification width.

ESWT with hyperextended arm position versus ESWT with neutral arm position

One trial compared ESWT treatment given in a neutral arm position compared with a hyperextended arm position (Tornese 2011).

Major outcomes

Pain

There was no statistically significant difference in pain when comparing hyperextended arm position ESWT with neutral arm position ESWT at 3 months' follow-up (mean pain using 0- to 15-point VAS, 15 indicating worst pain: 10.9 with hyperextended arm position ESWT versus 9.2 with neutral arm position ESWT; MD 1.70, 95% CI –0.55 to 3.95; 35 participants; Analysis 12.1).

Function

There was a statistically significant but clinically unimportant increase in function when comparing hyperextended arm position ESWT with neutral arm position ESWT at three months' follow-up (mean function using Constant score 0 to 100, 100 indicating best function: 76.9 with hyperextended arm position ESWT versus 67.9 with neutral arm position ESWT; MD 9.00, 95% CI 0.72 to 17.28; 35 participants; Analysis 12.2).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, treatment success, quality of life, withdrawals due to adverse events and number of participants experiencing any adverse event.

Minor outcomes

Calcification size: greater than 80% reduction of calcified surface on anteroposterior view

There was no difference in number of participants who achieved greater than 80% reduction of calcified surface on anteroposterior view at the end of the trial (12/18 participants with hyperextended arm position ESWT versus 6/17 with neutral arm position ESWT; RR 1.89, 95% CI 0.92 to 3.89; Analysis 12.3).

Other minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM and mean calcific deposit width.

ESWT versus ultrasound-guided percutaneous lavage

One study investigated ESWT versus ultrasound-guided percutaneous lavage (Del Castillo-Gonzales 2016).

Major outcomes

Pain

There was no evidence of a difference in mean pain (0- to 10-point VAS, 10 indicating worst pain) when comparing ESWT to ultrasound-guided percutaneous lavage at zero to six weeks (MD –0.10, 95% CI –0.26 to 0.06; 201 participants; Analysis 6.1).

There was a statistically and clinically significant increase in mean pain (0- to 10-point VAS, 10 indicating worst pain) when comparing ESWT to ultrasound-guided percutaneous lavage at six weeks to three months (MD 1.90, 95% CI 1.54 to 2.26; 201 participants; Analysis 6.1).

There was a statistically significant increase in mean pain of uncertain clinical significance (0- to 10-point VAS, 10 indicating worst pain) when comparing ESWT to ultrasound-guided percutaneous lavage at three to six months (MD 1.80, 95% CI 1.36 to 2.24; 201 participants; Analysis 6.1).

There was a statistically significant increase in mean pain of uncertain clinical significance (0- to 10-point VAS, 10 indicating worst pain) when comparing ESWT to ultrasound-guided percutaneous lavage (MD 1.90, 95% CI 1.34 to 2.46; 201 participants; Analysis 6.1).

Participant-reported success

There was no statistically significant difference in treatment success (proportion of participants who were pain-free) when comparing ESWT to ultrasound-guided percutaneous lavage at the end of the trial (RR 0.91, 95% CI 0.81 to 1.03; 201 participants; Analysis 6.2).

Number of participants experiencing any adverse event

There was a statistically significant increase in the risk of experiencing an adverse event when comparing ESWT to ultrasound-guided percutaneous lavage at the end of the trial (RR 0.08, 95% CI 0.00 to 1.36; 243 participants; Analysis 6.3).

Minor outcomes

Calcification size

There was a statistically significant decrease in calcification size when comparing ESWT to ultrasound-guided percutaneous lavage at zero to six weeks (MD –2.00 mm, 95% CI –2.94 to –1.06; 201 participants; Analysis 6.4).

There was a statistically significant increase in calcification size when comparing ESWT to ultrasound-guided percutaneous lavage at six weeks to three months (MD 2.00 mm, 95% CI 1.17 to 2.83; 201 participants; Analysis 6.4).

There was a statistically significant increase in calcification size when comparing ESWT to ultrasound-guided percutaneous lavage at three to six months (MD 2.40 mm, 95% CI 1.44 to 3.36; 201 participants; Analysis 6.4).

There was a statistically significant increase in calcification size when comparing ESWT to ultrasound-guided percutaneous lavage at six to twelve months (MD 3.10 mm, 95% CI 2.07 to 4.13; 201 participants; Analysis 6.4).

Calcification size (complete resolution)

There was a statistically significant increase in the chance of complete resolution of calcification when comparing ESWT to ultrasound-guided percutaneous lavage at the end of the trial (RR 0.65, 95% CI 0.53 to 0.80; 201 participants; Analysis 6.5).

ESWT versus ultrasound-guided hyaluronic acid injection

One study compared shock wave therapy to ultrasound-guided hyaluronic acid injection (Frizziero 2017).

Major outcomes

Pain

The study measured pain on the DASH scale postintervention and at three months' follow-up. We did not use these data in our review.

Function

There was evidence of a difference in function when comparing the ESWT group with the ultrasound-guided hyaluronic acid injection group at three months' follow-up (mean function using Constant score 0 to 100, 100 indicating best function: 76.5 (SD 20.6) with ESWT versus 81.8 with ultrasound-guided hyaluronic acid injection; SMD −0.26, 95% CI −0.94 to 0.41; 34 participants; Analysis 14.1).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, participant-reported success, quality of life, proportion of participants with adverse events and withdrawals.

Minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, ROM, size of the calcification and number of participants with complete or partial resolution.

rESWT plus physiotherapy versus physiotherapy

One study compared rESWT plus physiotherapy with physiotherapy alone (Duymaz 2019).

Major outcomes

Pain

There was a statistically significant but clinically unimportant improvement in pain in the rESWT plus physiotherapy group compared to the physiotherapy group alone postintervention (mean pain measured on 0- to 10-point VAS, 10 indicating most pain: 1.3 with rESWT plus physiotherapy versus 2.5 with physiotherapy alone; MD −1.20, 95% CI −1.58 to −0.82; 80 participants; Analysis 15.1).

Function

There was a statistically significant and clinically important improvement in function in the rESWT plus physiotherapy group compared to the physiotherapy group alone (mean function measured on quickDASH scale of 0 to 100, 100 indicating most disability: 1.3 with rESWT plus physiotherapy versus 12.6 with physiotherapy alone; MD −11.30, 95% CI −14.75 to −7.85; 80 participants; Analysis 15.2).

Other major outcomes

The study did not report participant-reported pain relief of 30% or greater, quality of life, number of participant withdrawals and number of participants experiencing any adverse event.

Minor outcomes

Range of movement

There was a statistically significant improvement in flexion with rESWT plus physiotherapy compared to physiotherapy alone postintervention (measured using a goniometer: 171.1 with rESWT plus physiotherapy versus 139.5 with physiotherapy alone; MD 31.60, 95% CI 24.04 to 39.16; 80 participants; Analysis 15.3). There was a statistically significant improvement in extension with rESWT plus physiotherapy group compared to physiotherapy alone postintervention (measured using a goniometer: 33.8 with rESWT plus physiotherapy versus 16.8 with physiotherapy alone; MD 17.00, 95% CI 14.10 to 19.90; 80 participants; Analysis 15.4). There was a statistically significant improvement in abduction with rESWT plus physiotherapy group compared to physiotherapy alone postintervention (measured using a goniometer: 167 with rESWT plus physiotherapy versus 125.2 with physiotherapy alone; MD 41.80, 95% CI 32.79 to 50.81; 80 participants; Analysis 15.5). There was a statistically significant improvement in external rotation with rESWT plus physiotherapy compared to physiotherapy alone postintervention (measured using a goniometer: 49 with rESWT plus physiotherapy versus 25.8 with physiotherapy alone; MD 23.20, 95% CI 16.98 to 29.42; 80 participants; Analysis 15.6).

Other minor outcomes

The study did not report proportion of participants achieving pain score below 30/100 mm on VAS, size of the calcification and number of participants with complete or partial resolution.

DISCUSSION

Summary of main results

Compared to placebo, there was moderate-certainty evidence that shockwave therapy provides no clinically important improvement in pain and function at three months following treatment, and low-certainty evidence indicating there may also be no improvement in the number of participants with a pain reduction of 50% or more and the number with participant-reported treatment success. It is uncertain if therapy increases withdrawal rate and adverse events, due to the small number of events (Summary of findings for the main comparison). None of the studies measured quality of life. There were also no clinically important differences between shock wave therapy and placebo at any other time points.

Subgroup analyses indicated that pain and function outcomes did not differ between those participants who did or did not have calcific deposits.

Shock wave therapy was associated with an increased rate of complete resolution of calcium deposits by the end of the trial, but this was of uncertain clinical significance. The studies did not measure the proportion of participants achieving a pain score below 30/100 mm on VAS, ROM and number of participants with partial resolution of calcific deposits.

Evidence was downgraded due to the risk of selection, detection or reporting bias, or a combination of these biases, as well as imprecision or heterogeneity.

We are uncertain if shock wave therapy has any benefits over ultrasound-guided needling, TENS, supervised exercises, no treatment, percutaneous lavage or multiple versus single treatments, as there was only low- to very low-certainty evidence from single or few small studies.

There was very low-certainty evidence that high-dose shockwave therapy may provide a clinically important benefit compared with low-dose shock wave therapy at the end of the trial with respect to treatment success and function. Higher doses also had a benefit of uncertain clinical significance with respect to ROM and reduction of calcific deposits. High-dose therapy had a higher risk of adverse events but not withdrawals. There were no clinically important differences between high-dose and low-dose shock wave therapy at any other time points. Evidence was downgraded due to the risk of multiple biases, imprecision, heterogeneity and indirectness for pain and function.

Adverse events of shock wave therapy reported in the trials included treatment-related pain, bruising and bleeding, although these were self-limiting.

Rare and potential serious adverse events, such as osteonecrosis of the bone of the upper arm (loss of blood supply and bone death) while theoretically possible, were not reported in the studies.

Overall completeness and applicability of evidence

There was inconsistent reporting of major outcomes across trials (Table 3). Overall pain and function were reported commonly (96% of trials for both), but were often not reported fully, for example without measures of variance, or in some studies only reported in the treatment group, precluding their inclusion in the analyses. A lower proportion of trials measured the other major outcomes. No trial reported participant-reported pain relief of 30% or greater, although one trial reported pain relief of 50% or greater, which we reported. Fifty percent of trials reported treatment success, no trial included quality of life, 25% reported withdrawals and 64% reported withdrawals due to adverse events.

Inclusion of a core outcome measures in future trials would facilitate the ability to synthesise the evidence, compare results between trials and increase the certainty of our conclusions (Buchbinder 2017; Page 2015; Page 2016c; Page 2018).

Additionally, there was no standard approach to shock wave therapy in terms of type of shock wave, dose and frequency of treatment, and the placebo controls varied across trials. This resulted in marked clinical heterogeneity across studies leading to uncertainty in interpreting the pooled analyses.

While we did find that shock wave therapy, particularly in high doses, resulted in a greater number of people with complete resolution of calcific deposits when present, this did not appear to translate into improved patient-relevant outcomes of pain, function or treatment success.

Two RCTs that were potentially eligible for inclusion in this review did not have available results. However, we believe it is unlikely that inclusion of these studies in our review would change our conclusions.

Quality of the evidence

We used the GRADE approach to assess the certainty of the evidence (Schünemann 2011a). Moderate-certainty evidence suggests that compared to placebo, shock wave therapy results in a small but clinically uncertain improvement in mean pain and function. It did not appear to matter if participants had calcific deposits or not. Evidence was downgraded due to the potential for selection, performance, detection and reporting biases, There was also considerable heterogeneity, but, as it was largely driven by a pseudo-randomised trial with outlier results, we did not downgrade the evidence further.

Shock wave therapy may not have an effect on participant-reported pain relief of 50% or greater and treatment success, but as this is based on low-certainty evidence, we could not be certain. Evidence was downgraded due potential bias arising from inadequate study design and imprecision: only a single poorly designed study reported pain relief of 50% or more, and although 287 participants from six poorly reported studies reported treatment success, CIs around the effect estimate were wide, due to the small number of events in most studies. Low-certainty evidence was also available from seven studies for withdrawals and five studies for adverse events. Evidence was downgraded due to potential for bias and imprecision. We are uncertain if withdrawals or adverse events differed between groups due to the small number of events. Shock wave therapy did result in more people with complete resolution of calcium deposits compared to placebo. Quality of life was not measured.

We are uncertain if shock wave therapy has any benefits over ultrasound-guided glucocorticoid needling, TENS, exercise or no treatment, or different regimens of shock wave therapy as there was only low-certainty evidence from single or few small studies, subject to bias and imprecision.

We are uncertain if higher doses of shock wave therapy has any benefit and more adverse events over lower doses, due to very low-certainty evidence. Evidence was downgraded due to imprecision, bias, heterogeneity and indirectness due to variability and lack of consensus in recommended treatment dose.

Potential biases in the review process

We performed a thorough search of CENTRAL, MEDLINE, Embase, ClinicalTrials.gov and WHO International Clinical Trials Registry Platform databases using a sensitive search strategy without restricting by date or language to identify published and unpublished studies, so it is unlikely that we missed any relevant studies. We could not fully assess publication bias because we did not have enough trials. However, unpublished trials may be more likely to show no benefit of shock wave therapy and are, therefore, unlikely to change our conclusions.

We identified five ongoing studies, one comparing needle aspiration of calcific deposits versus ESWT (NTR7093), one comparing rESWT to ultrasound-guided needle puncture or to a combination of both interventions (NCT02677103), one comparing focussed ESWT to rESWT (ChiCTR1900022932), another comparing high energy ESWT to low energy ESWT to sham (NCT03779919), and one comparing ESWT to steroid injection (PACTR201910650013453). As these studies have varied comparators and would be presented as single studies in stand-alone comparisons, it appears that inclusion of the results when available are unlikely to impact on the conclusions of this review.

Two review authors independently assessed the trials for inclusion, extracted data and assessed the risk of bias, and a third review author adjudicated when any discrepancy arose. Review questions of interest were defined with full knowledge of the possible comparisons that could be undertaken, but no knowledge of the results of any comparisons. To prevent selective inclusion of results we used predefined decision rules to select data from trials when multiple measurement scales, time points and analyses were reported.

A limitation of the review was that many trials did not report major outcomes or presented outcome data incompletely and attempts to obtain unpublished data from trialists were largely unsuccessful.

We identified nine studies published in languages other than English that we could not translate at the time of submission of the review, and thus these studies are still awaiting classification. We do not consider that the results of these studies are likely to alter the conclusions of the review substantially.

Agreements and disagreements with other studies or reviews

Two other systematic reviews comparing shock wave therapy to placebo have been published (Bannuru 2014; Ioppolo 2013). However, Bannuru 2014 did not identify the time points at which it was extracting data and stratified its included trials based on higher doses versus sham to lower dose versus sham, as well as for studies with higher doses versus calcification and lower doses versus calcifications. Ioppolo 2013 only synthesised the data for calcific deposit resolution for meta-analysis. We identified two other meta-analysis of ESWT; however, one only compared high-dose to low-dose therapy (Verstraelen 2014) and one pooled data for ESWT versus any other treatment (Vavken 2009). Therefore, to our knowledge ours is the most comprehensive review of shock wave therapy for rotator cuff disease.

Our conclusions about the benefits and harms of ESWT are consistent with other reviews in that it is likely to help resolve calcification deposition, but that this is of uncertain clinical significance. Our review also suggests that higher-dose therapy may be more beneficial than lower-dose therapy. Where our review differs, is that Bannuru 2014 and Ioppolo 2013 both recommend ESWT as an effective treatment over sham. These discrepancies appear to derive from how these reviews handled their data. Due to the high heterogeneity of studies, Bannuru 2014 did not synthesise the data from its included studies for meta-analysis. Instead it appears to have based its recommendations on visualisations of the mean and 95% CIs for studies, and further narrowed its recommendations to "high-dose" studies including only people with calcifications. These results should be interpreted cautiously, however, as even within these high-dose trials treatment regimens varied greatly. Furthermore, from the published information, it was not possible to determine which time points Bannuru 2014 was referring to, which groups it extracted its data for (as one included high-dose trial had three arms) and it should be noted that they considered a trial which compared ESWT to no treatment as sham, where our review considered no treatment at all as not equitable to a sham treatment. Finally, due to the great differences between treatment regimens, our review did not pool all trials with calcifications, but only used trials which reported data separately for people with and without calcifications to consider the potential different effectiveness of ESWT on these groups. As for Ioppolo 2013, the study authors did not synthesise data for outcomes other than calcification resorption for meta-analysis. Their recommendations about the effectiveness of ESWT over sham for pain and function outcomes are based on the mean change in mean for the treatment groups in their included studies' outcome scores (such as VAS or Constant score), but did not include considerations of CIs or MDs. Meanwhile, our review based its recommendations on how ESWT performed when compared to sham on the MD between treatment and control groups, and considered that for a change to be clinically important its 95% CIs must not have left the range of clinical importance.

Finally, discrepancies over the recommendations that can be made from the results of these meta-analyses appear to be driven by less frequent consideration of the overall certainty of evidence in these reviews (i.e. while study risk of bias was assessed, other domains of the GRADE approach (imprecision, inconsistency, indirectness and publication bias) were not).

AUTHORS' CONCLUSIONS

Implications for practice

Based upon the currently available low- to moderate-certainty evidence, our review indicates few clinically important benefits of shock wave therapy compared with placebo, ultrasound-guided needling, transcutaneous electrical nerve stimulation, supervised exercises or percutaneous lavage for the treatment of rotator cuff disease with or without calcific deposits. There is also uncertainty regarding its safety. Wide clinical heterogeneity and varying treatment protocols means that we do not know whether 'subtherapeutic' doses were tested in some trials underestimating any potential benefits.

Implications for research

Further trials of shock wave therapy for rotator cuff disease should be based upon a strong rationale, be of high quality, include a core set of outcomes and be adequately powered to test for important patient-relevant benefits. To reduce research wastage, further trials should only be conducted with explicit consideration of whether or not they would alter the conclusions of this review. A standard dose and treatment protocol should be defined and evaluated in a consistent and comparable manner. Updates of this review will only be performed if new trials that may change the conclusions of this review become available.

ACKNOWLEDGEMENTS

We are grateful to Louise Falzon, Trial Search Co-ordinator, Cochrane Musculoskeletal Group for designing the original search

strategy and Tamara Rader, Trial Search Co-ordinator, Cochrane Musculoskeletal Group for updating and executing the searches. We would also like to thank Juliana Roos for her substantial contribution to the protocol.

We would like to acknowledge the peer-referees:

- Hans Lund, Western Norway University of Applied Sciences (Cochrane Musculoskeletal Editor);
- Professor Susanna Proudman, Rheumatology Unit, Royal Adelaide Hospital and Discipline of Medicine, University of Adelaide, South Australia;
- Professor G David Baxter, Centre for Health, Activity and Rehabilitation Research, University of Otago.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Albert 2007

Methods	**Study design:** single-centre, parallel group, two-arm RCT **Setting:** outpatient setting, Rennes University Hospital, France **Trial time period:** December 2002 to August 2004 **Interventions:** high-dose ESWT vs low-dose ESWT **Sample size calculation:** 40 people per treatment group required to achieve 95% power to detect a difference of ≥ 15% in the change in CMS between the active treatment and control groups at 3 months' follow-up **Analysis:** ITT
Participants	**Number of participants:** • screened for eligibility: 108 (25 not meeting inclusion criteria; 3 refused to participate) • enrolled: 80 • randomised: 80 (40 per group) • included in analyses at 3 months' follow-up: 80 (40 per group)

Albert 2007 *(Continued)*

Inclusion criteria:

- radiographically verified calcifying tendonitis of the shoulder, either type A calcification (sharp contours and a homogeneous structure) or type B calcification (sharp contours and a non-homogeneous structure), as defined by Mole and the French Arthroscopy Association
- symptom duration ≥ 3 months
- referred by regional rheumatologists and orthopaedic surgeons
- failure to respond to an oral course of analgesic or NSAID, subacromial steroid injection, calcification needling or physiotherapy
- aged 18–75 years

Exclusion criteria:

- pregnancy
- clotting disorders
- anticoagulant or antiplatelet treatment
- cardiac pacemaker
- chronic inflammatory joint disease
- infections or tumours of the shoulder
- adhesive capsulitis
- hyperalgia of the shoulder due to resorption of a calcific deposit
- calcification of type C (irregular contours) or type D (linear contours), as defined by the French Arthroscopy Association

Baseline characteristics:

High-dose ESWT (40 participants):

- mean age (range): 46.6 (31–64) years
- number male/female: 9/31
- mean (range) duration of symptoms: 41.2 (6–120) months; affected side (right:left): 30:10
- location of the calcific deposit: 36 supraspinatus tendon, 4 infraspinatus tendon
- number of calcific deposits: 30 had 1, 10 had 2
- previous treatment: 26 subacromial injection; 20 physiotherapy; 3 needling of calcification
- mean (range) pain VAS 0–10: 5.6 (0.4–9.7)
- mean (range) Constant score: total 50.7 (33.2–70.2); pain 5.9 (2.5–12); ADL 10.6 (5–15); ROM 25.6 (12.0–38.0); power 8.6 (0–25.0)

Low-dose ESWT*(40 participants):*

- mean age (range): 47.5 (32–69) years
- number male/female: 10/30
- mean (range) duration of symptoms: 36.4 (7–160) months; affected side (right:left): 25:15
- location of the calcific deposit: 33 supraspinatus tendon, 7 infraspinatus tendon
- number of calcific deposits: 33 had 1; 7 had 2
- previous treatment: 31 subacromial injection; 18 physiotherapy; 5 needling of calcification
- mean (range) pain VAS 0–10: 5.6 (1.2–9.4)
- mean (range) Constant score: total 50.3 (28.2–83.8); pain 5.8 (1.0–11.0); ADL 10.3 (5.0–16.0); ROM 25.7 (10.0–40.0); power 8.5 (3.0–20.8)

Pretreatment group differences: participants in high-dose ESWT group had a longer duration of symptoms compared with low-dose group. The low-dose participants had more subacromial injections in past than those in high-dose group.

Interventions	**High-energy ESWT:** • method of administration: participants were placed in a supine position and the calcific deposit was identified using fluoroscopy. US gel was applied on the skin of the participant. Analgesic pre-

Albert 2007 *(Continued)*

	medications consisting of 1 × 100 mg tablet of ketoprofen and 2 capsules of a paracetamol-dextropropoxyphene combination (400 mg/30 mg per capsule) were given 1 hour before each session. An anaesthetic patch with lidocaine 25 mg and prilocaine 25 mg (Emla Patch, Astra Zeneca, Switzerland) was placed on the skin, in the field of contact with the shock wave generator head. A Modulith SLK (Storz Medical AG, Tägerwilen, Switzerland) electromagnetic shock wave generator with fluoroscopic and sonographic guidance was used to deliver the sessions • dose: 2500 impulses; frequency 1 Hz (1 impulse per second) for the first 200 and 2 Hz thereafter to the maximum energy level tolerated by the participant, without exceeding 0.45 mJ/mm² per impulse. Mean cumulative EFD administered was 1210 mJ/mm² (610–1700 mJ/mm²). • frequency: 2 sessions, 14 days apart • co-interventions: participants were given half a day's sick leave and were prescribed analgesic and anti-inflammatory drugs in case they experienced severe pain. No restrictions were imposed on the participants regarding their activities except for workers performing heavy duties, who were given 2 days' sick leave **Low-energy ESWT:** • method of administration: as described above • dose: frequency was 1 Hz (1 impulse per second) for the first 200 impulses, then 2 Hz thereafter. The energy intensity was gradually increased from 0.02 mJ/mm² per impulse to 0.06 mJ/mm² per shock (i.e. 145 mJ/mm² per session) • frequency: 2 sessions, 14 days apart • co-interventions: as described above
Outcomes	Measured at baseline and 3 months **Outcomes included in review:** • mean function: CMS 0–100, higher score indicating better function • mean change in pain: VAS 0–10, higher score indicating worse pain • proportion with adverse events: e.g. pain during treatment, skin lesions • self-reported treatment success: 5-point scale (very effective, effective, moderately effective, poorly effective, not at all effective), we extracted proportion of participants who considered treatment very effective, effective or moderately effective • change in size of calcifications: viewed on lateral and anteroposterior shoulder views in neutral, external and internal rotation, and taken as number who achieved total or subtotal resorption (over 80% reduction of calcified surface on anteroposterior view) • withdrawals: due to adverse events, intolerance to treatment or other reasons **Other outcomes in trial, excluded from review:** • mean pain toleration during treatment • subscores of the CMS • type and location of calcifications • proportion of participants with ≥ 15-point improvement in Constant score
Source of funding	Funding by Clinical Research Commission of Rennes University Hospital. The electronic dynamometer was provided by Smith-Nephew France (ZITournes-Cliron BP 1109, Tournes, France).
Notes	**Trial registration:** not registered **Time points included in review:** 3 months **Data analysis:** range was the only measure of variance reported for pain and function; we used SD for change in pain from Gerdesmeyer 2003, and SD for mean function score from Ioppolo 2012 **Withdrawals:** 1/40 in high-dose group due to resolution of symptoms and 1/40 in low-dose group due to a panic attack **Adverse events:**

Albert 2007 *(Continued)*

High-dose ESWT:

- serious adverse events: 0/40
- other adverse events: 15/40 (skin lesions)

Low-dose ESWT:

- serious adverse events: 0/40
- other adverse events: 1/40 (panic attack)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Centralised randomisation list using block sizes of 4 used.
Allocation concealment (selection bias)	Low risk	Allocation concealment centralised; thus, risk of selection bias was probably low.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were reported as blinded, the physician measuring outcomes at the follow-up was not blinded; however, authors stated that "the assignment chart was not consulted before the assessment was completed."
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants were blinded to their treatment group, and self-reported outcomes of pain, function and treatment success were unlikely to be affected by bias.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiological assessment performed by an assessor unaware of treatment allocation. The other 'assessing physician' although unblinded did not have access to the assignment chart until measurements were completed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2/80 withdrew (1/40 in each group); follow-up data was collected from both participants but the low-dose group participant refused to attend the clinic visit so data collection was done via telephone.
Selective reporting (reporting bias)	Low risk	No published study protocol, but results included all major outcomes, thus the risk of reporting bias was probably low.
Other bias	Low risk	No other biases apparent.

Cacchio 2006

Methods	**Study design**: single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** San Salvatore Hospital of L'Aquila, Coppito-L Aquila, Italy **Trial time period:** November 2002 to December 2003 **Interventions:** high-dose RSWT vs low-dose RSWT **Sample size calculation:** not performed **Analysis:** ITT
Participants	**Number of participants**

Cacchio 2006 *(Continued)*

- screened for eligibility: 95 (2 not meeting inclusion criteria; 3 meeting exclusion criteria)
- enrolled: 90
- randomised: 90 (45 per group)
- at 6 months' follow-up: 84 (45 in high-dose group; 39 in low-dose group)
- included in analyses at 6 months: 90 (45 in each group)

Inclusion criteria:

- calcific tendinitis of the shoulder as detected on standardised X-rays and defined according to the Gärtner and Simons radiograph classification as type I (homogeneous and with well-defined borders); or type II (heterogeneous in structure with sharp outline or homogeneous in structure with no defined border)
- symptoms for ≥ 6 months, including a pain score ≥ 4 cm on a VAS 0–10 cm
- failure of previous conservative treatments (anti-inflammatory drugs, US and exercises, laser therapy and exercises, electrical stimulation and exercises, acupuncture, steroid injection)

Exclusion criteria:

- rotator cuff tear
- glenohumeral or acromioclavicular arthritis or acromioclavicular spur to rule out alternative explanations for the pain
- pregnancy
- implanted pacemaker
- blood coagulation disorders or use of anticoagulant drugs
- aged < 18 years
- inflammatory or neoplastic disorders
- presence of type III (cloudy and transparent) calcifications according to the Gärtner and Simons radiographic classification
- conservative treatments administered in last 4 weeks

Baseline characteristics:

High-dose RSWT (45 participants):

- mean (SD) age: 56.1 (2.0) years
- number male/female: 27/18
- mean (SD) calcification size: 21.30 (7.50) mm
- type of calcification: 11 type 1; 34 type 2
- mean (SD) duration of symptoms: 14 (4.95) months
- treatment history: 42 anti-inflammatory drugs, 13 US and exercise, 10 laser therapy and exercise, 16 TENS, 3 acupuncture, 39 steroid injection
- mean (SD) baseline pain score on VAS 0–10 cm: 7.96 (0.88)
- mean (SD) baseline function score (UCLA 0–100): 10.25 (2.08)

Low-dose shock wave therapy (45 participants):

- mean (SD) age: 56.4 (2.1) years;
- number male/female: 28/17
- mean (SD) calcification size: 19.70 (8.30) mm
- type of calcification: 13 type 1; 32 type 2
- mean (SD) duration of symptoms: 13 (5.03) months
- treatment history: 40 anti-inflammatories, 16 US and exercise, 8 laser therapy and exercise, 12 TENS, 3 acupuncture, 33 steroid injection
- mean (SD) baseline pain score on VAS 0–10 cm: 7.72 (1.03)
- mean (SD) baseline function score (UCLA 0–100): 10.14 (1.96)

Pretreatment group differences: none

Cacchio 2006 *(Continued)*

Interventions	**High-dose RSWT:** • method of administration: participants were seated with the shoulder abducted at 45 degrees, the elbow flexed at 90 degrees and the forearm resting on a flat surface. The shock wave applicator was placed in direction of the calcifications. The RSWT was administered using a 15-mm head applicator. The treatment area was prepared with a coupling gel (Aquasonic 100) to minimise the loss of shock wave energy at the interface between applicator tip and skin. No local anaesthetics or analgesic drugs were administered before or during the treatment. The RSWT was administered using a Physio Shock Wave Therapy device (Elettronica Pagarii Sri, Via De Nicola 4/D. 20037 Paderno Dugiiano (MI), Italy) with a 15-mm head applicator • dose: 2500 impulses per session (500 impulses with a pressure of 1.5 bar and a frequency of 4.5 Hz and 2000 impulses with a pressure of 2.5 bar and a frequency of 10 Hz), an EFD of 0.10 mJ/mm, and a fixed impulse time of 2 milliseconds • frequency: 4 sessions at 1-week intervals • co-intervention: none **Low-dose RSWT group:** • method of administration: as described above • dose: 25 impulses per session (5 impulses with a pressure of 1.5 bar and a frequency of 4.5 Hz and 20 impulses with a pressure of 2.5 bar and a frequency of 10 Hz) • frequency: 4 sessions at 1-week intervals • co-intervention: none
Outcomes	Measured at 1 week and 6 months after treatment **Outcomes included in review:** • function: UCLA Shoulder Rating score, out of a maximum of 35 with a higher score indicating better function • pain: measured on a VAS 0–10 cm, higher score indicating greater pain • change in calcification size: measured in millimetres by callipers from an anteroposterior X-ray of the shoulder obtained in 45 degrees of external rotation and 45 degrees of internal rotation • treatment success: proportion of participants with 34–35 out of maximum score 35 on UCLA score • proportion of participants with adverse effects • withdrawals: due to adverse events, intolerance to treatment or other reasons • ROM: active range of flexion (degrees) **Outcomes excluded from review:** • mean participant strength: UCLA Shoulder Rating Scale • mean participant satisfaction: UCLA subscore 0–5, 5 being most satisfied
Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 1 and 6 months **Data analysis:** we used the enrolled population (45 participants per group) as the denominator to measure treatment success. We extracted data that included transformed data for 6 participants in low-dose group who had received additional treatment for pain and function at 6 months. **Withdrawals:** 0/45 in high-dose group; 6/45 in low-dose group as they received local steroid injections **Adverse events:** *High-dose RSWT:*

Cacchio 2006 *(Continued)*

- serious adverse events: 0/45
- other adverse events: 3/45 (haematoma lasting 4–6 days)

Low-dose RSWT:

- serious adverse events**:** 0/45
- other adverse events: 0/45

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated 1:1 randomisation scheme.
Allocation concealment (selection bias)	Unclear risk	Used 'sealed envelopes'; insufficient information to determine if this was adequate to conceal the random sequence.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and personnel unaware of treatment group.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants blinded. Low risk of bias in self-reported outcomes.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Outcome assessors and the radiologist blinded to treatment.
Incomplete outcome data (attrition bias) All outcomes	High risk	6/90; 0/45 in high-dose group, 6/45 (13%) in low-dose group as they received local steroid injections; however, their data were included in final analysis. The trialists used the final mean change recorded in per-protocol completer population instead, possibly overestimating the benefits of high-dose shock wave.
Selective reporting (reporting bias)	Low risk	Although there was no trial protocol, data reported for all outcomes measured (as reported in methods).
Other bias	Low risk	No other biases apparent

Cosentino 2003

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** Italy **Trial time period:** not reported **Interventions:** ESWT vs sham procedure **Sample size calculation:** not performed **Analysis:** method was not described
Participants	**Number of participants**

Cosentino 2003 *(Continued)*

- screened for eligibility: not reported
- randomised: 70 (35 per treatment group)
- included in analyses: 70 at 1 month (35 per group), 47 at 6 months (35 in shock wave and 12 in placebo)

Inclusion criteria

- chronic, symptomatic, calcifying tendinitis of the shoulder (with a minimum diameter of 10 mm in anteroposterior X-ray films), with pain for a minimum of 10 months
- calcific deposits were non-homogeneous and located in supraspinatus tendon
- unsuccessful conservative treatment during the 6 months before referral to the research based at the hospital

Exclusion criteria

- local and generalised arthritis
- osteoarthritis
- algodystrophy
- pregnancy
- infectious or tumour diseases
- skin ulcerations
- neurological abnormalities
- dysfunction in neck or thoracic region or both
- partial or complete ruptures of the rotator cuff seen by sonography

Baseline characteristics:

ESWT (35 participants):

- number male/female: 15/20
- mean (range) duration of symptoms: 15 (10–20) months
- mean Constant 0–100 score: total 45, pain 5.2, ADL 9.6, ROM 23.2, power 7
- treatment history: 35 analgesics and NSAIDs, 25 local steroid injections, 10 physiotherapy, 2 needling
- calcification size: not reported

Sham procedure (35 participants):

- number male/female: 12/23
- mean (range) duration of symptoms: 14.5 (10–18) months
- mean Constant 0–100 score: 48 (range 22–84 points) other values not reported
- treatment history: 35 analgesics and NSAIDs, 28 local steroid injections, 7 physiotherapy, 3 needling
- calcification size: not reported

Pretreatment group differences: not reported

Interventions

ESWT:

- description of modality: ESWT system Orthima by Direx Medical System Ltd
- method of administration: participants were seated in front of the shock wave generator and the shock wave source was placed in direction of the calcification that was identified during sonographic examination. No local anaesthetics, analgesics or NSAIDs were used during the procedure
- dose: 1200 shocks with a frequency of 120 shocks per minute delivered each treatment. Because pain could occur mostly during the first treatment, all participants were treated with a low-energy density of 0.03 mJ/mm^2 for the first 5 minutes, which was then progressively increased to 0.28 mJ/mm^2. Successive treatments used an energy density of 0.28 mJ/mm^2.
- frequency: 4 treatments (1 every 4–7 days)
- co-interventions: none

Sham procedure:

Cosentino 2003 *(Continued)*

- description of modality: as above
- method of administration: as above
- dose: 1200 shocks with a frequency of 120 shocks per minute, the energy density was set to 0 mJ/mm^2
- frequency: 4 treatments (1 every 4–7 days)
- co-interventions: none

Outcomes	Pain and function measured at baseline, end of treatment, 1 month and 6 months; calcifications measured at 1 month **Outcomes included in review:** • mean pain measured by CMS, maximum: 15 points, with a higher score indicating less pain • function measured by CMS, maximum: 100 points, with a higher score indicating better function • variations in dimension of the calcification evaluated by anteroposterior X-ray film. Modification of the calcification (reduction of size > 2 mm) was indicated as disintegration; the total disappearance was indicated as dissolution • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • ADL • power • ROM
Source of funding	No source of funding reported
Notes	**Trial registration:** not registered **Time points included in review:** 1 and 6 months **Data analysis:** trialists did not report pain for the sham group, thus we excluded this study from Analysis 1.2. Trialists did not report the number of withdrawals from the shock wave group; we excluded this study from Analysis 1.5. The mean Constant score was extracted using the WebPlotDigitier program found at arohatgi.info/WebPlotDigitizer/app. It was unclear whether the graph also displayed SE or SD; we assumed SD. Where extracted numbers differed from a reported figure, the reported figure was used. Proportion of participants with adverse events was reported as 0 for both groups (apart from initial transient treatment pain, although the number of participants with the event in each group was not explicitly reported) **Withdrawals:** 23/35 participants from the sham group and 0/35 from the shock wave group at 6 months' follow-up. No reasons for withdrawal were given. **Adverse events:** *ESWT:* • serious adverse events: 0/35 • other adverse events: 0/35 *Sham procedure:* • serious adverse events: 0/35 • other adverse events: 0/35

Risk of bias

Bias	Authors' judgement	Support for judgement

Cosentino 2003 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Method of randomisation not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Study personnel not blinded; however, the radiologist assessing calcifications was blinded. Participants blinded to group allocations.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Due to blinding of participants, there was low risk of bias in reporting of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiologist who measured calcification size blinded to the group allocations, objective outcomes in Constant score were not used in this review.
Incomplete outcome data (attrition bias) All outcomes	High risk	23/35 (66%) participants were lost from the sham group at 6 months, with no reason given; 0/35 lost from the shock wave group.
Selective reporting (reporting bias)	High risk	Study outcomes not reported clearly, means given but ranges were missing for baseline values. Pain scores given only for the treatment group and not for the sham group.
Other bias	Low risk	No other biases apparent

De Boer 2017

Methods	**Study design:** single-centre, parallel-group, two-arm, RCT **Setting:** outpatient clinic, Department of Orthopaedic Surgery, Hospital in the Netherlands **Trial time period:** May 2010 and March 2011 **Interventions:** RSWT vs US-guided needling **Sample size calculation:** in initial power calculation of the medical ethical committee, 40 participants were needed for inclusion (20 in each group) **Analysis:** as-treated
Participants	**Number of participants:** • screened: not reported • enrolled: 25 • randomised: 25 (14 in shock wave group; 11 in needling group) • included in analyses at 12 months: 19 (9 in shock wave group as 5 crossed over to needling group; 10 in needling group as 1 crossed over to shock wave group) **Inclusion criteria:** • shoulder pain persisting > 6 months • calcification in rotator cuff region type I or II according to Gärtner on a standard shoulder X-ray

De Boer 2017 *(Continued)*

- pain on NRS ≥ 4
- previous conservative therapy (physiotherapy, NSAIDs, cortisone infiltration) had failed

Exclusion criteria:

- insufficient knowledge of Dutch language
- aged < 18 years
- inability to receive informed consent
- participation in other study
- other pathology which could cause shoulder or upper limb pain (e.g. rotator cuff tears, acromioclavicular arthropathy, frozen shoulder, cervical disc hernia)
- people with inflammatory, malignant or clotting disease
- pregnant women

Baseline characteristics:

RSWT (14 participants):

- mean (95% CI) age: 53 (48–58) years
- number male/female: 7/7
- mean (95% CI) Gärtner classification: 1.1 (0.7–1.5)
- mean (95% CI) NRS: 7.9 (6.9–8.8)
- mean (95% CI) Oxford score: 38.5 (34.0–43.0)
- mean (95% CI) Constant score: 57.5 (48.9–66.1)

US-guided needling (11 participants):

- mean (95% CI) age: 53 (50–57) years
- number male/female: 6/5
- mean (95% CI) Gärtner classification: 1.2 (0.7–1.6)
- mean (95% CI) NRS: 7.5 (6.5–8.6)
- mean (95% CI) Oxford score: 38.5 (33.3–43.6)
- mean (95% CI) Constant score: 55.7 (46.1–65.4)

Interventions

RSWT:

- description of modality used: a Masterpuls MP 100 (Storz Medical, Tägerwilen, Switzerland) used in combination with a standard US transfer gel
- method of administration: RSWT was performed by a specialist physical therapist that initially treated 20 participants who were not included in study, to pass the learning curve
- dose: 500 pulses of 1.5 bar (150 kPa) with frequency of 4.5 Hz, followed by 2000 pulses of 2.5 bar (250 kPa) with a frequency of 10 Hz; EFD 0.10 mJ/mm. Duration of pulses 2 ms
- frequency: 4 sessions, 1-week apart
- co-interventions: none

US-guided needling:

- method of administration: the calcification was localised with US and pierced several times with 2 hollow 18-gauge needles. A saline solution was flushed through both needle portals to wash out the calcium. All procedures were done by the senior author who was a shoulder surgeon experienced in ultrasonography.
- any additional treatment during trial: before the start of the treatment, 1 mL corticosteroid 40 mg (Depo-Medrol 40 mg/mL, Pfizer Medical, New York City, NY, USA) was left inside the subacromial bursa without US guidance. Then a local anaesthetic (lidocaine 1%) was administered to the skin, bursa and tendon
- frequency: single treatment
- co-interventions: none

De Boer 2017 *(Continued)*

Outcomes	Measured at baseline, 6 weeks and 12 months **Outcomes included in review:** • pain: NRS, from 0–10, 10 indicating greater pain and any non-whole numbers rounded up • change in calcification size: proportion of participants with complete resolution of deposits • treatment success: proportion of participants free of complaints • function: CMS, 2–100, higher score indicating better function • function: Oxford shoulder score, 12-item questionnaire from 12 to 60, higher score indicating better function • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons Note that both function scores were extracted as the Constant score was not reported at 1 year **Outcomes excluded from review:** • change in calcification size: change in Gärtner score
Source of funding	None reported
Notes	**Trial registration:** not registered **Time points included in review:** 6 weeks and 12 months **Data analysis:** outcome data extracted at 6 weeks and 12 months **Withdrawals:** 5/14 in shock wave group (severe pain); 1/11 in US needling group (severe pain) **Adverse events:** *RSWT:* • serious adverse events: 0/14 • other adverse events: 5/14 (severe pain) *US-guided needling:* • serious adverse events: 0/11 • other adverse events: 1/11 (1underwent subacromial debridement and decompression because of unacceptable persistent pain)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was done by allowing the patient to choose an unmarked envelope containing the treatment protocol for either UN or RSWT from a box. The envelopes were randomized in blocks (6 envelopes, 3 of each treatment). When a block was finished, the next block was started."
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither participants nor personnel were blinded.

De Boer 2017 *(Continued)*

Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Participants were not blinded to their treatment group due to the nature of their intervention, and this was likely to affect the measurement of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	The X-ray results were collected by a nurse practitioner and though it was not clear if they were blinded, this was unlikely to affect the data.
Incomplete outcome data (attrition bias) All outcomes	High risk	6/25; 5/14 (35.7%) in shock wave group (severe pain) and 1/11 (9%) in US needling group. The trialists did not use an ITT analysis and excluded these 6 participants from the follow-up analysis.
Selective reporting (reporting bias)	High risk	No access to the study protocol and trial was not registered. In outcome data, 12-month Constant scores not reported.
Other bias	High risk	Data Safety Monitoring Board prematurely terminated inclusion because of the higher pain score in shock wave group.

Del Castillo-Gonzales 2016

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** Centro Medico Deyre, Madrid, Spain **Trial time period:** January 2007 to December 2013. **Interventions:** ESWT vs US-guided percutaneous lavage **Sample size calculation:** not described **Analysis:** only performed in participants who completed study
Participants	**Number of participants:** • screened: 294 (41 total/partial tendon rupture; 8 calcification < 5 mm; 2 no consent) • enrolled: 243 • randomised: 243 (121 in shock wave group; 122 in lavage group) • included in analyses: 201 (80 in shock wave group; 121 in lavage group) **Inclusion criteria:** • minimum calcification of 5 mm in diameter • minimum VAS pain score of 6 (VAS 0–10, 10 indicating maximum pain) • no allergies to medications used **Exclusion criteria:** • total or partial tendon rupture • calcification size < 5 mm **Baseline characteristics:** not provided
Interventions	**ESWT:** • method of administration: ESWT (Swiss DolorClast device) performed with participant seated and facing the physician. A conducting gel was placed on the area where the waves were to be transmitted. The calcification was localised by fluoroscopy, and the point on the skin where the shock waves would

Del Castillo-Gonzales 2016 *(Continued)*

	be delivered was identified. ESWT was delivered with the shock wave emitter in direct contact with the skin. After each session, the participant was monitored to observe for complications before discharge. The procedure did not require a local anaesthetic. • dose: total of 2000 impacts (2 series of 1000 each) at a frequency of 8–10 Hz and an energy density of 0.20 mJ/mm^2 • frequency: twice per week for 4 weeks • co-interventions: participants were instructed to take the same oral NSAID (ibuprofen 600 mg/12 hours) for 3 days if there was no contraindication. All participants were told to continue their normal lives, but to avoid overloading the affected shoulder for 1 week. **US-guided percutaneous lavage:** • method of administration: a prior US examination was used to determine the position of the shoulder that would leave the calcification most accessible from the cutaneous plane. The procedure was performed with the participant seated and facing the physician, with the shoulder rotated internally and the forearm placed on the back. Under aseptic conditions, 10 mL of 2% mepivacaine was injected into the skin using a syringe with a 20-gauge needle, and placing the US probe over the trajectory (from the entry point to the calcification). The needle was gradually pushed towards the calcification, anaesthetising from the point of entry in the skin through to the subacromial bursa. The needle was then placed below the calcification, and the remaining anaesthetic used to begin its fragmentation and lavage, working the plunger with a forward pumping movement only, i.e. without aspiration. These impulses were maintained until the calcified material began to leave the calcification and enter the syringe. When the syringe body was full it was replaced by a syringe containing physiological saline, but without removing the needle form its position. The same lavage and pumping action were then performed again. The procedure was repeated until no more calcified material could be withdrawn, the calcification had completely fragmented, or until the participant showed signs of discomfort. At this point the syringe body was switched (without withdrawing the needle) for that containing 2 mL triamcinolone. The needle was then gradually extracted as far as the bursa where the syringe contents were emptied, before being completely removed. The insertion point in the skin was then covered with a sterile gauze. In participants with a hard calcification, or in which the needle became blocked due to the entry of dense material, the needle was switched for an 18-gauge. • dose: 5 mL triamcinolone and several syringes containing normal saline • frequency: once • co-interventions: participants were provided an anxiolytic (bromazepam 1.5 mg) 30 minutes before the procedure to reduce the possibility of the appearance of vagal syndrome.
Outcomes	Measured at baseline, 3, 6 and 12 months **Outcomes included in review:** • pain: mean VAS 0–10, higher score indicated worse pain • change in calcification size: change in calcification size measured on X-ray in millimetres • change in calcification size: proportion of participants with complete resolution of calcifications • treatment success: proportion of participants with complete resolution of pain • adverse events • withdrawals due to non-completion of treatment, adverse events or other reasons **Outcomes excluded from review:** • physical activity and relationship with rotator cuff calcific tendonitis, as per the 4 activity groups according to the energy expenditure or profession-determined energy demand based on the National Institute of Health of Spain criteria
Source of funding	Partly funded by grant awarded by the Santander Group to the Foundation Alfonso X el Sabio University
Notes	**Trial registration:** not registered **Time points included in review:** 3, 6 and 12 months

Del Castillo-Gonzales 2016 *(Continued)*

Data analysis: review data extracted at 3, 6 and 12 months. Mild discomfort during shock wave was not counted as an adverse event in this review.

Withdrawals: 41/121 in ESWT group (38 did not complete intervention, 3 did not attend examinations) vs 1/122 in lavage group (lost to follow-up)

Adverse events:

ESWT:

- serious adverse events: 0/121
- other adverse events: 121/121 (mild discomfort during shock wave)

US-guided percutaneous lavage:

- serious adverse events: 0/122
- other adverse events: 6/122 (vagal reaction either during or immediately after the procedure)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Using tables of randomized numbers (www.randomized.org), a collaborator who took no further part in the study randomly assigned patients to undergo either ESWT (N=121) or UGPL [ultrasound-guided percutaneous lavage] (N=122)."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants not blinded but study staff were blinded to the group allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	As participants were not blinded it is likely that the self-reported outcome (pain) was subject to bias.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Outcome assessors blinded to the group allocation so low risk of bias in measurement of calcifications.
Incomplete outcome data (attrition bias) All outcomes	High risk	41/121 (34%) in ESWT group (38 not completing intervention, 3 not attending examinations) vs 1/122 (0.8%) in lavage group. As-treated analysis performed.
Selective reporting (reporting bias)	Low risk	No access to a protocol, but results were reported for all outcomes listed as measured in methods.
Other bias	Low risk	No other biases apparent

Duymaz 2019

Methods	**Study design:** single-centre, parallel-group, two-arm, RCT **Setting:** Istanbul Bilgi University Faculty of Health Sciences, Turkey

Duymaz 2019 *(Continued)*

Trial time period: August 2017 to April 2018

Interventions: rESWT plus conventional physiotherapy vs conventional physiotherapy

Sample size calculation: standard effect size of 0.72 and ≥ 80 cases with a 95% CI and a power of 80% so 40 participants were recruited for each arm.

Analysis: ITT

Participants	**Number of participants:** • screened: not reported • enrolled: not reported • randomised: 80 (40 per group) • analysed: 80 (40 per group) **Inclusion criteria:** • minimum of 12 months of shoulder pain • calcification of the rotator cuff • aged 30–70 years **Exclusion criteria:** • local or generalised arthritis (excluded by clinical examination) • algodystrophy • pregnancy • acute infection • skin ulcerations • neurological abnormalities • dysfunction in neck or thoracic region or both • acute (severely painful) calcific shoulder tendinopathies • history of previous surgery or malignancy • corticosteroid injection within preceding 6 months • previous ESWT treatment **Baseline characteristics:** *rESWT plus physiotherapy group:* • mean (SD) age: 54.33 (9.88) years • mean (SD) BMI: 28.29 (0.47 • mean (SD) pain on VAS 0–10: 7.4 (0.8) • mean (SD) function on QuickDASH (0–100, 0 no disability): 24.0 (23.0) • mean (SD) ROM flexion: 133.5 (18.9) • mean (SD) ROM extension: 17.1 (6.9) • mean (SD) ROM abduction: 115.8 (21.8) • mean (SD) ROM external rotation: 25.8 (16.9) *Physiotherapy group:* • mean (SD) age: 51.31 (8.86) • mean (SD) BMI: 25.50 (3.11) • mean (SD) pain on VAS 0–10: 7.3 (0.9) • mean (SD) function on QuickDASH (0–100, 0 no disability): 13.3 (11.0) • mean (SD) ROM flexion: 135.9 (20.2) • mean (SD) ROM extension: 14.9 (7.1) • mean (SD) ROM abduction: 120.1 (28.8)

Duymaz 2019 *(Continued)*

	• mean (SD) ROM external rotation: 23.0 (17.2) **Pretreatment group differences: f**unction was worse in rESWT group compared with the control group at baseline.
Interventions	**rESWT plus conventional physiotherapy:** • method of administration: rESWT was conducted using a ShockMaster 500 device (GymnaUniphy NV, Bilzen, Belgium) once a week for 4 weeks in total. An isotonic gel was used as an intermediate before the probe was applied to the participant's shoulder, and no local anaesthetic was used. The application was carried out without any anaesthesia to better localise the area to be treated and to detect the amount of energy used. The rESWT procedure was performed by positioning the participant at the internal and external rotations at a maximum of 15 degrees with the participant in an upright sitting position. • dose: each treatment consisted of 1500 shocks with a frequency of 150 shocks per minute. The dimensions of the focal zone were 5.5 mm, 5.5 mm and 35.3 mm, and the cutout was 95 mm. When minimal energy was generated, the flux density was calculated to be 1.23 mJ and the total energy to be 2.59 mJ. The energy at 5 MPa was 1.77 mJ and 4.03 mJ, the focal region was 0.91 mJ at 5 mm and 1.91 mJ. Since pain could occur mostly during the first treatment, all participants were treated with a low energy density of 0.03 mJ/mm^2 for the first 5 minutes, which was then progressively increased to 0.28 mJ/mm^2. Each rESWT session lasted about 10 minutes. rESWT application was performed on the supraspinatus, infraspinatus, teres minor and subscapularis tendons. Successive treatments used an energy density of 0.28 mJ/mm^2. The maximum EFD did not exceed 0.28 mJ/mm^2, taking into account the participant's level of tolerance. All participants received a total of 20 physiotherapy treatments (described below), 5 days a week for 4 weeks. **Conventional physiotherapy:** • traditional physiotherapy programme included US (1.0 MHz, 5 minutes, continuous), TENS (conventional, 20 minutes), shoulder joint ROM and stretching exercises, and ice applications (15 minutes). The physiotherapy programme was applied 5 days a week for 4 weeks.
Outcomes	Measured at end of treatment **Study outcomes:** • pain measured using VAS 0–10, 10 indicating most pain • function measured using quickDASH (0–100 scale, 100 indicating worst disability) • ROM: flexion, extension, abduction and external rotation using a goniometer **Outcomes used in review:** • pain measured using VAS 0–10, 10 indicating most pain • function measured using quickDASH (0–100 scale, 100 indicating worst disability) • ROM: flexion, extension, abduction and external rotation using a goniometer
Source of funding	Authors reported that they did not receive any funding for this study
Notes	**Trial registration:** not registered **Withdrawals:** none **Adverse events:** none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number sequence used to generate the random schedule.

Duymaz 2019 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Unclear how allocation to groups was concealed.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and study personnel not reported.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Unclear whether participants were blinded; unclear risk of bias in measurement of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Unclear risk	Unclear whether outcome assessors were blinded; unclear risk of bias in measurement of ROM.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals reported.
Selective reporting (reporting bias)	Low risk	Although the trial was not registered and there was no study protocol, results for all prespecified outcomes were clearly reported.
Other bias	Low risk	Function scores were lower in control group; however, this did not affect the study findings.

Engebretsen 2009

Methods	**Study design:** parallel-group, two-arm, single-blind, RCT **Setting:** outpatient clinic of the Physical Medicine and Rehabilitation Department at Ullevaal University Hospital, Oslo, Norway **Trial time period:** July 2006 to August 2007 **Interventions:** rESWT vs supervised exercises **Sample size calculation:** study designed to detect a difference of 10 points in SPADI score between groups with $\alpha = 0.05$ (type I error) and $\beta = 0.2$ (type II error). 48 participants were required per group to detect a 10-point change in SPADI score with a 20-point SD. **Analysis:** ITT
Participants	**Number of participants:** • screened for eligibility: 141 (31 not meeting inclusion criteria, 2 refused participation, 4 other reasons) • randomised: 104 (52 in rESWT; 52 in supervised exercises) • included in analyses at 6 weeks: 90 (44 in rESWT; 46 in supervised exercises) • at 12 weeks' follow-up: 102 (52 in rESWT; 50 in supervised exercises) • at 18 weeks' follow-up: 100 (50 in rESWT (2 crossed over to the exercise group); 50 in supervised exercises) • at 12 months' follow-up: 97 (48 in rESWT; 49 in supervised exercises) • included in analysis: 94 (46 in rESWT; 48 in supervised exercises) **Inclusion criteria**

Engebretsen 2009 *(Continued)*

- subacromial shoulder pain lasting ≥ 3 months and aged 18–70 years
- dysfunction or pain on abduction
- had a normal passive glenohumeral ROM
- pain during 2 of 3 isometric tests (abduction, external- or internal rotation at 0 degrees or 30 degrees)
- positive Hawkins-Kennedys test
- people with rotator cuff rupture were included if they fulfilled the above criteria

Exclusion criteria

- bilateral shoulder pain
- previous surgery on the affected shoulder
- had multidirectional instability
- clinical signs of a cervical syndrome
- rheumatoid arthritis
- clinical and radiological signs of glenohumeral or acromioclavicular joint pathology
- inability to understand spoken or written Norwegian
- considerable emotional distress
- needed anticoagulant medicine
- pregnancy
- previous experience of 1 of the study interventions
- unwillingness to accept either of the interventions in study

Baseline characteristics:

Radial ESWT (52 participants):

- mean (SD) age: 47 (11.7) years
- number male/female: 26/26
- number (%) of symptoms: at 3 to 6 months: 15 (29); at 6 to 12 months: 15 (29); at 12 to 24 months: 6 (12); at > 24 months: 16 (31)
- number (%) treatment history: 24 (46) physiotherapy, 20 (38) corticosteroid injection
- mean (SD) EQ-VAS 0–100, 100 indicating best health: 62.9 (20.1)
- Median (IQR) EQ-5D Index: 0.74 (0.58–0.76)
- mean (SD) pain at rest on VAS 0–9: 3.5 (2.1)
- mean (SD) function SPADI 0–100 score: 45.1 (22.1)

Supervised exercises (52 participants):

- mean (SD) age: 49 (9.3) years
- number male/female: 26/26
- number (%) of symptoms: at 3–6 months: 19 (37); at 6–12 months: 15 (29); at 12–24 months: 8 (15); at > 24 months: 10 (19)
- number (%) treatment history: 23 (44) physiotherapy, 27 (52) corticosteroid injection
- mean (SD) EQ-VAS 0–100, 100 indicating best health: 72.4 (15.2)
- Median (IQR) EQ-5D Index: 0.70 (0.53–0.76)
- mean (SD) pain at rest on VAS 0–9: 3.4 (1.9)
- mean (SD) function on SPADI 0–100 score: 48.8 (20.6)

Pretreatment group differences: groups similar at baseline with regard to demographic and outcome variables.

Interventions	**rESWT:** • description of modality used: Swiss Dolor Clast, EMS) was provided by a physiotherapist experienced in its use. • method of administration: 3–5 tender points were treated each time. Points were identified through a participant-oriented biofeedback process (insertion of supraspinatus tendon, dorsolaterally below

Engebretsen 2009 *(Continued)*

	the acromion and a maximum of 3 trigger points in rotator cuff muscles). rESWT uses low to medium energy shock waves generated when a projectile is accelerated by compressed air and hits an applicator. These impulses are delivered into the tissue and spread as spherical 'radial' waves (rather than being focused). Participants were informed that the suggested mechanism for pain relief was hyperstimulation analgesia and increased neurovascularisation that improves regeneration of tissue. Participants were advised to avoid activities that elicited pain • dose: 2000 pulses per session in a frequency of 12–8 Hz with a pressure 2.5–4.0 bar, depending on what the participant tolerated without an anaesthetic • frequency: 1 session weekly for 4–6 weeks • co-interventions: all participants were asked not to have any additional treatment except analgesics (including anti-inflammatory drugs) for their shoulder pain for the time between the start of treatment and the 18 weeks' follow-up **Supervised exercises:** • method of administration: the principle focus was on relearning of normal movement patterns, which could then be transferred to daily activities. The initial aim was to unload the stress on the rotator cuff and subacromial structures. During this phase, a mirror for awareness of posture, an elastic rubber band and a sling fixed to the ceiling were used. The participants received immediate feedback and correction (supervision) by the physiotherapist. Once dysfunctional neuromuscular patterns were normalised, endurance exercises were performed with gradually increasing resistance • dose: 45 minutes • frequency: 2 sessions weekly for up to 12 weeks • co-interventions: participants had an adjusted programme at home, which consisted of correction of alignment during daily living and simple low loaded exercises with a thin elastic cord to provide assistance and resistance to the movement. Simple advice was given. All the participants were asked not to have any additional treatment except analgesics (including anti-inflammatory drugs) for their shoulder pain for the time between the start of treatment and the 18 weeks' follow-up
Outcomes	Outcomes measured at baseline, 6 weeks, 12 weeks, 18 weeks and 1 year **Outcomes included in review** • function measured by SPADI; score: 0–100, higher score indicating worse shoulder pain and disability. A version adapted to Norwegian language and culture, translated and back-translated was used • rest pain in previous week measured on 1- to 9-point scale (1 no pain, 9 severe pain) • withdrawal due to adverse events, intolerance to treatment or other reasons • proportion of participants with adverse events • active range of abduction (at 5-degree intervals) **Outcomes excluded from review** • functional scales: can you carry a shopping bag (5 kg) and Can you take down something from a wall cupboard, measured on 1- to 7-point scale (1 easy, 7 impossible) • pain during activity • work status • use of drug treatment
Source of funding	Study supported by Health Region East, Norway
Notes	**Trial registration:** ClinicalTrials.gov identifier NCT00653081 **Time points included in review:** 6 weeks and 12 months **Data analysis:** author provided unpublished information: mean age of cohort participants and duration of symptoms, methods of randomisation and allocation concealment, attrition rates, active range of abduction (mean and SD). 13/52 in shock wave group and 3/52 in exercise group received additional treatment (cortisone injections, chiropractic treatment, physical therapy or supervised exercises) between 12 and 18 weeks.

Engebretsen 2009 *(Continued)*

Withdrawals: 4/52 in shock wave group (1 death, 1 loss to follow-up, 2 incomplete questionnaires) and 3/52 in exercise group (2 loss to follow-up, 1 incomplete questionnaire)

Adverse events:

RSWT:

- serious adverse events: 0/52
- other adverse events: 3/52 (severe pain following treatment and dropped out from intervention)

Supervised exercises:

- serious adverse events: 0/52
- other adverse events: 1/52 (increase in pain and stiffness consistent with adhesive capsulitis and discontinued intervention)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A statistician not involved in data collection or analysis randomly allocated patients to treatment groups in blocks of four to six. Randomisation was stratified by sex." Comment: adequate method used to generate the allocation sequence.
Allocation concealment (selection bias)	Low risk	Quote: "A person not involved in the treatments opened the sealed envelopes and assigned appointments according to treatment group." Comment: adequate method likely used to conceal the allocation sequence.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Participants and personnel could not be blinded for this trial." Comment: given the nature of the interventions, participants were not blind to treatment, and may have had different expectations about the benefits of each intervention.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Comment: unblinded participants, who may have had different expectations about the benefits of the intervention they received.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Quote: "A blinded physiotherapist made the baseline and follow-up measurements. The patients were instructed not to discuss their treatment with the blinded physiotherapist." Comment: assessor of objective outcomes was likely blinded to the intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: 10 participants per group did not return for all follow-up measures, and while reasons for loss to follow-up were not reported, an ITT analysis was performed; 7/104; 4/52 in shock wave group (1 death, 1 loss to follow-up, 2 incomplete questionnaires) and 3/52 in exercise group (2 loss to follow-up, 1 incomplete questionnaire).
Selective reporting (reporting bias)	Low risk	Active ROM data were not reported; the authors supplied the unpublished data upon request. Function, work status were not listed in trial protocol but were in results paper.
Other bias	High risk	More people in shock wave group received additional treatments outside of the trial setting, including injection, physiotherapy or chiropractice (13 from

Engebretsen 2009 *(Continued)*

	shock wave vs 3 from exercise), which may have biased the results in their favour.

Farr 2011

Methods	**Study design:** prospective, parallel-group, two-arm, single-blind, RCT **Setting:** orthopaedic department's outpatient clinic, Austria **Trial time period:** not reported **Interventions:** single high-dose ESWT vs 2 treatments of low-dose ESWT **Sample size calculations:** not performed for this study, the authors reported that 200 participants per group would be required to detect differences between groups for the VAS (at rest) and Constant score **Analysis:** study did not report using an ITT analysis
Participants	**Number of participants:** • screened: 30 • randomised: 30 (15 per group) • included in 6-week analysis: 27 (13 in high-dose group; 14 in low-dose group) • included in 3-month analysis: 27 (13 in high-dose group; 14 in low-dose group) **Inclusion criteria:** • radiologically verified calcific tendinitis (Gärtner Grade I, II or III) • persisting pain for ≥ 6 months • minimum of 2 failed long-term (> 6 months) conservative treatments (e.g. repetitive subacromial infiltrations, NSAIDs, physiotherapy, iontophoresis, US or deep friction) **Exclusion criteria: n**ot reported **Baseline characteristics:** *High-dose* ESWT*(15 participants):* • mean (SD) age: 49.7 (9.0) years • mean (SD) pain at rest, VAS 0–10: 3.2 (1.7) • mean (SD) function, Constant score 0–100: 67.7 (14.7) • calcification size: not reported *Low-dose* ESWT*(15 participants):* • mean (SD) age: 48.6 (7.3) years • mean (SD) pain at rest, VAS 0–10: 4.4 (2.5) • mean (SD) function, Constant score 0–100: 60.2 (15.6) • calcification size: not reported **Pretreatment group differences:** no significant differences in age, sex, weight, VAS (rest), Constant score at baseline. Duration of symptoms and treatment history not reported.
Interventions	**High-dose ESWT:** • description of modality: Storz Modulith SLK lithotripter in combination with a fluoroscopy-guided, 3-dimensional computer-assisted navigation device (Storz Lithotrack; Storz Medical Products Kreuzlingen, Switzerland) was used

Farr 2011 *(Continued)*

- method of administration: single subacromial infiltration with local anaesthetic (5mL of xylocaine) was administered. The calcific deposit was located in the centre of a crosshair by fluoroscopy in 2 layers, with the computer calculating the angle and distance for maximum precision. The distance of the shock wave focus to the calcific deposit was stated in millimetres on the monitor of the navigation device. To achieve maximum precision, the navigation device was centred to the calcific deposit within 1–2 mm in all cases
- dose: 3200 impulses of middle-energetic ESWT (0.3 mJ/mm^2) at a frequency of 4 Hz
- frequency: 1 treatment
- co-interventions: none. For minor pain symptoms, NSAIDs in standard dosage were recommended

Low-dose ESWT:

- description of modality: as above
- method of administration: as above
- dose: 1600 impulses of middle-energetic ESWT (0.2 mJ/mm^2) at a frequency of 4 Hz
- frequency: 2 applications with 1-week interval
- co-interventions: none. For minor pain symptoms, NSAIDs in standard dosage were recommended

Outcomes	Measured at 6 and 12 weeks **Outcomes included in review:** • pain at rest measured by VAS 0–10, higher score indicating worse pain • function measured by CMS: 0–100 score, higher score indicating better function • radiological changes of the calcific deposit measured by X-rays. Changes were rated as improvement, unchanged or worsening • adverse events • withdrawals: due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • pain on stress (weight-bearing situations) measured by VAS 0–10
Source of funding	Not reported
Notes	**Trial registration:** not reported **Time points included in review:** 6 and 12 weeks **Data analysis:** function and pain at rest extracted at 6 and 12 weeks. Radiological changes extracted at study conclusion (12 weeks) **Withdrawals:** 2/15 in high-dose group and 1/15 in low-dose group were lost to follow-up **Adverse events:** *High-dose shock wave therapy:* • serious adverse events: 0/15 • other adverse events: 0/15 *Low-dose shock wave therapy* • serious adverse events: 0/15 • other adverse events: 0/15

Risk of bias

Bias	Authors' judgement	Support for judgement

Farr 2011 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Details of randomisation method were not reported.
Allocation concealment (selection bias)	Unclear risk	Methods of allocation concealment were not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	'Observers' were blinded and participants were not blinded.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Due to the nature of the intervention participants were unable to be blinded; thus, there was a potential risk of bias in the self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Outcome assessors were blinded so there was low risk of bias in the assessment of radiographic outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2/15 in high-dose group and 1/15 in low-dose group were lost to follow-up, data were not collected from them for the final analysis.
Selective reporting (reporting bias)	Low risk	There was no published study protocol, but results were reported for all outcomes as mentioned in methods, and included major outcomes.
Other bias	Low risk	No other biases were apparent in study.

Frizziero 2017

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** Department of Physical Medicine and Rehabilitation, University of Padua, Italy **Trial time period:** not reported **Interventions:** LMW-HA injection vs low-energy ESWT **Sample size calculation:** not reported **Analysis:** ITT
Participants	**Number of participants:** • screened: not reported • enrolled: 34 • randomised: 34 (17 per group) • included in analyses at 3 months: 34 (17 per group) **Inclusion criteria:** • shoulder pain that exacerbated in overhead movements • pain for ≥ 3 months not responding adequately to conventional therapy with NSAIDs or physiotherapy (or both) • aged 18–85 years

Frizziero 2017 *(Continued)*

- pain on palpation at the site of insertion of rotator cuff tendons on humeral head and positive clinical test for the pathology of the rotator cuff
- instrumental diagnosis (US or MRI) of the rotator cuff tendonitis
- reduced joint movement of the shoulder in flexion, abduction, internal and external rotation

Exclusion criteria:

- complete rupture of cuff tendons diagnosed by US or MRI
- calcifications of diameter > 1 cm in rotator cuff tendons at US evaluation
- pregnancy or breast-feeding
- tumours, coagulation disorders or rheumatic diseases in acute phase
- significant trauma to the target shoulder within 6 months
- history of allergies or hypersensitivity to chicken proteins or hyaluronic acid
- steroid therapy in last 3 months, steroid therapy in contralateral shoulder in last 4 weeks, viscosupplementation in target shoulder in last 24 weeks, oral NSAIDs in past 48 hours

Baseline characteristics:

Low-energy ESWT (17 participants):

- mean age: 58.5 years
- number male/female: 4/13
- mean DASH score: 78.2
- mean (SD) Constant score: 56.7 (16.6)

LMW-HA (17 participants):

- mean age: 58.2 years
- number male/female: 4/13
- mean DASH score: 80.3
- mean (SD) Constant score: 51.8 (24.6)

Pretreatment group differences: mean Constant scores were higher in low-energy ESWT group, while the DASH scores were slightly higher in LMW-HA group.

Interventions

LMW-HA:

- method of administration: all injections were administered by the same trained physician. Subacromial injections were given under US guidance (to identify the subacromial space) using a standard sterile method using a 21-gauge needle, following the principles of safety and sterility in a sequential procedure
- dose: LMW-HA (HYALGAN 20 mg/2 mL) in a total of 3 injections
- frequency: 1 injection weekly for 3 weeks
- co-interventions: none

Low-energy ESWT:

- description of modality: MODULITH SLK, Storz Medical, Tagerwilen, Switzerland
- method of administration: participants were asked to lie in supine position. A transparent and odourless gel which facilitated the propagation of waves to biological tissues was applied to the skin. The head of the generator was then positioned under US guidance to focus shock waves on the target area. ESWT was then delivered starting from a minimum level and gradually increasing it to values compatible with the tolerance of the participant to the discomfort or pain caused by the treatment, without ever exceeding an energy density of 0.15 mJ/mm^2. Overall, each session of ESWT had a mean duration of about 10 minutes.
- dose: each session consisted of 1600 shots of ESWT at a frequency of 4 Hz.
- frequency: 1 session weekly for 4 weeks
- co-interventions: none

Frizziero 2017 *(Continued)*

Outcomes	Measured at baseline, postintervention and 3 months **Outcomes used in review:** • function measured on CMS **Outcomes excluded from review:** • pain measured on DASH scale
Source of funding	Not reported
Notes	**Trial registration:** not reported **Time points included in review:** 3 months **Data analysis:** author provided SDs and SEs for DASH and Constant scores which were not published in paper. **Withdrawals:** none **Adverse events:** not measured

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation performed using a computer-generated schedule.
Allocation concealment (selection bias)	Unclear risk	Unclear whether concealment of the group allocation was done.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unable to be blinded, study personnel were blinded to the treatment allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Due to the nature of the interventions, participants could not be blinded; there was risk of bias in measurement of self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Study personnel were blinded so there was low risk of bias in measurement of objective outcomes of function using the CMS.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals.
Selective reporting (reporting bias)	Low risk	Author provided SDs and SEs, as well as information on method of randomisation upon request.
Other bias	Low risk	No other biases apparent.

Galasso 2012

Methods	**Study design:** parallel-group, two-arm, double-blind, randomised placebo-controlled trial **Setting:** outpatients, Italy **Trial time period:** not reported **Interventions:** ESWT vs sham therapy **Sample size calculation:** not performed **Analysis:** as-treated
Participants	**Number of participants:** • screened for eligibility: not reported • randomised: 21 (11 in ESWT group; 10 in sham group) • included in analyses at 6 weeks: 20 (11 in ESWT group; 9 in sham group) • included in analyses at 12 weeks: 20 (11 in ESWT group; 9 in sham group) **Inclusion criteria** • men and non-pregnant women aged ≥ 18 years (women of child-bearing potential must have had a negative serum pregnancy test performed within 1–14 days prior to the treatment procedure) with chronic non-calcific supraspinatus tendinopathy as diagnosed by X-ray, MRI and physical examination • not responded to a standard course of non-pharmacological and non-surgical conservative treatment for a minimum of 4 months (therapeutic exercise, US, iontophoresis, cryotherapy, and immobilisation or activity modification) • not responded to non-surgical, pharmacological conservative treatment and had ≥ 1 subacromial steroid injection and ≥ 1 course of the standard dose of prescribed NSAIDs or other pharmacological therapy a minimum of 30 days prior to shock wave therapy • diagnosis of supraspinatus tendinopathy is only in 1 shoulder • had free passive ROM and ≥ 90 degrees active abduction in affected shoulder • willing to participate in study and return for all scheduled follow-up visits • gave written informed consent **Exclusion criteria** • history of uncontrolled severe hypertension • unstable or uncontrolled angina, uncontrolled heart failure or serious uncontrolled ventricular arrhythmias • white blood cell count < 2000 or > 15,000; platelet count < 50,000; or both • bleeding disorder or on anticoagulant therapy • current treatment with a narcotic or NSAIDs; had used analgesics or NSAIDs within the 72 hours prior to the intervention; or both • prior shoulder pain treatment research study within 30 days prior to the intervention • prior shoulder surgery • pain in both shoulders • malignancy • cardiac pacemaker implant • anatomical malformations preventing the focusing of the shock wave device in the area of the supraspinatus tendon (e.g. extensive scarring, misalignment of side fractures, non-unions or delayed fracture healing, congenital malformation, etc.) • upper extremity neurological disorder (e.g. thoracic outlet syndrome, reflex sympathetic dystrophy) • full-thickness rotator cuff tear of any of 4 tendons as seen on MRI • acromiohumeral interval < 7 mm as measured on a standard anteroposterior X-ray or severe symptomatic degenerative changes in the glenohumeral or acromioclavicular joint • acute subacromial bursitis • generalised polyarthritis, rheumatoid arthritis

Galasso 2012 *(Continued)*

- allergic to local anaesthetic

Baseline characteristics:

ESWT (11 participants):

- mean (SD) age: 50.7 (8.44) years
- number male/female: 7/4
- mean (SD) duration of symptoms: 45.36 (34.33) months
- mean (SD) function, Constant 0–100 score: 42.45 (9.83)
- mean (SD) pain: Constant 0–15 subscore, 15 indicating no pain: 2.72 (2.61)

Sham group (9 participants)

- mean (SD) age: 51.11 (13.26) years
- number male/female: 4/5
- mean (SD) duration of symptoms: 61.22 (24.04) months
- mean (SD) function, Constant 0–100 score: 41.67 (12.53)
- mean (SD) pain, Constant 0–15 subscore: 3.33 (2.5)

Pretreatment group differences: no differences in baseline, except BMI

Interventions	**ESWT:** • description of modality: Modulith SLK system (Storz Medical AG, Tagerwilen, Switzerland)- electromagnetic therapy source. • method of administration: participants received a subcutaneous injection of 2 mL of 2% lidocaine above the subacromial space of the affected shoulder. Heart rate, blood pressure, body temperature and respiration rate were measured before and immediately after each treatment. Treatments were performed as outpatient procedures. Shock waves were focused at an area 1 cm proximal to the insertion of the tendon in the bone, with the participant in a supine position. Localisation and targeting were achieved by means of an in-line 7.5 MHz US transducer with a scanning depth range of 3–15 cm, located in the centre of the therapy source • dose: 3000 shock waves at an EFD of 0.068 mJ/mm^2 • frequency: 2 treatment sessions, separated by 7-day interval • co-interventions: paracetamol 1000 mg/day if needed for pain **Sham shock wave therapy:** • description of modality: Modulith SLK system used with the shock wave generator disconnected • method of administration: participants received a subcutaneous injection of 2 mL of 2% lidocaine above the subacromial space of the affected shoulder. Heart rate, blood pressure, body temperature and respiration rate were measured before and immediately after each treatment. Treatments were performed as outpatient procedures. A compact disc player with a prerecorded sound of the ramp-up shocks produced the sound characteristic of the device as if it had been normally activated. The speakers were stored under the upper cover of the shock wave generator • co-interventions: paracetamol 1000 mg/day if needed for pain
Outcomes	Measured at baseline, 6 and 12 weeks **Outcomes included in review:** • function measured by CMS; score: 0–100, higher score indicating better function • pain measured by CMS: 0–15, higher score indicating less pain • adverse events measured by telephone recall • treatment success, defined by improvement of ≥ 30 points on CMS or CMS at the study's endpoint that was ≥ 80% of the standard age- and gender-related value • withdrawals: due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:**

Galasso 2012 *(Continued)*

- ROM: Constant subscore: 0–40, higher score indicating better range in a combination of forward elevation, lateral elevation, internal rotation and external rotation
- use of medications after treatment and during follow-up
- imaging studies
- satisfaction with ESWT and willingness to undergo treatment again measured by telephone recall (only measured in active treatment group, not sham)

Source of funding	Study supported, in part, by Storz Medical AG, Tagerwilen, Switzerland
Notes	**Trial registration:** ISRCTN registry ISRCTN41236511 **Time points included in review:** 6 and 12 weeks **Data analysis:** the Constant pain subscore was subtracted from 15 to reverse the direction of the scale (lower score would indicate less pain). We e-mailed the study contact to ask for clarification of methods of allocation concealment (no response at time of publication of this review) **Withdrawals:** 0/11 in ESWT group; 1/9 in sham group were lost to follow-up **Adverse events:** *ESWT:* • serious adverse events: 0/11 • other adverse events: 3/11 (pain during treatment) *Sham treatment:* • serious adverse events: 0/9 • other adverse events: 1/9 (pain during treatment)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Stratified random permuted blocks with an allocation ratio of 1:1.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and outcome assessors were blinded; local anaesthetic was used in all participants to mask active or placebo treatment.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants were blinded so low risk of bias in measurement of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Outcome assessors who measured radiographic outcomes were blinded to treatment allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	0/11 in ESWT group and 1/10 in sham group (lost to follow-up).

Galasso 2012 *(Continued)*

Selective reporting (reporting bias)	Low risk	All outcomes listed in study protocol were reported in results paper.
Other bias	Low risk	No other biases apparent.

Gerdesmeyer 2003

Methods	**Study design:** multicentre, parallel-group, three-arm, double-blind, randomised, placebo-controlled trial **Setting:** 7 orthopaedic departments in Germany and Austria **Trial time period:** February 1997 to March 2001 **Interventions:** high-energy ESWT vs low-energy ESWT vs sham therapy **Sample size calculation:** 144 participants would have 90% power to find a 15% difference in Constant score between therapy and placebo, given α = 0.025. **Analysis:** ITT analysis was used for primary outcomes, with missing data imputed using last observation carried forward
Participants	**Number of participants:** • screened: 164 (20 excluded: 12 did not meet inclusion, 7 refused participation, 1 withdrew with no reason reported) • randomised: 144 (48 per group) • in 3-month analysis: 132 (44 in high-dose group; 46 in low-dose group; 42 in placebo group) • in 6-month analysis: 134 (47 in high-dose group; 46 in low-dose group; 41 in placebo group) • in 12-month analysis: 111 (35 in high-dose group; 44 in low-dose group; 32 in placebo group) **Inclusion criteria:** • pain or tenderness from idiopathic calcific tendonitis, for a minimum of 6 months • type I or II Gärtner calcific deposits • resistant to conservative treatment • calcific deposits of ≥ 5 mm in diameter on radiography • aged ≥ 18 years • previous conservative treatments, including both physiotherapy (active and passive exercise, mobilisation, manual therapy and massage, muscle strengthening) and local anaesthetic or corticosteroid injection, NSAID **Exclusion criteria:** • rotator cuff tears • subacromial bursitis • type III Gärtner calcific deposits • rheumatic disease • connective tissue disease • diabetes • coagulation disturbance • pregnancy • glenohumeral or acromioclavicular joint arthritis • previous surgery for shoulder pain • bursitis or infection of the shoulder • tumour of the shoulder

Gerdesmeyer 2003 *(Continued)*

- instability of the shoulder or rotator cuff tear
- abnormal peripheral neurological findings
- unsuccessful prior ESWT

Baseline characteristics:

High-dose ESWT (48 participants):

- mean (SD) age: 51.6 (8.5) years
- number male/female: 13/35
- mean (SD) calcific deposit size: 182 (135) mm^2
- number (%) deposit classification: type I = 34 (71), type II = 14 (29)
- mean (SD) duration of pain: 42.6 (23.2) months
- mean (SD) function, Constant 0–100: 60 (11)
- mean (SD) pain score, VAS 0–10: 6.5 (1.3)

Low-dose ESWT (48 participants)

- mean (SD) age: 47.3 (8.5) years
- number male/female: 16/32
- mean (SD) calcific deposit size: 195 (166) mm^2
- number (%) deposit classification: type I = 30 (63), type II = 18 (37)
- mean (SD) duration of pain: 42.8 (25.2) months
- mean (SD) function, Constant 0–100: 62.7 (14.0)
- mean (SD) pain score, VAS 0–10: 5.7 (1.9)

Sham treatment (48 participants):

- mean (SD) age: 52.3 (9.8) years
- number male/female: 28/20
- mean (SD) calcific deposit size: 128 (112) mm^2
- number (%) deposit classification: type I = 32 (67), type II = 16 (33)
- mean (SD) duration of pain: 41.3 (28.6) months
- mean (SD) function, Constant 0–100: 64.2 (12.8)
- mean (SD) pain score, VAS 0–10: 5.6 (1.6)

Pretreatment group differences: no group differences were found at baseline with the exception of the calcific deposit which was smaller in sham group compared to the ESWT group

Interventions	**High-energy ESWT:** • description of modality: ESWT device (Domier Medlizintechnilk, Wessling, Germany) • method of administration: all participants had ≥ 1-month therapy-free period before the first treatment with ESWT. Participants were placed in prone position. Using fluoroscopy in an anteroposterior view, the shoulder was rotated until the calcific deposit was identified in a free position. A shock wave head was coupled to the shoulder with a thin sheet of polyethylene foil placed between the shock wave head and the participant. Coupling gel was used between the shock head and the foil and between the foil and the shoulder. • dose: 1500 shock waves of 0.32 mJ/mm^2 per treatment. 120 impulses were applied per minute. • frequency: 2 treatment sessions. Second session after 12–16 days • co-interventions: 10 physiotherapy sessions after the intervention (included active and passive exercise mobilisation techniques, massage and manual therapy to prevent worsening in ROM, muscular deficit or imbalance). Adequate intravenous analgesia and sedation were provided as necessary. Local anaesthetics were prohibited. Rescue medication allowed during the entire study (paracetamol 2 g/day for up to 14 days following the last ESWT; if needed thereafter paracetamol 2 g/week). No other treatment or other NSAIDs were allowed until after the 6 months' follow-up. **Low-energy ESWT:**

Gerdesmeyer 2003 *(Continued)*

- description of modality: ESWT device (Domier Medlizintechnilk, Wessling, Germany)
- method of administration: as described above
- dose: 6000 shock waves of 0.08 mJ/mm^2 per treatment. 120 impulses were applied per minute.
- frequency: 2 treatment sessions. Second session after 12–16 days
- co-interventions: as above

Sham treatment:

- description of modality: ESWT device (Domier Medlizintechnilk, Wessling, Germany) shock waves blocked by an air-chambered polyethylene foil
- method of administration: an air-chambered polyethylene foil with coupling gel was placed against the participant's skin, but no coupling gel was applied to the site of the shock wave head. The foil was placed between the participant and the water cushion of the ESWT device in same technique as the above-mentioned ESWT groups. Measurements with glass-fibre hydrophones demonstrated that no shock waves could pass through the foil. The participant's prone position prevented them from seeing the device but they could hear the typical sound of shock waves being generated
- dose: 1500 shock waves per treatment with 120 impulses per minute were delivered after the energy level reached the assigned treatment level of 0.32 mJ/mm^2; however, none of the shock waves were transmitted to the participants
- frequency: 2 treatment sessions. Second session after 12–16 days
- co-interventions: as above

Outcomes	Measured at baseline, 3, 6 and 12 months **Outcomes included in review:** • mean change from baseline in function measured by CMS, maximum score: 100 points, higher score indicating better function • mean change from baseline in pain measured on VAS 0–10, 10 indicating unbearable pain • radiographic change in size of calcific deposits. The localisation of calcifications within a specific tendon was determined by anteroposterior X-rays of the shoulder obtained in 45 degrees external and 45 degrees internal rotation • adverse events • treatment success measured by proportion with 30% improvement measured by a 30% increase from baseline on CMS • withdrawals: due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • ROM: change in Constant subscores from baseline; combined score of forward elevation, lateral elevation, internal rotation and external rotation from 0–40 with a higher score indicating better range
Source of funding	Supported by the German Association for Orthopedics and Orthopedic Surgery (DGOCC). Shock wave equipment supplied by Domier Medlizintechnilk, Wessling, Germany.
Notes	**Trial registration:** not reported **Time points included in review:** 3, 6 and 12 months **Data analysis:** as there were 2 intervention groups, the low-energy group data were used for the comparison ESWT vs sham as it was more consistent with the energy levels used in other trials. The high-energy group and low-energy group were used for the comparison high vs low dose. The 95% CI was converted to a SD using the following equation in excel: (('upper CI' – 'lower CI')/3.92) × √'population'). Results were then rounded to 1 decimal place. Proportion of participants with ≥ 30% increase in CMS, noted in trial as a clinically relevant improvement, was taken as the measure of treatment success. As proportion of participants who experienced adverse events was reported by category of adverse event, the largest number from any category was used in data extraction as a best estimate. **Withdrawals:** 13/48 in high-dose ESWT group (7 refused follow-up visit, 6 reported no reason): 4/48 in low-dose ESWT group (2 had drug therapy and 2 had surgery) and 18/48 in placebo group (7 had drug

Gerdesmeyer 2003 *(Continued)*

therapy, 5 had surgery, 5 refused follow-up visits, 1 moved). We assumed 4/48 in ESWT and 12/48 in placebo were intolerant to treatment (Analysis 1.5).

Adverse events:

High-dose ESWT:

- serious adverse events: 0/48
- other adverse events: 36/48 (36/48 reported pain during treatment (20 moderate pain;16 severe pain out of which 8 required intravenous analgesics); 36/48 reported petechiae, bleeding, erythema or haematoma)

Low-dose ESWT:

- serious adverse events: 0/48
- other adverse events: 32/48 (27/48 reported pain during treatment (22 moderate pain; 5 severe pain out of which 2 had intravenous analgesics); 32/48 reported petechiae, bleeding, erythema or haematoma)

Sham treatment:

- serious adverse events: 0/48
- other adverse events: 25/48 (25/48 reported pain (21 moderate pain; 4 severe pain out of which 1 had intravenous analgesics); 8/48 reported petechiae, bleeding, erythema or haematoma)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation using a computer-generated sequence at a central location.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes stored at a central location, allocation by telephone.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and evaluators were reported as blinded to treatment; however as intravenous analgesics and sedation were offered 'as needed', and local anaesthetic was not allowed, it was unclear if participants could guess their assignment.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Unclear if participants may have guessed their treatment group, thus reporting of pain, function and treatment success could have been subject to bias.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiologists who assessed calcification were blinded to treatment allocation.
Incomplete outcome data (attrition bias) All outcomes	High risk	33/144; 13/48 (27%) in high-dose ESWT group (7 refused follow-up visit, 6 withdrawn), 4/48 (8.3%) in low-dose ESWT group (no reasons given) and 16/48 (33%) in sham group (5 refused follow-up visits, 11 withdrawn).
Selective reporting (reporting bias)	Low risk	No published study protocol, but results were reported for all outcomes as mentioned in the methods, and included major outcomes. Low risk of reporting bias.
Other bias	Low risk	No other biases apparent in the study.

Haake 2002

Methods	**Study design:** parallel-group, two-arm, single-blind, RCT **Setting:** Germany **Trial time period:** participant enrolment from September 1998 to December 1999 **Interventions:** ESWT focused on the origin of supraspinatus tendon vs ESWT focused on the calcific deposit **Sample size calculation:** sample size calculation not performed **Analysis:** ITT
Participants	**Number of participants:** • screened: not reported • enrolled: 50 • randomised: 50 (25 in ESWT to calcific deposit group and 24 in ESWT to supraspinatus tendon (tuberculum majus) group); 1 participant in ESWT to supraspinatus tendon group never returned after the initial visit • included in analyses at 12 weeks: 47 (24 in ESWT to calcific deposit group and 23 in ESWT to supraspinatus tendon group) • included in analyses at 12 months: 49 (25 in ESWT to calcific deposit group and 24 in ESWT to supraspinatus tendon group) **Inclusion criteria** • symptomatic calcifying shoulder tendinopathy • symptoms for ≥ 6 months • Gärtner Stage I or II deposit • ≥ 0.5 cm diameter • free ROM or ≥ 90 degrees abduction and free rotation • failed conservative treatment including a minimum of: 10 sessions of physiotherapy plus 2 subacromial injections plus 6 sessions of physical therapy plus intake of NSAIDs • no treatment in past 4 weeks **Exclusion criteria** • glenohumeral or acromioclavicular joint arthrosis • previous operations to the treated shoulder • acute bursitis of the shoulder • instability of the shoulder • local tumours or infections • neurological disorders • rotator cuff lesion • allergy to mepivacaine • aged < 18 years • pregnancy **Baseline characteristics:** *ESWT to supraspinatus tendon (25 participants):* • mean (SD) pain during rest NRS 0–11 scale: 7.17 (2.53) • mean (SD) pain during activity, NRS 0–11 scale: 8.54 (1.91) • mean (SD) function Constant 0–100 score: 47.17 (11.53) • calcification size: not reported

Haake 2002 *(Continued)*

	ESWT to calcific deposit (25 participants): • mean (SD) pain during rest, NRS 0–11 scale: 7.08 (2.74) • mean (SD) pain during activity, NRS 0–11 scale: 8.56 (1.58) • mean (SD) function Constant 0–100 score: 49.96 (10.87) • calcification size: not reported **Pretreatment group differences:** none
Interventions	**ESWT to supraspinatus tendon** • description of modality: adapted shock wave generator Storz Minilith SL-1 (Storz Medical AG, CH 8280 Kreuzlingen, Switzerland • method of administration: subacromial local anaesthesia was given using 15 mL mepivacaine 1%. • dose: 2000 impulses of a positive EFD of 0.35 mJ/mm^2 measured with a membrane hydrophone at 120 impulses per minute were applied using fluoroscopic localisation at the origin of the supraspinatus tendon • frequency: 2 sessions at 1 week apart **ESWT to calcific deposit** • description of modality: as above • method of administration: as described above with 1 difference, shock waves were aimed specifically at the calcific deposit • dose: as above • frequency: as above
Outcomes	Measured at 12 weeks and 1 year **Outcomes included in review:** • function measured by CMS 0–100 with a higher score indicate better function • pain at rest measured on visual NRS 0–11, 11 indicating maximum pain • complete resorption of calcific deposit • participant satisfaction with treatment • adverse events • withdrawals: due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • pain during activity measured on VAS 0–11, 11 indicating maximum pain • treatment success rate: success defined as 80% of the normal value in age-corrected CMS
Source of funding	Not reported
Notes	**Trial registration:** not reported **Time points included in review:** 12 weeks and 12 months **Data analysis:** function and pain at rest extracted at 12 weeks and 1 year; resorption of calcific deposit extracted at 1 year; participant satisfaction extracted at end of study period. Participant satisfaction was extracted as the measure to represent treatment success, over the number achieving 80% of the normal value for the age-standardised Constant score **Withdrawals:** 1/25 in ESWT to supraspinatus tendon group (withdrew consent after randomisation); 0/25 in ESWT to calcific deposit group **Adverse events:** *ESWT to supraspinatus tendon:*

Haake 2002 *(Continued)*

- serious adverse events: 0/25
- other adverse events: 0/25

ESWT to calcific deposit:

- serious adverse events: 0/25
- other adverse events: 0/25

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation in permutated blocks.
Allocation concealment (selection bias)	Unclear risk	Methods not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and outcome assessors blinded to treatment assignments.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants blinded to treatment allocation, thus there was a low risk of detection bias in reporting of self-reported outcomes (including pain, function and patient satisfaction).
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Blinded independent observers assessed other outcomes, such as radiographic assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	1/25 in ESWT to supraspinatus tendon group (withdrew consent after randomisation) and 0/25 in ESWT to calcific deposit group.
Selective reporting (reporting bias)	Low risk	No published study protocol, but results reported for all outcomes as mentioned in methods, and included major outcomes.
Other bias	Low risk	No other biases apparent.

Hearnden 2009

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind randomised placebo-controlled trial **Setting:** orthopaedics referrals from general practice, Wrightington Hospital, UK **Trial time period:** not reported **Interventions:** ESWT vs placebo **Sample size calculation:** not performed **Analysis:** ITT
Participants	**Number of participants:** • screened: 27 (7 did not meet inclusion criteria)

Hearnden 2009 *(Continued)*

- randomised: 20 (11 in ESWT group; 9 in placebo group)
- included in analyses: 20 (11 in ESWT group; 9 in placebo group)

Inclusion criteria:

- Gärtner type I or II calcific deposit on X-ray
- shoulder pain secondary to supraspinatus tendonitis (diagnosed using MRI in 8 participants or US scan in 15 participants)
- pain for > 12 months
- failure of conservative therapy

Exclusion criteria:

- rotator cuff rupture
- local arthritic changes or generalised polyarthropathies
- neurogenic syndromes
- pregnancy
- infection
- coagulation disorders

Baseline characteristics: numerical data were not reported

Pretreatment group differences: authors reported that participants in both groups were well matched in demographics, symptoms and calcific deposits (no numerical data reported)

Interventions

ESWT:

- description of modality: not reported
- method of administration: location of the calcific deposit was marked on the skin using high-resolution US by the radiographer. The area was the infiltrated with 20 mL 0.5% marcaine. The lithotripter was then placed on the shoulder and using the in-line US imaging the ESWT was focused on the deposit, applying the appropriate dose.
- dose: 2000 shocks fixed at 0.28 mJ/mm^2
- frequency: 1 dose
- co-interventions: none

Placebo

- description of modality: not reported
- method of administration: as above
- dose: 20 shocks with a negligible EFD of 0.03 mJ/mm^2
- frequency: 1 dose
- co-interventions: none

Outcomes

Measured at 6 months

Outcomes included in review:

- mean change in function measured by CMS, 0–100 with a higher score indicating better function
- calcification size measured by X-ray and US
- mean pain associated with treatment measured on VAS 0–10 cm, higher score indicating more pain
- treatment success: participant-reported global assessment of satisfaction as a dichotomous outcome
- adverse events
- withdrawals due to adverse events, intolerance to treatment or other reasons

Outcomes excluded from review:

- time to return to work

Hearnden 2009 *(Continued)*

- participant-reported success of outcome measured on a categorical scale (worse, no change, some improvement, complete resolution)

Source of funding	Not reported
Notes	**Trial registration:** not reported **Time points included in review:** 6 months **Data analysis:** function was extracted at 6 months, treatment success was extracted at the study's conclusion (6 months). Pain, calcification size and adverse events could not be extracted as the data were only reported for the intervention group. As no SDs were reported for function and there were none available in study, the SD at 6 months for active and sham groups were taken from Gerdesmeyer 2003. **Withdrawals:** none **Adverse events:** *ESWT:* • serious adverse events: 0/11 • other adverse events: 9/11 (9/11 had pain following shock wave after the effect of the anaesthetic wore off. 7/11 had bruising following shock waves which resolved quickly) *Placebo:* • serious adverse events: 0/9 • other adverse events: 0/9

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation 'using a centralised list in blocks to get two equal groups'.
Allocation concealment (selection bias)	Low risk	Treatment allocations were kept in sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants blinded to treatment allocation, not reported if outcome assessors were blinded.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants unaware of treatment received, thus the risk of bias was low for self-reported outcomes (pain, function and treatment success).
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Unclear risk	Not reported if the radiographer measuring calcification was blinded to the group allocations.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals.

Hearnden 2009 *(Continued)*

Selective reporting (reporting bias)	High risk	There was no published study protocol. The summary data for both groups were not reported. VAS pain scores and calcification changes in placebo group were not reported.
Other bias	Low risk	No other biases apparent.

Hsu 2008

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** hospital outpatient clinic, China **Trial time period:** enrolment July 2002 to February 2004 **Interventions:** ESWT vs sham treatment **Sample size calculations:** not performed **Analysis:** ITT
Participants	**Number of participants:** • screened: not reported • randomised: 46 (33 in ESWT group; 13 in sham group) • included in analyses: 46 (33 in ESWT group; 13 in sham group) **Inclusion criteria:** • shoulder pain attributable to calcific tendinitis that failed to respond to ≥ 3 months of non-operative treatment (including NSAIDs, corticosteroid injections, physical therapy, exercise programme, immobilisation of shoulder in a sling, etc.) **Exclusion criteria:** • history of previous shoulder surgery • pregnancy • rotator cuff tear • malignancy • local infection • presence of cardiac pacemaker • use of anticoagulants • clotting problems • generalised polyarthritis • arthritis of the shoulder • aged < 18 years **Baseline characteristics** *ESWT (33 participants):* • mean (range) age: 54.4 (30–70) years • number male/female: 15/18 • mean (range) duration of symptoms: 12.3 (6–72) months • mean Constant score: 57.3 • mean pain VAS 0–10: 7.2 • mean (SD) width of calcific deposits: 11.9 (5.4)

Hsu 2008 *(Continued)*

	Sham treatment (13 participants): • mean (range) age: 57.8 (44 to 82) years • number male/female: 4/9 • mean (range) duration of symptoms: 11.1 (6 to 30) months • mean Constant score: 56.2 • mean pain VAS 0–10: 7.4 • mean (SD) width of calcific deposits: 10.5 (6.4) **Pretreatment group differences:** no statistically significant differences between groups at baseline
Interventions	**ESWT:** • description of modality used: OrthoWave machine (MTS, Konstanz, Germany) • method of administration: 10 mL of 2% lidocaine was injected into the affected area from a lateral approach with a 24-gauge needle. US gel was used as a contact medium between the transducer head and the skin • dose: 1000 acoustic shock waves with the machine set at level 5 at 2 pulses per second at energy density of 0.55 mJ/mm^2 • frequency: 2 sessions 2 weeks apart • co-interventions: after treatment each participant was instructed to ice the shoulder for 48 hours **Sham treatment:** • description of modality used: OrthoWave machine (MTS, Konstanz, Germany) set at level 5 with a dummy electrode attached to the machine • method of administration: as above • dose: as above • frequency: 2 sessions 2 weeks apart • co-interventions: as above
Outcomes	Measured at 6 weeks, 12 weeks, 6 months and 12 months **Outcomes included in review:** • function assessed by Constant score: 0–100, higher score indicating better function • pain measured by VAS 0–10, 10 indicating severe pain • radiographic assessment of calcific deposits resorption graded as none, partial or complete • proportion with adverse events • treatment success: participant satisfaction • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • calcification morphology
Source of funding	Not reported
Notes	**Trial registration:** not reported **Time points included in review:** 6 weeks, 6 months and 12 months **Data analysis:** the mean Constant score was extracted using the WebPlotDigitier program found at arohatgi.info/WebPlotDigitizer/app. It was not reported whether the graphs were reporting SD or SE; we assumed SDs were reported. The numbers were extracted and rounded to 1 decimal place. Where measured numbers differed from a reported figure, the reported figure was used. **Withdrawals:** none reported **Adverse events:**

Hsu 2008 *(Continued)*

ESWT:

- serious adverse events: 0/33
- other adverse events: 3/33 (local erythematous changes over shock wave site)

Sham treatment:

- serious adverse events: 0/13
- other adverse events: 0/13

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Systematic random sampling in multiples of 3, allocation ratio set to 2:1 for intervention:placebo.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Although local anaesthetic was used, the study did not report if participants were blinded, but outcome assessors were blinded.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Blinding of participants was not reported so there was a risk of bias in self-reported outcomes of pain, function and treatment success.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiologist who assessed calcification was reported as blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals.
Selective reporting (reporting bias)	High risk	There was no published study protocol, and participant satisfaction was measured but results were not reported. SDs for all outcomes were not reported. All study outcomes presented only as graphs without numerical tables.
Other bias	Low risk	No other biases apparent.

Ioppolo 2012

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind RCT **Setting:** outpatients at university hospital, Italy **Trial time period:** enrolment November 2008 to June 2010 **Interventions:** high-energy ESWT vs low-energy ESWT **Sample size calculation:** a sample size of 46 participants achieved a power over 80% to detect a 15% difference in Constant score. The statistical level of significance was set at α = 0.05, and the assumed SD was set at 17.7 points

Ioppolo 2012 *(Continued)*

Analysis: ITT analysis used, with missing data imputed with the last observation carried forward

Participants	**Number of participants:** • screened: 68 • enrolled: 46 (16 fulfilled exclusion criteria, 6 refused to participate) • randomised: 46 (23 per group) • included in analyses at 3 and 6 months: 46 (23 per group), • included in analyses at 12 months: 36 (16 in high-energy group; 20 in low-energy group) **Inclusion criteria:** • with medium and large calcific deposits according to the Bosworth classification • with type I and II calcific deposits according to the Gärtner classification • shoulder pain that has failed to respond to conservative treatment • current episode of shoulder pain lasting ≥ 4 to 6 months **Exclusion criteria:** • clinical signs of partial or complete tear of the rotator cuff (evaluated with Jobe and full can test and MRI if necessary) • presence of tiny calcific deposits according to the Bosworth classification • type III calcific deposits according to the Gärtner classification • aged < 18 years • diabetes • coagulation diseases or undergoing anticoagulant therapy • tumours • bone infections • previous shoulder surgery • pregnancy • use of a pacemaker • acute bursitis demonstrated by US imaging • rheumatoid arthritis • other connective tissue diseases **Baseline characteristics:** *High-energy ESWT (23 participants):* • mean (SD) age: 57.09 (16.40) years • number male/female: 8/15 • type of calcification: 5 Gärtner I; 18 Gärtner II • mean (SD) duration of pain: 6.95 (1.06) months • mean (SD) pain VAS 0–10: 8.45 (0.67) • mean (SD) function Constant 0–100 score: 49.26 (8.56) *Low-dose* ESWT*(23 participants):* • mean (SD) age: 51.66 (12.23) years • number male/female: 7/16 • type of calcification: 6 Gärtner I, 17 Gärtner II • mean (SD) duration of pain: 7.22 (1.20) months • mean (SD) pain VAS 0–10: 8.36 (0.78) • mean (SD) function Constant 0–100 score: 47.70 (12.23) **Pretreatment group differences:** none

Ioppolo 2012 *(Continued)*

Interventions	**High-energy ESWT:** • description of modality: ESWT (Modulith SLK system, Storz Medical, Tager-wilen, Switzerland), with an electromagnetic extracorporeal shock wave generator equipped with an in-line US positioning system on the target zone • method of administration: participants underwent ESWT by lying on a bed with the affected arm positioned in adduction, the elbow flexed at 90 degrees and the hand on the abdomen • dose: 2400 pulses in each session at 0.20 mJ/mm^2 • frequency: 4 sessions, once per week • co-interventions: participants were instructed to use oral NSAIDs (dexibuprofene 400 mg) 1 hour before treatment to provide pain relief during treatment. Local anaesthesia not administered **Low-dose ESWT:** • description of modality: as above • method of administration: as above • dose: 2400 pulses in each session at 0.10 mJ/mm^2 • frequency: as above • co-interventions: as above
Outcomes	Measured at 3, 6 and 12 months **Outcomes included in review:** • mean function: CMS, 0–100 with a higher score indicating better function • mean pain measured by VAS 0–10, 10 indicating worst pain ever • mean change in size of calcific deposit (mm) measured radiographically • proportion with adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • pain relief assessed using an 11-point NRS
Source of funding	Study supported by a grant from 'La Sapienza' University of Rome.
Notes	**Trial registration:** ClinicalTrials.gov identifier NCT01602653 **Time points included in review:** 3, 6 and 12 months **Data analysis:** mean pain and function extracted at 3 and 6 months; mean change in calcific size extracted at 6 months. As no measure of variance was reported for pain or function, the SD was taken from Schofer 2009 **Withdrawals:** 7/23 in high-dose ESWT group and 3/23 in low-dose ESWT group, no reasons given in either group **Adverse events:** *High-dose ESWT:* • serious adverse events: 0/23 • other adverse events: 0/23 *Low-dose ESWT:* • serious adverse events: 0/23 • other adverse events: 0/23

Risk of bias

Ioppolo 2012 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated 1:1 randomisation scheme used.
Allocation concealment (selection bias)	Low risk	An adequate method of numbered, opaque envelopes used to conceal the randomisation scheme.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Protocol explicitly reported that investigators were blinded to treatment but no information on whether participants were blinded or not.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Unclear if participants were aware of their treatment group, so reporting of pain and function may have been affected by bias.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiographer who assessed calcific deposits was reported as blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	10/46; 7/23 (30%) in high-dose ESWT group and 3/23 (13%) in low-dose ESWT group no reasons for withdrawal given.
Selective reporting (reporting bias)	High risk	VAS and Constant score outcomes were only reported in exact figures for 6 months' follow-up and only graphically with no measures of variance at other time points, and 12 months' follow-up date were not reported at all.
Other bias	Low risk	No other biases apparent.

Kim 2014

Methods	**Study design:** single-centre, parallel-group, two-arm, RCT **Setting:** orthopaedic surgery outpatient department, St Mary's Hospital, the Catholic University of Korea, Seoul, South Korea **Trial time period:** November 2005 to March 2011 **Interventions:** ESWT vs US-guided needling **Sample size calculation:** 30 participants per group were needed to detect a significant difference (mean difference 8 points; SD 12 points) between groups in ASES scores, with power of 80%, at a type I error level of 0.05 **Analysis:** not ITT
Participants	**Number of participants:** • screened for eligibility: 73 (11 excluded; 6 did not meet inclusion, 5 refused to participate) • randomised: 62 randomised (32 to ESWT group; 30 to US-guided glucocorticoid needling group) • included in analyses: 54 (29 from ESWT group; 25 from US-guided glucocorticoid needling group) **Inclusion criteria:**

Kim 2014 *(Continued)*

- diagnosed with unilateral calcium deposition at the supraspinatus tendon, confirmed on radiological examination
- disease duration > 3 months

Exclusion criteria:

- other shoulder disease, such as rotator cuff tear, adhesive capsulitis, arthritis, fracture, infection
- history of treatment for the affected shoulder

Baseline characteristics:

ESWT (32 participants):

- mean (range) age: 57.4 (47–78) years
- number male/female: 3/26
- mean (range) calcium deposit size: 11 (4.9–19.3) mm
- mean pain, VAS 0–10: 6.3
- mean function ASES 0–100 score: 49.9

US-guided glucocorticoid needling (30 participants):

- mean (range) age: 53.9 (45–76) years
- number male/female: 2/23
- mean (range) calcium deposit size: 14.8 (6.6–31) mm
- mean pain, VAS 0–10: 6.8
- mean function ASES 0–100 score: 41.5

Pretreatment group differences: none

Interventions	**ESWT:** • description of modality used: ESWT • method of administration: all participants underwent US examination to evaluate the characteristics of calcium deposits at the affected shoulder in sitting position. All procedures were performed in sitting position by 1 technician. Treatment was aimed at the maximum sore spot according to anatomic targeting • dose: 1000 impulses, 0.36 mJ/mm^2 • frequency: 3 sessions, 1 week apart • co-interventions: oral NSAIDs were prescribed at the end of the procedure for 7 days. Participants were permitted to perform daily normal activities to the extent possible, without any immobiliser brace **US-guided needling:** • description of modality used: US-guided needling • method of administration: all US-guided needling procedures were performed by 1 orthopaedic surgeon with a single needle without lavage. The procedure was performed by sterile technique and surgical gloves. A diagnostic US examination was performed to evaluate the characteristics of calcium deposits at the affected shoulder in sitting position. The skin was then cleaned with a 10% iodopovidone solution 3 times and antiseptically draped. After administration of local anaesthesia (2% lidocaine), the participants in this group underwent multiple percutaneous punctures for each deposit with an 18-gauge needle under real-time monitoring with US. The final step in procedure was an injection of 1 mL methylprednisolone acetate 40 mg into the subacromial space under US guidance • dose: 1 mL methylprednisolone acetate 40 mg (Depo-Medrol; Pharmacia & Upjohn, Kalamazoo, MI, USA; 40 mg/mL) • frequency of administration: once • co-interventions: as above
Outcomes	Measured at 6 weeks, 12 weeks, 6 months, 12 months, and last follow-up visit. Mean follow-up: 23.0 (range 12.1–28.5) months after treatment

Kim 2014 *(Continued)*

Outcomes included in review:

- calcification size: complete or partial resolution
- calcification size: size in mm on sonography using the Picture Archiving and Communications System by use of a mouse cursor with automated distance calculation
- ASES score: 0–100 with a higher score indicating better function
- pain VAS 0–10, higher score indicating worse pain

Other outcomes in trial, excluded from review

- function: SST, higher score indicating better function

Source of funding	The authors, their immediate families, and any research foundation with which they were affiliated received no financial payments or other benefits from any commercial entity related to the subject of the article
Notes	**Trial registration:** not reported **Time points included in review:** 3, 6 and 12 months **Data analysis:** no SDs or any other measures of variance were reported or could be calculated for the pain scores or the function scores at follow-up, thus we could not analyse these outcomes. The size of calcific deposits was extracted at last follow-up (12 months) **Withdrawals:** 3/32 in ESWT group, 5/30 in needling group were lost to follow-up **Adverse events:** not measured

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization was conducted by an independent statistician who provided us with a computer-generated randomization list." Comment: adequate.
Allocation concealment (selection bias)	Unclear risk	Not reported if the randomisation list was concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither participants nor personnel were blinded to treatment allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Participants were not blinded to treatment allocation, thus there was risk of detection bias in reporting of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Unclear risk	It was not reported if the radiographer assessing calcification size was blinded and the effect on measurement of this outcome was unclear.
Incomplete outcome data (attrition bias) All outcomes	High risk	3/32 (9%) in ESWT group and 5/30 (16.6%) in needling group were lost to follow-up.
Selective reporting (reporting bias)	High risk	There was no published study protocol, and measures of variance were not reported at follow-up for most data.

Kim 2014 *(Continued)*

Other bias	Low risk	No other biases apparent.

Kolk 2013

Methods	**Study design:** multicentre, parallel-group, two-arm, double-blind, randomised placebo-controlled trial **Setting:** outpatient clinics of 5 Dutch hospitals **Trial time period:** enrolment 2001–2003 **Interventions:** rESWT vs placebo **Sample size calculation:** sample size calculation was based on an unpublished pilot study, estimated that 35 participants per group were needed to detect a 50% difference in pain (VAS) between groups **Analysis:** ITT. Missing values were included in analyses using the 'last case carried forward' principle
Participants	**Number of participants:** • screened: not reported • enrolled: 94 (12 excluded as they were 'not randomised') • randomised: 82 (44 in rESWT group; 38 in placebo group) • included in analyses at 6 months: 69 (35 in rESWT group; 34 in placebo group) **Inclusion criteria:** • symptoms for ≥ 6 months • clinical signs of chronic tendinitis on painful arc and a positive empty can test (pain or weakness with downward pressure in 90-degree elevation in scapular plane and full internal rotation) • aged 18–67 years • no treatment for cuff tendinitis for ≥ 6 weeks before study **Exclusion criteria:** • pregnancy • blood coagulation disorders • systemic diseases • tumours of the shoulder region • presence of a pacemaker • glenohumeral arthritis • history of frozen shoulder (distinguished by a capsular restriction during passive exorotation or elevation, or both) • rotator cuff tear (US examination if suspected) • history of shoulder surgery **Baseline characteristics:** *rESWT (44 participants):* • mean (range) age: 48 (29–65) years • number male/female: 12/32 • number (%) radiographic findings: normal 20 (45), calcified 23 (52), acromio-clavicular arthrosis 1 (2) • mean (range) duration of symptoms: 24 (6–78) months • mean (SD) Constant score: 55 (13.8) • mean (SD) pain VAS: 65 (20) • mean (SD) SST: 4.8 (2.9)

Kolk 2013 *(Continued)*

- number (%) treatment history: rest 22 (50), physiotherapy 32 (73), medication 21 (48), corticosteroid injections 37 (84)

Placebo (38 participants)

- mean (range) age: 46 (24–67) years
- number male/female: 13/25
- number (%) radiographic findings: normal 17 (45), calcified 17 (45), acromio-clavicular arthrosis 2 (5)
- mean (range) duration of symptoms: 29 (6–180) months
- mean (SD) Constant score: 60.4 (14.4)
- mean (SD) pain VAS: 70 (16)
- mean (SD) SST: 5.3 (2.6)
- number (%) treatment history: rest 15 (39), physiotherapy 27 (71), medication 20 (53), corticosteroid injections 25 (66)

Pretreatment group differences: none

Interventions	**rESWT:** • description of modality: Swiss DolorClast radial shock wave device (EMS, Nyon, Switzerland) • method of administration: participants were supine and treatment was applied at the anterolateral side of the acromion by a single physiotherapist for all participants. No pain medication or local anaesthetic was used. • dose: 2000 pulses of 0.11 mJ/mm^2 at a frequency of 8 Hz at a pressure of 2.5 bar • frequency: 3 sessions at an interval of 10–14 days • co-interventions: ice applied for 10 minutes after each treatment and participants advised to use their arm normally and continue with their usual pain medication. **Placebo:** • description of modality: as above. A placebo probe that emitted the same sounds as the real probe was used. • method of administration: as above • dose: as above • frequency: as above • co-interventions: as above
Outcomes	Measured at 3 and 6 months **Outcomes included in review:** • function measured by the CMS: 0–100, higher score indicating better function • pain, VAS 0–100, 100 indicating worst pain imaginable • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • SST
Source of funding	Study supported by EMS. Although none of the authors received benefits for personal or professional use from a commercial party related directly or indirectly to the subject of the article.
Notes	**Trial registration:** not reported **Time points included in review:** 3 and 6 months

Kolk 2013 *(Continued)*

Data analysis: the VAS and CMS were extracted at 6 months. The study contact was e-mailed to gain further information on the mean duration of symptoms of the overall cohort of study participants and for the methods of allocation concealment

Withdrawals: 9/44 in rESWT group (2 lack of treatment effect, 1 lack of confidence in physiotherapist, 6 unspecified) and 4/38 in placebo group (2 failure of clinician instructions, 2 unspecified). We assumed withdrawals due to adverse events or intolerance to treatment was 3/44 in rESWT group and 2/38 in placebo group

Adverse events:

rESWT:

- serious adverse events**:** 0/44
- other adverse events: 0/44

Placebo:

- serious adverse events: 0/38
- other adverse events: 0/38

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "An independent coordinator, who was not involved in the treatment or evaluation of the patients performed the randomisation by a closed envelope system."
Allocation concealment (selection bias)	Unclear risk	A closed envelope system was used; however, it was not reported if the envelopes were opaque.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and surgeon were blinded to treatment allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Local anaesthesia was not used so participants may have been able to guess their allocation.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Low risk of bias in assessor-reported outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	13/82; 9/44 (20%) in rESWT group (2 lack of treatment effect, 1 lack of confidence in physiotherapist, 6 unspecified) and 4/38 (10%) in placebo group (2 failure of clinician instructions, 2 unspecified) were lost to follow-up.
Selective reporting (reporting bias)	Low risk	No published study protocol and trial was not registered; however, all specified outcomes were measured and reported.
Other bias	Low risk	No other biases apparent.

Kvalvaag 2017

Methods	**Study design:** single-centre, parallel-group, two-arm, double-blind, randomised sham-controlled trial

Kvalvaag 2017 *(Continued)*

Setting: outpatient shoulder clinic, Department of Physical Medicine and Rehabilitation, Oslo University hospital, Norway

Trial time period: enrolment 1 January 2012 to 15 April 2014

Interventions: supervised exercises plus rESWT vs supervised exercises plus sham rESWT

Sample size calculation: study was designed to detect a clinically relevant difference of 10 points (SD 20 points) between the groups with significance level (a) of 0.05 and power (b) of 80%. The sample size was calculated as 50 in each group. We included 143 participants to account for dropouts.

Analysis: ITT

Participants	**Number of participants:** • screened: 265 (62 not meeting inclusion criteria; 60 declined to participate) • enrolled: 143 • randomised: 143 (69 in supervised exercises plus rESWT group; 74 in supervised exercises plus sham group) • included in analyses at 24 weeks: 143 (69 in supervised exercises plus rESWT group; 74 in supervised exercises plus sham group) **Inclusion criteria:** • aged 25–70 years • subacromial pain lasting for 3 months • dysfunction or pain on abduction • pain on 1 of 2 isometric tests (abduction or external rotation) • positive Hawkins sign • normal passive glenohumeral ROM • people with bilateral shoulder pain were included if both shoulders fulfilled the inclusion criteria. **Exclusion criteria:** • previous surgery on affected shoulder • instability • total rupture of the rotator cuff (evaluated clinically or by US) • clinical signs of a cervical syndrome • infection in area • considered unable to fill out questionnaires or to go through the treatment • use of anticoagulant drugs or bleeding disorder • pregnancy • previous experience of 1 of the study interventions • corticosteroid injection in past 6 weeks • SPADI < 20 **Baseline characteristics:** *Supervised exercises plus rESWT (69 participants)* • mean (SD) age: 47.6 (9.9) years • number male/female: 32/37 • number (%) taking daily analgesics: 11 (15.9) • number (%) of symptoms: at 3–6 months: 12 (17.4), at 6–12 months: 18 (26.1), at 12–24 months: 14 (20.3), at ≥ 24 months: 25 (36.2) • mean (SD) emotional distress (1–4): 1.6 (0.4) • mean (SD) EQ-VAS 0–100: 63.8 (19.5)

Kvalvaag 2017 *(Continued)*

- number (%) US examination: bursal thickening or effusion: 23 (33.3), tendinopathy in rotator cuff: 53 (76.8)
- calcification in rotator cuff: 23 (33.3), partial thickness tear of rotator cuff: 28 (40.6), full-thickness tear of rotator cuff: 2 (2.9)
- mean (SD) SPADI score: 51.8 (17.5)
- mean (SD) pain at rest (0–10 score, 10 indicating worst pain): 4.4 (2.4)
- mean (SD) pain during activity (0–10 score): 6.4 (2.1)
- mean (SD) function: carrying bag 4.9 (3.2), taking an item down from a shelf: 6.6 (2.4)

Supervised exercises plus sham rESWT (74 participants)

- mean (SD) age: 46 (10.9) years
- number male/female: 33/41
- number (%) on daily analgesics: 9 (12.2)
- number (%) of symptoms: at 3–6 months: 17 (23), at 6–12 months: 19 (25.7), at 12–24 months: 13 (17.6); at ≥ 24 months: 25 (33.8)
- mean (SD) emotional distress (1–4): 1.6 (0.5)
- mean (SD) EQ-VAS 0–100: 65.8 (20.0)
- number (%) US examination: bursal thickening or effusion: 32 (43.8); tendinopathy in rotator cuff50 (67.6), tendinopathy in rotator cuff: 50 (67.6)
- calcification in rotator cuff: 23 (31.1), partial thickness tear of rotator cuff: 35 (47.3), full-thickness tear of rotator cuff: 4 (5.4)
- mean (SD) SPADI score: 51.9 (16.7)
- mean (SD) pain at rest (0–10 score, 10 indicating worst pain): 4.3 (2.3)
- mean (SD) pain during activity (0–10 score): 6.7 (1.8)
- mean (SD) function: carrying bag 5.5 (2.8), taking an item down from a shelf: 6.4 (2.9)

Pretreatment group differences: none.

Interventions

Supervised exercises plus rESWT:

Supervised exercises:

- method of administration: experienced physiotherapists supervised the exercise regimen which were conducted 1:1. The first session included gathering of medical history and bilateral inspection of alignment, including scapula and the glenohumeral joint. Movement pattern, the immediate cocontraction, and timing of the scapula and the arm were observed during elevation to obtain a functional diagnosis for individual guidance of treatment. The principal treatment focus was on relearning of normal movement patterns, which could then be transferred to daily activities. The initial aim was to unload the stress on the rotator cuff and subacromial structures. This phase entailed awareness of posture and the use of manual techniques for tense muscles, an elastic rubber band for relaxed repetitive movements, exercises for periscapular muscles and a vertically fixed sling. The focus in next phase was to increase the eccentric force when the participant was lowering the arm in standing position. This training incorporates scapular control and dynamic scapular stability. The participants received immediate feedback from and correction (supervision) by the physiotherapist. Subsequently, endurance exercises with gradually increasing resistance were performed. The participants also performed exercises at home, usually with a thin elastic cord.
- dose: each exercise session lasted 40 minutes
- frequency: once a week for 4 weeks followed by twice a week for the next 8 weeks
- co-interventions: none reported

rESWT:

- description of modality used: EMS Swiss DolorClast/Enimed
- method of administration: rESWT was applied on the muscle tendon(s) that were painful on isometric tests using a power handpiece, which gives a maximum energy of 0.35 mJ/mm^2. rESWT was performed by physiotherapists who underwent an application course and training before the study started.

Kvalvaag 2017 *(Continued)*

- dose: 2000 impulses on each painful tendon with pressure 1.5–3 bar, depending on participant tolerance.
- frequency: once a week for 4 weeks
- co-interventions: none reported

Supervised exercises plus sham rESWT:

Supervised exercises:

- as above

Sham rESWT:

- method of administration: the EMS Swiss DolorClast/Enimed was used to deliver sham RSWT on the muscle tendon(s) that were painful on isometric tests; however, there was no information on how the therapy was delivered as a sham procedure. The sham handpiece was similar to the real handpiece in design, shape and sound, and vibrated exactly like the real handpiece, but no real shock waves were conducted
- frequency: once a week for 4 weeks
- co-interventions: none reported

Outcomes	Measured at baseline, 12 and 24 weeks **Outcomes included in review:** • SPADI score 0–100, higher score indicating worse pain and disability • pain at rest measured on a 11-point Likert type scale, 10 indicating worst possible pain/function) • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • pain during activity measured on a 11-point Likert-type scale, 10 indicating worst possible pain/function) • function measured on a 11-point Likert type scale
Source of funding	Sophies Minde Ortopedi, Norway
Notes	**Trial registration:** ClinicalTrials.gov identifier NCT01441830 **Time points included in review:** 12 and 24 weeks **Data analysis:** function measured on SPADI and pain on the 11-point Likert-type scale were extracted at 12 and 24 weeks **Withdrawals:** 4/69 in shock wave group (2 loss to follow-up, 2 discontinued intervention (1 developed adhesive capsulitis and 1 developed synovial chondromatosis)) and 4/74 in sham group (1 loss to follow-up, 3 discontinued intervention, (1 developed adhesive capsulitis, 1 developed increased pain, 1 developed other serious disorder)) **Adverse events:** *Supervised exercise plus rESWT:* • serious adverse events: 0/69 • other adverse events: 2/69 *Supervised exercise plus sham rESWT:* • serious adverse events: 0/74 • other adverse events: 3/74

Kvalvaag 2017 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation in blocks of 20 in a 1:1 ratio used.
Allocation concealment (selection bias)	Low risk	Allocation concealed using sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding of participants and study personnel was done.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Blinding of participants resulted in low risk of bias in self-reported outcomes of pain, disability and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Blinding of outcome assessors was done; however, not applicable in the measurement of study outcomes which were all self-reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	8 withdrawals from this study, 4/69 in supervised exercise plus rESWT group and 4/74 in supervised exercise plus sham group, however none were excluded from the analysis in both groups.
Selective reporting (reporting bias)	Unclear risk	Study protocol and trial registration accessible to review authors. All measured outcomes were reported; however, the protocol stated return to work and health-related quality of life as secondary outcomes, which were not measured in study.
Other bias	Low risk	No other biases apparent.

Li 2017

Methods	**Study design:** single-centre, parallel-group, two-arm, double-blind, randomised, placebo-controlled trial **Setting:** First Hospital of Harbin City, China **Trial time period:** February 2015 to January 2017 **Interventions:** ESWT vs placebo **Sample size calculation:** sample size calculation was based on the 50% difference in NRS score with $\alpha = 0.5$, $\beta = 0.8$, and assuming a 20% dropout rate. Therefore, the required sample size of the present study was estimated to be 84 participants, with 42 assigned to each group. **Analysis:** all outcome data by ITT
Participants	**Number of participants:** • screened: 125 (20 not meeting inclusion criteria, 10 meeting exclusion criteria, 11 refused to participate) • at enrolment: 84

Li 2017 *(Continued)*

- randomised: 84 (42 per group)
- included in analyses: 69 (35 in ESWT group; 34 in placebo group)

Inclusion criteria:

- diagnosis of chronic rotator cuff tendinopathy without calcification by physical examination, a painful arc and positive empty can test result
- aged 18–65 years
- history of clinical signs of chronic tendinitis for > 6 months
- no alternative therapy, including ESWT, within 1 month before enrolment in study
- informed consent before enrolment in study

Exclusion criteria:

- pregnant or breastfeeding
- blood coagulation disorders
- history of surgery
- history or presence of tumours, pacemaker, frozen shoulder, systematic diseases
- skin disease, cancer, severe mental disorders

Baseline characteristics:

ESWT (42 participants):

- mean (SD) age: 48.4 (9.7) years
- mean (SD) duration of symptoms: 27.5 (11.9) months
- number (%) treatment side: left: 12 (28.6); right: 30 (71.4)
- number (%) no calcification in X-rays: 42 (100)
- mean (SD) NRS: 6.8 (3.0)
- mean (SD) CMS: 53.7 (14.1)
- mean (SD) SST: 4.9 (2.4)
- number (%) treatment history: medication: 19 (45.2); corticosteroid injections: 22 (52.4); physiotherapy: 15 (35.7)

Placebo (42 participants):

- mean (SD) age: 46.9 (10.1) years
- mean (SD) duration of symptoms: 30.1 (12.3) months
- number (%) treatment side: left: 15 (35.7); right: 27 (64.3)
- number (%) no calcification in X-rays: 42 (100)
- mean (SD) NRS: 7.0 (3.1)
- mean (SD) CMS 56.2 (14.4)
- mean (SD) SST 5.2 (2.6)
- number (%) treatment history: medication: 21 (50); corticosteroid injections: 26 (61.9); physiotherapy: 17 (40.5)

Pretreatment group differences: none

Interventions	**ESWT:** • description of modality used: ESWT using the Pain Treatment System of Radial shock wave Device (Sonothera, Hanil Tm Co. Ltd, Korea) • method of administration: not described • dose: 3000 pulses of 0.11 mJ/mm^2 at frequency of 15 Hz. Pressure set at 3 bar • frequency: 5 sessions, 3 days apart • co-interventions: not reported **Placebo:**

Li 2017 *(Continued)*

- description of modality used: a placebo probe looking identical to the ESWT probe. The probe could emit the same sounds as the ESWT probe
- method of administration: not described
- dose: not applicable
- frequency: 5 sessions, 3 days apart
- co-interventions: not reported

Outcomes	Measured at 4 and 8 weeks **Outcomes included in review:** • pain: NRS • function: CMS • rate of adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • SST score
Source of funding	Study funded by grants from the Science and Technology Talents Program of Harbin (2014RFXGJ041, 2014RFQGJ094), Harbin First Hospital postdoctoral fellowship program (HRBSDYYYBSH-1); Postdoctoral Fund (160780); Harbin high level talent fund (HRBGCCRCJJ-6, 2013SYYRCYJ01–1); China Postdoctoral Science Foundation, Heilongjiang Natural Science Foundation (QC2016102, H2016002)
Notes	**Trial registration:** not registered **Time points included in review:** 4 and 8 weeks **Data analysis:** only changes from baseline values were reported for all study outcomes at both time points. **Withdrawals:** 7/42 in ESWT group (2 withdrawal of consent, 5 lost to follow-up) and 8/42 in placebo group (1 withdrawal of consent, 7 lost to follow-up). As reasons for withdrawal of consent were not reported, we assumed it may have been due to treatment intolerance, and included these data in Analysis 1.5: 2/42 in ESWT group and 1/42 in placebo group. **Adverse events:** *rESWT:* • serious adverse events: 0/42 • other adverse events: 0/42 *Placebo:* • serious adverse events: 0/42 • other adverse events: 0/42

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization schedule was operated by a computerized number generated using SAS package (Version 8.2; SAS Institute Inc. Cary, NC) at a 1:1 ratio."
Allocation concealment (selection bias)	Low risk	Quote: "All information of assignments and allocation were concealed in sequentially numbered, opaque, and sealed envelopes."

Li 2017 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Both participants and study personnel were blinded to treatment allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	As participants were blinded to group allocation, there was unlikely to have been any effect on subject outcome data.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Quote: "the outcome assessors and data analysts were also blinded in this study."
Incomplete outcome data (attrition bias) All outcomes	Low risk	7/42 in ESWT group (2 withdrawal of consent, 5 lost to follow-up) and 8/42 in placebo group (1 withdrawal of consent, 7 lost to follow-up).
Selective reporting (reporting bias)	Unclear risk	The review author did not have access to a protocol, the results were reported as change from baseline and no summary data were given for each group for all study outcomes.
Other bias	Low risk	No other biases apparent.

Loew 1999

Methods	**Study design:** single-centre, parallel-group, four-arm randomised trial **Setting:** outpatient clinic **Trial time period:** July 1993 to December 1994 **Interventions:** no treatment vs single session low-dose ESWT vs single session high-dose ESWT vs dual session high-dose ESWT **Sample size calculation:** not reported **Analysis:** not reported if ITT analysis was used, but seemed that all allocated to treatments were followed up
Participants	**Number of participants:** • screened: not reported • enrolled: 195 (80 allocated to Part A; 115 allocated to Part B) • randomised (Part A): 80 (20 per group in 4 groups – no treatment, low-dose ESWT, single session high-dose ESWT, dual session high-dose ESWT) • at 3 months' follow-up: 80 (20 per group in 4 groups) • allocated to treatment (Part B): 115 (56 to the single session high-dose ESWT group; 59 to the dual session high-dose ESWT group) **Inclusion criteria:** • shoulder pain for ≥ 12 months, which had been resistant to regular physiotherapy and subacromial injections of steroid • area of radiological calcification ≥ 1.5 cm in diameter, with signs of disintegration or resorption and type I or II according to the classification of Gärtner **Exclusion criteria:**

Loew 1999 *(Continued)*

- degenerative changes in glenohumeral or acromioclavicular joint
- sonographic evidence of a rotator cuff tear, acute subacromial bursitis
- acute subacromial bursitis
- any neurogenic disorder

Baseline characteristics:

No treatment (20 participants):

- mean (SD) Constant score mean: 44.5 (8.3)
- calcification size: not reported

Low-dose ESWT (20 participants):

- mean (SD) Constant score: 39.4 (11.2)
- calcification size: not reported

Single session high-dose ESWT (20 participants):

- mean (SD) Constant score: 39.0 (11.8)
- calcification size: not reported

Dual session high-dose ESWT (20 participants):

- mean (SD) Constant score: 43.5 (13.1)
- calcification size: not reported

Pretreatment group differences: no differences in Constant scores but data on demographic variables were not reported.

Interventions	**PART A:** **Low-dose ESWT:** • description of modality used: electrohydraulic lithotripter (MFL 5000; Philips, Hamburg, Germany). • method of administration: participants received treatment as outpatients, after subcutaneous infiltration of local anaesthetic (15–20 mL bupivacaine hydrochloride 0.5%). The calcification was visualised using fluoroscopy before and at intervals during treatment. The treatment started with low shock wave intensities which increased to the planned energy level within the first 300 impulses • dose: 2000 impulses of low-energy treatment (EFD 0.1 mJ/mm^2) • frequency: 1 session • co-interventions: not reported **Single session high-dose ESWT:** • description of modality used: as above • method of administration: as above • dose: 2000 impulses of high-energy treatment (EFD 0.3 mJ/mm^2) • frequency: 1 session • co-interventions: not reported **Dual session high-dose ESWT:** • description of modality used: electrohydraulic lithotripter (MFL 5000; Philips, Hamburg, Germany). • dose: 2000 impulses of high-energy treatment at 0.3 mJ/mm^2 • frequency: 2 sessions, 1 week apart • co-interventions: not reported **No treatment control:** • no interventions given

Loew 1999 *(Continued)*

	PART B: **Single session high-dose ESWT:** • description of modality used: electromagnetic lithotripter (Compact; Dornier MedTech, Wessling, Germany). • method of administration: as above • dose: 2000 impulses of high-energy treatment (EFD 0.3 mJ/mm^2) • frequency: 1 session • co-interventions: not reported **Dual session high-dose ESWT:** • description of modality used: Electromagnetic lithotripter (Compact; Dornier MedTech, Wessling, Germany). • method of administration: as above • dose: 2000 impulses of high-energy treatment (EFD 0.3 mJ/mm^2) • frequency: 2 sessions, 1 week apart • co-interventions: not reported
Outcomes	Measured at baseline and 3 months (Part A) and 6 months (Part B). **Outcomes included in review (Part A only):** • function: CMS: 0–100, higher score indicating better function. The CMS contains 65-point subjective arm and a 35-point objective arm. • calcification size (complete resolution): radiographic resolution or disintegration of calcification on anteroposterior view in internal and external rotation and a supraspinatus outlet view • treatment success: participant-reported freedom from pain or slight discomfort after activity • rate of adverse events in both groups • withdrawals due to adverse events, intolerance to treatment or other reasons
Source of funding	Authors reported that they did not receive any funding
Notes	**Trial registration:** not registered **Time points included in review:** 3 months **Data analysis:** data from Part A were included in this review. As Part B was probably not a randomised study, it was excluded from this review **Withdrawals:** 0 in Part A. Part B data not included in this review **Adverse events:** *Low-dose* ESWT*:* • serious adverse events: 0/20 • other adverse events: 0/20 *Single session high-dose* ESWT*:* • serious adverse events: 0/20 • other adverse events: 0/20 Small haematomas in high-dose group, the exact number of participants was not reported *Dual session high-dose* ESWT*:* • serious adverse events: 0/20 • other adverse events: 0/20

Loew 1999 *(Continued)*

Small haematomas in high-dose group, the exact number of participants was not reported

No treatment:

- serious adverse events: 0/20
- other adverse events: 0/20

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "In order of their entry to the trial, 80 patients were divided into groups of 20." Comment: method of randomisation not reported.
Allocation concealment (selection bias)	Unclear risk	Concealment of allocation not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither participants nor personnel were blinded to treatment group.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	As participants were aware of their treatment group, this may have biased self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	High risk	As assessors were not blinded, there was risk of bias in radiographic assessment of calcific deposits
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals
Selective reporting (reporting bias)	High risk	There was no published study protocol, important outcomes, such as pain were not reported. Adverse events were measured, but incompletely reported.
Other bias	Unclear risk	Unclear how participants were enrolled in study, baseline characteristics of each of the 4 groups were not provided.

Melegati 2000

Methods	**Study design:** single-centre, parallel-group, three-arm, RCT **Setting:** Department of Physical Therapy and Rehabilitation, Istituto Ortopedico G. Pini, Milan, Italy **Trial time period:** December 1998 to May 1999 **Interventions:** ESWT plus kinesitherapy vs kinesitherapy alone vs control (postural advice only) **Sample size calculation:** not reported **Analysis:** not reported
Participants	**Number of participants:**

Melegati 2000 *(Continued)*

- screened for eligibility: not reported
- randomised: 90 (30 per group) randomised and included in analyses

Inclusion criteria:

- subacromial impingement syndrome (Neer stage I or II)

Exclusion criteria:

- calcific tendinitis of the cuff
- Neer stage III
- neuropathy
- rheumatoid arthritis
- aged < 18 or > 65 years
- prior cortisone injections
- pregnancy
- inflammation
- tumours
- coagulopathy

Baseline characteristics:

Kinesitherapy (30 participants):

- mean (SD) age: 53.66 (7.35) years
- number male/female: 7/23
- mean (SD) Constant score: 47.68 (8.9)

ESWT plus kinesitherapy (30 participants):

- mean (SD) age: mean: 53.66 (8.98) years
- number male/female: 13/17
- mean (SD) Constant score: 50.25 (12.96)

Control (postural hygiene) (30 participants):

- mean (SD) age: 55.76 (13.08) years
- number male/female: 11/19
- mean (SD) Constant score: 53.73 (17.28)

Pretreatment group differences: none

Interventions

Kinesitherapy:

- method of administration: performed under the direction of a rehabilitation therapist: Codman exercises (passive shoulder pendulum exercises); capsular stretching; isometric exercises for the rotators deltoid; elastic resistance exercises for the rotators, deltoid and trapezius. Participants were asked to continue the exercises at home on alternate days
- dose: 40-minute sessions
- frequency: 6 times at 3-week intervals
- co-interventions: postural hygiene and joint economy advice, as described below

ESWT plus exercises:

- description of modality used: Epos Ultra electromagnetic apparatus (Dornier, MedTech, Wessling, Germany) fitted with a 7.5 MHz linear echographic sound
- method of administration: the therapeutic head was positioned to direct the pressure pulses on and around the rotator cuff tendon insertions on the greater tubercle of the humerus. Local anaesthesia was never needed. 2 × 15-minute cryotherapy sessions were recommended on the treatment day, followed by 5 minutes of Codman exercises twice a day afterwards

Melegati 2000 *(Continued)*

- dose: each treatment: 2000 shots at an applied energy density of 0.22 mJ/mm^2 reached in 400 shots
- frequency: 3 treatments at 1-week intervals
- co-interventions: kinesitherapy programme was begun after 3 ESWT sessions. Postural hygiene and joint economy advice, as described below

Control (advice only):

- method of administration: postural hygiene and joint economy advice was given during desk work, rest the elbow on a support abducting the shoulder 30–40 degrees; avoid long hanging of the upper limb; do not sleep on the affected shoulder and apply a small pillow under the armpit; when handling tools, keep the weight near the trunk so as to shorten the lever arm

Outcomes	Measured at 8 months **Outcomes included in review:** • function: Constant score, from 0–100, with a higher score indicating better function **Outcomes excluded from review:** none
Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 8 months **Data analysis:** 2 treatment groups were included in this review for the comparison: ESWT plus kinesitherapy vs kinesitherapy alone. Function measured by Constant score 8 months after last intervention. An e-mail requesting information (population in follow-up outcomes, Constant subscore of pain) was not able to be sent to the study author because an e-mail address was not reported in published study. **Withdrawals:** none **Adverse events:** not measured

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation methods not reported.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment methods not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding methods not reported.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Unknown whether the participants were blinded, hence there was a risk of bias in self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	No assessor-reported outcomes.

Melegati 2000 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals
Selective reporting (reporting bias)	Low risk	No published study protocol, but the study outcome was reported (function).
Other bias	Low risk	No other biases apparent.

Pan 2003

Methods	**Study design:** single-centre, parallel-group, two-arm, RCT **Setting:** outpatient clinics of the departments of Physical Medicine and Rehabilitation and of Orthopedics and Traumatology, Taipei Veterans General Hospital, Taiwan **Trial time period:** January 2001 to January 2002 **Interventions:** ESWT vs TENS **Sample size calculation:** not performed **Analysis:** unclear if ITT analysis was planned; dropouts did not contribute data
Participants	**Number of participants:** • screened for eligibility: not reported; • randomised: 60 (63 shoulders); 32 to ESWT (33 shoulders); 28 to TENS (30 shoulders) • included in analyses: 59 participants at 4 weeks' follow-up (32 from ESWT (33 shoulders); 27 from TENS (29 shoulders)); 59 participants at 12 weeks' follow-up (32 from ESWT and 27 from TENS) **Inclusion criteria:** • calcific tendinitis that was radiographically and sonographically verified • moderate pain (VAS score ≥ 4; range 0–10) or a minimum period of continuous pain for 6 months **Exclusion criteria:** • systemic diseases such as rheumatic disease and coagulation disorder • cardiac pacemaker or other implanted devices • neuropathic, malignant or infectious causes of pain • rotator cuff tear • previous surgery for calcification, percutaneous needle aspiration, or glucocorticosteroid injection in shoulder within 3 months • pregnant **Baseline characteristics:** *ESWT (32 participants):* • mean age (SD): 55.21 (2.01) years • number male/female: 12/20 • number (%) location of calcification: supraspinatus 31 (70.5); infraspinatus 4 (9.1); subscapularis 8 (18.2); teres minor 1 (2.3) • mean (SD) maximal calcification size: 9.22 (4.08) mm • number (%) type of calcification: arc 19 (57.6); fragment 8 (24.2); nodule 6 (18.2); cyst 0 • mean (SD) duration of symptoms: 24.55 (6.45) months

Pan 2003 *(Continued)*

- mean (SD) Constant score: 63.77 (14.22)
- mean (SD) VAS 0–10: 6.50 (1.81)

TENS (28 participants):

- mean age (SD): 58.00 (1.83) years
- number male/female: 9/19
- number (%) location of calcification: supraspinatus 27 (69.2); infraspinatus 3 (7.7); subscapularis 9 (23.1); teres minor 0
- mean (SD) maximal calcification size: 9.17 (5.45) mm
- number (%) type of calcification: arc 12 (40); fragment 12 (40); nodule 4 (13.3); cyst 2 (6.7)
- mean (SD) duration of symptoms: 23.90 (5.32) months
- mean (SD) Constant score: 65.66 (15.84)
- mean (SD) VAS 0–10: 6.70 (1.4)

Pretreatment group differences: no baseline differences between the 2 groups

Interventions	**ESWT:** • description of modality used: Orthospec (a spark gap generator in a mobile unit). The therapeutic zone was ellipsoid in shape, 95 mm in height and 25mm in diameter. There was about 0.29 mJ/mm^2 of energy density at the edge of therapeutic zone • method of administration: the contact head was positioned at the marked painful area, which was defined by sonography before each treatment so that the acoustic shock wave could be transmitted effectively. All sessions were delivered by the same therapist • dose: 2000 shock waves at 2 Hz. Energy level 0.26–0.32 mJ/mm^2/session depending on the intensity, which was adjusted to the patient's tolerance • frequency: 2 sessions, 14 days apart • co-interventions: not reported **TENS:** • description of modality used: electrostimulator, Neurosan50 and hydrocollator pack • method of administration: TENS was delivered using the above modality in a constant square wave pulse stimulation current with a 0.5 ms pulse width and a 10 ms interval length to an active electrode secured firmly on the skin at the subacromion painful area. All sessions were delivered by the same therapist • dose: delivered at a frequency of 95 Hz and intensity increased until local contraction of adjacent muscles. Total session time about 20 minutes • frequency: 3 times a week for 4 weeks • co-interventions: not reported
Outcomes	Measured at baseline, 2, 4 and 12 weeks **Outcomes included in review:** • mean function measured by Constant score (0–100, higher score indicating better function) • mean pain measured by VAS 0–10, 10 indicating worst pain • changes of calcium deposits; size in mm measured on sonography • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • muscle power measured by the Manual Muscle Test • calcification type
Source of funding	Not reported

Pan 2003 *(Continued)*

Notes

Trial registration: not registered

Time points included in review: 4 and 12 weeks

Data analysis: Constant score, VAS scores and changes in calcification size were extracted at 4 and 12 weeks. Adverse events and withdrawal due to adverse events were extracted at the conclusion of the study (12 weeks). The number of shoulders rather than the number of participants was used in analysis of pain, function and calcification size.

Withdrawals: 0/32 in ESWT group, 1/28 in TENS group due to severe pain. The adverse events in ESWT group were not included as they subsided without treatment and did not affect intervention.

Adverse events:

ESWT:

- serious adverse events: 0/32
- other adverse events: 6/32 (5/32 had soreness in upper arm after shock wave which subsided before the next visit, 1/32 had palpitations due to anxiety during the first shock wave which subsided after taking a break)

TENS:

- serious adverse events: 0/28
- other adverse events: 1/28 (severe pain after the first session leading to withdrawal)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "All patients were randomly assigned to ESWT or TENS groups by draw." Comment: drawing lots was an adequate randomisation method.
Allocation concealment (selection bias)	Unclear risk	Allocation process not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel not reported.
Blinding of outcome assessment (detection bias) Self-reported outcomes	High risk	Participants were unblinded, there was a risk of bias in measurement of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Quote: "The baseline and posttreatment sonographic assessments were performed by the same radiologist, who was blind to the assignment of the subjects." Comment: low risk of bias for the measurement of calcification size.
Incomplete outcome data (attrition bias) All outcomes	Low risk	1/28 from the TENS group due to severe pain leading to withdrawal, 0/32 in ESWT group
Selective reporting (reporting bias)	Low risk	Comment: no published study protocol, but results were reported for all outcomes as mentioned in methods.

Pan 2003 *(Continued)*

Other bias	High risk	Unit of analysis bias: the trialist did not report if they adjusted for the non-independence between shoulders for the participants who had bilateral treatment. This may underestimate any treatment differences.

Perlick 2003

Methods	**Study design:** parallel-group, two-arm, RCT **Setting:** outpatient setting **Trial time period:** participant enrolment 1995–1998 **Interventions:** low-dose ESWT vs high-dose ESWT **Sample size calculation:** sample size calculation not performed **Analysis:** the study did not state whether ITT analysis was used
Participants	**Number of participants:** • screened: not reported • randomised: 80 (40 per group) • included in analyses: 80 (40 per group) **Inclusion criteria:** • shoulder pain for a minimum 12 months • resistant to regular physiotherapy and subacromial injections of steroids • area of radiological calcification ≥ 1 cm in diameter with no signs of disintegration or type I or II resorption according to the classification of Gärtner and Heyer was required **Exclusion criteria:** • cloudy and transparent calcifications (type III) • rotator cuff lesions diagnosed by sonography or MRI • evidence of subacromial impingement of the rotator cuff independent of the calcareous deposits • dysfunction in cervical spine • generalised polyarthritis • pregnancy • infection • previous tumour **Baseline characteristics** *Low-dose ESWT (40 participants):* • mean (SD) baseline pain, VAS 0–15: 3.2 (2.7) • mean (range) baseline Constant: 46.3 (not reported) • calcification size: not reported *High-dose ESWT (40 participants):* • mean (SD) baseline pain, VAS 0–15: 4.2 (2.5) • mean (range) baseline Constant: 48.4 (22 to 81) • calcification size: not reported **Pretreatment group differences:** demographic characteristics for each group were not reported.

Perlick 2003 *(Continued)*

Interventions	**Low-dose ESWT** • description of modality: Siemens Lithostar-Lithotripter • method of administration: performed as an outpatient procedure after subcutaneous infiltration of local anaesthetic (10 mL bupivacaine hydrochloride 0.5%). The calcific deposits were visualised using the in-line sector scanner prior to treatment. Shock wave application started with low-energy waves that was increased to the planned energy level within the first 300 shock waves • dose: 2000 impulses with an EFD of 0.23 mJ/mm^2 • frequency: 2 sessions with an interval of 3 weeks • co-interventions: none **High-dose ESWT** • description of modality: as above • method of administration: as above • dose: 2000 impulses EFD 0.42 mJ/mm^2 • frequency: 2 sessions with an interval of 3 weeks • co-interventions: none
Outcomes	Measured at 3 and 12 months **Outcomes included in review:** • function measured by CMS • pain measured by VAS 0–15 from CMS, higher score indicating less pain • calcification size: proportion of participants with complete resorption or partial resorption of calcium deposits as measured on X-ray • proportion of participants with adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • ROM reported as a Constant-Murley subscore, 0–40 scale
Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 3 and 12 months **Data analysis:** pain and function extracted at 3 and 12 months; calcification resorption and adverse events extracted at 12 months. Pain scores were reversed in direction by subtracting the score from 15 so that they could be compared with VAS scores of other studies (where VAS 0–10, 10 indicating most pain). SDs were not reported for function scores. The SD was imputed from Ioppolo 2012 at 6 months and Schofer 2009 at 12 months for analyses. No author contact details were provided, so we could not request missing data. We reported 5/40 adverse events in low-dose group and 15/40 adverse events in high-dose group. We did not include petechial bleeding as it was mild and local in both groups **Withdrawals:** none **Adverse events:** *Low-dose shock wave therapy:* • serious adverse events: 0/40 • other adverse events: 20/40 (15 mild local intracutaneous, petechial bleeding; 1 superficial haematoma; 2 acute pain immediately following treatment requiring oral analgesics; 2 acute bursitis subacromialis) *High-dose shock wave therapy*

Perlick 2003 *(Continued)*

- serious adverse events: 0/40
- other adverse events: 40/40 (40 mild local intracutaneous, petechial bleeding; 8 superficial haematoma; 3 acute pain immediately following treatment requiring oral analgesics; 4 acute bursitis subacromialis)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly assigned in a blinded fashion to two groups." Comment: method of randomisation not reported.
Allocation concealment (selection bias)	Unclear risk	Methods of allocation concealment not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of the personnel or study participants not described; however, local anaesthetic used in both groups.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	As the blinding of the participants was not adequately reported, there was an unclear risk of detection bias on the self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Unclear risk	Blinding of assessors not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals
Selective reporting (reporting bias)	High risk	No published study protocol, but results were reported for all outcomes as mentioned in methods. A measure of variance was not reported for function outcomes.
Other bias	Low risk	No other biases apparent.

Peters 2004

Methods	**Study design:** parallel-group, three-arm, double-blind, RCT **Setting:** not reported **Trial time period:** not reported **Interventions:** low-dose ESWT vs high-dose ESWT vs sham ESWT **Sample size calculation:** not done **Analysis:** did not report using ITT analysis
Participants	**Number of participants:** • screened: not reported

Peters 2004 *(Continued)*

- randomised: 90 (30 in low-dose ESWT group; 31 in high-dose ESWT group; 29 in sham group)
- included in analysis: 90 (30 in low-dose ESWT group; 31 in high-dose ESWT group; 29 in sham group)

Inclusion criteria:

- radiographically verified calcific tendinitis of 1 shoulder
- type I (clearly circumscribed and dense) or type II (clearly circumscribed or dense) calcifications according to the classification of Gärtner and Heyer
- shoulder pain for ≥ 6 months
- minimum 10 sessions of physiotherapy
- still had substantial restriction of shoulder mobility and pain that required taking anti-inflammatory drugs

Exclusion criteria:

- calcific deposits < 1 cm
- type III calcifications according to the Gärtner and Heyer classification
- MRI-confirmed rotator cuff tears
- degenerative changes of the acromioclavicular joint

Baseline characteristics: not reported

Interventions

Low-dose ESWT:

- description of modality used: ESWT performed using the miniaturised shock wave source Minilith (15 cm diameter, 15 cm length) (Storz Medical, Switzerland) with an in-line US device
- method of administration: the ESWT equipment was handled by trained technicians. Shock waves were always focused on the calcified area. Targeting of calcifications was achieved by using the in-line US transducer (7.5 MHz) of the Minilith
- dose: EFD of 0.15 mJ/mm^2, delivered via 1500 pulses
- frequency: treatments at 6-week intervals until pain was completely gone, 5 treatments were reached or the participant dropped out of the study
- co-interventions: none

High-dose ESWT:

- method of administration: see above
- dose: 0.44 mJ/mm^2, delivered via 1500 pulses
- frequency: as above
- co-interventions: none

Sham ESWT:

- method of administration: the same system as the other treatments was used, but an on-off switch introduced into the circuit was placed in the 'off' position.
- dose: zero
- frequency: as above
- co-interventions: none

Outcomes

Measured at 6 months

Outcomes included in review:

- adverse events (haematomas registered sonographically after the procedure)
- calcification size: number of participants with complete resolution of calcifications, assessed by internal and external rotation X-rays of the shoulder and read separately by 2 radiologists
- treatment success: freedom from pain without any anti-inflammatory medication, taken as the number of participants who did not have a relapse of symptoms at follow-up
- withdrawals due to adverse events, intolerance to treatment or other reasons

Peters 2004 *(Continued)*

Outcomes excluded from review:

- mean pain during the treatment measured on 10-point scale, 0 indicating severe pain
- number of ESWT sessions needed to fully resolve pain and restore mobility

Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 6 months **Data analysis:** as there were 2 active intervention groups, the low-dose ESWT data were included for the comparison ESWT vs placebo as it was more consistent with that in given in other studies. The high-dose group and low-dose group were used for the comparison high-dose vs low-dose ESWT. Pain during treatment was not considered by the study to be adverse events, and were, therefore, not able to be extracted as adverse events in this review. The outcome of 'treatment success' was obtained by the equation of: proportion of successes = 100% – proportion of relapses; or number of successes = total population – number of relapsed participants. **Withdrawals:** 0/30 in low-dose ESWT group, 0/31 in high-dose ESWT group, 3/29 in sham group (unresolved pain after 3 sessions). We assumed withdrawals due to intolerance were 0/30 in shock wave and 3/29 in placebo (Analysis 1.5) **Adverse events:** *Low-dose ESWT:* • serious adverse events: 0/30 • other adverse events: 2/30 4/30 had pain during ESWT 2/30 had haematomas *High-dose ESWT:* • serious adverse events: 0/31 • other adverse events: 6/31 31/31 had pain during shock wave 6/31 had haematomas *Sham shock wave therapy:* • serious adverse events: 0/29 • other adverse events: 0/29

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Spreadsheet used to generate a list of random numbers.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Both participants and study staff were blinded to treatment allocation. But local anaesthesia was not used for both groups so participants may have guessed if they were in placebo group.

Peters 2004 *(Continued)*

Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Since no local anaesthetic was used, participants may have been biased in reporting treatment success.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiologists assessing the X-rays were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	3/90; 0/30 in low-dose ESWT group, 0/31 in high-dose ESWT group, 3/29 in sham group (unresolved pain after 3 sessions)
Selective reporting (reporting bias)	High risk	No published study protocol; the study reported outcomes mentioned in methods but did not report SDs for pain
Other bias	Unclear risk	Authors reported that demographic data of the groups were comparable with regard to age, size and type of calcification. However, baseline data were not reported.

Pleiner 2004

Methods	**Study design:** single-centre, parallel-group, two-arm, double-blind, randomised placebo-controlled trial **Setting:** not reported **Trial time period:** not reported **Interventions:** ESWT vs placebo **Sample size calculations:** a sample size based on priori assumption of $\alpha = 0.05$ and $\beta = 0.20$, was performed, but the number of participants needed per group was not reported. **Analysis:** ITT analysis was used when assessing changes in Gärtner score for X-rays
Participants	**Number of participants:** • screened: 45 • randomised: 43 participants (57 shoulders) (23 in ESWT group (31 shoulders); 20 (26 shoulders) in placebo group) • included in analyses, at 1 week: 43 (23 in ESWT group; 20 in placebo group); at 3 months: 38 (20 in ESWT group; 18 in placebo group); 7 months: 33 (17 in ESWT group; 16 in placebo group) **Inclusion criteria:** • radiologically verified calcific tendonitis of ≥ 1 shoulder and chronic pain for ≥ 6 months • calcification > 5.0 mm in diameter • prior unsuccessful treatment with ≥ 3 of the following therapies: local infiltration with anaesthetics or glucocorticoids, physiotherapy, electrotherapy including US therapy, or oral analgesics **Exclusion criteria:** • malignant diseases • coagulation disorders • acute or systemic infections of bones and joints • cardiac pacemaker • pregnancy

Pleiner 2004 *(Continued)*

Baseline characteristics:

ESWT (23 participants)

- mean (SD) age: 54 (11) years
- number male/female: 8/15
- concurrent treatment: 2 participants were taking an analgesic
- mean (SD) pain at night, VAS 0–10: 5.5 (2.7)
- mean (SD) pain during the day, VAS 0–10: 4.8 (2.6)
- mean (SD) Constant score: 46 (21)
- calcification size: not reported

Placebo (20 participants)

- mean (SD) age: 50 (8) years
- number male/female: 4/16
- concurrent treatment: 3 participants were taking an analgesic
- mean (SD) pain at night, VAS 0–10: 4.8 (3.2)
- mean (SD) pain during the day, VAS 0–10: 4.3 (2.9)
- mean (SD) Constant score: 52 (22)
- calcification size: not reported

Pretreatment group differences: none

Interventions	**ESWT:** • description of modality used: electrohydraulic system (Orthospec, Medispec Inc, Montgomery Village, MD, USA) with a fixed focus of 25 × 95 mm. • method of administration: ESWT was conducted in a quiet room with ambient temperature. Participants were sitting in a comfortable position during the treatment. Aquasonic gel was used as couplant in all participants. The ESWT system used an enlarged therapy zone of 25 mm, compared to approximately 5 mm in most other devices, therefore no pretreatment analgesia was provided. Symptom-guided positioning of the shock wave device (clinical focusing) was used to focus the device on the point of maximum pain • dose: 0.28 mJ/mm^2 delivered via 2 × 2000 shocks at frequency 2.5 Hz at 2 different sessions • frequency: 2 sessions, 2 weeks apart • co-interventions: none **Placebo:** • description of modality used: as above. The shock wave was further dampened by a foam membrane (Medispec Inc) to reduce the effective energy reaching the shoulder • method of administration: as above • dose: < 0.07 mJ/mm^2 delivered via 2 × 2000 shocks at frequency 2.5 Hz at 2 different sessions • frequency: 2 sessions, 2 weeks apart • co-interventions: none
Outcomes	Measured at 1 week, 3 months and 7 months **Outcomes included in review:** • shoulder function assessed by change from baseline in Constant score 0–100, with a higher score indicating better function • night pain measured by VAS 0–10, higher score indicating worse pain • proportion with partial or complete resolution of shoulder calcifications were assessed using X-rays and the 3-point scale of Gärtner and Heyer (1 indicating no change; 2 a decrease of ≥ 50% and 3 complete remission of the calcification) • adverse events

Pleiner 2004 *(Continued)*

- withdrawals due to adverse events, intolerance to treatment or other reasons

Outcomes excluded from review:

- day pain measured on the VAS 0–10

Source of funding	Assistance and technical support from Werner Kostler and the Ad Rem Team and the Medispec team for providing Orthospeo ESWT system
Notes	**Trial registration:** not registered **Time points included in review:** 1 week, 3 months and 7 months **Data analysis:** unit of randomisation was the participant, so those with bilateral calcifications received the same intensity of shock wave therapy for both shoulders. Constant mean change in function and SE were only presented graphically; thus mean and SE were estimated from the graph and SD calculated from SE using the formula: SD = SE × N. We did not extract pain during shock wave as an adverse event **Withdrawals:** 6/23 in ESWT group had another treatment (US, surgery) and 4/20 in placebo group ('personal reasons'). We assumed the withdrawals in both groups were due to intolerance and included the data in Analysis 1.5. **Adverse events:** *ESWT:* • serious adverse events: 0/23 • other adverse events: 2/23 (pain requiring single dose of analgesic) *Placebo:* • serious adverse events: 0/20 • other adverse events: 3/20 (pain requiring single dose of analgesic)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Methods not reported, therefore, there was an unclear risk of selection bias.
Allocation concealment (selection bias)	Unclear risk	Methods not reported, therefore, there was an unclear risk of selection bias.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and study staff were blinded to treatment allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Due to participant blinding, low risk of bias in self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiologists were unaware of the treatment assignment, there was a low risk of bias in measurement of calcification size.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	10/43; 6/23 in ESWT group and 4/20 in placebo group; overall reasons included alternative treatment and loss to follow-up but reasons per group were not given.

Pleiner 2004 *(Continued)*

Selective reporting (reporting bias)	Low risk	No published study protocol and trial was not registered, but results were reported for all outcomes as mentioned in methods.
Other bias	High risk	Unit of analysis bias: there was a high risk of unit of analysis bias as trialist did not adjust for the non-independence between groups due to bilateral treatment. Therefore, the true difference between the groups may have been smaller than reported.

Rompe 1998

Methods	**Study design:** parallel-group, two-arm, RCT **Setting:** not reported **Trial time period:** 2-year trial exact time period not reported **Interventions:** low-dose ESWT vs high-dose ESWT **Sample size calculation:** sample size calculation not performed **Analysis:** study did not state if it used ITT analysis
Participants	**Number of participants:** • screened: not reported • at enrolment: 126 (26 excluded due to non-compliance) • randomised: 100 (50 per group) • included in analyses: 100 (50 per group) **Inclusion criteria:** • calcific tendinitis with shoulder pain > 12 months • unsuccessful conservative treatment in past 6 months • calcifications minimum 5 mm in diameter • type I and II Gärtner classification • chronic or subacute pain caused by impingement of the deposit against the edge of the coracoacromial arch (De Palma) **Exclusion criteria:** • type III calcifications (cloudy and transparent calcifications) • frozen shoulder • evidence of subacromial impingement of the rotator cuff detected by sonography or MRI • rupture of the detected by sonography or MRI • dysfunction in the neck or thoracic region • local arthritis, generalised polyarthritis • neurological abnormalities • pregnancy • infection • tumour • no other treatments or drugs were to be used, neither during the 6 weeks preceding the trial, nor within the follow-up period. **Baseline characteristics:** *Low-dose ESWT (50 participants)*

Rompe 1998 *(Continued)*

- mean (range) age: 49 (29–68) years
- number male/female: 25/25
- mean (range) duration of symptoms: 25 (12–84) months
- mean (range) function Constant score: 47 (21–90)
- calcification size: not reported

High-dose ESWT (50 participants)

- mean (range) age: 47 (29–60) years
- number male/female: 19/31
- mean (range) duration of symptoms: 33 (12–120) months
- mean (range) function Constant score: 53 (22–81)
- calcification size: not reported

Pretreatment group differences: none

Interventions	**Low-dose ESWT:** • description of modality used: ESWT with an experimental device characterised by the integration of an electromagnetic shock wave generator and a mobile fluoroscopy unit (Siemens AG, 91052 Erlangen, Germany). The machine generates shock waves by passing a strong electric current through a flat coil. This action induces a magnetic field in flat coil, which in turn induces another magnetic field in a metal membrane overlying the flat coil. The focal area has a length of 50 mm parallel to the shot 1 wave axis and a radius of 3.5 mm perpendicular to the shock wave axis. • method of administration: once the calcium deposit was located in the centre of the C-arm, the shock wave unit was docked to the shoulder by means of a water-filled cylinder. Regular US gel (University Hospital, Mainz, Germany) was used as a contact medium between cylinder and skin. Mean duration of each session 38 minutes (range 24–52 minutes). No anaesthesia was used. • dose: 1500 impulses of 0.06 mJ/mm^2 • frequency: 1 session per participant • co-interventions: physiotherapy for 3 days post-treatment and then home exercises **High-dose ESWT:** • description of modality used: as above • method of administration: as above but regional anaesthesia was used • dose: 1500 impulses of 0.28 mJ/mm^2 • frequency: as above • co-interventions: as above
Outcomes	Measured at 6 weeks and 6 months **Outcomes included in review:** • function measured by Constant score 0–100, higher score indicating better function • calcification size: number of participants with deposits which showed complete or partial resorption on anteroposterior and axial X-rays of the shoulder • participant satisfaction: proportion of participants who were satisfied with their treatment • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • additional treatment after ESWT • ROM: Constant score subscore • proportion of participants who rated their treatment results as excellent, good, fair or poor
Source of funding	Not reported

Rompe 1998 *(Continued)*

Notes

Trial registration: not registered

Time points included in review: 6 weeks and 6 months

Data analysis: function extracted at 6 weeks and 24 weeks. Complete and partial resorption of calcification and participant satisfaction extracted at 24 weeks. Pain was not able to be extracted as not reported in results section (this is subset of Constant score) as only ranges were reported by the study. The SD for the Constant score was extracted using the WebPlotDigitier program found at arohatgi.info/WebPlotDigitizer/app. As it was unclear whether the graph displayed SEs or SDs, it was agreed that the data would be treated as SDs. The data were extracted and rounded to the nearest whole number. Where measured numbers differed from a reported figure, the reported figure was used

Withdrawals: none

Adverse events:

Low-dose ESWT:

- serious adverse events**:** 0/50
- other adverse events: 0/50

High-dose ESWT:

- serious adverse events: 0/50
- other adverse events: 0/50

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly assigned in a blinded fashion to two groups." Method of randomisation not reported.
Allocation concealment (selection bias)	Unclear risk	Methods were not reported, therefore, there was an unknown risk of selection bias due to unknown allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information on blinding of study personnel or participants
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Methods of participant blinding were not reported, therefore, there was an unclear risk of detection bias regarding the self-reported outcomes of Constant score and treatment success.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Unclear risk	As blinding of assessors was not reported, there was risk of bias in the measurement of radiographic outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals in either group.
Selective reporting (reporting bias)	High risk	There was no published study protocol, but results were reported for all outcomes as mentioned in methods. The breakdown of the Constant score was not reported (including pain) and SDs were not provided for any outcome measure.

Rompe 1998 *(Continued)*

Other bias	Low risk	No other biases apparent.

Sabeti 2007

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** outpatient clinic in Department of Orthopedics, Vienna Medical School, Vienna, Austria **Trial time period:** not reported **Interventions:** low-dose ESWT vs high-dose ESWT **Sample size calculation:** not performed **Analysis:** not ITT
Participants	**Number of participants:** • screened: 50 • enrolled: 47 (3 excluded no reasons given) • randomised: 47 (22 in low-dose ESWT group; 25 in high-dose ESWT group) • included in analyses: 44 (21 in low-dose ESWT group; 23 in high-dose ESWT group) **Inclusion criteria:** • aged ≥ 18 years • pain refractive to therapy for > 6 months • calcifying tendinitis of the supraspinatus tendon verified by X-rays • ≥ 2 trials of different conservative treatments had to be attempted before recruitment **Exclusion criteria:** • history of malignant tumours • local skin conditions • radiologically verified osteoarthritis of the shoulder joint • cardiac pacemakers • cervicobrachial syndrome • pregnant women **Baseline characteristics:** *Low-dose ESWT (22 participants):* • mean (SD) age: 49.38 (8.37) years • mean (SD) pain, VAS 0–100: 69.95 (14.47) • mean (SD) function, Constant score 0–100: 49.71 (14.47) • calcification size: not reported *High-dose ESWT (25 participants):* • mean (SD) age: 53.57 (8.80) years • mean (SD) pain, VAS 0–100: 65.57 (22.37) • mean (SD) function, Constant score 0–100: 48.04 (11.54) • calcification size: not reported **Pretreatment group differences:** none
Interventions	**Low-dose ESWT:**

Sabeti 2007 *(Continued)*

- description of modality used: navigated and X-ray-assisted, focused shock wave treatment delivered by a lithotripter (Storz Modulith SLK, Storz Medical Products Kreuzlingen, Switzerland). The calcium deposit was localised with a 3-dimensional localisation device using X-rays Lithotrack (Storz Medical Products Kreuzlingen, Switzerland)
- method of administration: the calcium deposit was located in the centre of a crosshair by fluoroscopy in 2 planes. The computer calculated the angle and distance for achieving maximum precision, and the distance from the shock wave focus to the deposit was stated in millimetres on a monitor on the navigation device. A contact gel (Gerosonic, Geropharmazeutica Vienna, Austria) was used at the interface of lithotripter and skin. The therapy was delivered without local anaesthesia
- dose: 0.08 mJ/mm^2 by 1000 impulses
- frequency: 3 sessions at weekly intervals
- co-interventions: none

High-dose ESWT:

- description of modality used: as above
- method of administration: delivered with subacromial anaesthesia of Xyloneural 5mL (Gebro Pharma GmbH, Austria) was given under sterile conditions. The anaesthetic was infiltrated dorsally to keep the puncture area at a safe distance from the interface of skin and lithotripter
- dose: 0.2 mJ/mm^2 by 2000 impulses
- frequency: 2 sessions at weekly intervals
- co-interventions: none

Outcomes	Measured at baseline and 12 weeks **Outcomes included in review:** • function assessed by CMS 0–100 with a higher score indicating better function • pain assessed by VAS 0–100, higher score indicating more pain • calcification size: number of participants with complete resorption of calcification on X-ray (grade I on a 4-point grading scale) • treatment success: proportion of participants with function Constant score > 85 (i.e. excellent result) • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • calcification size: proportion of participants with grades 2, 3 or 4 on a 4-point scale • treatment success: proportion of participants with pain VAS < 15 (i.e. excellent result)
Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 12 weeks **Data analysis:** pain, function, calcification resorption and treatment success extracted at 12 weeks. The study contact was e-mailed to request further information on the methods of allocation concealment, and their response was used to guide the risk of bias assessment **Withdrawals:** 4/22 in low-dose group (2 excluded due to strong pain during therapy, 1 had urgent personal reasons, 1 was lost to follow-up) and 2/25 in high-dose group due to loss to follow-up **Adverse events:** *Low-dose ESWT:* • serious adverse events: 0/22 • other adverse events: 0/22

Sabeti 2007 *(Continued)*

High-dose ESWT

- serious adverse events: 0/25
- other adverse events: 0/25

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization into two groups was performed after every ten consecutive patients were enrolled, thus a total of five randomization procedures were carried out. Patients' names were written on cards that were put into envelopes, mixed and randomised."
Allocation concealment (selection bias)	Unclear risk	Response from study team: "One of the nurses, working with us in the treatment rooms wrote the names on cards, which were put in envelopes and sealed and put in a cup. As noted in the paper, as soon as ten patients were collected the nurse chose randomly 5 envelopes which were assigned to Group one, and the remaining 5 to Group two. The patients were recruited by the outpatient clinics and were consecutively included, meaning: the first eligible patient´s name was put in the envelope, – put in the Cup, – Cup with ten names,- random Distribution 5 vs 5." Comment: no information was provided on whether the envelopes used were opaque and sealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The study described itself as an "observer-blinded" study and participants were not blinded to treatment allocation. Quote: "The treatment room was the same for both groups, but patients were scheduled at different times so that individuals within the groups would not contact each other." Comment: as the 2 study groups differed in session number, dose and presence of anaesthesia, it was difficult to assess how the treatment results would have been affected.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	As there was no report of participant blinding, there was a risk of bias in self-reported outcomes of pain, function and treatment success.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Quote: "The clinical follow-up examination was carried out by an independent observer who had no information about the treatment protocol. X-rays were evaluated by an independent observer."
Incomplete outcome data (attrition bias) All outcomes	Low risk	6/50; 4/22 (18%) in low-dose group (2 excluded due to strong pain during therapy,1 urgent personal reason, 1 loss to follow-up) and 2/25 (8%) in high-dose group due to loss to follow-up.
Selective reporting (reporting bias)	Low risk	Comment: no published study protocol, but results were reported for all outcomes as mentioned in methods. There is, therefore, a low risk of reporting bias.
Other bias	Low risk	Comment: no other biases apparent.

Sabeti-Aschraf 2005

Methods	**Study design:** single-centre, parallel-group, two-arm, single-blind, RCT **Setting:** outpatient clinic in Department of Orthopedics, Vienna Medical School, Vienna, Austria **Trial time period:** not reported **Interventions:** palpation-guided ESWT vs imaging-guided ESWT **Sample size calculation:** sample size calculation was not performed **Analysis:** the study did not report if ITT analysis was used, and did not report if any participants dropped out
Participants	**Number of participants:** • screened: not reported • randomised: 50 (25 per group) • included in analyses: 50 (25 per group) **Inclusion criteria:** • calcific tendinitis, verified radiographically, with treatment resistant pain for > 6 months • mature skeleton • failed > 2 non-operative treatments **Exclusion criteria:** • tumour • pregnancy • local infection, skin disease, pacemaker • osteoarthritis of the shoulder **Baseline characteristics:** *Palpation-guided ESWT (25 participants)* • mean (SD) age: 52.96 (8.77) years • number male/female: 10/15 • mean (SD) pain, VAS 0–100: 68.36 (15.26) • mean (SD) function, Constant 0–100: 55.64 (12.5) • calcification size: not reported *Image-guided ESWT (25 participants)* • mean (SD) age: 52.4 (7.74) years • number male/female: 12/13 women • mean (SD) pain, VAS 0–100: 65.96 (21.71) • mean (SD) function, Constant 0–100: 49.4 (12.33) • calcification size: not reported **Pretreatment group differences:** none
Interventions	**Palpation-guided ESWT:** • description of modality used: ESWT delivered by a lithotripter (Modulith SLK, Storz Medical Products, Kreuzlingen, Switzerland) • method of administration: a contact gel was applied between the shoulder and the coupling unit of the lithotripter (Gerosonic, Geropharmazeutica, Vienna, Austria). Local anaesthesia was not applied. The participant and therapist located the point of maximum tenderness by palpation. The area was marked with a ballpoint pen. Through a window of the coupling unit of the lithotripter, the marked

Sabeti-Aschraf 2005 *(Continued)*

	area was located as the shock wave focus. The angle and distance between the coupling unit and shoulder were adjusted until the participant reported pain at the exact point of maximum tenderness • dose: 1000 impulses of 0.08 mJ/mm² with a frequency of 4 Hz • frequency: 3 times in weekly intervals • co-interventions: none **Image-guided ESWT:** • description of modality used: as above • method of administration: a contact gel was applied between the shoulder and the coupling unit of the lithotripter (Gerosonic, Geropharmazeutica, Vienna, Austria). Local anaesthesia was not applied. A radiographically guided, 3-dimensional, computer-assisted navigation device (Lithotrack system, Storz Medical Products) was used to guide therapy and the calcium deposit was located in the centre of a crosshairs by fluoroscopy in 2 planes. The computer calculated the angle and distance to provide maximum precision. On a monitor located on the navigation device, the distance of the shock wave focus to the deposit was stated in millimetres • dose: 1000 impulses of 0.08 mJ/mm² with a frequency of 4 Hz • frequency: 3 times in weekly intervals • co-interventions: none
Outcomes	Measured at baseline and 12 weeks **Outcomes included in review:** • function measured by CMS 0–100, higher score indicating better function • pain measured by the VAS 0–100, higher score indicating worse pain • change in size of calcification: complete resolution of the calcification (grade I) on X-ray or partial resolution (grade II) on X-ray indicated by a 4-point grading score • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • calcification change of grade III or IV on a 4-point grading scale
Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 12 weeks **Data analysis:** pain, function and calcification deposit data were extracted at 3 months **Withdrawals:** none **Adverse events:** *Palpation-guided ESWT:* • serious adverse events: 0/25 • other adverse events: 0/25 *Image-guided ESWT:* • serious adverse events: 0/25 • other adverse events: 0/25

Risk of bias

Bias	Authors' judgement	Support for judgement

Sabeti-Aschraf 2005 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomisation was performed by the Department of Medical Statistics, but the method of generating the sequence was not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were reported as blinded, and study personnel were not blinded; however, calcification was measured by an independent observer.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants were adequately blinded so there was a low risk of detection bias in regards to self-reported outcome assessment.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Radiographic outcomes (of calcification size) were analysed by an independent observer.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals in either group.
Selective reporting (reporting bias)	Low risk	There was no published study protocol, but results were reported for all outcomes as mentioned in methods.
Other bias	Low risk	No other biases apparent.

Schmitt 2001

Methods	**Study design:** parallel-group, two-arm, single-blind, randomised, placebo-controlled trial **Setting:** not reported **Trial time period:** enrolment from March 1999 to February 2000 **Interventions:** ESWT vs sham ESWT **Sample size calculation:** an a priori analysis gave a total sample size of 16,818 participants for a given power of 95% was needed to prove the study effect of ESWT **Analysis:** ITT
Participants	**Number of participants:** • screened: not reported • enrolled: 40 (1 withdrew consent) • randomised: 39 (19 to sham group; 20 to ESWT group) • analysed at 6 weeks: 37 (18 in sham group; 19 in ESWT group) • analysed at 12 weeks: 38 (18 in sham group; 20 in ESWT group) **Inclusion criteria:** • clinical diagnosis of chronic tendinitis of supraspinatus • absence of calcification • free ROM or abduction of ≥ 90 degrees and free rotation

Schmitt 2001 *(Continued)*

- failed conservative treatment: minimum of 10 sessions of physiotherapy, ≥ 2 subacromial injections, intake of NSAIDs
- no treatment in last 4 weeks

Exclusion criteria:

- glenohumeral or acromioclavicular arthritis
- tear of the rotator cuff
- allergy to mepivacaine
- former operations to the treated shoulder
- local tumours of infections
- aged < 18 years
- neurological disorders
- acute bursitis of the shoulder

Baseline characteristics:

ESWT group (20 participants):

- mean (SD) function: Constant score: 40.70 (13.29)
- mean (SD) pain: VAS 0–10 score at rest: 5.35 (2.54)

Sham group (19 participants):

- mean (SD) function: Constant score: 42.20 (13.04)
- mean (SD) pain: VAS 0–10 score at rest: 5.40 (3.00)

Pretreatment group differences: none

Interventions	**ESWT:** • description of modality used: ESWT using shock wave generator Storz Minilith SL 1 (Storz Medical AG, Kreuzlingen, Switzerland) • method of administration: the origin of the supraspinatus tendon was localised with US and 10 mL of mepivacaine was given as subacromial local anaesthesia • dose: 2000 impulses of an EFD of 0.11 mJ/mm^2 (measured by a PVDF-Hydrophone, equivalent to 0.33 mJ/mm^2 measured by a fibreoptic-hydrophone) at 120 impulses per minute • frequency: 3 sessions at 1-week intervals • co-interventions: none **Sham ESWT:** • description of modality used: as above • method of administration: the origin of the supraspinatus tendon was localised with US and 10 mL of mepivacaine was given as subacromial local anaesthesia. A foil was placed between the participants and the water cushion to prevent the shock wave from reaching them. • dose: as above • frequency: 3 sessions at 1-week intervals • co-interventions: none
Outcomes	Measured at 6 and 12 weeks **Outcomes included in review:** • function measured by Constant score 0–100, higher score indicating better function • pain at rest measured by VAS 0–10, 10 indicating maximum pain • success 12 weeks after last treatment, defined by the increase in age-corrected Constant score of ≥ 30 points or an absolute score of 80% of the normal value • adverse events

Schmitt 2001 *(Continued)*

- withdrawals due to adverse events, intolerance to treatment or other reasons

Outcomes excluded from review:

- pain during activity measured by VAS 0–10 with a higher score indicating worse pain

Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 6 and 12 weeks **Data analysis:** function and pain at rest extracted at 6 and 12 weeks and treatment success and adverse events was extracted at 12 weeks. Although 12-months follow-up data were reported, participants who reported no improvement at 12 weeks were told of their treatment group and allowed to cross-over to the ESWT treatment if they had placebo previously; we considered this part of the trial no longer randomised and did not include the 12-month data. It is possible that treatment success was possibly added post-hoc **Withdrawals:** 0/20 in ESWT group and 2/20 in placebo group (1 loss to follow-up, 1 withdrew consent just after randomisation). We assumed no withdrawals in either group due to adverse events or treatment intolerance **Adverse events:** *ESWT:* • serious adverse events: 0/20 • other adverse events: 0/20 *Sham:* • serious adverse events: 0/20 • other adverse events: 0/20

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Treatment allocation was done using random permutated blocks through telephone hotline.
Allocation concealment (selection bias)	Low risk	Participants were centrally allocated via a telephone hotline.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Both participants and study personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	Participants were likely unaware of treatment, thus there was low risk of detection bias in reporting of function and treatment success.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	An 'independent observer' who was unaware of treatment measured other outcomes.
Incomplete outcome data (attrition bias)	Low risk	2/40; 0/20 in ESWT group and 2/20 in sham group due to loss to follow-up.

Schmitt 2001 *(Continued)*
All outcomes

Selective reporting (reporting bias)	Unclear risk	There was no published study protocol, and all outcomes were reported; however, it is possible that treatment success was possibly added post-hoc.
Other bias	High risk	At 12 weeks, 16 participants reported they were not satisfied with treatment so they were unmasked and informed of their treatment group, and participants in placebo group were offered ESWT, effectively ending the randomised part of the study.

Schofer 2009

Methods	**Study design:** parallel-group, two-arm, double-blind, RCT **Setting:** outpatient clinic, Department of Orthopedics, University Hospital Marburg, Germany **Trial time period:** not reported **Interventions:** high-dose ESWT vs low-dose ESWT **Sample size calculation:** a priori analysis using GPower to find the sample size for a larger confirmatory study gave a total sample of 156 participants for the 12-week Constant score (effect size d = 0.384 at α = 0.05 and power 80%) and total sample of 94 participants for 12-month Constant score (effect size d = 0.518 at α = 0.05 and 80% power). **Analysis:** the study did not report using ITT analysis
Participants	**Number of participants:** • screened: 46 • enrolled: 40 (4 did not meet inclusion criteria, 2 refused to participate) • randomised: 40 (20 per group) • analysed at 12 weeks: 39 (20 in low-dose ESWT group; 19 in high-dose ESWT group) • analysed at 12 months: 37 (19 in low-dose ESWT group; 18 in high-dose ESWT group) **Inclusion criteria:** • clinical diagnosis of chronic rotator cuff tendinopathy • absence of calcifications • failed conservative treatment of chronic rotator cuff tendinopathy (minimum of 10 sessions of physiotherapy or 2 subacromial injections with steroids or intake of NSAIDs) • no treatment in past 4 weeks • ≥ 6 months' duration of symptoms • free ROM ≥ 90-degree abduction and free rotation **Exclusion criteria:** • glenohumeral or acromioclavicular joint arthrosis • rotator cuff tears • allergic response to mepivacaine • former operations to the treated shoulder • local tumours or infections • aged < 18 years • pregnancy • neurological disorders • acute bursitis of the shoulder

Schofer 2009 *(Continued)*

	Baseline characteristics: *High-dose ESWT (20 participants):* • mean (SD) Constant 0–100 score: 46.3 (22.4) • mean (SD) pain at rest VAS 0–10: 5.6 (2.5) • mean (SD) pain during activity VAS 0–10: 7.1 (2.4) *Low-dose ESWT (20 participants):* • mean (SD) Constant 0–100 score: 49 (20.5) • mean (SD) pain at rest VAS 0–10: 3.4 (2.4) • mean (SD) pain during activity VAS 0–10: 7.4 (1.8) **Pretreatment group differences:** prior to treatment there was no significant difference in primary outcome parameter. In 1 of the secondary outcome measurements (pain at rest) there was a statistically significant difference of 2 points on the VAS.
Interventions	**High-dose ESWT** • description of modality used: ESWT was given with the Minilith SL 1 shock wave generator (Storz Medical, Switzerland) • method of administration: US was used to localise the origin of the supraspinatus tendon (also the point of maximum pain). A subacromial local anaesthesia was given using 10 mL mepivacaine 1% before the treatment • dose: 2000 high-energy ESWT (energy level setting 7 = positive EFD of 0.78 mJ/mm^2) impulses at 120 impulses per minute • frequency: 3 sessions at 1-week intervals • co-interventions: none reported **Low-dose ESWT** • description of modality used: ESWT was given with the Minilith SL 1 shock wave generator (Storz Medical, Switzerland) • method of administration: US was used to localise the origin of the supraspinatus tendon (also the point of maximum pain). A subacromial local anaesthesia was given using 10 mL mepivacaine 1% before the treatment • dose: 2000 low-dose ESWT (energy level setting 4 = positive EFD of 0.33 mJ/mm^2) impulses at 120 impulses per minute • frequency: 3 sessions at 1-week intervals • co-interventions: none reported
Outcomes	Measured at 3 and 12 months **Outcomes included in review:** • function measured by Constant score 0–100, higher score indicating higher function • pain at rest measured by VAS 0–10, higher score indicating worse pain • proportion of participants who experienced adverse effects • withdrawals due to adverse events, intolerance to treatment or other reasons **Outcomes excluded from review:** • pain with activity measured by VAS 0–10, higher score indicating worse pain
Source of funding	No benefits or funds were received in support of this study
Notes	**Trial registration:** not registered **Time points included in review:** 3 and 12 months

Schofer 2009 *(Continued)*

Data analysis: function and pain at rest extracted for review at 3 and 12 months. Adverse events extracted at study end

Withdrawals: 2/20 in high-dose group (1 loss to follow-up, 1 underwent surgery) and 1/20 in low-dose group (1 loss to follow-up)

Adverse events:

High-dose ESWT:

- serious adverse events: 0/20
- other adverse events: 0/20

Low-dose ESWT:

- serious adverse events: 0/20
- other adverse events: 1/20 (shoulder pain 10 days after ESWT)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patients were randomised externally using random permuted blocks." Comment: low risk of selection bias.
Allocation concealment (selection bias)	Unclear risk	No information on how the allocation was concealed.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding of participants and study personnel was done. All participants received local anaesthetics making it more likely participants were blinded to high-dose vs low-dose treatment; however, as personnel were not blinded, there was an unclear risk of performance bias.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Low risk	As participants were blinded to group allocation there was low risk of bias in measurement of subjective outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Low risk of bias in Constant score measurements (assessed by blinded assessors).
Incomplete outcome data (attrition bias) All outcomes	Low risk	3/40; 2/20 in high-dose group (1 loss to follow-up, 1 underwent surgery) and 1/20 in low-dose group (1 loss to follow-up).
Selective reporting (reporting bias)	Low risk	No published study protocol, but results were reported for all outcomes as mentioned in methods.
Other bias	Low risk	No other bias apparent.

Speed 2002

Methods	**Study design:** single-centre, parallel-group, two-arm, double-blind randomised, placebo-controlled trial

Speed 2002 *(Continued)*

Setting: not reported

Trial time period: not reported

Interventions: ESWT vs placebo

Sample size calculation: sample size calculation not performed

Analysis: ITT analysis reported but not performed

Participants

Number of participants:

- screened: not reported
- randomised: 74 (34 in ESWT group and 40 in placebo group)
- included in analyses: 74 at 1 month' follow-up (34 in ESWT group; 40 in placebo group); 74 at 3 months' follow-up (34 in ESWT group; 40 in placebo group); 59 at 6 months' follow-up (27 in ESWT group; 32 in placebo group)

Inclusion criteria:

- pain in shoulder for ≥ 3 months with clinical signs of a unilateral tendonitis of the rotator cuff (including a painful arc or an impingement sign and pain (or both), without weakness on resisted testing or ≥ 1 musculotendinous units of the rotator cuff)
- X-rays and US revealed no evidence of calcification before treatment
- aged ≥ 18 years

Exclusion criteria:

- demonstrable shoulder pathology including glenohumeral or acromioclavicular arthritis
- instability, polyarthritis
- neck pain
- local dermatological condition
- neurological abnormalities
- anticoagulant therapy
- treatment to the affected shoulder within the previous 6 weeks
- pregnancy
- diabetes
- connective tissue or infectious diseases
- vasculitis
- malignancy

Baseline characteristics:

ESWT:

- mean (range) age: 50.7 (26–72) years
- number male/female: 13/21
- mean (SD) duration of symptoms: 23 (31) months
- mean (SD) function on SPADI score: 53.6 (20.2)
- mean (SD) pain at night, VAS 0–100: 60.9 (24.6)
- Treatment history: 18 analgesics; 22 NSAIDs; 16 local steroid injection; 25 physiotherapy

Placebo:

- mean (range) age: 54.2 (25–75) years
- number male/female: 18/22
- mean (SD) duration of symptoms: 23.3 (21.0) months
- mean (SD) function on SPADI score: 59.5 (16.1)
- mean (SD) pain at night, VAS 0–100: 67.7 (25.7)

Speed 2002 *(Continued)*

	• Treatment history: 16 analgesics; 22 NSAIDs; 20 local steroid injection; 21 physiotherapy **Pretreatment group differences:** none
Interventions	**ESWT:** • description of modality used: Sonocur Plus Unit (Siemens, Munich, Germany) which generated mechanical shock waves from an electromagnetic generator • method of administration: area was localised by US, and the focus altered according to the site of maximal tenderness. No local anaesthesia was used • dose: ESWT at 1500 pulses at 0.12 mJ/mm^2 • frequency: 3 treatments at monthly intervals • co-interventions: no other treatments were allowed during the period of study **Placebo:** • description of modality used: as above • method: the area was localised by US, the treatment head deflated, no coupling gel was applied and standard contact with the skin was avoided. The machine made a noise as each shock wave was delivered and in order to enhance the sham design, minimal energy pulses (0.04 mJ/mm^2) were generated. No local anaesthesia was used • dose: minimal energy pulses were generated (0.04 mJ/mm^2), while allowing for the usual noise as each shock wave was delivered • frequency: 3 treatments at monthly intervals • co-interventions: no other treatments were allowed during the period of study
Outcomes	Measured at baseline, 1, 2, 3 and 6 months **Outcomes included in review:** • 50% improvement in pain: proportion of participants achieving a ≥ 50% improvement in night pain scores • pain: mean night pain, VAS 0–10, 10 indicating maximum pain • function: mean SPADI 0–100 score, 100 indicating worst score) • treatment success: proportion of participants achieving a positive response on the SPADI (≥ 50% improvement) • adverse events • withdrawals due to adverse events, intolerance to treatment or other reasons
Source of funding	Not reported
Notes	**Trial registration:** not registered **Time points included in review:** 1, 3 and 6 months **Data analysis:** we extracted pain and function at 1, 3 and 6 months. For SPADI function, we subtracted total from 100 so that higher score indicated better function. Treatment success and withdrawals were extracted at last follow-up **Withdrawals:** 11/34 in ESWT group (4 did not complete treatment (1 did not tolerate treatment, 3 did not give a reason) and 7 completed treatment but did not attend follow-up) and 13/40 in placebo group (5 did not complete treatment (1 did not tolerate treatment due to worsening symptoms, 4 did not give a reason) and 8 completed treatment but did not attend follow-up). We assumed 4/34 in ESWT group and 5/40 in placebo group withdrew due to intolerance (Analysis 1.5) **Adverse events:** *Shock wave therapy:* • serious adverse events: 0/34

Speed 2002 *(Continued)*

- other adverse events: 1/34 (not tolerate treatment)

Sham therapy:

- serious adverse events: 0/40
- other adverse events: 1/40 (did not tolerate treatment)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of generating the random sequence generation was not reported.
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment was not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported if blinding was used.
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	Unclear if participants were blinded.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	There were no assessor-reported outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	24/74; 11/34 (32%) in shock wave group (4 did not complete treatment, 7 did not attend follow-up assessments) and 13/40 (32%) in sham group (5 did not complete treatment, 8 did not attend follow-up assessments) reasons for non-completion of treatment were not clearly reported.
Selective reporting (reporting bias)	Unclear risk	No published protocol for this study; but all measured outcomes were reported. The number of withdrawals was unclear, number of participants in final outcome measurement was not clearly reported.
Other bias	Low risk	No other biases apparent.

Tornese 2011

Methods	**Study design:** parallel-group, two-arm, RCT **Setting:** Outpatient Department of the Center for Sports Rehabilitation of the Galeazzi Orthopedics Institute in Milan, Italy **Trial time period:** participant enrolment January 2009 to September 2009 **Interventions:** ESWT neutral position technique vs ESWT with hyperextended internal rotation technique **Sample size calculation:** not performed **Analysis:** study did not report using ITT analysis

Tornese 2011 *(Continued)*

Participants	**Number of participants:** • screened: 105 (70 excluded) • enrolled: 35 • randomised: 35 (17 in neutral position group; 18 in internal rotation group) • included in analysis: 35 (17 in neutral position group; 18 in internal rotation group) **Inclusion criteria:** • calcifying tendinopathy with a deposit of ≥ 1 cm diameter confirmed by a recent anteroposterior view X-ray (obtained within 4 weeks prior to presentation to the outpatient clinic) **Exclusion criteria:** • deposits with a cloud, transparent appearance (Gärtner type III) • neurological abnormalities • rheumatoid arthritis • aged < 18 years • pregnancy • infectious diseases • tumours and disorders of coagulation • previous local steroid injections • any type of previous physical therapy (ESWT, TENS, iontophoresis, US therapy, radiotherapy, etc.) within 6 weeks prior to the first ESWT session **Baseline characteristics:** *ESWT neutral position technique (17 participants):* • mean (SD) age: 53 (9.2) years • number male/female: 8/9 • mean (SD) pain, Constant subscore: 6.7 (1.6) • mean (SD) function, Constant score: 55.6 (12.6) • change in calcification size: not reported *ESWT with hyperextended internal rotation technique (18 participants):* • mean (SD) age: 52.2 (10.8) years • number male/female: 6/12 • mean (SD) pain, Constant subscore: 7.5 (2.7) • mean (SD) function, Constant score: 61 (7.1) • change in calcification size: not reported **Pretreatment group differences:** none
Interventions	**ESWT with neutral position technique:** • description of modality used: treatment was delivered with an electromagnetic lithotriptor (Epos Ultra; Dornier MedTech, Wessling, Germany), fitted with a linear ultrasonographic probe (7.5 MHz) • method of administration: US-guided therapy was performed with the participant's affected limb in either the neutral or the hyperextended internal rotation position, depending on treatment allocation. Local anaesthesia was not used. The participant lay supine with the elected shoulder in neutral rotation, the arm placed alongside the trunk and the hand resting on the abdomen. The same physician performed all the sessions. • dose: 1800 pulses delivered at an energy density of up to 0.22 mJ/mm^2 which was reached within 400 pulses, resulting in a uniform application of energy in all participants • frequency: total of 3 sessions, 1 session per week

Tornese 2011 *(Continued)*

- co-interventions: a rehabilitation programme during treatment and follow-up periods including self-assisted stretching of the posterior capsula of the shoulder and Codman's pendulum exercises, as instructed by an expert physiotherapist. For the self-assisted exercises, the participants had to stretch the posterior capsula 3 times a day and hold the position for 30 seconds; for the Codman's pendulum exercises, the participants had to exercise with a 500 g weight for 2 minutes 3 times a day

ESWT with hyperextended internal rotation technique:

- description of modality used: as above
- method of administration: US-guided therapy was performed with the participant's affected limb in either the neutral or the hyperextended internal rotation position, depending on treatment allocation. Local anaesthesia was not used. The participant lay supine with the elected shoulder in hyperextension and internal rotation with the hand placed under the buttock of the same side and the palm facing down on the treatment table. The same physician performed all the sessions.
- dose: as above
- frequency: as above
- co-interventions: as above

Outcomes	Measured at 3 months **Outcomes Included in review:** • function: CMS 0–100, higher score indicating better function • pain: Constant subscore on VAS 0–15 with a higher score indicating less pain • change in calcification size: total or subtotal resorption defined by > 80% reduction of calcified surface on anteroposterior view **Outcomes excluded from review:** • ROM • function • ADL subscore from CMS
Source of funding	Research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors
Notes	**Trial registration:** not registered **Time points included in review:** 3 months **Data analysis:** pain, function and calcification size data were extracted at 3 months **Withdrawals:** none **Adverse events:** not measured

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomized assignment was by a casual number generation software into two groups." Comment: low risk of selection bias.
Allocation concealment (selection bias)	Unclear risk	Comment: methods not reported, therefore, there was an unclear risk of selection bias.
Blinding of participants and personnel (performance bias)	Unclear risk	Study reported assessors were blinded but it was not clear whether participants were blinded.

Tornese 2011 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) Self-reported outcomes	Unclear risk	As participants were not reported to be blinded there was risk of bias in self-reported outcomes of pain and function.
Blinding of outcome assessment (detection bias) Assessor-reported outcomes	Low risk	Assessors were blinded so low risk of bias in radiographic assessments.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants completed follow-up assessments.
Selective reporting (reporting bias)	Low risk	There was no published study protocol, but results were reported for all outcomes as mentioned in methods.
Other bias	Low risk	No other biases apparent.

ADL: activities of daily living; ASES: American Shoulder and Elbow Surgeons; BMI: body mass index; CI: confidence interval; CMS: Constant Score; DASH: Disabilities of the Arm, Shoulder and Hand; EFD: energy fluctuation density; EMS: Electro Medical Systems; ESWT: extracorporeal shock wave therapy; EQ-VAS: EuroQol-Visual Analogue Scale; EQ-5D: EuroQol-5D; IQR: interquartile range; ITT: intention to treat; LMW-HA: low molecular weight hyaluronic acid; MRI: magnetic resonance imaging; NRS: Numerical Rating Scale; NSAID: non-steroidal anti-inflammatory drug; RCT: randomised controlled trial; rESWT: radial extracorporeal shock wave therapy; ROM: range of movement; RSWT: radial shock wave therapy; SD: standard deviation; SE: standard error; SPADI: Shoulder Pain And Disability Index; SST: Simple Shoulder Test; TENS: transcutaneous electric nerve stimulation; UCLA: University of California at Los Angeles; US: ultrasound; VAS: visual analogue scale.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Adamietz 2003	Not an RCT
Ali 2016	Examined treatment of myofascial trigger points of rotator cuff muscle dysfunction.
Astore 2003	Not an RCT
Avancini-Dobrovic 2011	Not an RCT
Barnsley 2001	Not an RCT
Boxberg 1996	Not an RCT
Bringmann 2001	Not investigating shock wave therapy
Buch 1999	Not an RCT
Buselli 2010	Not an RCT
Bytomski 2006	Not an RCT
Charrin 2001	Not an RCT
Cheing 2003	Not an RCT

Study	Reason for exclusion
Chow 2007	Studied ESWT therapy for heel pain
Cosentino 2004	Not an RCT
Costa 2002	Not an RCT
Cyteval 2003	Not an RCT
Friedberg 2010	Not an RCT
Garcia Marti 2004	Not an RCT
Hayes 2005	Not an RCT
Jakobeit 2002	Not an RCT
Kim 2012	Participants were postsurgical repair
Krasny 2005	Studied ultrasound-guided needling
Labek 1999	Not an RCT
Lee 2011	Not an RCT
Lippincott 2010	Not an RCT
Liu 2012	Study was on bicipital tenosynovitis
Loew 1995	Not an RCT
Lorbach 2008	Not an RCT
Magosch 2003	Not an RCT
Maier 2000	Not an RCT
Mangone 2010	Not an RCT
Manske 2004	Not an RCT
Meier 2000	Not an RCT
Moretti 2005	Not an RCT
Mundy 2004	Not an RCT
Njawaya 2018	Study had planned inclusion of participants in 3 arms – those with calcific supraspinatus tendinopathy, plantar fasciitis and Achilles tendinopathy. However, due to poor recruitment in first arm (2 participants), they abandoned this arm of the study and have excluded these 2 participants from the results. Hence, the study did not include participants with rotator cuff disease,
Noel 1999	Not an RCT
Notarnicola 2011	Not an RCT

Study	Reason for exclusion
Pigozzi 2000	Not an RCT
Polimeni 2003	Did not study ESWT
Rebuzzi 2008	Not an RCT
Rees 2009	Not an RCT
Rompe 1995	Not an RCT
Rompe 2000	Not an RCT
Rompe 2001	Not an RCT
Rompe 2003	Not an RCT
Sabeti-Aschraf 2004	Not an RCT
Saggini 2010	Did not study ESWT
Sarrat 2004	Not an RCT
Seil 2006	Not an RCT
Sistermann 1998	Not an RCT
Speed 2005	Not an RCT
Spindler 1998	Not an RCT
Steinacker 2001	Not an RCT
Thigpen 2010	Not an RCT
Wang 2001	Not an RCT
Wang 2003	Not an RCT
Wiley 2002	Commentary, not an RCT

ESWT: extracorporeal shock wave therapy; RCT: randomised controlled trial.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Berner 2004

Methods	Requires translation
Participants	
Interventions	
Outcomes	

Berner 2004 *(Continued)*

Notes	

Diehl 2011

Methods	Requires translation
Participants	
Interventions	
Outcomes	
Notes	

Gross 2002

Methods	Requires translation
Participants	
Interventions	
Outcomes	
Notes	

Loew 1995

Methods	Requires translation
Participants	
Interventions	
Outcomes	
Notes	

Mao 2003

Methods	Requires translation
Participants	
Interventions	
Outcomes	

Mao 2003 *(Continued)*

Notes	

Paternostro-Sluga 2004

Methods	Requires translation
Participants	
Interventions	
Outcomes	
Notes	

Rompe 1997a

Methods	Requires translation
Participants	
Interventions	
Outcomes	
Notes	

Rompe 1997b

Methods	Requires translation
Participants	
Interventions	
Outcomes	
Notes	

Seil 1999

Methods	Requires translation
Participants	
Interventions	
Outcomes	

Seil 1999 *(Continued)*

Notes	

Characteristics of ongoing studies *[ordered by study ID]*

ChiCTR1900022932

Trial name or title	Effect of focused versus radial extracorporeal shock-wave therapy for tendonitis of rotator cuff
Methods	**Study design:** parallel-group, two-arm, randomised controlled trial **Setting:** China Japan Friendship Hospital, China **Intervention:** focused ESWT vs rESWT **Analysis:** not reported
Participants	**Inclusion criteria:** • diagnosis initially made by clinical symptoms, such as pain or disability, which lasted for > 6 months, confirmed by ultrasonography, X-ray, CT or MRI • age 25–78 years **Exclusion criteria:** • pregnancy • coagulopathy • acute infection or malignancy • people with full-thickness tear and injury
Interventions	**Intervention:** focused ESWT **Control:** rESWT
Outcomes	**Outcomes:** Visual Analogue Scale; Constant Score
Starting date	4 May 2019
Contact information	Sun Wei 2 Yinghua Street East, Chaoyang District, Beijing, China Tel: +86 17801203237 E-mail: Sun887@126.com
Notes	**Estimated completion date:** 23/04/2020 **Trial registration:** ChiCTR1900022932. Date of first enrolment: 30 April 2019. Retrospective registration. Status on 11 November 2019 recruitment continuing.

NCT02677103

Trial name or title	Extracorporeal shock-wave therapy for supraspinatus calcifying tendonitis: a randomized clinical trial comparing two different energy levels
Methods	**Study design:** Parallel, three-arm, randomised controlled trial **Setting:** Shin Kong Wu Ho-Su Memorial Hospital, Tapei, Taiwan **Interventions:** rESWT vs US-guided needle puncture vs rESWT plus US-guided needle puncture **Analysis:** not reported
Participants	**Inclusion criteria:** • calcific tendonitis of the shoulder • age 20–75 years **Exclusion criteria:** • pregnancy • clotting disorders • anticoagulant or antiplatelet treatment • cardiac pacemaker • chronic inflammatory joint disease • infections or tumours of the shoulder • adhesive capsulitis • hyperalgia of the shoulder due to resorption of a calcific deposit • calcification of type III as defined by Gärtner or nodular or cystic type of calcification defined by Chiou
Interventions	**rESWT:** • description of modality used: rESWT • dose: an energy level of 0.26 mJ/mm^2, 2000 shock waves at 2 Hz • frequency: once per week, for 3 weeks • any additional treatment during trial: NA **US-guided needle puncture:** • dose: 3 mL 1% xylocaine • method of administration: all needle punctures will be guided by US. The puncture needle is a 3.8 cm 22-gauge needle attached on a 5 mL syringe. Before puncture, the skin of the puncture site will be sterilised with iodine, and the transducer will be covered with a sterilised plastic bag. After injecting 3 mL 1% xylocaine in subcutaneous tissue, muscle layer and subdeltoid bursa, multiple back-and-forth puncture about 10–20 times (depending on the size of the plaques) within the calcific plaques will be performed. The needle tract will be monitored by US to make sure the needle penetrated through the calcific plaque, but does not penetrate the rotator cuff • frequency: single treatment **rESWT plus US-guided needle puncture:** • US-guided needle puncture, as described above, followed by rESWT, as described above
Outcomes	**Outcomes included in review:** • pain (VAS) (6 weeks, 3 months after treatment) • active ROM and passive ROM (6 weeks, 3 months after treatment) • quality of life: general health status: SF–36 (6 weeks, 3 months after treatment) • treatment success: participant satisfaction (6 weeks, 3 months after treatment)

NCT02677103 *(Continued)*

	Outcomes excluded from review: • shoulder problems (6 weeks, 3 months after treatment)
Starting date	April 2013
Contact information	Lin-Fen Hsieh, MD, Shin Kong Wu Ho-Su Memorial Hospital
Notes	**Estimated completion date:** study completed, no results posted **Trial registration:** ClinicalTrials.gov identifier NCT02677103. Status on 9 May 2018: recruitment completed, 61 participants enrolled, no study results available. Last update posted on 25 March 2016 on the ClinicalTrials.gov website.

NCT03779919

Trial name or title	The therapeutic effect of the extracorporeal shock wave therapy on shoulder calcific tendinitis
Methods	**Study design:** parallel, three-arm, triple-blind, randomised controlled trial **Setting:** ChiMei Medical Center, Taiwan **Interventions:** high-energy ESWT vs low-energy ESWT vs sham therapy **Analysis:** not reported
Participants	**Inclusion criteria:** • aged 20–70 years with calcific tendinitis via sonography or X-ray in rotator cuff **Exclusion criteria:** • no shoulder fracture, no abnormality, gout or autoimmune disease
Interventions	**High-energy ESWT:** • ESWT with 0.3 mJ/mm^2 of 3000 shots will be administered via sonographic guidance of the target calcific tendinitis **Low-energy ESWT:** • ESWT with 0.05 mJ/mm^2 of 3000 shots will be administered via sonographic guidance of the target calcific tendinitis **Sham:** • ESWT with 0 mJ/mm^2 of 3000 shots will be administered via sonographic guidance of the target calcific tendinitis
Outcomes	**Primary outcome:** • changes from baseline in calcium deposits at 1 and 3 months after shock wave (calcium deposits will be measured via X-ray or sonography) **Secondary outcomes:** • functional score at 1 and 3 months after shock wave. The 100-point Constant score will be used to provide an overall clinical assessment of the shoulder with respect to the degree of pain, the participant's ability to perform normal tasks of daily living (maximal score 35), and the active ROM and power of the shoulder, or torque (maximal score 65)

NCT03779919 *(Continued)*

	• pain score at 1 and 3 months after shock wave. The severity of pain at night and during the day, both on movement and at rest, is assessed by VAS 0–10, 10 indicating severe pain
Starting date	19 December 2018
Contact information	Hsin-Han Cheng, MD Tel: +886926722119 E-mail: a11010147@gmail.com
Notes	**Estimated completion date: 31** May 2020 **Trial registration:** NCT03779919; status on 11 November 2019, recruiting participants

NTR7093

Trial name or title	Needle aspiration of calcific deposits versus extracorporeal shock wave therapy for conservative therapy resistant calcifying tendinitis of the shoulder
Methods	**Study design:** parallel, two-arm, randomised controlled trial **Setting:** Maxima Medical Centre, Netherlands **Interventions:** needle aspiration of calcific deposits vs ESWT **Analysis:** not reported
Participants	**Inclusion criteria:** • aged > 18 years • chronic shoulder complaints > 6 months • calcifications on conventional X-rays: type I and II calcifications according to the Gärtner classification; minimal diameter of calcification of 10 mm on anteroposterior view • able and willing to comply to study protocol **Exclusion criteria:** • clinical signs of a frozen shoulder or adhesive capsulitis • history of operations of the affected shoulder • needle aspiration of calcific deposits or ESWT during last 6 months • clinical and radiological signs of acute subacromial bursitis • full-thickness lesion of the rotator cuff tendon(s) on sonography • clinical and radiological signs of acromioclavicular osteoarthritis • rheumatic arthritis or fibromyalgia • other intra-articular pathology: cartilage lesions, biceps pathology • any contraindication for the specific treatments (e.g. coagulopathies, malignancies in treated area
Interventions	**Needle aspiration of calcific deposits:** sonographically guided removal of the calcific deposits will be performed **ESWT:** participants will receive a focused ESWT Both procedures will be conducted according to a standardised protocol
Outcomes	**Outcomes included in review:**

NTR7093 *(Continued)*

- recovery of functional outcome score of the Constant Score (baseline to 12 months)
- pain scores (baseline to 12 months)
- quality of life scores (baseline to 12 months)
- medication use and adverse events (12 months)

Outcomes excluded from review:

- cost-effectiveness
- the 'Diagnose & Behandel Combinatie (DBC)' to find a difference in procedural costs of the 2 treatment modalities

Starting date	1 April 2018
Contact information	Dr Max Reijman PhD, Maxima Medical Centre, Netherlands
Notes	**Estimated completion date:** 1 January 2021 **Trial registration:** NTR7093. Status on 8 May 2018, recruitment not yet commenced.

PACTR201910650013453

Trial name or title	Shock wave therapy versus local corticosteroid injection in shoulder impingement syndrome
Methods	**Study design:** parallel, two-arm, randomised controlled trial **Setting:** Cairo, Egypt **Intervention:** shock wave therapy vs local corticosteroid injection **Analysis:** not reported
Participants	**Inclusion criteria:** • both genders • duration of symptoms > 3 months • positive ≥ 3 of impingement tests (Neer and Hawkins-Kennedy impingement tests, the Painful Arc Test, Jobe's Test, and the External Rotation Resistance Test • pain > 5 on VAS • unilateral shoulder involvement • impingement syndrome stage II Neer classification. • unilateral impingement syndrome **Exclusion criteria:** • frozen shoulders • arthritis of the shoulder • shoulder instability • pregnancy • pacemaker • previous shoulder surgery • history of dislocation of the shoulder • internal metallic fixation • malignancy • previous corticosteroid injection • rheumatoid arthritis • full thickness tear of the rotator cuff

PACTR201910650013453 *(Continued)*	• cervical radiculopathy • previous experience with shock wave therapy
Interventions	Shock wave Corticosteroid injection Strengthening exercise for rotator cuff muscles and scapular stabilisers and shoulder mobilisation
Outcomes	**Primary outcomes:** • Shoulder pain and Disability Index • Shoulder ROM **Secondary outcomes:** • 3-D shoulder ultrasonography
Starting date	30 September 2019
Contact information	Ahmed Elerian Elmaadi 0025 Cairo Egypt Tel: 002201116752333 E-mail: dr_ahmed_elerian77@yahoo.com
Notes	**Estimated completion date:** not reported **Trial registration:** PACTR201910650013453 prospectively registered on 16 September 2019. Status on 11 November 2019, recruitment commenced and ongoing

CT: computer tomography; ESWT: extracorporeal shock wave therapy; MRI: magnetic resonance imaging; NA: not available; rESWT: radial extracorporeal shock wave therapy; ROM: range of movement; SF-36: 36-Item Short-Form Health Survey; US: ultrasound; VAS: Visual Analogue Scale.

DATA AND ANALYSES

Comparison 1. Shock wave therapy (ESWT) versus placebo

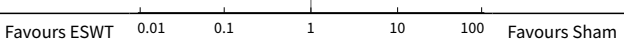
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion of participants with ≥ 50% improvement in pain	1	74	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.62, 1.94]
2 Mean pain (various scales, lower score indicates less pain)	9		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 6 weeks	6	304	Mean Difference (IV, Random, 95% CI)	-2.10 [-3.58, -0.62]
2.2 3 months	9	608	Mean Difference (IV, Random, 95% CI)	-1.95 [-3.45, -0.44]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.3 6 months	5	419	Mean Difference (IV, Random, 95% CI)	-1.53 [-3.49, 0.43]
2.4 12 months	3	155	Mean Difference (IV, Random, 95% CI)	-2.42 [-5.79, 0.95]
3 Mean function (various scales)	11		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 6 weeks	7	374	Std. Mean Difference (IV, Random, 95% CI)	0.79 [0.30, 1.28]
3.2 3 months	9	612	Std. Mean Difference (IV, Random, 95% CI)	0.62 [0.13, 1.11]
3.3 6 months	7	486	Std. Mean Difference (IV, Random, 95% CI)	0.91 [0.24, 1.57]
3.4 12 months	3	155	Std. Mean Difference (IV, Random, 95% CI)	1.45 [-0.21, 3.12]
4 Treatment success	6	287	Risk Ratio (M-H, Random, 95% CI)	1.59 [0.87, 2.91]
5 Withdrawals due to adverse events and treatment intolerance	7	581	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.43, 1.31]
6 Total withdrawals	8	621	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.52, 1.07]
7 Proportion of participants with adverse events	5	295	Risk Ratio (M-H, Random, 95% CI)	3.61 [2.00, 6.52]
8 Calcification size (complete resolution)	3	159	Risk Ratio (M-H, Random, 95% CI)	4.78 [1.31, 17.39]
9 Calcification size (partial resolution)	3	159	Risk Ratio (M-H, Random, 95% CI)	3.41 [0.95, 12.23]
10 Mean or change in mean calcification width (mm)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
10.1 3 months	1	88	Mean Difference (IV, Random, 95% CI)	-24.00 [-85.77, 33.77]
10.2 6 months	1	87	Mean Difference (IV, Random, 95% CI)	-36.7 [-94.86, 21.46]
10.3 12 months	2	122	Mean Difference (IV, Random, 95% CI)	-21.76 [-60.99, 17.46]
11 Subgroup analysis: pain (various scales, lower score indicates less pain)	9		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 Calcification	5	256	Std. Mean Difference (IV, Random, 95% CI)	-0.59 [-1.33, 0.14]
11.2 No calcification	5	253	Std. Mean Difference (IV, Random, 95% CI)	-0.39 [-0.70, -0.09]
12 Subgroup: function (various scales, higher score is better function)	9		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
12.1 Calcification	5	260	Std. Mean Difference (IV, Random, 95% CI)	0.84 [-0.20, 1.89]
12.2 No calcification	5	253	Std. Mean Difference (IV, Random, 95% CI)	0.29 [-0.04, 0.61]

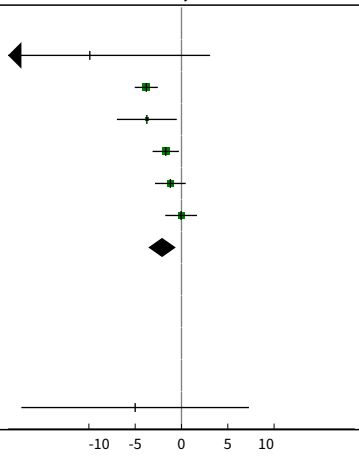
Analysis 1.1. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 1 Proportion of participants with ≥ 50% improvement in pain.

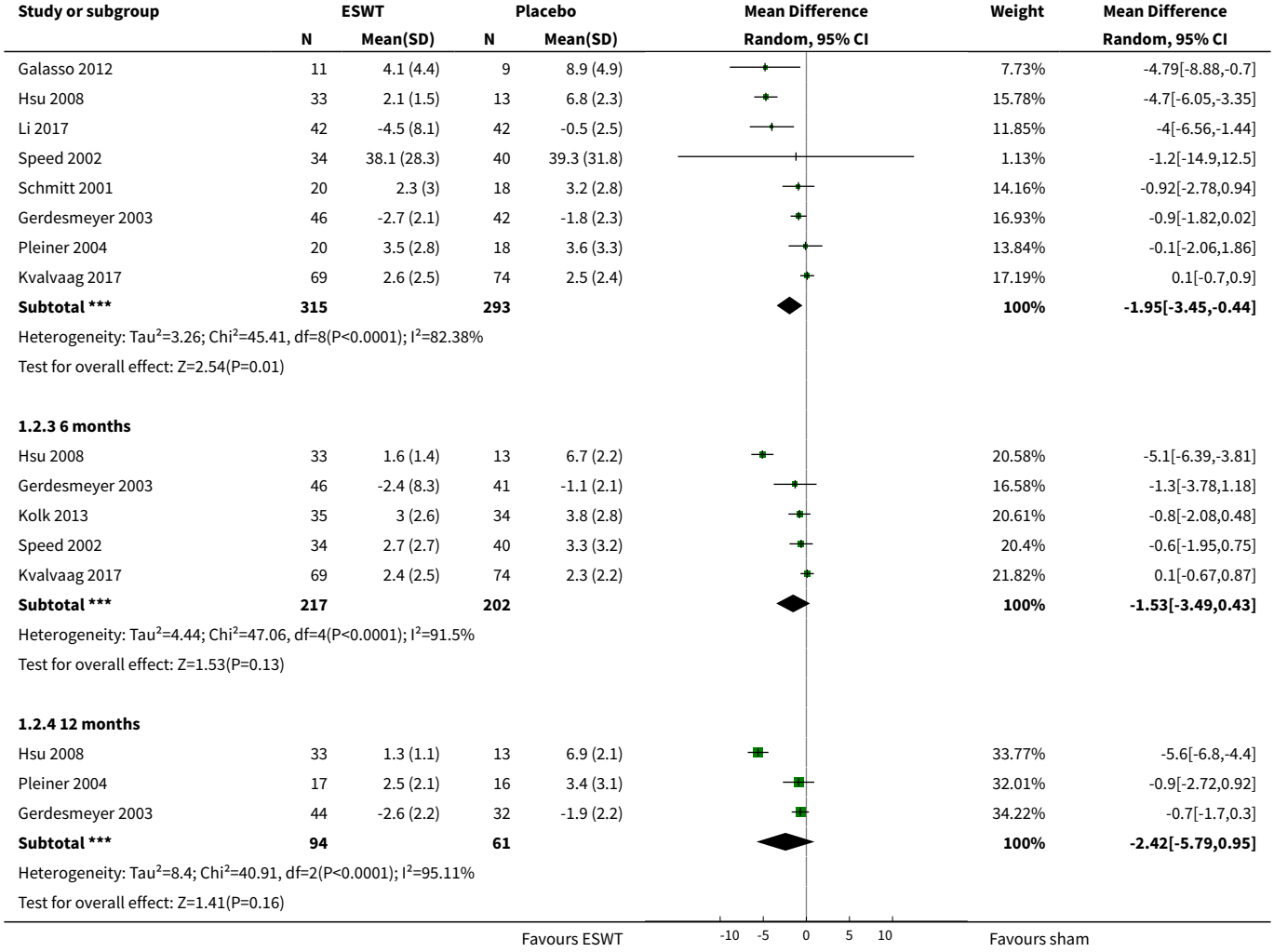
Study or subgroup	ESWT n/N	Sham n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Speed 2002	14/34	15/40		100%	1.1[0.62,1.94]
Total (95% CI)	**34**	**40**		**100%**	**1.1[0.62,1.94]**
Total events: 14 (ESWT), 15 (Sham)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.32(P=0.75)					



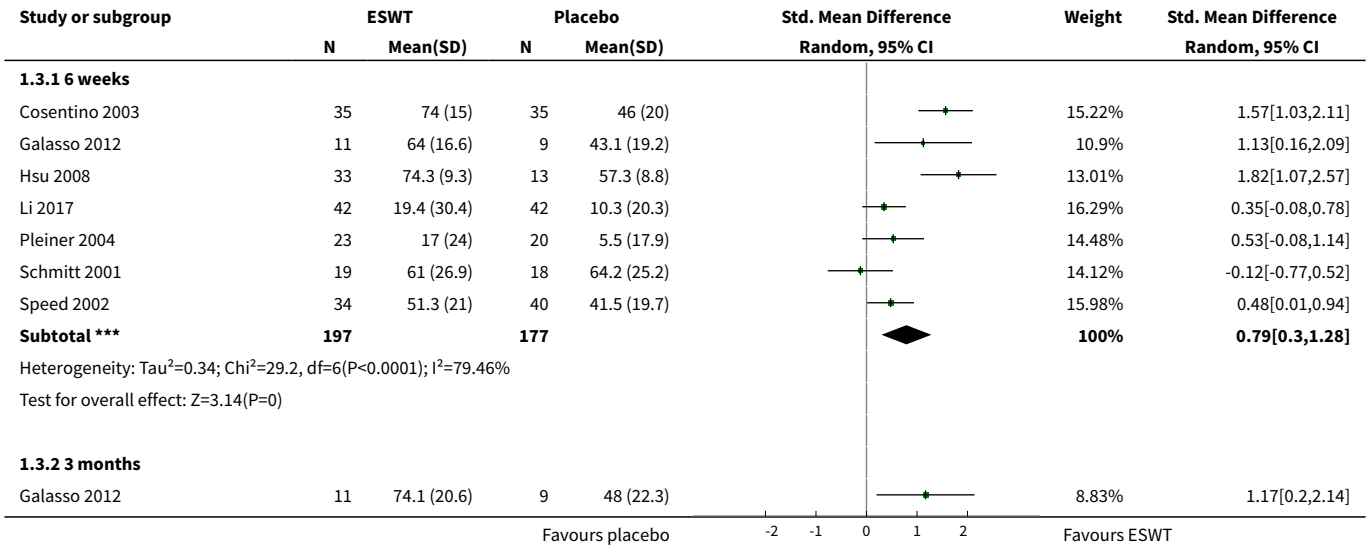
Analysis 1.2. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 2 Mean pain (various scales, lower score indicates less pain).

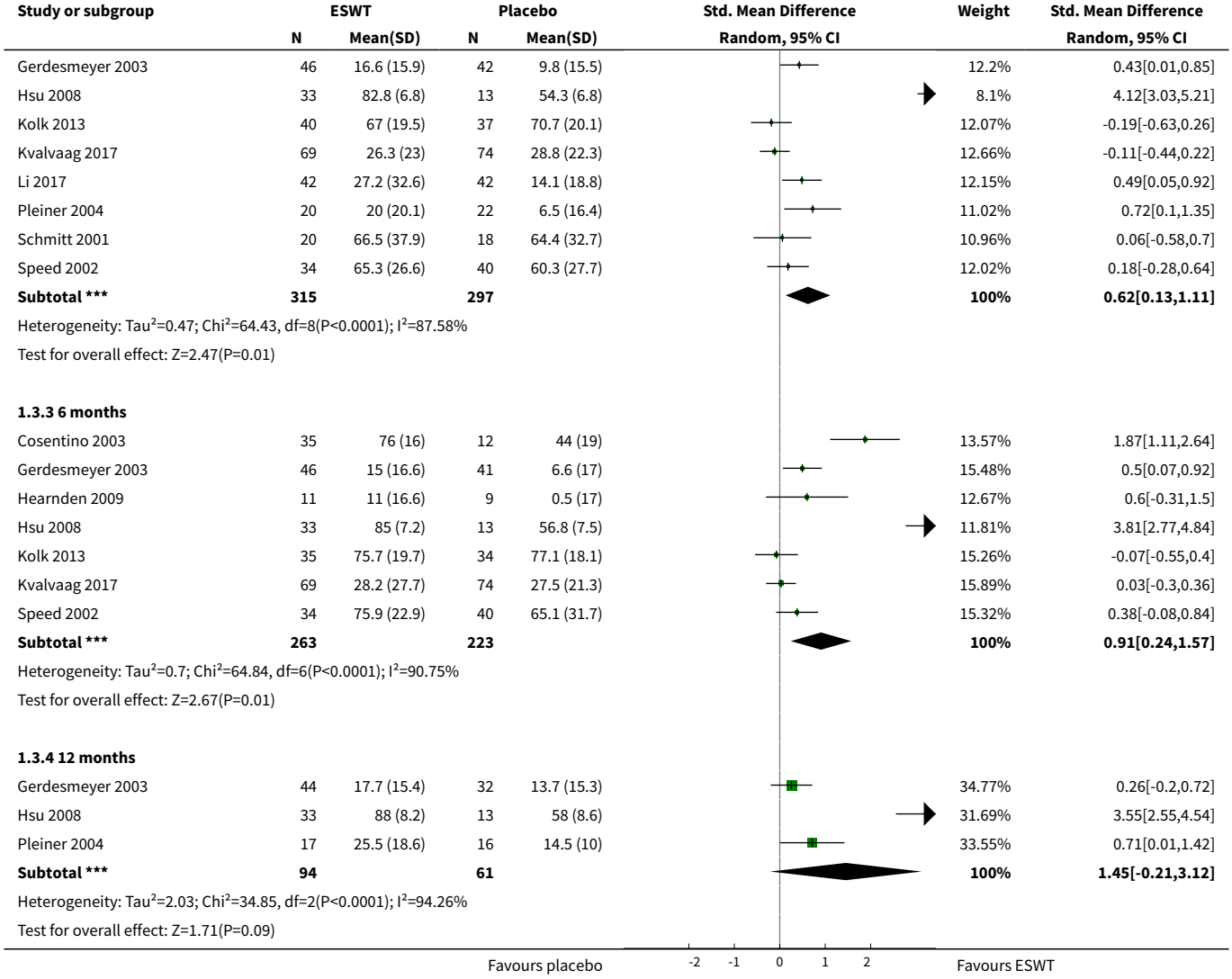
Study or subgroup	ESWT N	ESWT Mean(SD)	Placebo N	Placebo Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
1.2.1 6 weeks							
Speed 2002	34	47.8 (28)	40	57.7 (28.9)		1.24%	-9.9[-22.89,3.09]
Hsu 2008	33	3.7 (1)	13	7.5 (2.2)		23.39%	-3.8[-5.04,-2.56]
Galasso 2012	11	6.8 (3.4)	9	10.6 (3.9)		11.99%	-3.74[-6.97,-0.51]
Li 2017	42	-1.9 (4.1)	42	-0.2 (2.3)		22.26%	-1.7[-3.12,-0.28]
Pleiner 2004	23	3.7 (2.6)	20	4.9 (2.9)		20.74%	-1.2[-2.86,0.46]
Schmitt 2001	19	2.7 (2.6)	18	2.8 (2.7)		20.37%	-0.04[-1.75,1.67]
Subtotal ***	**162**		**142**			**100%**	**-2.1[-3.58,-0.62]**
Heterogeneity: Tau^2=2.04; Chi^2=16.53, df=5(P=0.01); I^2=69.76%							
Test for overall effect: Z=2.78(P=0.01)							
1.2.2 3 months							
Kolk 2013	40	47 (28)	37	52 (27)		1.38%	-5[-17.29,7.29]



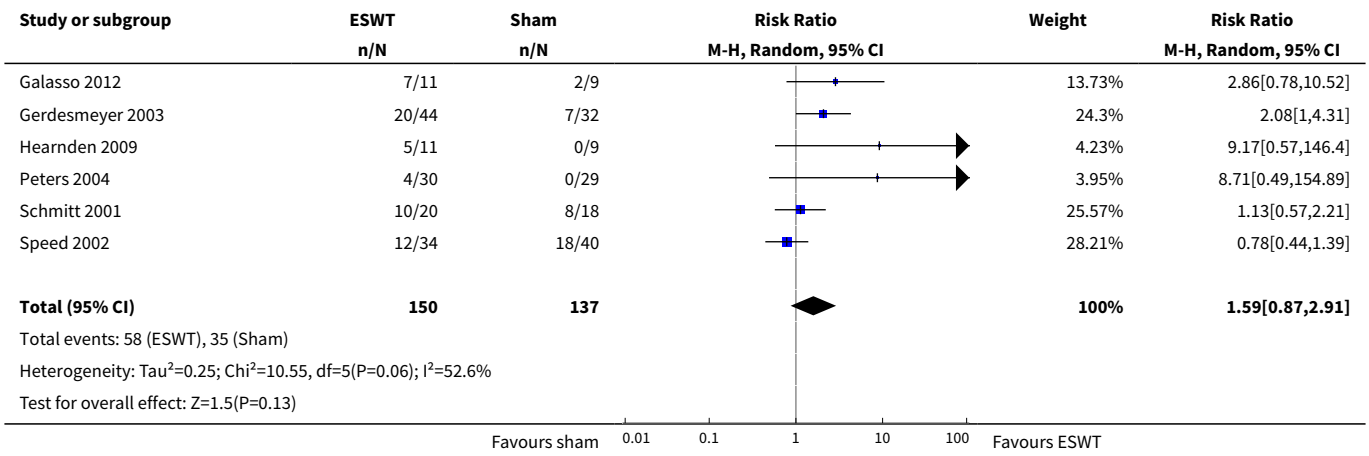


Analysis 1.3. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 3 Mean function (various scales).

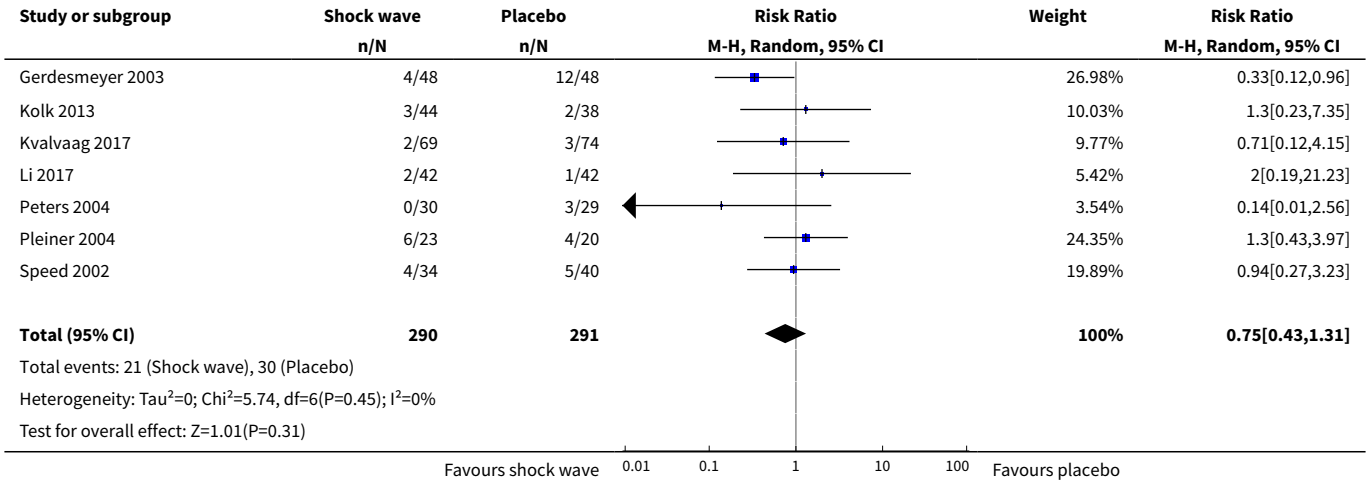




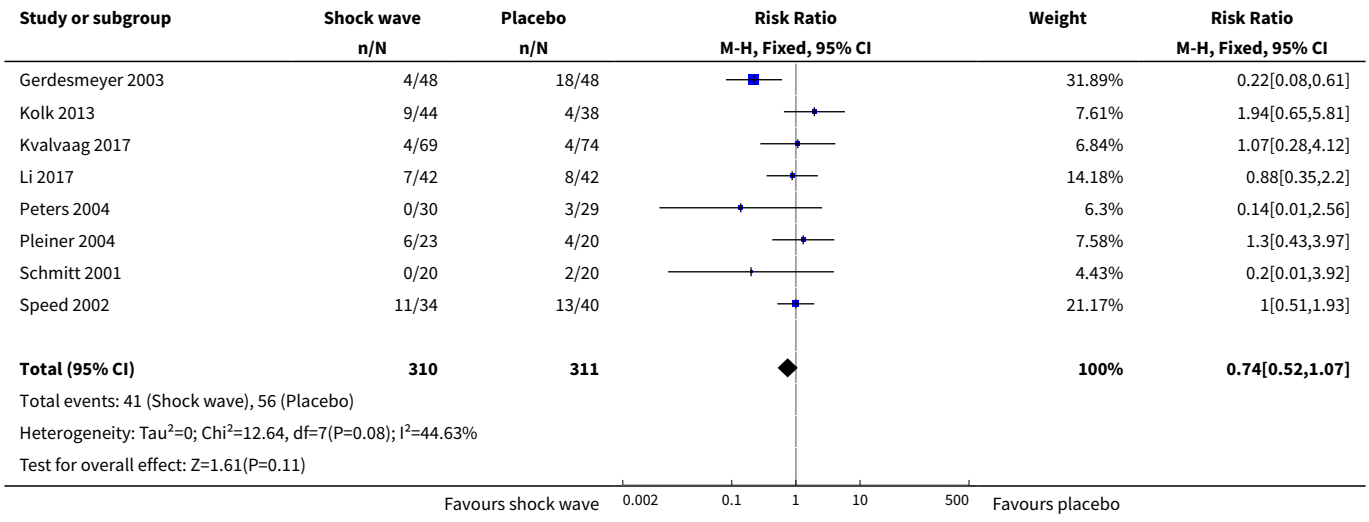
Analysis 1.4. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 4 Treatment success.



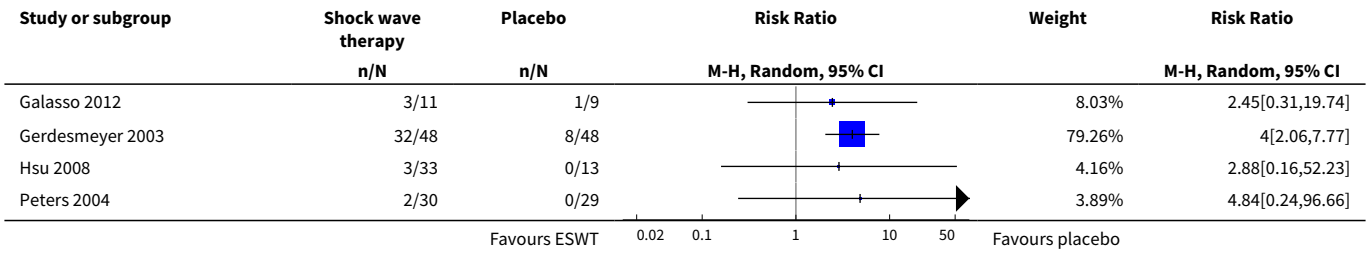
Analysis 1.5. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 5 Withdrawals due to adverse events and treatment intolerance.

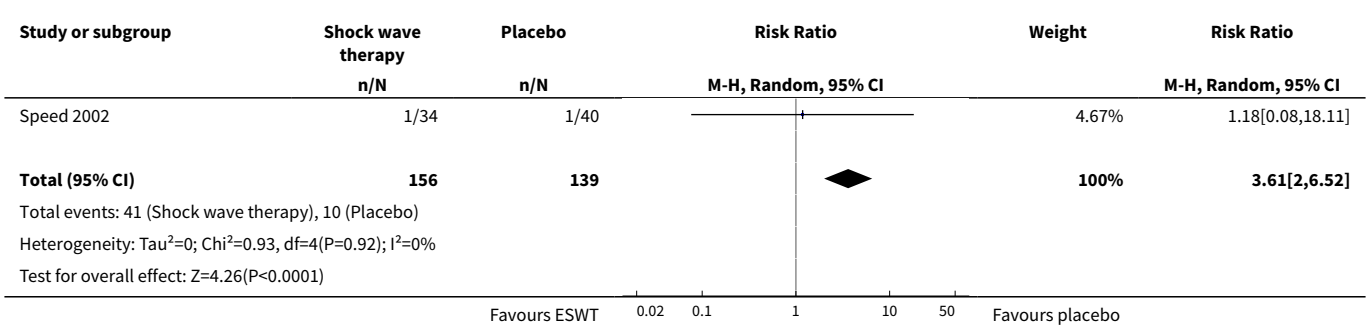


Analysis 1.6. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 6 Total withdrawals.

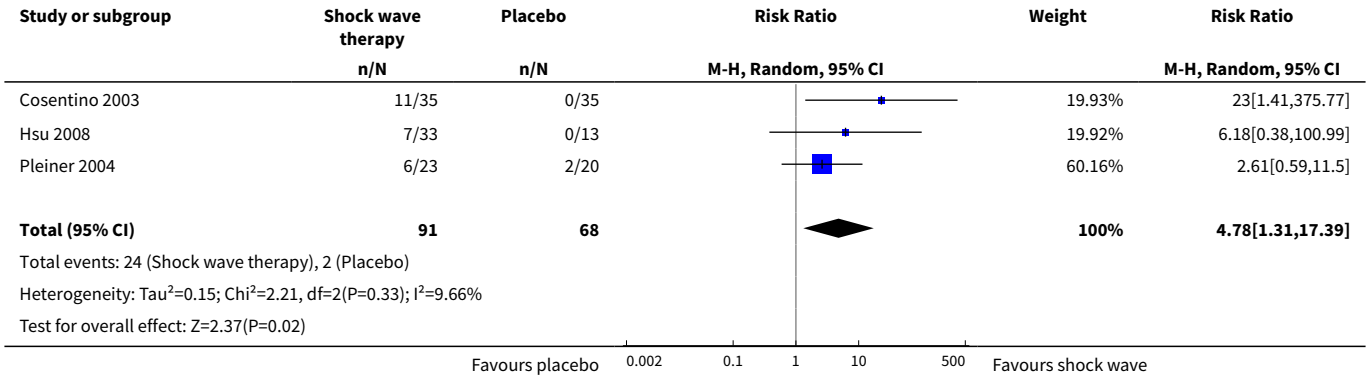


Analysis 1.7. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 7 Proportion of participants with adverse events.

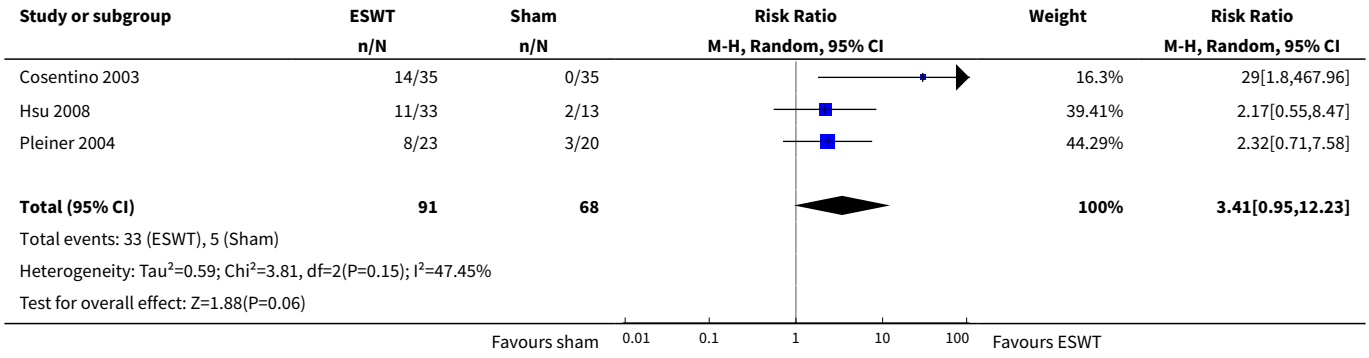




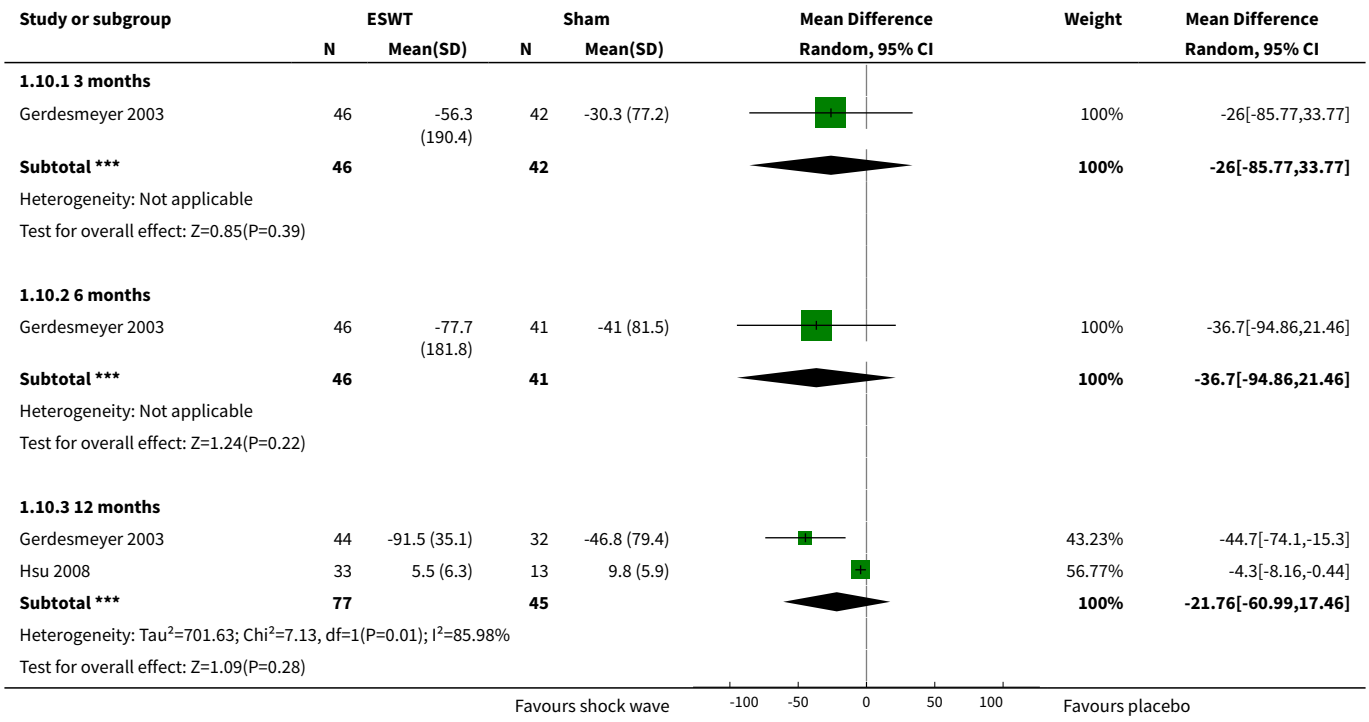
Analysis 1.8. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 8 Calcification size (complete resolution).



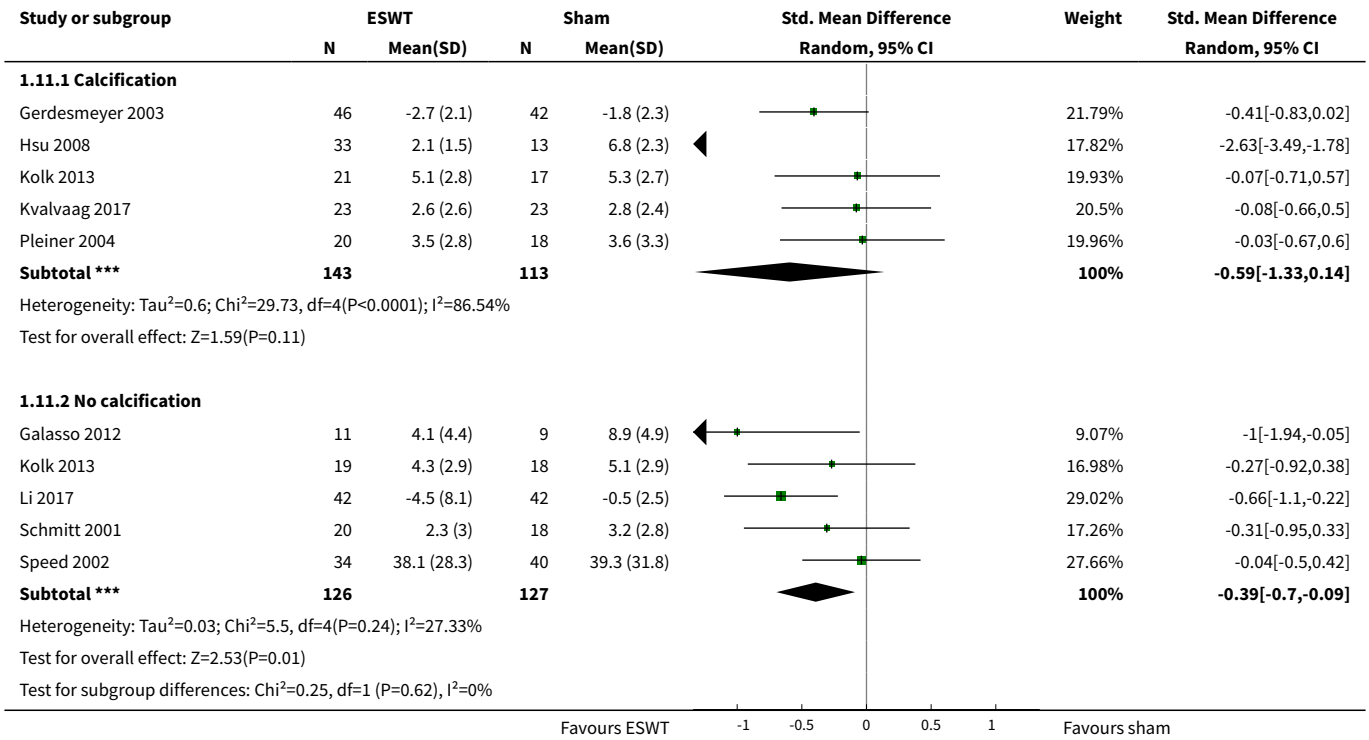
Analysis 1.9. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 9 Calcification size (partial resolution).



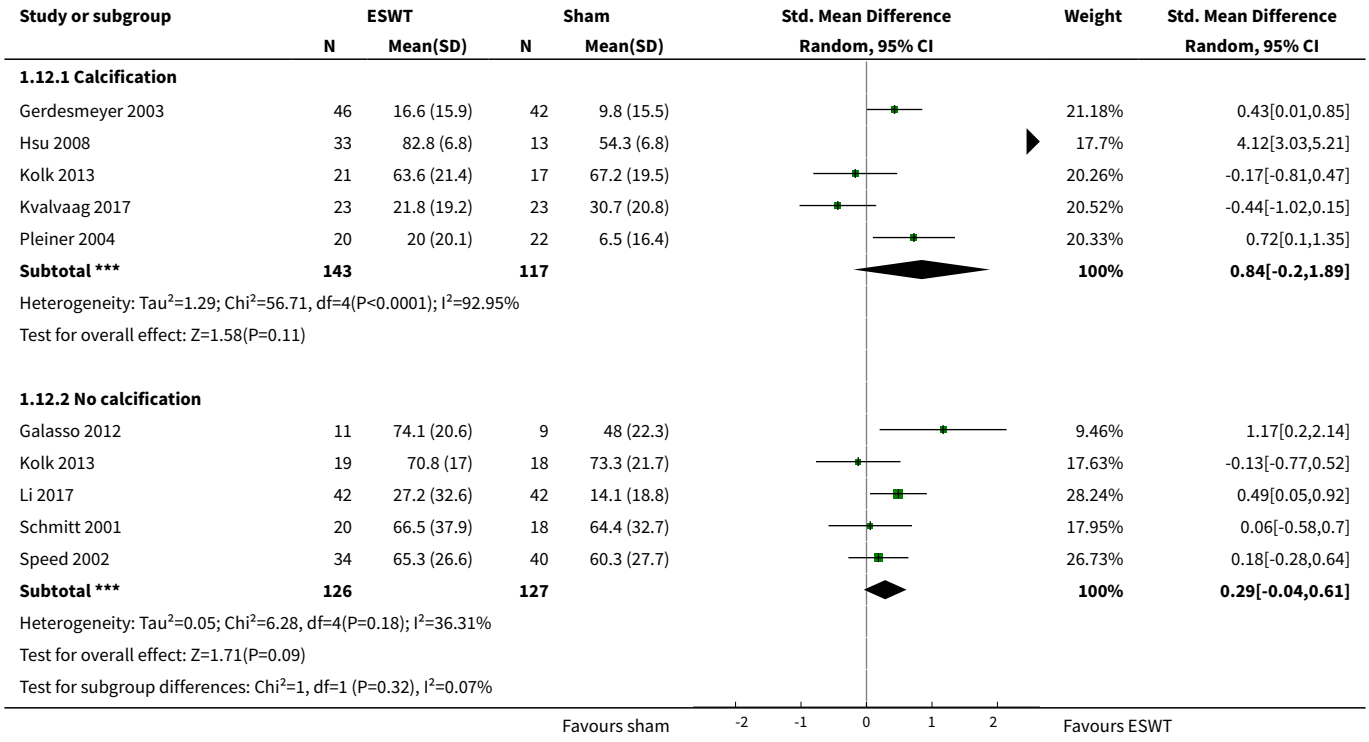
Analysis 1.10. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 10 Mean or change in mean calcification width (mm).



Analysis 1.11. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 11 Subgroup analysis: pain (various scales, lower score indicates less pain).



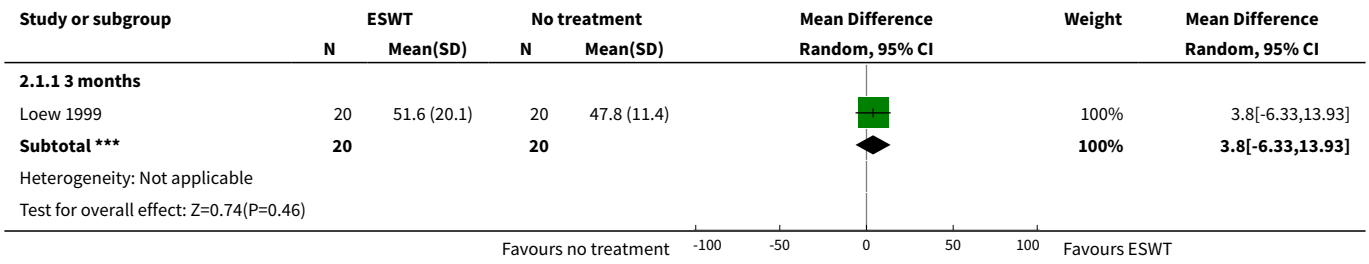
Analysis 1.12. Comparison 1 Shock wave therapy (ESWT) versus placebo, Outcome 12 Subgroup: function (various scales, higher score is better function).



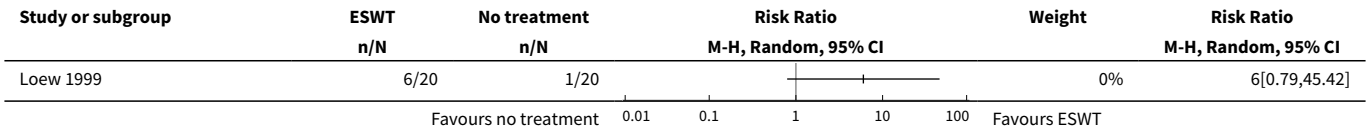
Comparison 2. Shock wave therapy (ESWT) versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean function (Constant score 0–100, 100 indicating best)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 3 months	1	40	Mean Difference (IV, Random, 95% CI)	3.80 [-6.33, 13.93]
2 Treatment success as determined by participant	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3 Calcification size (complete resolution)	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

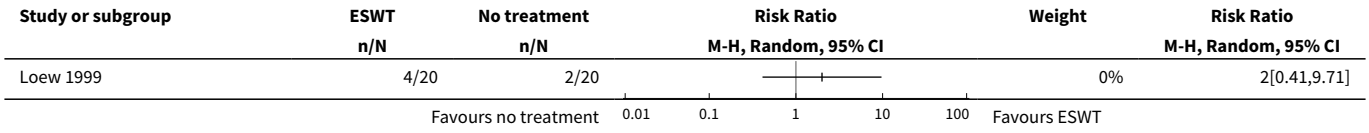
Analysis 2.1. Comparison 2 Shock wave therapy (ESWT) versus no treatment, Outcome 1 Mean function (Constant score 0–100, 100 indicating best).



Analysis 2.2. Comparison 2 Shock wave therapy (ESWT) versus no treatment, Outcome 2 Treatment success as determined by participant.



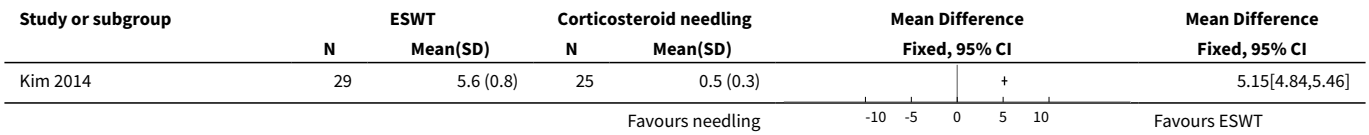
Analysis 2.3. Comparison 2 Shock wave therapy (ESWT) versus no treatment, Outcome 3 Calcification size (complete resolution).



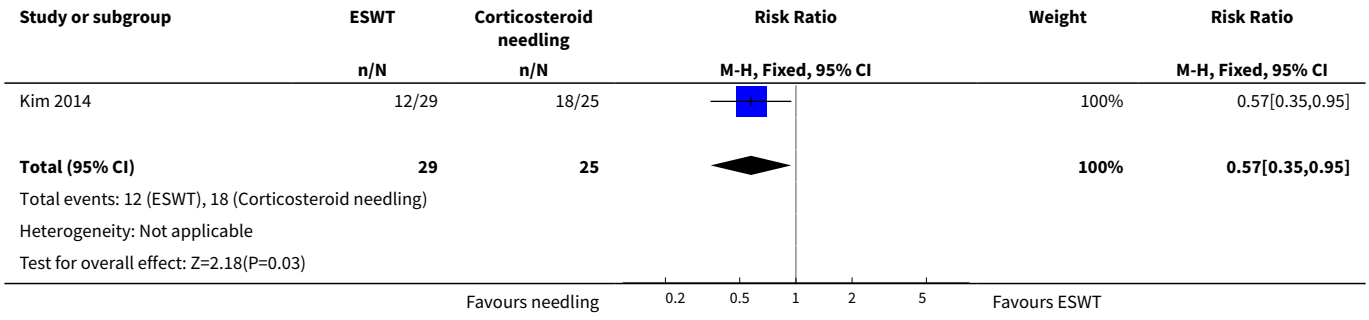
Comparison 3. Shock wave therapy (ESWT) versus ultrasound-guided needling with glucocorticoid

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean calcification size	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2 Calcification size (complete resolution)	1	54	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.35, 0.95]
3 Calcification size (partial resolution)	1	54	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.38, 5.42]

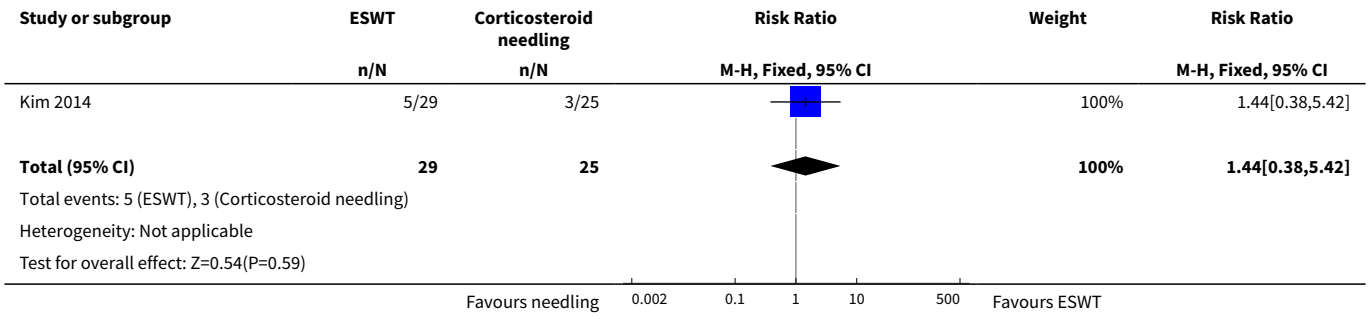
Analysis 3.1. Comparison 3 Shock wave therapy (ESWT) versus ultrasound-guided needling with glucocorticoid, Outcome 1 Mean calcification size.



Analysis 3.2. Comparison 3 Shock wave therapy (ESWT) versus ultrasound-guided needling with glucocorticoid, Outcome 2 Calcification size (complete resolution).



Analysis 3.3. Comparison 3 Shock wave therapy (ESWT) versus ultrasound-guided needling with glucocorticoid, Outcome 3 Calcification size (partial resolution).



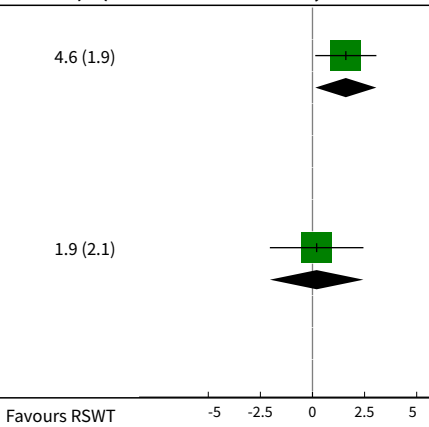
Comparison 4. Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean pain (Numerical Rating Scale, 0–10, higher score indicating worse pain))	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 6 weeks	1	25	Mean Difference (IV, Random, 95% CI)	1.60 [0.13, 3.07]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2 12 months	1	19	Mean Difference (IV, Random, 95% CI)	0.20 [-2.05, 2.45]
2 Function (Constant score, 0–100, higher score indicating better function)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 6 weeks	1	25	Mean Difference (IV, Random, 95% CI)	-11.70 [-24.79, 1.39]
3 Function (Oxford Score 12–60)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 6 weeks	1	25	Mean Difference (IV, Random, 95% CI)	-2.30 [-9.30, 4.70]
3.2 12 months	1	19	Mean Difference (IV, Random, 95% CI)	-4.10 [-15.74, 7.54]
4 Treatment success (proportion of participants with no complaints)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5 Proportion of participants with adverse events	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6 Calcification size (complete resolution)	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

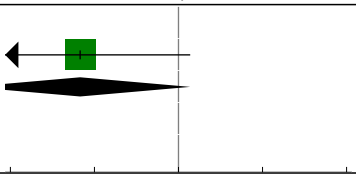
Analysis 4.1. Comparison 4 Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid, Outcome 1 Mean pain (Numerical Rating Scale, 0–10, higher score indicating worse pain)).

Study or subgroup	RSWT N	RSWT Mean(SD)	Needling N	Needling Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.1.1 6 weeks							
De Boer 2017	14	6.2 (1.8)	11	4.6 (1.9)		100%	1.6[0.13,3.07]
Subtotal ***	**14**		**11**			**100%**	**1.6[0.13,3.07]**
Heterogeneity: Not applicable							
Test for overall effect: Z=2.14(P=0.03)							
4.1.2 12 months							
De Boer 2017	9	2.1 (2.8)	10	1.9 (2.1)		100%	0.2[-2.05,2.45]
Subtotal ***	**9**		**10**			**100%**	**0.2[-2.05,2.45]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.17(P=0.86)							
Test for subgroup differences: Chi^2=1.05, df=1 (P=0.31), I^2=4.5%							



Analysis 4.2. Comparison 4 Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid, Outcome 2 Function (Constant score, 0–100, higher score indicating better function).

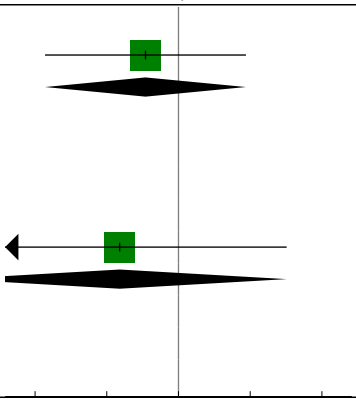
Study or subgroup	RSWT N	RSWT Mean(SD)	Needling N	Needling Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.2.1 6 weeks							
De Boer 2017	14	61.1 (16.3)	11	72.8 (16.8)		100%	-11.7[-24.79,1.39]
Subtotal ***	**14**		**11**			**100%**	**-11.7[-24.79,1.39]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.75(P=0.08)							



Favours needling — Favours RSWT

Analysis 4.3. Comparison 4 Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid, Outcome 3 Function (Oxford Score 12–60).

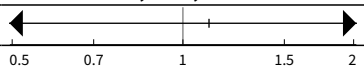
Study or subgroup	RSWT N	RSWT Mean(SD)	Needling N	Needling Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.3.1 6 weeks							
De Boer 2017	14	45.1 (8.7)	11	47.4 (9)		100%	-2.3[-9.3,4.7]
Subtotal ***	**14**		**11**			**100%**	**-2.3[-9.3,4.7]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.64(P=0.52)							
4.3.2 12 months							
De Boer 2017	9	49.1 (15.2)	10	53.2 (9.8)		100%	-4.1[-15.74,7.54]
Subtotal ***	**9**		**10**			**100%**	**-4.1[-15.74,7.54]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.69(P=0.49)							
Test for subgroup differences: Chi^2=0.07, df=1 (P=0.8), I^2=0%							



Favours ESWT — Favours needling

Analysis 4.4. Comparison 4 Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid, Outcome 4 Treatment success (proportion of participants with no complaints).

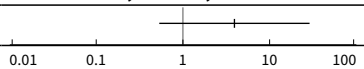
Study or subgroup	RSWT n/N	Needling n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
De Boer 2017	4/9	4/10		0%	1.11[0.39,3.19]



Favours needling — Favours RSWT

Analysis 4.5. Comparison 4 Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid, Outcome 5 Proportion of participants with adverse events.

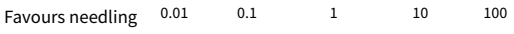
Study or subgroup	RSWT n/N	Needling n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
De Boer 2017	5/14	1/11		0%	3.93[0.53,28.93]



Favours RSWT — Favours needling

Analysis 4.6. Comparison 4 Radial shock wave therapy (RSWT) versus ultrasound-guided needling with corticosteroid, Outcome 6 Calcification size (complete resolution).

Study or subgroup	RSWT n/N	Needling n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
De Boer 2017	1/14	5/11		0%	0.16[0.02,1.16]

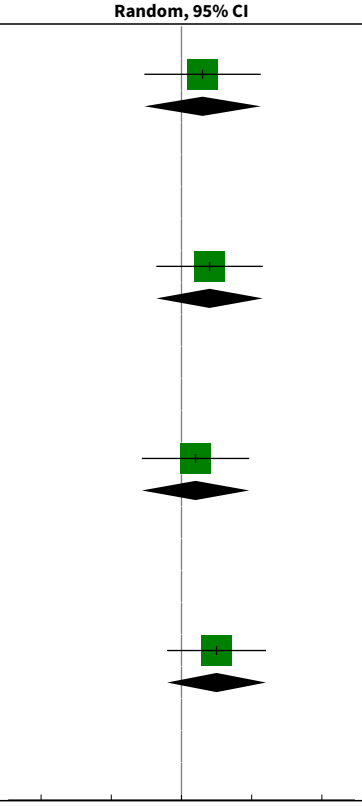


Comparison 5. Radial extracorporeal shock wave therapy (rESWT) versus supervised exercises

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean pain (9-point Likert, 9 is most pain)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 6 weeks	1	90	Mean Difference (IV, Random, 95% CI)	0.30 [-0.53, 1.13]
1.2 3 months	1	102	Mean Difference (IV, Random, 95% CI)	0.40 [-0.36, 1.16]
1.3 6 months	1	100	Mean Difference (IV, Random, 95% CI)	0.20 [-0.56, 0.96]
1.4 12 months	1	97	Mean Difference (IV, Random, 95% CI)	0.5 [-0.20, 1.20]
2 Mean function (SPADI 0–100, 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2.1 6 weeks	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 3 months	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.3 6 months	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.4 12 months	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
3 Proportion of participants who withdrew due to adverse events	1	104	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.32, 27.91]
4 Proportion of participants who experienced adverse events	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
5 Active range of abduction	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 3 months	1	104	Mean Difference (IV, Random, 95% CI)	-1.95 [-10.50, 6.60]
5.2 6 months	1	104	Mean Difference (IV, Random, 95% CI)	-11.82 [-25.37, 1.73]

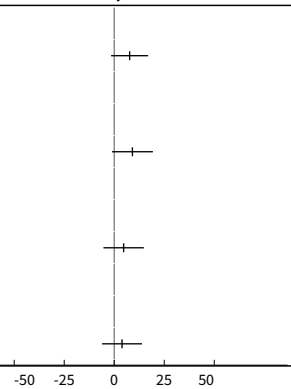
Analysis 5.1. Comparison 5 Radial extracorporeal shock wave therapy (rESWT) versus supervised exercises, Outcome 1 Mean pain (9-point Likert, 9 is most pain).

Study or subgroup	rESWT N	rESWT Mean(SD)	Supervised exercises N	Supervised exercises Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
5.1.1 6 weeks							
Engebretsen 2009	44	2.9 (2.1)	46	2.6 (1.9)		100%	0.3[-0.53,1.13]
Subtotal ***	**44**		**46**			**100%**	**0.3[-0.53,1.13]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.71(P=0.48)							
5.1.2 3 months							
Engebretsen 2009	52	2.9 (2.1)	50	2.5 (1.8)		100%	0.4[-0.36,1.16]
Subtotal ***	**52**		**50**			**100%**	**0.4[-0.36,1.16]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.03(P=0.3)							
5.1.3 6 months							
Engebretsen 2009	50	2.7 (2)	50	2.5 (1.9)		100%	0.2[-0.56,0.96]
Subtotal ***	**50**		**50**			**100%**	**0.2[-0.56,0.96]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.51(P=0.61)							
5.1.4 12 months							
Engebretsen 2009	48	2.6 (2)	49	2.1 (1.5)		100%	0.5[-0.2,1.2]
Subtotal ***	**48**		**49**			**100%**	**0.5[-0.2,1.2]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.39(P=0.16)							
Test for subgroup differences: Chi^2=0.35, df=1 (P=0.95), I^2=0%							

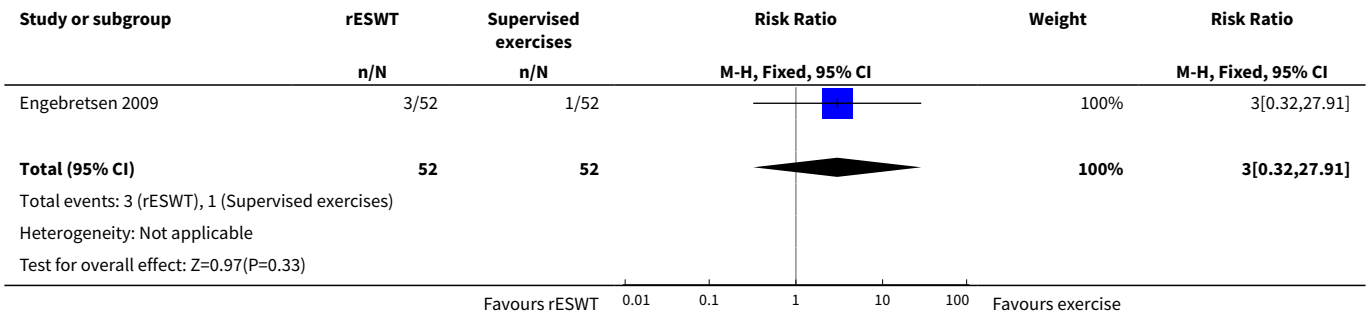


Analysis 5.2. Comparison 5 Radial extracorporeal shock wave therapy (rESWT) versus supervised exercises, Outcome 2 Mean function (SPADI 0–100, 100 is best).

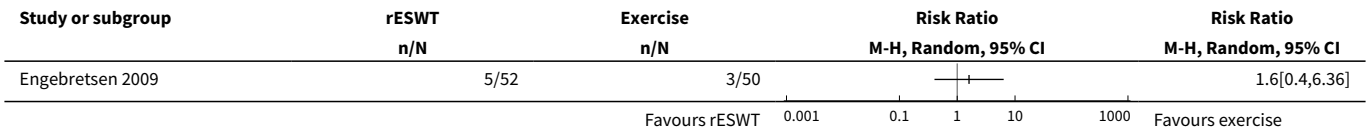
Study or subgroup	rESWT N	rESWT Mean(SD)	Supervised exercises N	Supervised exercises Mean(SD)	Mean Difference Random, 95% CI	Mean Difference Random, 95% CI
5.2.1 6 weeks						
Engebretsen 2009	44	33.5 (23.3)	46	25.8 (21.5)		7.7[-1.57,16.97]
5.2.2 3 months						
Engebretsen 2009	52	36.1 (28.4)	50	27 (24.2)		9.1[-1.13,19.33]
5.2.3 6 months						
Engebretsen 2009	50	29.2 (25.9)	50	24.5 (25.6)		4.7[-5.39,14.79]
5.2.4 12 months						
Engebretsen 2009	48	27.9 (26.6)	49	24 (23.4)		3.9[-6.08,13.88]



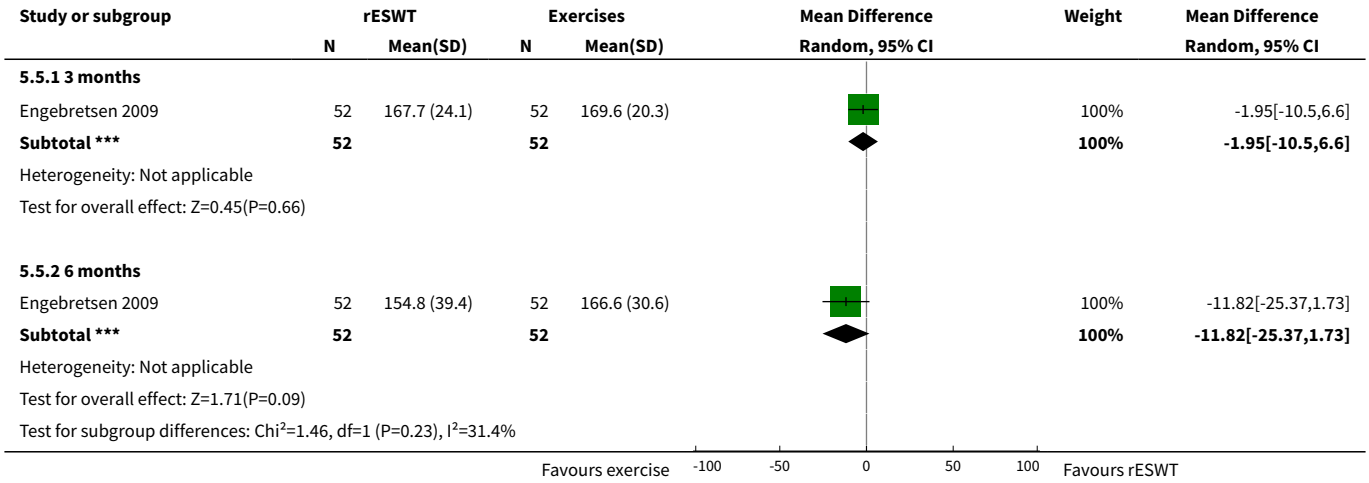
Analysis 5.3. Comparison 5 Radial extracorporeal shock wave therapy (rESWT) versus supervised exercises, Outcome 3 Proportion of participants who withdrew due to adverse events.



Analysis 5.4. Comparison 5 Radial extracorporeal shock wave therapy (rESWT) versus supervised exercises, Outcome 4 Proportion of participants who experienced adverse events.



Analysis 5.5. Comparison 5 Radial extracorporeal shock wave therapy (rESWT) versus supervised exercises, Outcome 5 Active range of abduction.

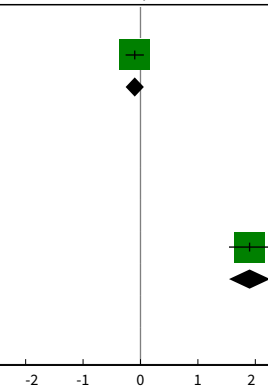


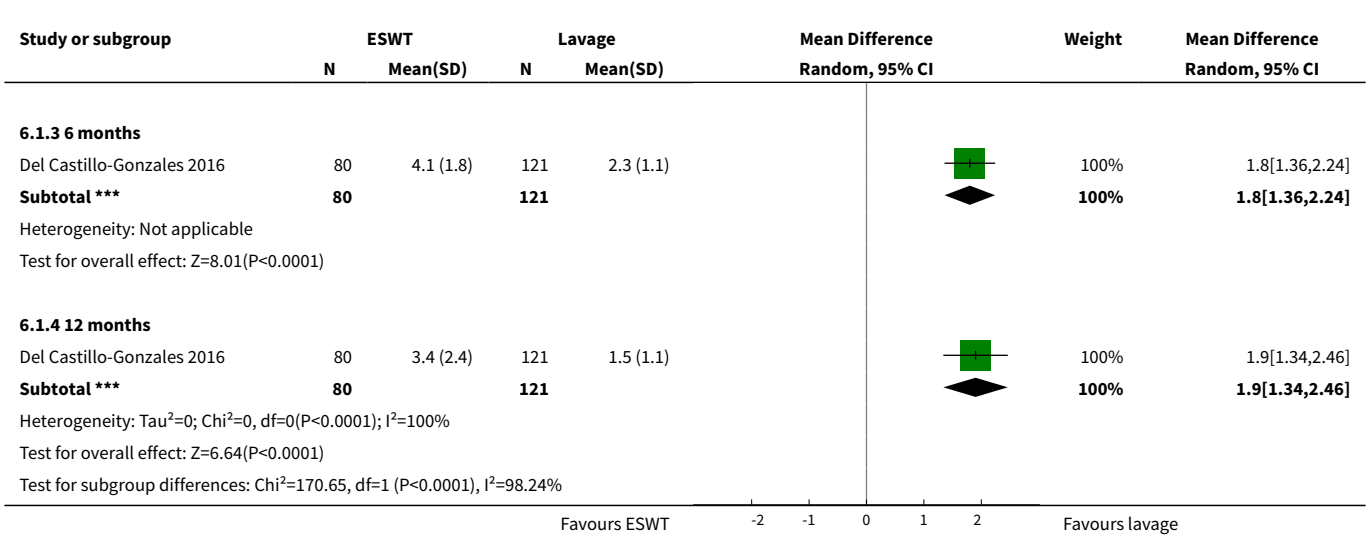
Comparison 6. Extracorporeal shock wave therapy (ESWT) versus ultrasound-guided percutaneous lavage

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain (VAS 0–10, higher score indicating worse pain)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 6 weeks	1	201	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.26, 0.06]
1.2 3 months	1	201	Mean Difference (IV, Random, 95% CI)	1.9 [1.54, 2.26]
1.3 6 months	1	201	Mean Difference (IV, Random, 95% CI)	1.80 [1.36, 2.24]
1.4 12 months	1	201	Mean Difference (IV, Random, 95% CI)	1.90 [1.34, 2.46]
2 Treatment success (pain free)	1	201	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.81, 1.03]
3 Proportion of participants with adverse events	1	243	Risk Ratio (M-H, Random, 95% CI)	0.08 [0.00, 1.36]
4 Calcification size	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 6 weeks	1	201	Mean Difference (IV, Random, 95% CI)	-2.0 [-2.94, -1.06]
4.2 3 months	1	201	Mean Difference (IV, Random, 95% CI)	2.0 [1.17, 2.83]
4.3 6 months	1	201	Mean Difference (IV, Random, 95% CI)	2.40 [1.44, 3.36]
4.4 12 months	1	201	Mean Difference (IV, Random, 95% CI)	3.1 [2.07, 4.13]
5 Calcification size (proportion with complete resolution)	1	201	Risk Ratio (M-H, Random, 95% CI)	0.65 [0.53, 0.80]

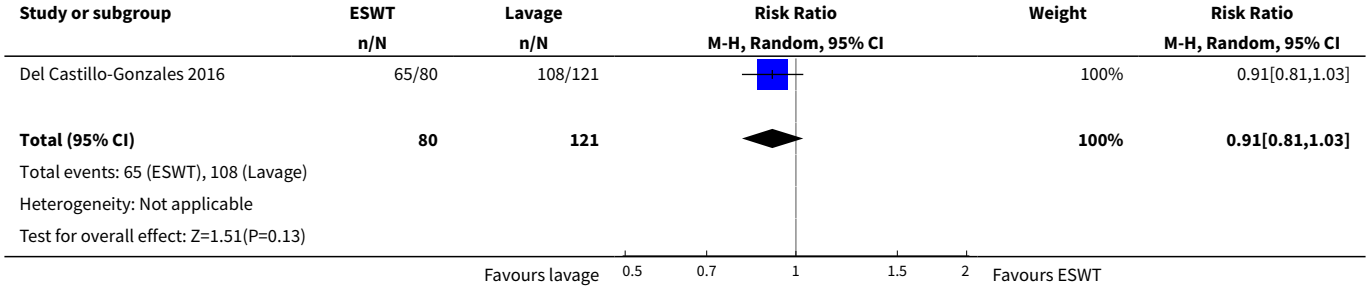
Analysis 6.1. Comparison 6 Extracorporeal shock wave therapy (ESWT) versus ultrasound-guided percutaneous lavage, Outcome 1 Pain (VAS 0–10, higher score indicating worse pain).

Study or subgroup	ESWT N	ESWT Mean(SD)	Lavage N	Lavage Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
6.1.1 6 weeks							
Del Castillo-Gonzales 2016	80	7.3 (0.6)	121	7.4 (0.5)		100%	-0.1[-0.26,0.06]
Subtotal ***	**80**		**121**			**100%**	**-0.1[-0.26,0.06]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.23(P=0.22)							
6.1.2 3 months							
Del Castillo-Gonzales 2016	80	5.3 (1.5)	121	3.4 (0.8)		100%	1.9[1.54,2.26]
Subtotal ***	**80**		**121**			**100%**	**1.9[1.54,2.26]**
Heterogeneity: Not applicable							
Test for overall effect: Z=10.39(P<0.0001)							

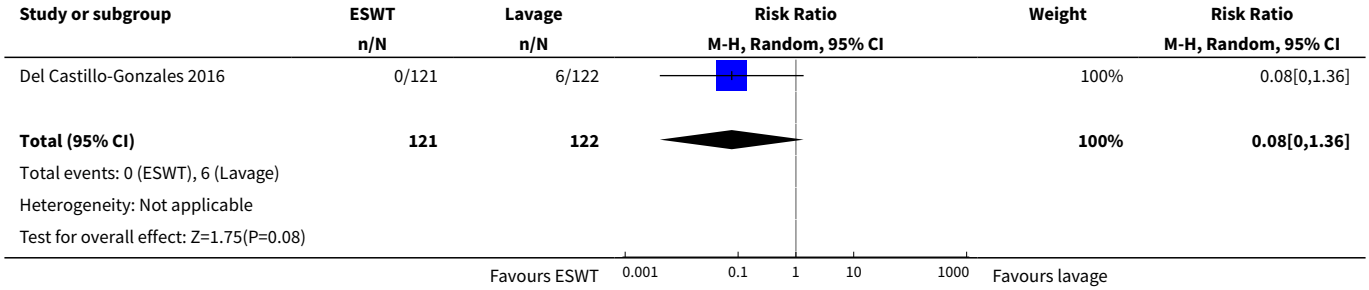




Analysis 6.2. Comparison 6 Extracorporeal shock wave therapy (ESWT) versus ultrasound-guided percutaneous lavage, Outcome 2 Treatment success (pain free).

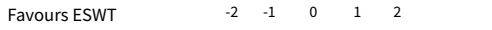


Analysis 6.3. Comparison 6 Extracorporeal shock wave therapy (ESWT) versus ultrasound-guided percutaneous lavage, Outcome 3 Proportion of participants with adverse events.



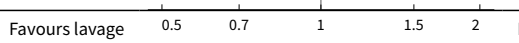
Analysis 6.4. Comparison 6 Extracorporeal shock wave therapy (ESWT) versus ultrasound-guided percutaneous lavage, Outcome 4 Calcification size.

Study or subgroup	ESWT N	ESWT Mean(SD)	Lavage N	Lavage Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
6.4.1 6 weeks							
Del Castillo-Gonzales 2016	80	10.6 (3.8)	121	12.6 (2.5)		100%	-2[-2.94,-1.06]
Subtotal ***	**80**		**121**			**100%**	**-2[-2.94,-1.06]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.15(P<0.0001)							
6.4.2 3 months							
Del Castillo-Gonzales 2016	80	7.7 (3.5)	121	5.7 (1.8)		100%	2[1.17,2.83]
Subtotal ***	**80**		**121**			**100%**	**2[1.17,2.83]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.72(P<0.0001)							
6.4.3 6 months							
Del Castillo-Gonzales 2016	80	5.9 (4.1)	121	3.5 (1.9)		100%	2.4[1.44,3.36]
Subtotal ***	**80**		**121**			**100%**	**2.4[1.44,3.36]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.9(P<0.0001)							
6.4.4 12 months							
Del Castillo-Gonzales 2016	80	4.5 (4.5)	121	1.4 (1.6)		100%	3.1[2.07,4.13]
Subtotal ***	**80**		**121**			**100%**	**3.1[2.07,4.13]**
Heterogeneity: Not applicable							
Test for overall effect: Z=5.92(P<0.0001)							
Test for subgroup differences: Chi^2=66.45, df=1 (P<0.0001), I^2=95.49%							



Analysis 6.5. Comparison 6 Extracorporeal shock wave therapy (ESWT) versus ultrasound-guided percutaneous lavage, Outcome 5 Calcification size (proportion with complete resolution).

Study or subgroup	ESWT n/N	Lavage n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Del Castillo-Gonzales 2016	45/80	105/121		100%	0.65[0.53,0.8]
Total (95% CI)	**80**	**121**		**100%**	**0.65[0.53,0.8]**
Total events: 45 (ESWT), 105 (Lavage)					
Heterogeneity: Not applicable					
Test for overall effect: Z=4.14(P<0.0001)					

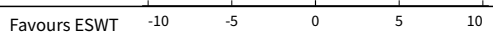


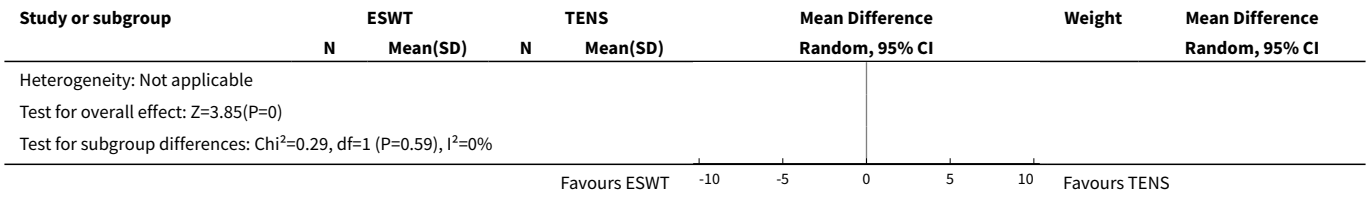
Comparison 7. Extracorporeal shock wave therapy (ESWT) versus transcutaneous electrical nerve stimulation (TENS)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in mean pain from baseline (0–10 VAS, 0 is no pain)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 6 weeks	1	62	Mean Difference (IV, Random, 95% CI)	-1.9 [-2.98, -0.82]
1.2 3 months	1	62	Mean Difference (IV, Random, 95% CI)	-2.34 [-3.53, -1.15]
2 Mean function (Constant score 0–100, 0 is worst and 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2.1 6 weeks	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 3 months	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
3 Withdrawals	1	62	Risk Ratio (M-H, Random, 95% CI)	0.29 [0.01, 6.95]
4 Proportion of participants with adverse events	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
5 Reduction in calcification size (mm)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
5.1 6 weeks	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
5.2 3 months	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

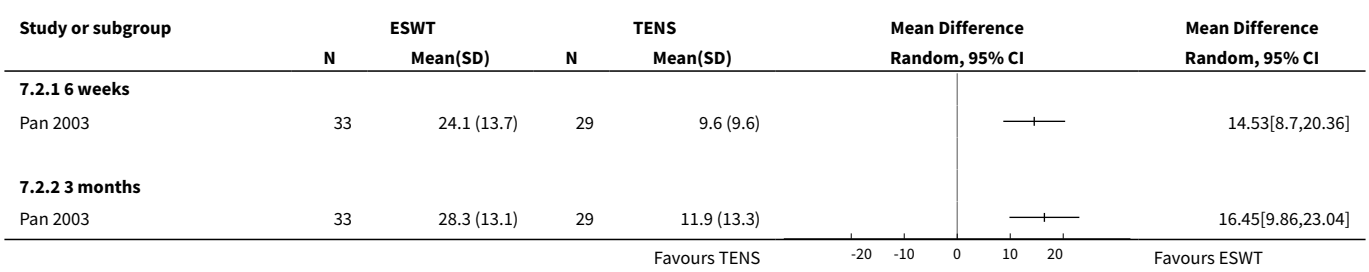
Analysis 7.1. Comparison 7 Extracorporeal shock wave therapy (ESWT) versus transcutaneous electrical nerve stimulation (TENS), Outcome 1 Change in mean pain from baseline (0–10 VAS, 0 is no pain).

Study or subgroup	ESWT N	ESWT Mean(SD)	TENS N	TENS Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
7.1.1 6 weeks							
Pan 2003	33	-3 (2.4)	29	-1.1 (1.9)		100%	-1.9[-2.98,-0.82]
Subtotal ***	**33**		**29**			**100%**	**-1.9[-2.98,-0.82]**
Heterogeneity: Not applicable							
Test for overall effect: Z=3.44(P=0)							
7.1.2 3 months							
Pan 2003	33	-4.1 (2.6)	29	-1.7 (2.2)		100%	-2.34[-3.53,-1.15]
Subtotal ***	**33**		**29**			**100%**	**-2.34[-3.53,-1.15]**

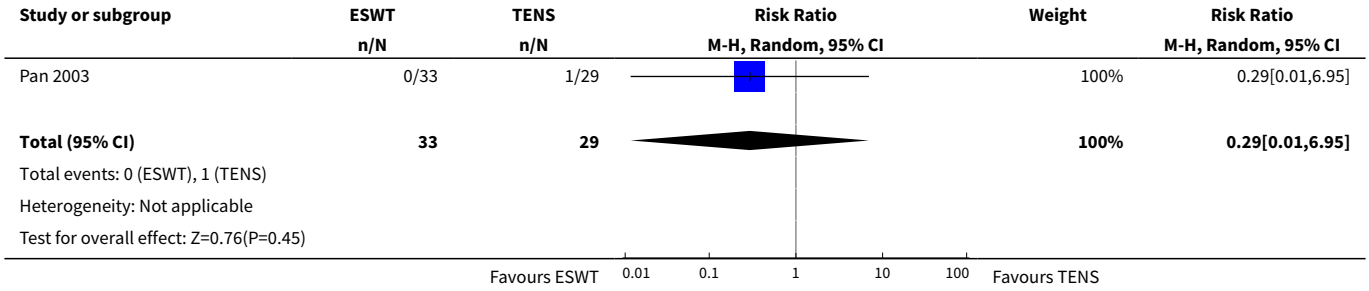




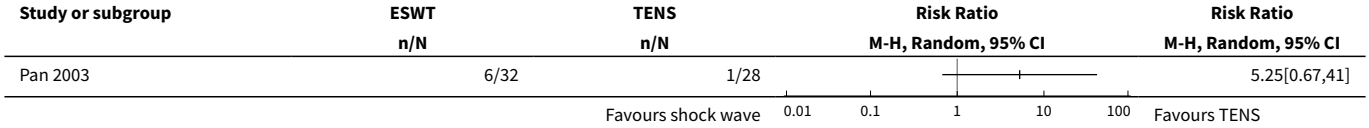
Analysis 7.2. Comparison 7 Extracorporeal shock wave therapy (ESWT) versus transcutaneous electrical nerve stimulation (TENS), Outcome 2 Mean function (Constant score 0–100, 0 is worst and 100 is best).



Analysis 7.3. Comparison 7 Extracorporeal shock wave therapy (ESWT) versus transcutaneous electrical nerve stimulation (TENS), Outcome 3 Withdrawals.



Analysis 7.4. Comparison 7 Extracorporeal shock wave therapy (ESWT) versus transcutaneous electrical nerve stimulation (TENS), Outcome 4 Proportion of participants with adverse events.



Analysis 7.5. Comparison 7 Extracorporeal shock wave therapy (ESWT) versus transcutaneous electrical nerve stimulation (TENS), Outcome 5 Reduction in calcification size (mm).

Study or subgroup	ESWT N	ESWT Mean(SD)	TENS N	TENS Mean(SD)	Mean Difference Random, 95% CI	Mean Difference Random, 95% CI
7.5.1 6 weeks						
Pan 2003	33	-3.2 (4.1)	29	-0.7 (1.7)		-2.41[-3.94,-0.88]
7.5.2 3 months						
Pan 2003	33	-4.4 (3.8)	29	-1.6 (2.8)		-2.74[-4.39,-1.09]

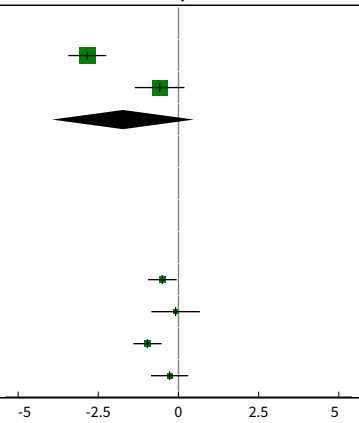
Comparison 8. Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose

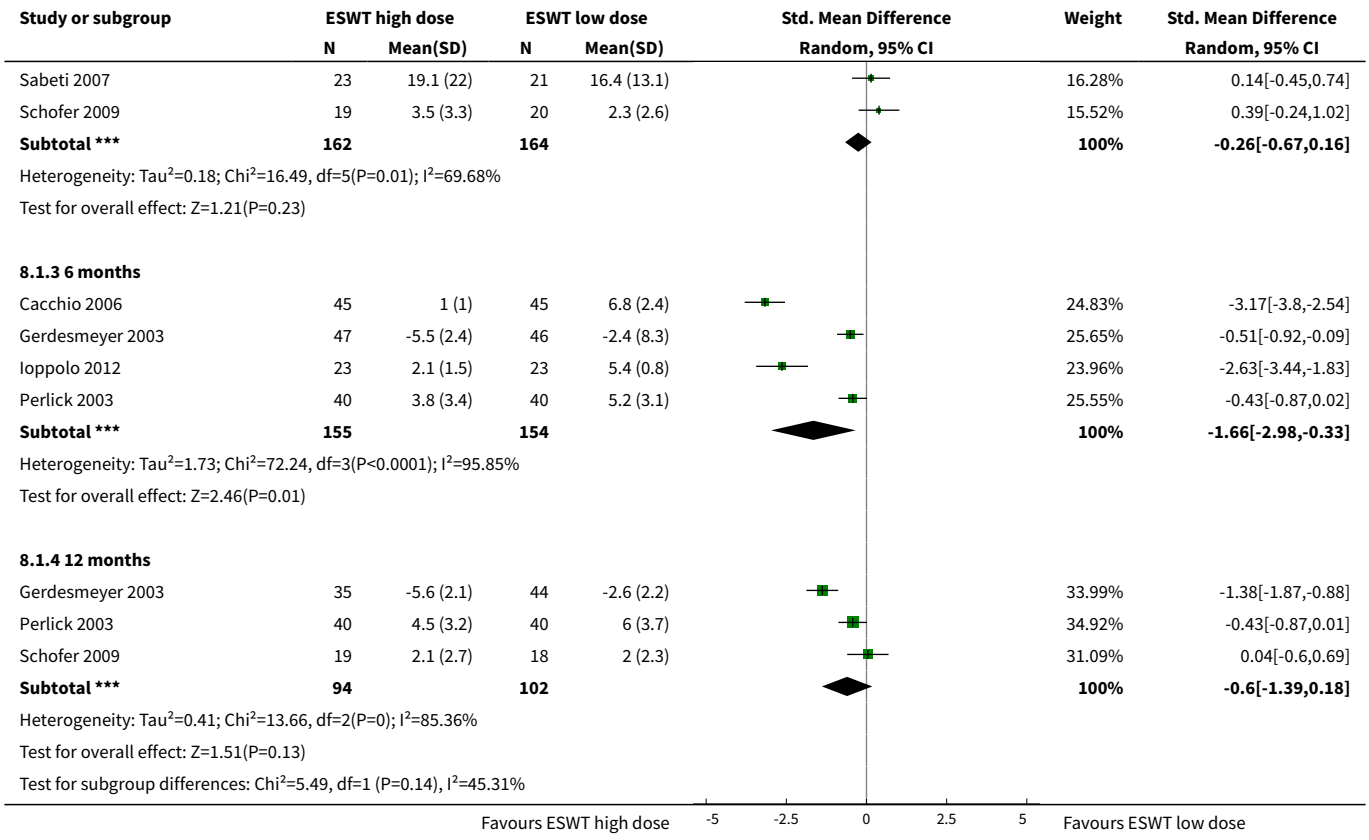
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean pain (various scales, lower score indicates less pain)	8		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 6 weeks	2	117	Std. Mean Difference (IV, Random, 95% CI)	-1.73 [-3.94, 0.48]
1.2 3 months	6	326	Std. Mean Difference (IV, Random, 95% CI)	-0.26 [-0.67, 0.16]
1.3 6 months	4	309	Std. Mean Difference (IV, Random, 95% CI)	-1.66 [-2.98, -0.33]
1.4 12 months	3	196	Std. Mean Difference (IV, Random, 95% CI)	-0.60 [-1.39, 0.18]
2 Mean function (various scales, higher score is better function)	10		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 6 weeks	2	117	Std. Mean Difference (IV, Random, 95% CI)	3.71 [-3.71, 11.14]
2.2 3 months	7	366	Std. Mean Difference (IV, Random, 95% CI)	0.31 [0.08, 0.53]
2.3 6 months	5	409	Std. Mean Difference (IV, Random, 95% CI)	2.29 [1.05, 3.52]
2.4 12 months	3	196	Std. Mean Difference (IV, Random, 95% CI)	0.50 [-0.03, 1.02]
3 Treatment success as determined by participant	6	450	Risk Ratio (M-H, Random, 95% CI)	2.74 [1.58, 4.77]
4 Withdrawals	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Proportion of participants who experienced adverse events	5	351	Risk Ratio (M-H, Random, 95% CI)	3.51 [1.53, 8.03]
6 Range of movement (University of California at Los Angeles subscore, active flexion measured in degrees)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
6.1 6 weeks	1	90	Mean Difference (IV, Random, 95% CI)	49.35 [37.39, 61.31]
6.2 6 months	1	90	Mean Difference (IV, Random, 95% CI)	62.0 [50.59, 73.41]
7 Resolution of calcification	4	281	Risk Ratio (M-H, Random, 95% CI)	2.91 [1.04, 8.15]
8 Partial resolution of calcification	2	180	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.73, 1.75]
9 Calcification size (mm)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
9.1 6 months	3	229	Mean Difference (IV, Random, 95% CI)	-24.19 [-44.83, -3.55]
9.2 12 months	1	79	Mean Difference (IV, Random, 95% CI)	-70.70 [-141.05, -0.35]
10 Calcification size (> 80% reduction of calcified surface on anteroposterior view)	1	80	Risk Ratio (M-H, Random, 95% CI)	3.0 [0.64, 13.98]

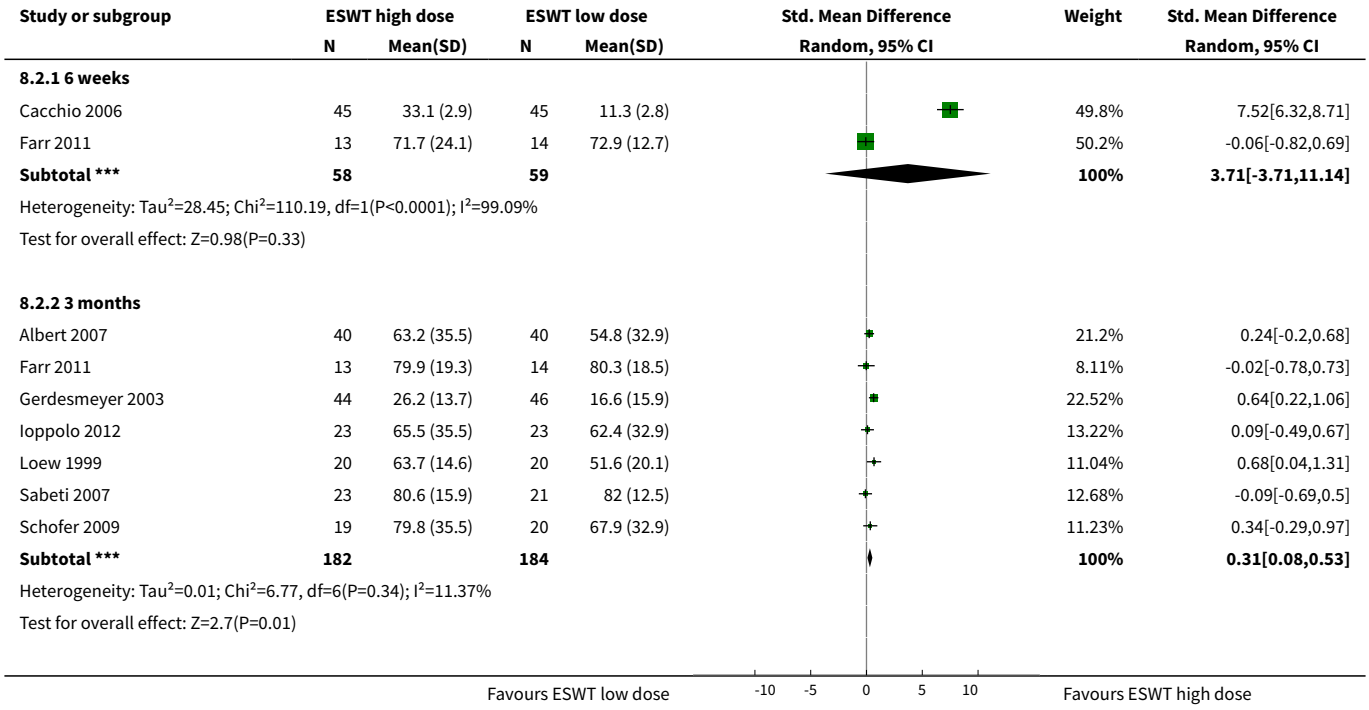
Analysis 8.1. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 1 Mean pain (various scales, lower score indicates less pain).

Study or subgroup	ESWT high dose N	ESWT high dose Mean(SD)	ESWT low dose N	ESWT low dose Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
8.1.1 6 weeks							
Cacchio 2006	45	0.9 (1)	45	5.9 (2.2)		50.63%	-2.84[-3.44,-2.25]
Farr 2011	13	3 (3.1)	14	4.7 (2.5)		49.37%	-0.59[-1.36,0.19]
Subtotal ***	**58**		**59**			**100%**	**-1.73[-3.94,0.48]**
Heterogeneity: Tau²=2.42; Chi²=20.59, df=1(P<0.0001); I²=95.14%							
Test for overall effect: Z=1.53(P=0.13)							
8.1.2 3 months							
Albert 2007	40	-2.3 (2.6)	40	-1.1 (2.1)		19.05%	-0.5[-0.95,-0.06]
Farr 2011	13	3 (3.5)	14	3.3 (3)		13.47%	-0.09[-0.84,0.67]
Gerdesmeyer 2003	44	-5 (2.6)	46	-2.7 (2.1)		19.19%	-0.97[-1.41,-0.53]
Ioppolo 2012	23	5.5 (3.3)	23	6.4 (2.6)		16.49%	-0.28[-0.86,0.3]

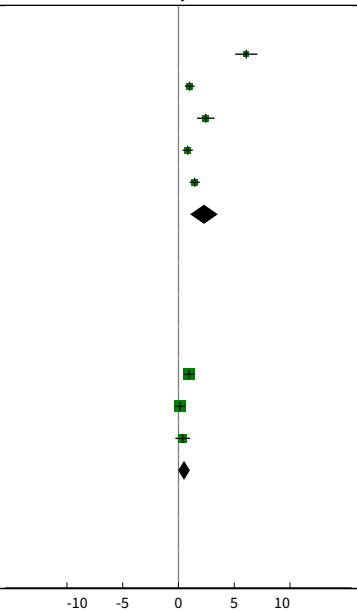




Analysis 8.2. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 2 Mean function (various scales, higher score is better function).

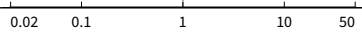


Study or subgroup	ESWT high dose N	ESWT high dose Mean(SD)	ESWT low dose N	ESWT low dose Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
8.2.3 6 months							
Cacchio 2006	45	32.1 (3)	45	10.6 (4)		18.61%	6.07[5.08,7.07]
Gerdesmeyer 2003	47	31 (15)	46	15 (16.6)		20.65%	1[0.57,1.44]
Ioppolo 2012	23	79.4 (10.3)	23	57.9 (6.5)		19.53%	2.45[1.67,3.23]
Perlick 2003	40	76.4 (10.3)	40	69.2 (6.5)		20.58%	0.83[0.37,1.28]
Rompe 1998	50	88 (13)	50	71 (10)		20.62%	1.45[1.01,1.9]
Subtotal ***	**205**		**204**			**100%**	**2.29[1.05,3.52]**
Heterogeneity: Tau²=1.87; Chi²=99.99, df=4(P<0.0001); I²=96%							
Test for overall effect: Z=3.63(P=0)							
8.2.4 12 months							
Gerdesmeyer 2003	35	31.6 (13.1)	44	17.7 (15.4)		35.36%	0.95[0.48,1.42]
Perlick 2003	40	73.2 (32)	40	68.3 (33.9)		36.68%	0.15[-0.29,0.59]
Schofer 2009	19	88 (32)	18	75.5 (33.9)		27.96%	0.37[-0.28,1.02]
Subtotal ***	**94**		**102**			**100%**	**0.5[-0.03,1.02]**
Heterogeneity: Tau²=0.14; Chi²=6.22, df=2(P=0.04); I²=67.82%							
Test for overall effect: Z=1.86(P=0.06)							
Test for subgroup differences: Chi²=10.53, df=1 (P=0.01), I²=71.5%							



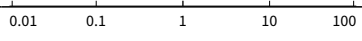
Analysis 8.3. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 3 Treatment success as determined by participant.

Study or subgroup	ESWT high dose n/N	ESWT low dose n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Albert 2007	27/40	11/40		19.83%	2.45[1.42,4.24]
Cacchio 2006	39/45	0/45		3.46%	79[5,1247.18]
Gerdesmeyer 2003	33/35	20/44		22.58%	2.07[1.49,2.9]
Loew 1999	12/20	6/20		16.82%	2[0.94,4.27]
Peters 2004	31/31	4/30		15.49%	6.78[2.88,15.95]
Rompe 1998	32/50	20/50		21.82%	1.6[1.07,2.38]
Total (95% CI)	**221**	**229**		**100%**	**2.74[1.58,4.77]**
Total events: 174 (ESWT high dose), 61 (ESWT low dose)					
Heterogeneity: Tau²=0.32; Chi²=24.44, df=5(P=0); I²=79.54%					
Test for overall effect: Z=3.58(P=0)					

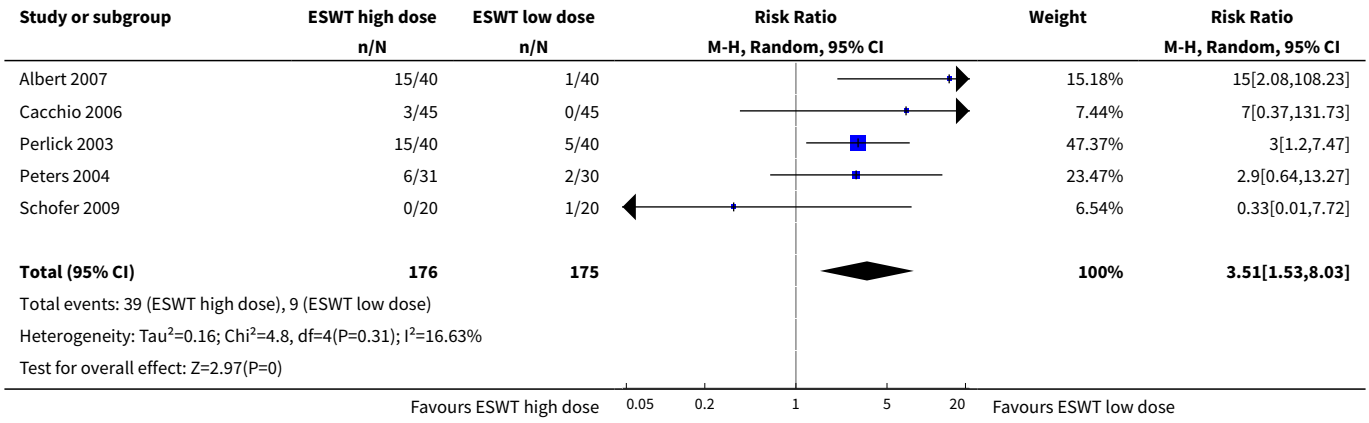


Analysis 8.4. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 4 Withdrawals.

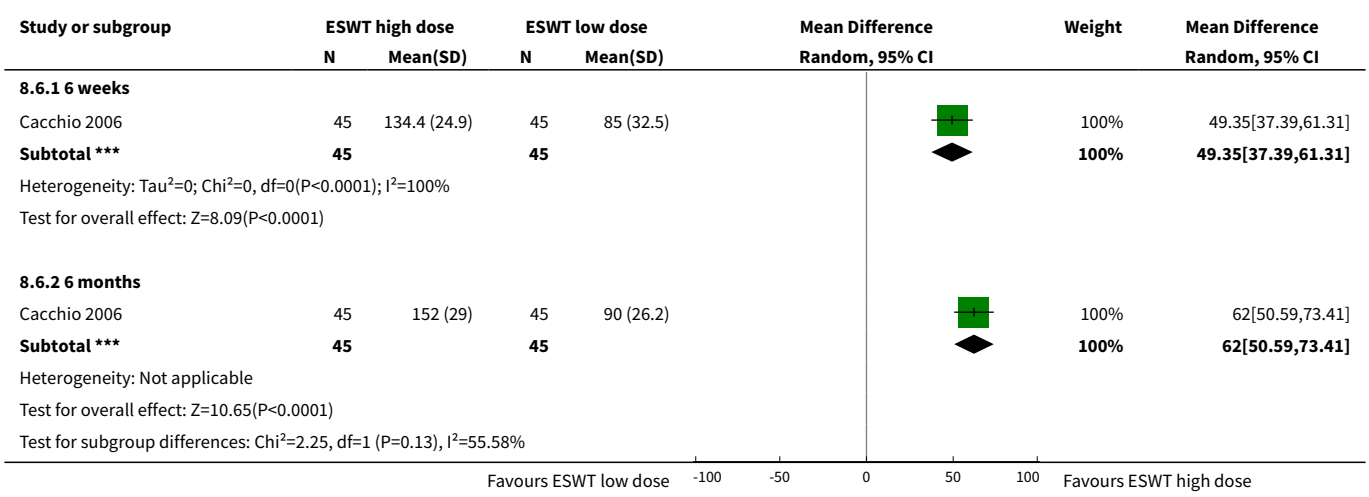
Study or subgroup	ESWT high dose n/N	ESWT low dose n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Albert 2007	1/40	1/39		0%	0.98[0.06,15.05]



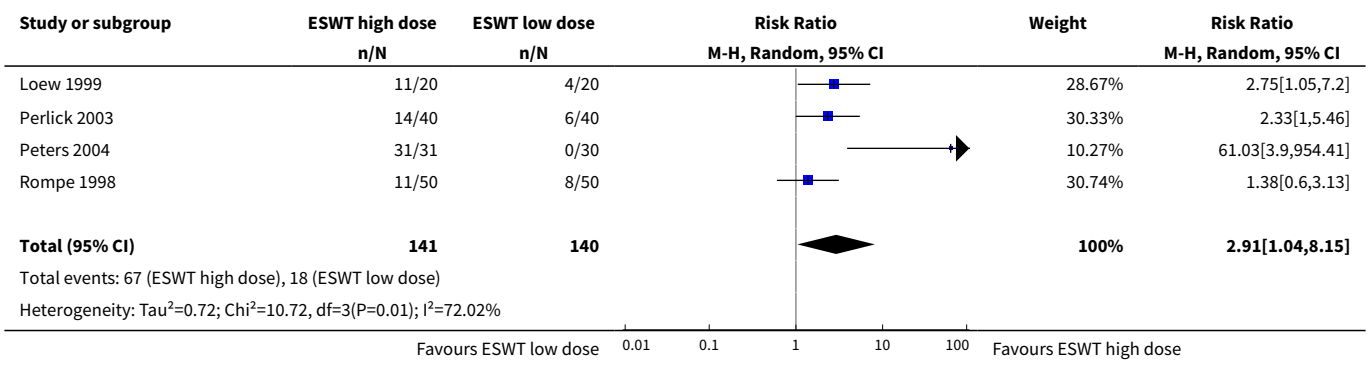
Analysis 8.5. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 5 Proportion of participants who experienced adverse events.



Analysis 8.6. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 6 Range of movement (University of California at Los Angeles subscore, active flexion measured in degrees).



Analysis 8.7. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 7 Resolution of calcification.

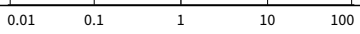


Study or subgroup	ESWT high dose n/N	ESWT low dose n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Test for overall effect: Z=2.03(P=0.04)					

Favours ESWT low dose — Favours ESWT high dose

Analysis 8.8. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 8 Partial resolution of calcification.

Study or subgroup	ESWT high dose n/N	ESWT low dose n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Perlick 2003	8/40	9/40		26.31%	0.89[0.38,2.07]
Rompe 1998	21/50	17/50		73.69%	1.24[0.75,2.05]
Total (95% CI)	**90**	**90**		**100%**	**1.13[0.73,1.75]**
Total events: 29 (ESWT high dose), 26 (ESWT low dose)					
Heterogeneity: Tau^2=0; Chi^2=0.43, df=1(P=0.51); I^2=0%					
Test for overall effect: Z=0.56(P=0.57)					



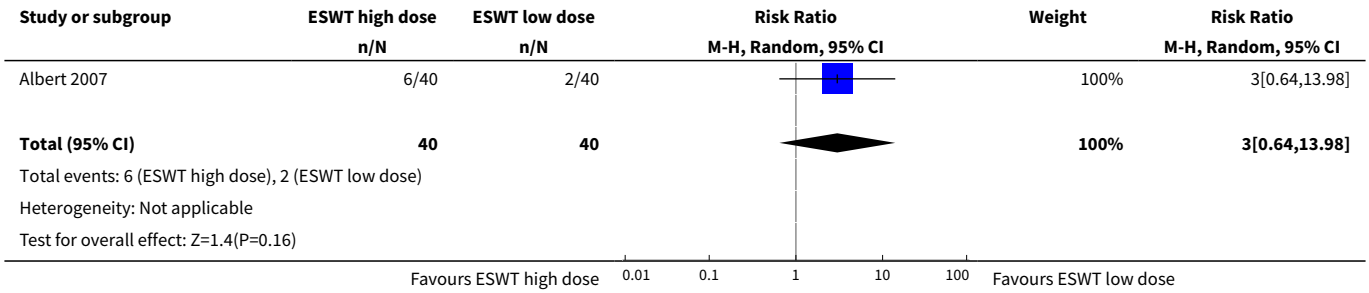
Favours ESWT high dose — Favours ESWT low dose

Analysis 8.9. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 9 Calcification size (mm).

Study or subgroup	ESWT high dose N	ESWT high dose Mean(SD)	ESWT low dose N	ESWT low dose Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
8.9.1 6 months							
Cacchio 2006	45	0.9 (1.2)	45	18.9 (6.4)		73.89%	-18[-19.9,-16.1]
Gerdesmeyer 2003	47	-152.8 (148.7)	46	-77.7 (181.8)		8.29%	-75.1[-142.68,-7.52]
Ioppolo 2012	23	-135.9 (71.7)	23	-109.7 (75.7)		17.83%	-26.18[-68.8,16.44]
Subtotal ***	**115**		**114**			**100%**	**-24.19[-44.83,-3.55]**
Heterogeneity: Tau^2=149.13; Chi^2=2.88, df=2(P=0.24); I^2=30.55%							
Test for overall effect: Z=2.3(P=0.02)							
8.9.2 12 months							
Gerdesmeyer 2003	35	-162.2 (126.8)	44	-91.5 (191)		100%	-70.7[-141.05,-0.35]
Subtotal ***	**35**		**44**			**100%**	**-70.7[-141.05,-0.35]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.97(P=0.05)							

Favours ESWT high dose — Favours ESWT low dose

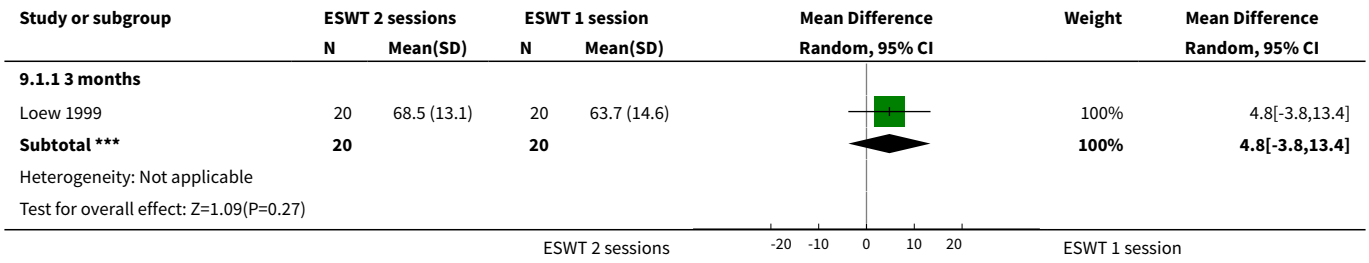
Analysis 8.10. Comparison 8 Extracorporeal shock wave therapy (ESWT) high dose versus ESWT low dose, Outcome 10 Calcification size (> 80% reduction of calcified surface on anteroposterior view).



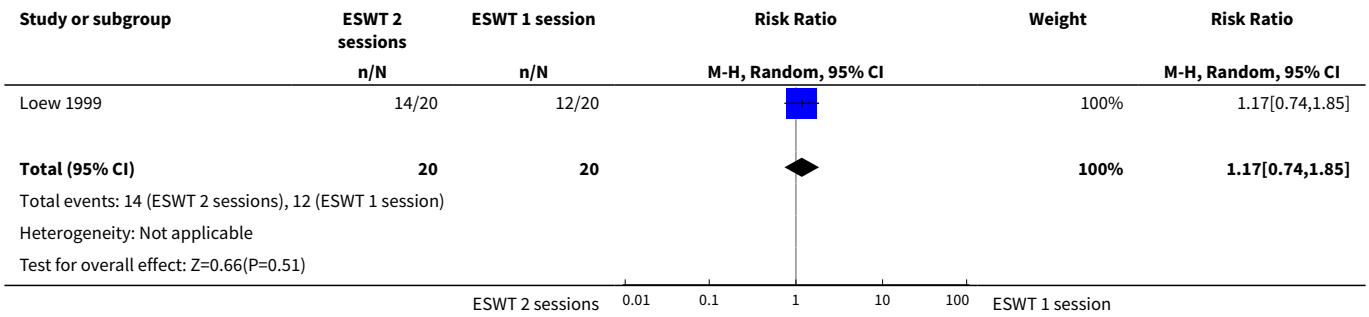
Comparison 9. Extracorporeal shock wave therapy (ESWT) two sessions versus ESWT one session

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean function (Constant score, 0–100, 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 3 months	1	40	Mean Difference (IV, Random, 95% CI)	4.80 [-3.80, 13.40]
2 Treatment success as determined by participant	1	40	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.74, 1.85]
3 Resolution of calcification	1	40	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.64, 1.86]

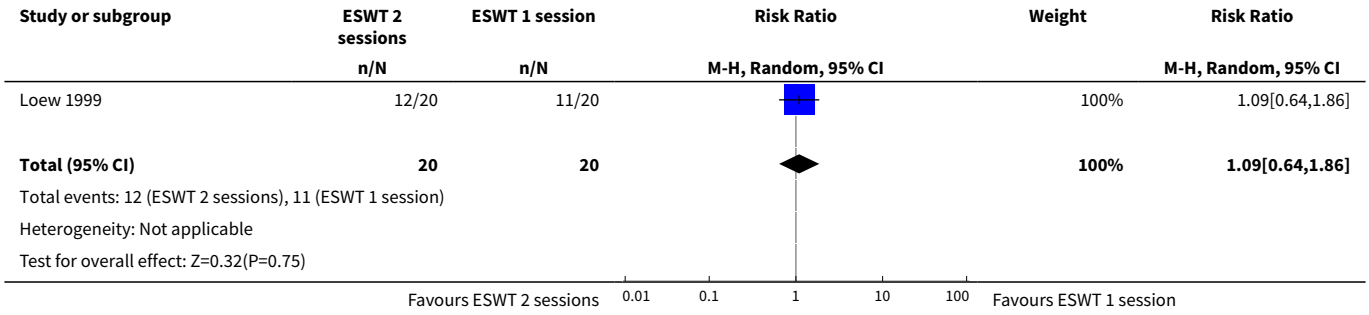
Analysis 9.1. Comparison 9 Extracorporeal shock wave therapy (ESWT) two sessions versus ESWT one session, Outcome 1 Mean function (Constant score, 0–100, 100 is best).



Analysis 9.2. Comparison 9 Extracorporeal shock wave therapy (ESWT) two sessions versus ESWT one session, Outcome 2 Treatment success as determined by participant.



Analysis 9.3. Comparison 9 Extracorporeal shock wave therapy (ESWT) two sessions versus ESWT one session, Outcome 3 Resolution of calcification.



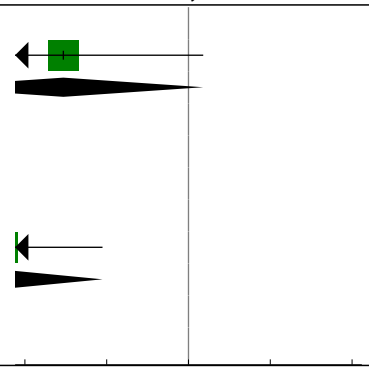
Comparison 10. Extracorporeal shock wave therapy (ESWT) calcification-focused versus ESWT supraspinatus origin-focused

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean pain (0–10 point NRS, 0 is no pain)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 3 months	1	47	Mean Difference (IV, Random, 95% CI)	-1.53 [-3.24, 0.18]
1.2 12 months	1	49	Mean Difference (IV, Random, 95% CI)	-2.27 [-3.49, -1.05]
2 Mean function (Constant score 0–100, 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 6 months	1	47	Mean Difference (IV, Random, 95% CI)	31.51 [16.33, 46.69]
2.2 12 months	1	49	Mean Difference (IV, Random, 95% CI)	32.73 [20.40, 45.06]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Treatment success as determined by participant satisfaction	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4 Calcification size (complete resolution)	1	46	Risk Ratio (M-H, Random, 95% CI)	1.60 [0.84, 3.07]

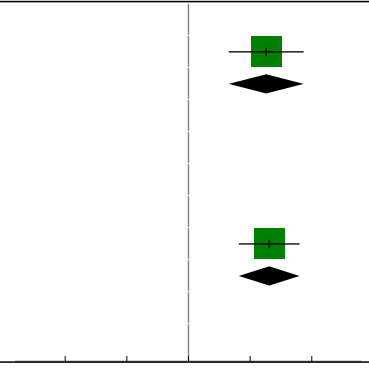
Analysis 10.1. Comparison 10 Extracorporeal shock wave therapy (ESWT) calcification-focused versus ESWT supraspinatus origin-focused, Outcome 1 Mean pain (0–10 point NRS, 0 is no pain).

Study or subgroup	Calcific-focused N	Calcific-focused Mean(SD)	Supraspinatus-focused N	Supraspinatus-focused Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
10.1.1 3 months							
Haake 2002	24	3.2 (2.9)	23	4.7 (3.1)		100%	-1.53[-3.24,0.18]
Subtotal ***	**24**		**23**			**100%**	**-1.53[-3.24,0.18]**
Heterogeneity: Tau²=0; Chi²=0, df=0(P<0.0001); I²=100%							
Test for overall effect: Z=1.75(P=0.08)							
10.1.2 12 months							
Haake 2002	25	1.5 (0.9)	24	3.8 (2.9)		100%	-2.27[-3.49,-1.05]
Subtotal ***	**25**		**24**			**100%**	**-2.27[-3.49,-1.05]**
Heterogeneity: Not applicable							
Test for overall effect: Z=3.65(P=0)							

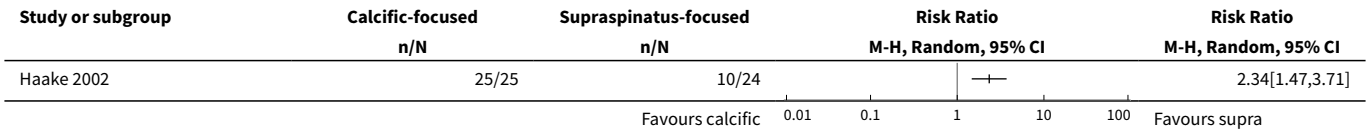


Analysis 10.2. Comparison 10 Extracorporeal shock wave therapy (ESWT) calcification-focused versus ESWT supraspinatus origin-focused, Outcome 2 Mean function (Constant score 0–100, 100 is best).

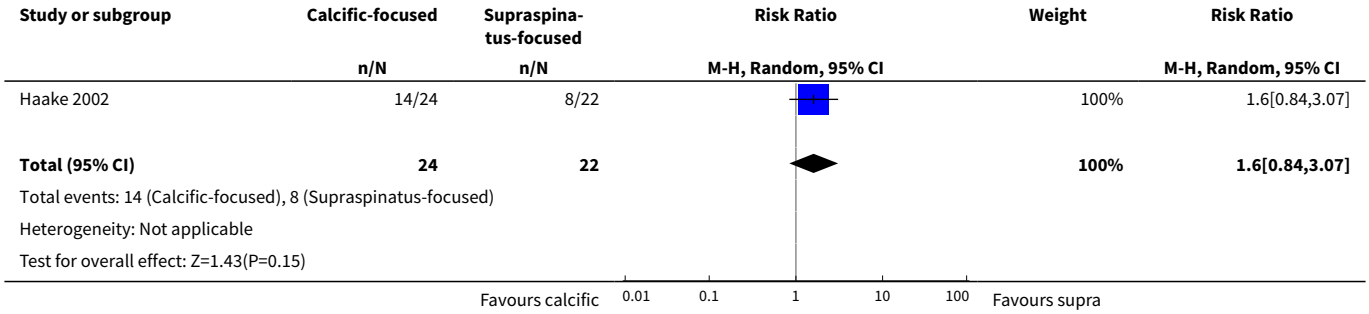
Study or subgroup	Calcific-focused N	Calcific-focused Mean(SD)	Supraspinatus-focused N	Supraspinatus-focused Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
10.2.1 6 months							
Haake 2002	24	104.6 (23.1)	23	73.1 (29.4)		100%	31.51[16.33,46.69]
Subtotal ***	**24**		**23**			**100%**	**31.51[16.33,46.69]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.07(P<0.0001)							
10.2.2 12 months							
Haake 2002	25	116.2 (16.2)	24	83.5 (26.4)		100%	32.73[20.4,45.06]
Subtotal ***	**25**		**24**			**100%**	**32.73[20.4,45.06]**
Heterogeneity: Not applicable							
Test for overall effect: Z=5.2(P<0.0001)							



Analysis 10.3. Comparison 10 Extracorporeal shock wave therapy (ESWT) calcification-focused versus ESWT supraspinatus origin-focused, Outcome 3 Treatment success as determined by participant satisfaction.



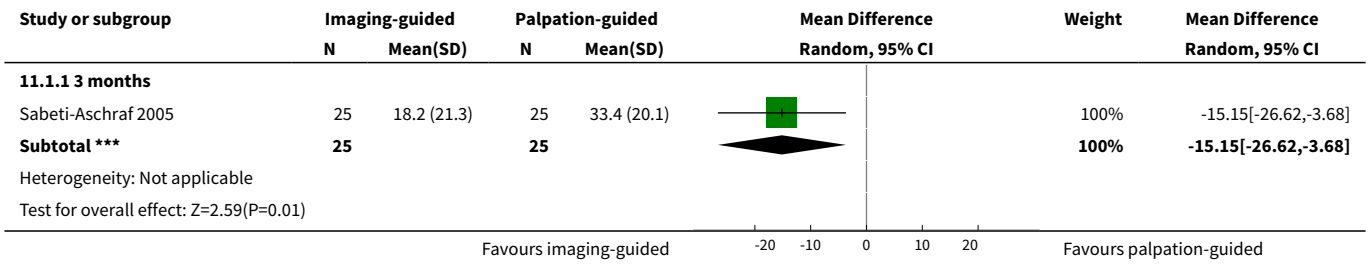
Analysis 10.4. Comparison 10 Extracorporeal shock wave therapy (ESWT) calcification-focused versus ESWT supraspinatus origin-focused, Outcome 4 Calcification size (complete resolution).



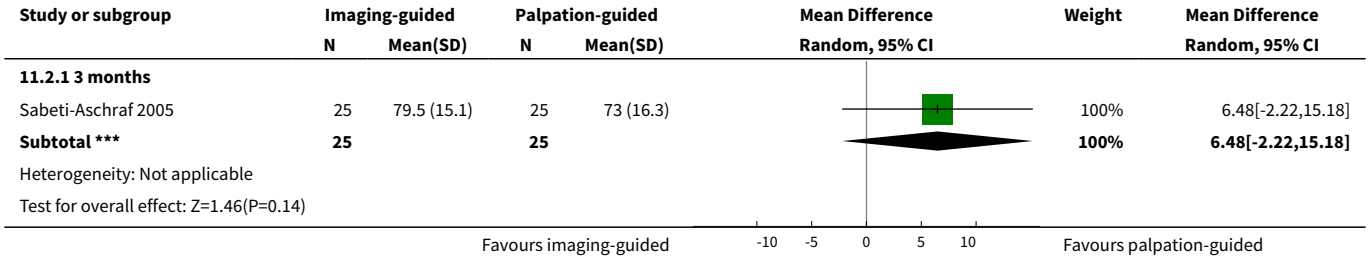
Comparison 11. Extracorporeal shock wave therapy (ESWT) image-guided versus ESWT palpation-guided

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean pain (0–100 VAS, 0 is no pain)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 3 months	1	50	Mean Difference (IV, Random, 95% CI)	-15.15 [-26.62, -3.68]
2 Mean function (Constant score 0–100, 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 3 months	1	50	Mean Difference (IV, Random, 95% CI)	6.48 [-2.22, 15.18]
3 Calcification size (complete resolution)	1	50	Risk Ratio (M-H, Random, 95% CI)	6.0 [0.78, 46.29]
4 Calcification size (partial resolution)	1	50	Risk Ratio (M-H, Random, 95% CI)	1.4 [0.51, 3.82]

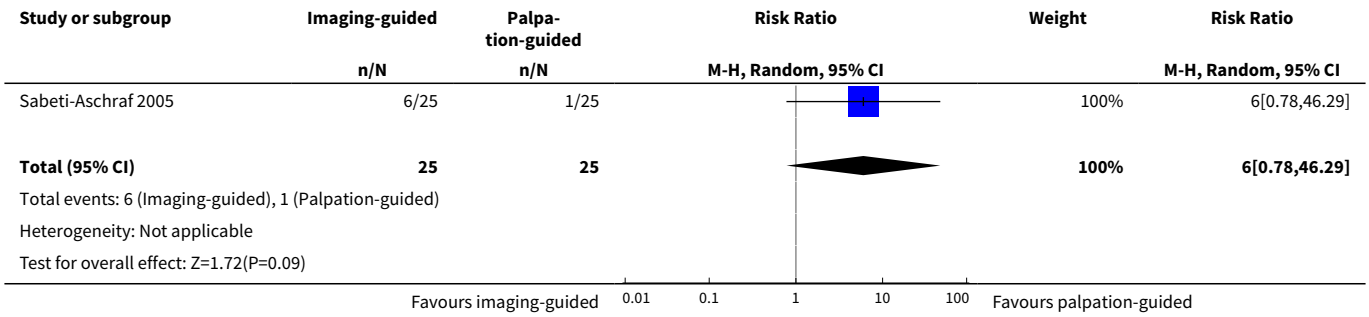
Analysis 11.1. Comparison 11 Extracorporeal shock wave therapy (ESWT) image-guided versus ESWT palpation-guided, Outcome 1 Mean pain (0–100 VAS, 0 is no pain).



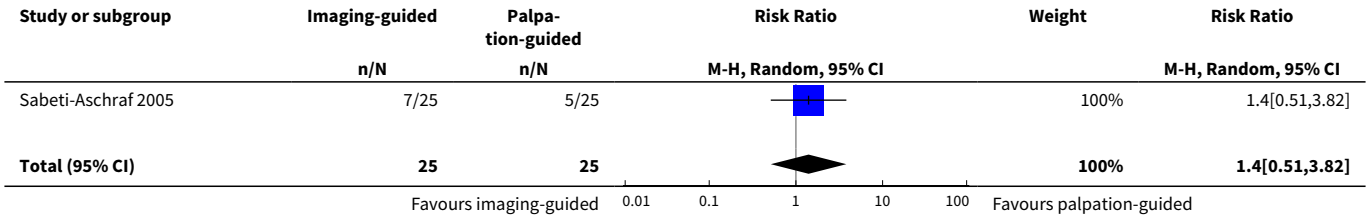
Analysis 11.2. Comparison 11 Extracorporeal shock wave therapy (ESWT) image-guided versus ESWT palpation-guided, Outcome 2 Mean function (Constant score 0–100, 100 is best).

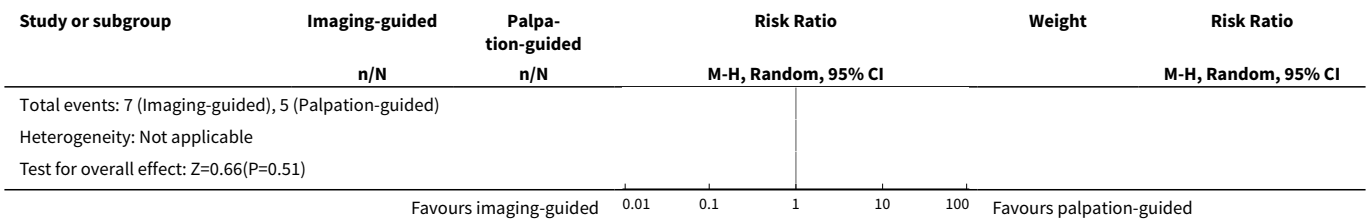


Analysis 11.3. Comparison 11 Extracorporeal shock wave therapy (ESWT) image-guided versus ESWT palpation-guided, Outcome 3 Calcification size (complete resolution).



Analysis 11.4. Comparison 11 Extracorporeal shock wave therapy (ESWT) image-guided versus ESWT palpation-guided, Outcome 4 Calcification size (partial resolution).

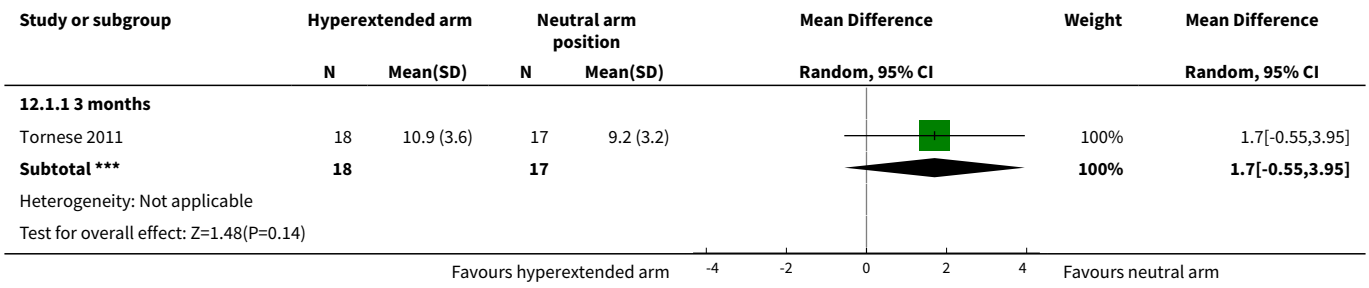




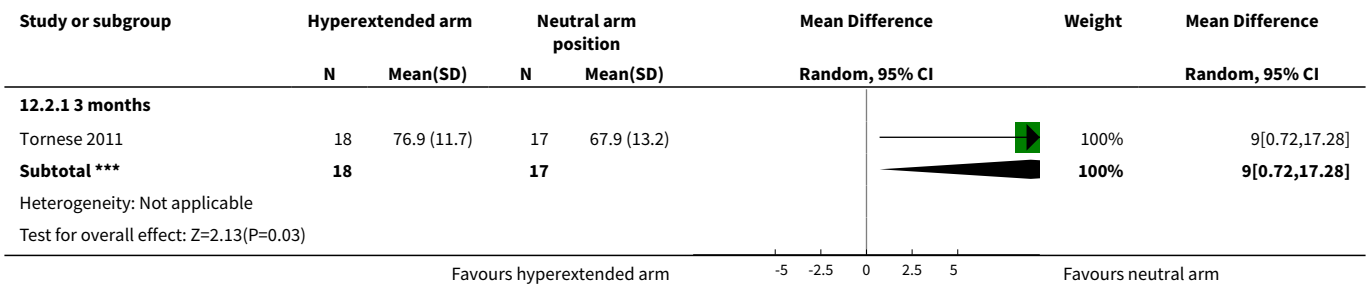
Comparison 12. Extracorporeal shock wave therapy (ESWT) with hyperextended arm position versus ESWT with neutral arm position

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mean pain (0–15 VAS, 15 is worst pain)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 3 months	1	35	Mean Difference (IV, Random, 95% CI)	1.70 [-0.55, 3.95]
2 Mean function (Constant score 0–100, 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 3 months	1	35	Mean Difference (IV, Random, 95% CI)	9.0 [0.72, 17.28]
3 Calcification size (> 80% reduction of calcified surface on anteroposterior view)	1	35	Risk Ratio (M-H, Random, 95% CI)	1.89 [0.92, 3.89]

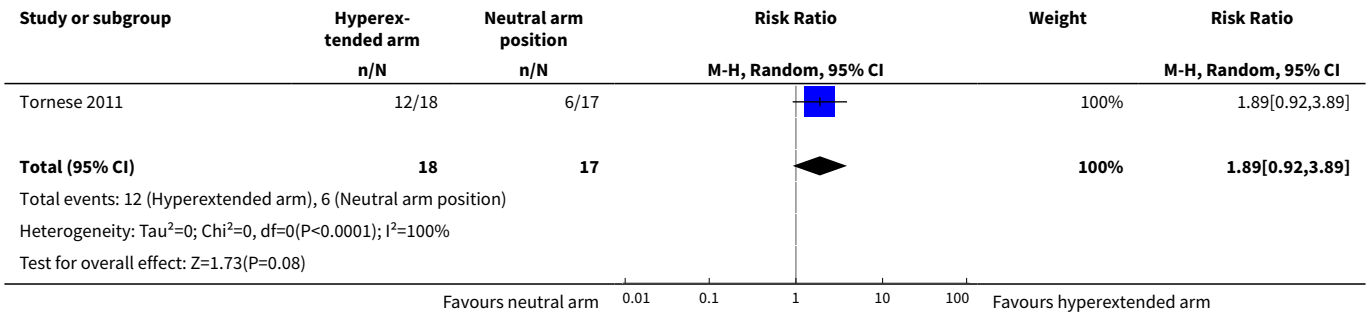
Analysis 12.1. Comparison 12 Extracorporeal shock wave therapy (ESWT) with hyperextended arm position versus ESWT with neutral arm position, Outcome 1 Mean pain (0–15 VAS, 15 is worst pain).



Analysis 12.2. Comparison 12 Extracorporeal shock wave therapy (ESWT) with hyperextended arm position versus ESWT with neutral arm position, Outcome 2 Mean function (Constant score 0–100, 100 is best).



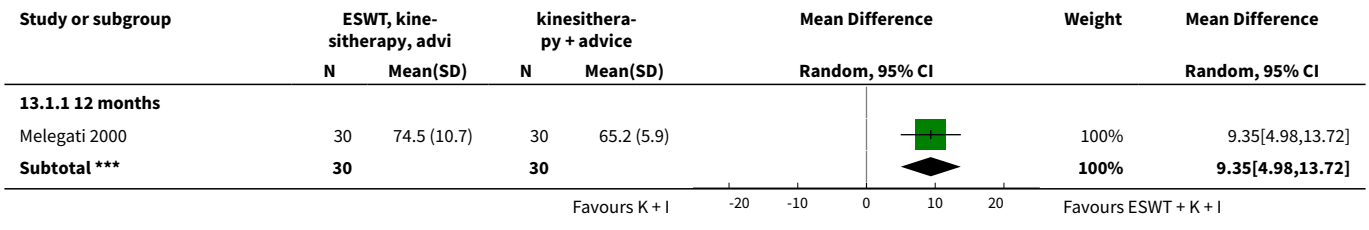
Analysis 12.3. Comparison 12 Extracorporeal shock wave therapy (ESWT) with hyperextended arm position versus ESWT with neutral arm position, Outcome 3 Calcification size (> 80% reduction of calcified surface on anteroposterior view).

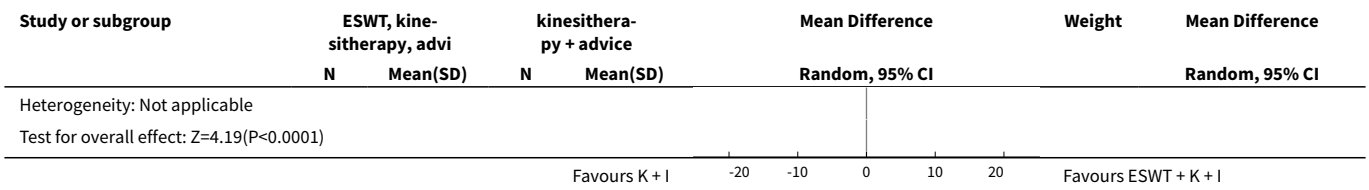


Comparison 13. Extracorporeal shock wave therapy (ESWT) and exercise and advice versus exercise and advice

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Mean function (Constant score 0–100, 100 is best)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 12 months	1	60	Mean Difference (IV, Random, 95% CI)	9.35 [4.98, 13.72]

Analysis 13.1. Comparison 13 Extracorporeal shock wave therapy (ESWT) and exercise and advice versus exercise and advice, Outcome 1 Mean function (Constant score 0–100, 100 is best).

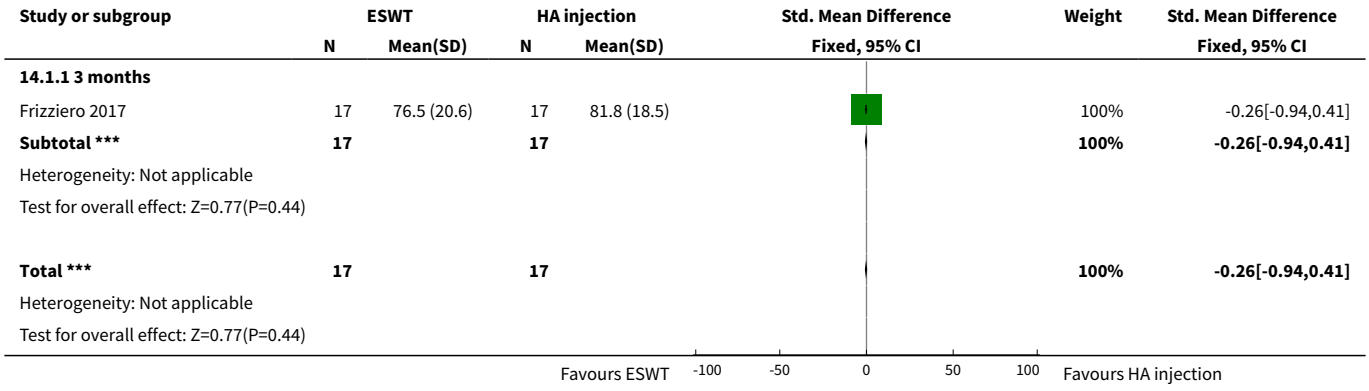




Comparison 14. Shock wave therapy (ESWT) versus ultrasound guided hyaluronic acid (HA) injection

Outcome or sub-group title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Function	1	34	Std. Mean Difference (IV, Fixed, 95% CI)	-0.26 [-0.94, 0.41]
1.1 3 months	1	34	Std. Mean Difference (IV, Fixed, 95% CI)	-0.26 [-0.94, 0.41]

Analysis 14.1. Comparison 14 Shock wave therapy (ESWT) versus ultrasound guided hyaluronic acid (HA) injection, Outcome 1 Function.



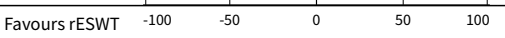
Comparison 15. Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Mean pain	1	80	Mean Difference (IV, Fixed, 95% CI)	-1.20 [-1.58, -0.82]
2 Mean function	1	80	Mean Difference (IV, Fixed, 95% CI)	-11.30 [-14.75, -7.85]
3 Range of movement (ROM) flexion	1	80	Mean Difference (IV, Fixed, 95% CI)	31.60 [24.04, 39.16]
4 ROM extension	1	80	Mean Difference (IV, Fixed, 95% CI)	17.00 [14.10, 19.90]
5 ROM abduction	1	80	Mean Difference (IV, Fixed, 95% CI)	41.8 [32.79, 50.81]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 ROM external rotation	1	80	Mean Difference (IV, Fixed, 95% CI)	23.2 [16.98, 29.42]

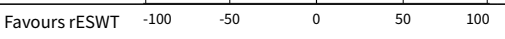
Analysis 15.1. Comparison 15 Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy, Outcome 1 Mean pain.

Study or subgroup	rESWT plus physiotherapy N	rESWT plus physiotherapy Mean(SD)	Physiotherapy N	Physiotherapy Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Duymaz 2019	40	1.3 (0.7)	40	2.5 (1)		100%	-1.2[-1.58,-0.82]
Total ***	**40**		**40**			**100%**	**-1.2[-1.58,-0.82]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=6.22(P<0.0001)							



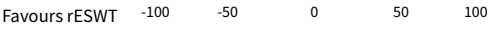
Analysis 15.2. Comparison 15 Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy, Outcome 2 Mean function.

Study or subgroup	rESWT plus physiotherapy N	rESWT plus physiotherapy Mean(SD)	Physiotherapy N	Physiotherapy Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Duymaz 2019	40	1.3 (1.8)	40	12.6 (11)		100%	-11.3[-14.75,-7.85]
Total ***	**40**		**40**			**100%**	**-11.3[-14.75,-7.85]**
Heterogeneity: Not applicable							
Test for overall effect: Z=6.41(P<0.0001)							

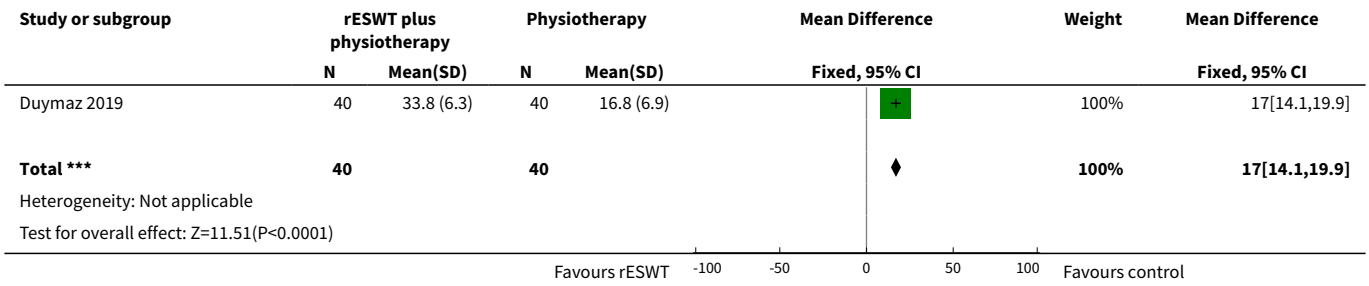


Analysis 15.3. Comparison 15 Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy, Outcome 3 Range of movement (ROM) flexion.

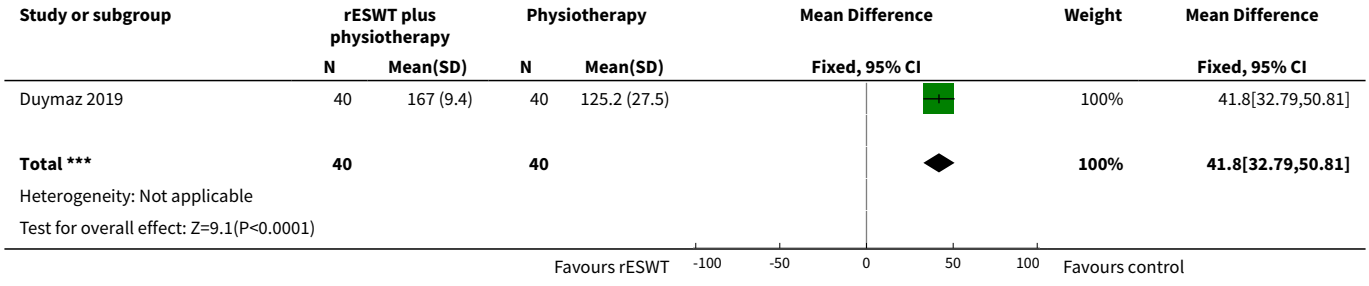
Study or subgroup	rESWT plus physiotherapy N	rESWT plus physiotherapy Mean(SD)	Physiotherapy N	Physiotherapy Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Duymaz 2019	40	171.1 (8.4)	40	139.5 (22.9)		100%	31.6[24.04,39.16]
Total ***	**40**		**40**			**100%**	**31.6[24.04,39.16]**
Heterogeneity: Not applicable							
Test for overall effect: Z=8.19(P<0.0001)							



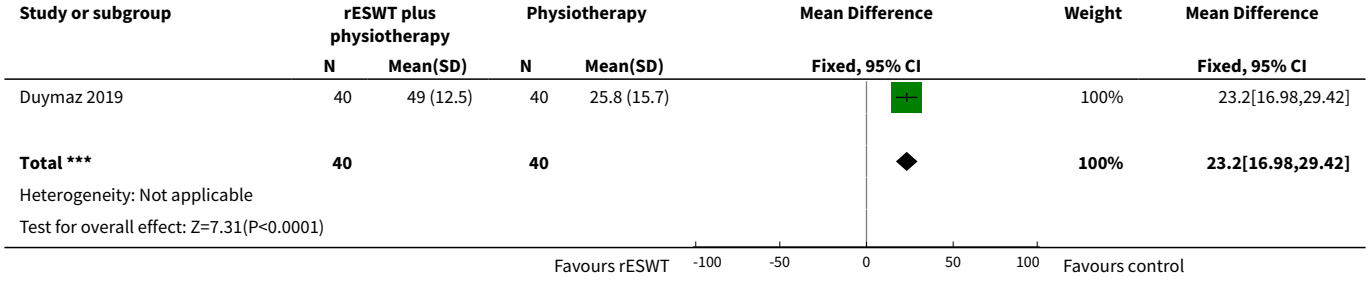
Analysis 15.4. Comparison 15 Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy, Outcome 4 ROM extension.



Analysis 15.5. Comparison 15 Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy, Outcome 5 ROM abduction.



Analysis 15.6. Comparison 15 Radial extracorporeal shock wave therapy (rESWT) plus physiotherapy versus physiotherapy, Outcome 6 ROM external rotation.



ADDITIONAL TABLES

Table 1. Characteristics of interventions used in included trials

Study ID	Shock wave machine	Type of shock wave	Number, frequency and dose	Comparison	Use of anaesthesia	Number of treatments

Table 1. Characteristics of interventions used in included trials *(Continued)*

Albert 2007	Modulith SLK (Storz Medical AG, Tagerwilen, Switzerland) electromagnetic shock wave generator with fluoroscopic and sonographic guidance	ESWT	High-dose shock wave: 2500 impulses, frequency 1 Hz for first 200 and 2 Hz thereafter. Goal intensity was maximum energy level tolerated by participant without exceeding 0.45 mJ/mm² per impulse	Low dose: 2500 impulses, frequency 1 Hz for first 200 and 2Hz thereafter. The energy intensity gradually increased from 0.02 mJ/mm² to 0.06 mJ/mm² per shock	None	2 sessions 14 days apart
Cacchio 2006	Physio Shock Wave Therapy device consisting of a control unit, a handpiece with 3 different head applicators and medical air compressor	rESWT	High dose: 2500 impulses per session (500 impulses with pressure 1.5 bar and frequency 10 Hz), EFD 0.10 mJ/mm² and fixed impulse time of 2 ms	Low dose: 25 impulses per session (5 impulses with a pressure of 1.5 bar and frequency of 4.5 Hz and 20 impulses with pressure 2.5 bar and frequency 10 Hz), EFD 0.10 mJ/mm² and fixed impulse time of 2 ms	None	4 sessions 7 days apart
Cosentino 2003	'Orthima' by Direx Medical System Ltd	ESWT	Shock wave: 1200 shocks at 120 shocks/minute of 0.03 mJ/mm²	Placebo: 1200 shocks at 120 shock/minute of 0 mJ/mm²	None	4 sessions 4–7 days apart
De Boer 2017	Masterpuls MP 100 (Storz Medical, Tagerwilen, Switzerland)	rESWT	Shock wave: 500 pulses of 1.5 bar (150 kPa) with a frequency of 4.5 Hz, followed by 2000 pulses of 2.5 bar (250 kPa) with a frequency 10 Hz; EFD)0.10 mJ/mm², duration of pulses was 2 ms	Ultrasound-guided needling	None	4 sessions, 1 week apart
Del Castillo-Gonzales 2016	Swiss DolorClast device	ESWT	Shock wave: Total of 2000 impacts (2 series of 1000 each) at frequency 8–10 Hz and EFD 0.20 J/mm²	Ultrasound-guided percutaneous lavage	None	Twice per week for 4 weeks
Duymaz 2019	ShockMaster 500 device (GymnaUniphy NV, Bilzen, Belgium)	rESWT	Shock wave: 1500 shocks with a frequency of 150 shocks per minute. all participants were treated with a low-energy density of 0.03 mJ/mm² for the first 5 minutes, which was then progressively increased to	Physiotherapy: ultrasound (1.0 MHz, 5 minutes, continuous), TENS (conventional, 20 minutes), shoulder joint ROM and stretching exercises, and ice application	None	1 session weekly for 4 weeks

Table 1. Characteristics of interventions used in included trials *(Continued)*

			0.28 mJ/mm^2. Duration of pulses was 10 minutes			
Engebretsen 2009	Swiss Dolor Clast, EMS	rESWT	Shock wave: 8–12 Hz at 2000 impulses/second with a pressure of 2.5–4.0 bar	Supervised exercises	None	1 session weekly for 4–6 weeks for rESWT OR 2 × 45-minute sessions weekly for up to 12 weeks for supervised exercises
Farr 2011	Storz Modulith SLK lithotripter in combination with a fluoroscopy-guided 3D computer-assisted navigation device	ESWT	High dose: 3200 impulses at 0.3 mJ/mm^2; twice	Low dose: 1600 impulses at 0.02 mJ/mm^2; once	5 mL xylocaine subacromially	Once only for low dose OR 2 sessions 7 days apart for high dose
Frizziero 2017	Modulith SLK (Storz Medical AG, Tagerwilen, Switzerland)	ESWT	Shock wave (low dose): 1600 impulses at a frequency of 4 Hz not exceeding 0.15 mJ/mm^2	Ultrasound-guided injection with low molecular weight hyaluronic acid	None	Weekly shock wave sessions for 4 weeks OR 1 injection weekly for 3 weeks
Galasso 2012	Modulith SLK system	ESWT	Shock wave: 3000 shocks of 0.068 mJ/mm^2	Placebo: Same protocol but with shock wave generator disconnected	Subcutaneous injection of 2 mL of 2% lidocaine above the subacromial space of the affected shoulder prior to each treatment	2 sessions 7 days apart
Gerdesmeyer 2003	Not reported	ESWT	Shock wave (low dose): 6000 shocks at 120 impulses/minute of 0.08 mJ/mm^2	High dose: 6000 shocks at 120 impulses/minute of 0.32 mJ/mm^2 OR Placebo:	None	2 sessions 12–16 days apart

Table 1. Characteristics of interventions used in included trials *(Continued)*

				1500 shocks at 120 impulses/minute of 0.32 mJ/mm² with participant insulated from shock waves		
Haake 2002	Adapted shock wave generator Storz Minilith SL-1 (Storz Medical AG, CH 8280 Kreuzlingen, Switzerland)	ESWT	At site of calcification: 2000 impulses of a positive EFD 0.35 mJ/mm² measured with a membrane hydrophone (equivalent to 0.78 mJ/mm² measured with a fibreoptic hydrophone) at 120 impulses/minute	Supraspinatus site: 2000 impulses of a positive EFD 0.35 mJ/mm² measured with a membrane hydrophone (equivalent to 0.78 mJ/mm² measured with a fibreoptic hydrophone) at 120 impulses/minute	15 mL mepivacaine 1% subacromially	2 sessions 7 days apart
Hearnden 2009	Not reported	ESWT	Shock wave: 2000 shocks of 0.28 mJ/mm²	Placebo: 20 shocks of 0.03 mJ/mm²	20 mL of 0.5% marcaine at site of calcific deposit	1 session
Hsu 2008	OrthoWave machine (MTS, Konstanz, Germany)	ESWT	Shock wave: 1000 shocks at 2 wave pulses/second of 0.55 mJ/mm²	Placebo: dummy electrode	10 mL of 2% lidocaine injected into affected area from a lateral approach with a 24-gauge needle	2 sessions 14 days apart
Ioppolo 2012	ESWT (Modulith SLK system, Storz Medical, Tagerwilen, Switzerland) equipped with an in-line ultrasound positioning system on the target zone	ESWT	Low dose: 2400 impulses at 0.10 mJ/mm²	High dose: 2400 impulses at 0.20 mJ/mm²	None	4 sessions 7 days apart
Kim 2014	Not reported	ESWT	Shock wave: 1000 impulses, 0.32 mJ/mm²	Glucocorticoid needling 1 mL Depo-Medrol (glucocorticoid) ultrasound guidance	2% lidocaine in the corticosteroid group	3 sessions 1 week apart for ESWT OR 1 steroid injection
Kolk 2013	Swiss DolorClast radial shock wave device (EMS Electro Medical Systems, Nyon, Switzerland)	rESWT	Shock wave: 2000 impulses of 0.11 mJ/mm²	Placebo: 2000 impulses of 0.11 mJ/mm² with a sham probe	None	3 sessions 10–14 days apart

Table 1. Characteristics of interventions used in included trials *(Continued)*

Kvalvaag 2017	EMS Swiss Dolor-Clast/Enimed	rESWT	Shock wave: 2000 impulses at 0.35 mJ/mm^2 pressure 1.5–3 bar, depending on what the participant tolerated	Placebo: 2000 impulses at 0.35 mJ/mm^2 with a sham probe	None	1 session weekly for 4 weeks
Li 2017	Pain Treatment System of Radial shock wave Device (Sonothera, Hanil Tm Co. Ltd, Korea)	ESWT	Shock wave: 3000 pulses of 0.11 mJ/mm^2 at frequency 15 Hz. Pressure 3 bar	Placebo: identical-looking placebo probe used	None	5 sessions, 3 days apart
Loew 1999	Electrohydraulic lithotripter (MFL 5000; Philips, Hamburg, Germany)	ESWT	Group 1: 1 dose of 2000 impulses of 0.1 mJ/mm^2 Group 2: 1 dose of 2000 impulses of 0.3 mJ/mm^2 Group 3: 2 doses of 2000 impulses of 0.3 mJ/mm^2 1 week apart	No treatment	15–20 mL bupivacaine hydrochloride	1 session OR 2 sessions 1 week apart
Melegati 2000	Epos Ultra electromagnetic apparatus fitted with a 7.5 MHz linear echographic sound	ESWT	200 shots of 0.22 mJ/mm^2 reached in 400 shots	Kinesitherapy	None	3 sessions 7 days apart for ESWT OR 6 × 40-minute sessions 3 weeks apart for kinesitherapy
Pan 2003	Orthospec (Medispec Ltd, Germantown, MD, USA)	ESWT	2000 shock waves at 2 Hz of 0.26–0.32 mJ/mm^2	TENS	None	2 sessions 14 days apart for ESWT OR 3 times a week for 4 weeks for TENS
Perlick 2003	Siemens Lithostar-Lithotripter	ESWT	2000 impulses of 0.23 mJ/mm^2	2000 impulses of 0.42 mJ/mm^2	10 mL bupivacaine hydrochloride 0.5%	2 sessions 3 weeks apart
Peters 2004	The miniaturised shock wave source Minilith (15 cm diameter, 15 cm length) (Stroz Medical, Switzerland)	ESWT	1500 impulses of 0.15 mJ/mm^2	1500 impulses of 0.44 mJ/mm^2 OR system turned off	None	1–5 sessions at 6-week intervals

Table 1. Characteristics of interventions used in included trials *(Continued)*

	with an in-line ultrasound device					
Pleiner 2004	Electrohydraulic system (Orthospec, Medispec Inc, Montgomery Village, MD, USA)	ESWT	High dose: 2 × 2000 impulses at frequency 2.5 Hz, dose 0.28 mJ/mm²	Placebo 2 × 2000 impulses at frequency 2.5 Hz, dose < 0.07 mJ/mm² dampened with a foam membrane	None	2 sessions
Rompe 1998	ESWT with an experimental device characterised by the integration of an electromagnetic shock wave generator and a mobile fluoroscopy unit (Siemens AG, 91052 Erlangen, Germany)	ESWT	1500 impulses of 0.06 mJ/mm²	1500 impulses of 0.28 mJ/mm²	None	1 session
Sabeti 2007	Lithotripter (Storz Modulith SLK, Storz Medical Products, Kreuzlingen, Switzerland)	ESWT	1000 impulses of 0.08 mJ/mm²	2000 impulses of 0.02 mJ/mm²	5 mL Xyloneural subacromially	3 sessions 7 days apart for low dose OR 2 sessions 7 days apart for higher dose
Sabeti-Aschraf 2005	Lithotripter (Modulith SLK, Storz Medical Products, Kreuzlingen, Switzerland)	ESWT	1000 impulses of 0.08 mJ/mm² with frequency 4 Hz	1000 impulses of 0.08 mJ/mm² with frequency 4 Hz	None	3 sessions 7 days apart
Schmitt 2001	Storz Minilith SL 1 (Storz Medical AG, Kreuzlingen, Switzerland)	ESWT	2000 impulses at 120 impulses/minute of 0.11 mJ/mm²	2000 impulses at 120 impulses/minute of 0.11 mJ/mm² with the participant insulated from the shock waves	10 mL mepivacaine subacromially	3 sessions 7 days apart
Schofer 2009	Minilith SL 1 shock wave generator (Storz Medical, Switzerland)	ESWT	2000 impulses at 120 impulses/second of 0.33 mJ/mm²	2000 impulses at 120 impulses/second of 0.78 mJ/mm²	10 mL mepivacaine 1% subacromially	3 sessions 7 days apart
Speed 2002	Sonocur Plus Unit (Siemens, Munich, Germany)	ESWT	1500 impulses of 0.12 mJ/mm²	1500 impulses of 0.04 mJ/mm² with the machine head deflated, no contact gel applied and	None	3 sessions 1 month apart

Table 1. Characteristics of interventions used in included trials *(Continued)*

				standard skin contact avoided		
Tornese 2011	Electromagnetic lithotriptor (Epos Ultra; Dornier MedTech Wessling, Germany) fitted with a linear ultrasonographic probe	ESWT	1800 pulses of up to 0.22 mJ/mm² which was reached within 400 impulses	1800 pulses of up to 0.22 mJ/mm² which was reached within 400 impulses	None	3 sessions 7 days apart

EFD: energy fluctuation density; ESWT: extracorporeal shock wave therapy; rESWT: radial extracorporeal shock wave therapy; ROM: range of movement; TENS: transcutaneous electrical nerve stimulation.

Table 2. Shock wave therapy versus placebo secondary outcomes

Outcome	Number of studies	Number of participants: shock wave	Number of participants: placebo	Statistic random-effects Mantel-Haenszel	Effect estimate (95% CI)
Proportion achieving pain score below 30/100 mm on VAS	0	Not reported	Not reported	Not reported	Not reported
Range of movement	0	Not reported	Not reported	Not reported	Not reported
Mean change in calcification width (mm) at 3 months	1	46	42	Mean difference (95% CI)	−26.00 (−85.77 to 33.77)
Proportion with complete calcification resolution	3	91	68	Risk ratio (95% CI)	4.78 (1.31 to 17.39)
Proportion with partial calcification partial resolution	3	91	68	Risk ratio (95% CI)	3.41 (0.95 to 12.23)

CI: confidence interval; VAS: Visual Analogue Scale.

Table 3. Outcome Reporting Bias In Trials (ORBIT) matrix

Study ID	Major outcomes						
	Participant-reported pain relief ≥ 50%	Pain	Function or disability	Treatment success	Quality of life	Withdrawal due to adverse events	Adverse events
Albert 2007	?	Full	Full	Full	?	?	Full
Cacchio 2006	?	Full	Full	Full	?	Full	Full
Cosentino 2003	?	Partial	Full	?	?	?	Full
De Boer 2017	?	Full	Full	Full	?	?	Full
Del Castillo-Gonzales 2016	?	Full	?	Full	?	?	Full
Duymaz 2019	?	Full	Full	?	?	?	?
Engebretsen 2009	?	Full	Full	?	?	Full	Full
Farr 2011	?	Full	Full	?	?	?	Full
Frizziero 2017	?	Partial	Full	?	?	?	?
Galasso 2012	?	Full	Full	Full	?	Full	Full
Gerdesmeyer 2003	?	Full	Full	Full	?	?	Full
Haake 2002	?	Full	Full	Full	?	?	Full
Hearnden 2009	?	Partial	Partial	Full	?	?	Partial
Hsu 2008	?	Full	Full	Full	?	?	Full
Ioppolo 2012	?	Full	Full	?	?	?	?
Kim 2014	?	Partial	Partial	?	?	?	?

Table 3. Outcome Reporting Bias In Trials (ORBIT) matrix *(Continued)*

Kolk 2013	?	Full	Full	?	?	?	?
Kvalvaag 2017	?	Full	Full	?	?	Full	Partial
Li 2017	?	Full	Full	?	?	?	Full
Loew 1999	?	Not measured	Full	Full	?	?	?
Melegati 2000	?	Not measured	Full	?	?	?	?
Pan 2003	?	Full	Full	?	?	Full	Full
Perlick 2003	?	Full	Partial	?	?	?	Full
Peters 2004	?	?	?	Full	?	Full	Full
Pleiner 2004	?	Full	Measured	?	?	?	?
Rompe 1998	?	Not measured	Partial	Full	?	?	?
Sabeti 2007	?	Full	Full	Full	?	?	?
Sabeti-Aschraf 2005	?	Full	Full	?	?	?	Full
Schmitt 2001	?	Full	Full	Full	?	Full	Full
Schofer 2009	?	Full	Full	?	?	?	Full
Speed 2002	Full	Partial	Full	Full	?	Full	Full
Tornese 2011	?	Full	Full	?	?	?	?

'Full': sufficient data for inclusion in a meta-analysis was reported (e.g. mean, standard deviation and sample size per group for continuous outcomes).
'Partial': insufficient data for inclusion in a meta-analysis was reported (e.g. means only, with no measures of variance).
'Measured': outcome was measured but no outcome data was reported.
'Not measured': outcome was not measured by the trialists.
'?': unclear whether the outcome was measured or not (as a trial protocol was unavailable).

APPENDICES

Appendix 1. Cochrane Central Register of Controlled Trials (CENTRAL, via the Cochrane library) search strategy

#1 shoulder (7054)

#2 MeSH descriptor: [Rotator Cuff] explode all trees (382)

#3 #1 or #2 (7127)

#4 MeSH descriptor: [Calcium] this term only (3250)

#5 MeSH descriptor: [Bursitis] explode all trees (248)

#6 #4 or #5 (3498)

#7 #3 and #6 (185)

#8 MeSH descriptor: [Shoulder Pain] this term only (637)

#9 MeSH descriptor: [Shoulder Impingement Syndrome] this term only (232)

#10 MeSH descriptor: [Rotator Cuff Injuries] this term only (201)

#11 rotator cuff:ti,ab or supraspinatus:ti,ab or infraspinatus:ti,ab or subscapular*:ti,ab or teres:ti,ab (1131)

#12 ((shoulder*:ti,ab or subacromial:ti,ab or rotator cuff:ti,ab) near/5 (tendon*:ti,ab or tendin*:ti,ab or bursitis:ti,ab or calcium:ti,ab or calcif*:ti,ab or impinge*:ti,ab or tear*:ti,ab or pain:ti,ab)) (2488)

#13 #7 or #8 or #9 or #10 or #11 or #12 (3184)

#14 shockwave or shock wave (1587)

#15 MeSH descriptor: [Radiation, Nonionizing] explode all trees (2866)

#16 hesw (4)

#17 extracorporeal shock (1135)

#18 radial shock (133)

#19 #14 or #15 or #16 or #17 or #18 (4451)

#20 #13 and #19 (114)

Appendix 2. MEDLINE (Ovid) search strategy

1 Shoulder/ (11707)

2 rotator cuff/ (5569)

3 1 or 2 (16726)

4 calcium/ (257945)

5 3 and 4 (21)

6 shoulder pain/ (4123)

7 Shoulder Impingement Syndrome/ (1590)

8 rotator cuff injuries/ (4607)

9 (rotator cuff or supraspinatus or infraspinatus or subscapular$ or teres).tw. (13379)

10 ((shoulder$ or subacromial or rotator cuff) adj5 (tendon$ or tendin$ or calcium or calcif$ or impinge$ or tear$ or pain)).tw. (12875)

11 or/5-10 (22171)

12 exp Radiation, Nonionizing/ (258404)

13 (shockwave$ or shock wave$).tw. (8449)

14 hesw.tw. (69)

15 ((extracorporeal or radial) adj shock$).tw. (5340)

16 or/12-15 (265915)

17 11 and 16 (203)

18 randomized controlled trial.pt. (461808)

19 controlled clinical trial.pt. (92422)

20 randomized.ab. (361584)

21 placebo.ab. (173004)

22 drug therapy.fs. (2023031)

23 randomly.ab. (250488)

24 trial.ab. (374968)

25 groups.ab. (1564818)

26 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 (3900446)

27 exp animals/ not humans.sh. (4463900)

28 26 not 27 (3328315)

29 17 and 28 (96)

30 limit 29 to ed=19740101-20180503 (96)

Appendix 3. Embase (Ovid) search strategy

1 shoulder/ (30686)

2 rotator cuff/ (5460)

3 1 or 2 (34156)

4 calcium/ (275714)

5 3 and 4 (171)

6 shoulder pain/ (13982)

7 shoulder impingement syndrome/ (2452)

8 rotator cuff injury/ (1836)

9 rotator cuff rupture/ (5831)

10 (rotator cuff or supraspinatus or infraspinatus or subscapular$ or teres).tw. (18794)

11 ((shoulder$ or subacromial or rotator cuff) adj5 (tendon$ or tendin$ or calcium or calcif$ or impinge$ or tear$ or pain)).tw. (19790)

12 or/5-11 (37690)

13 exp radiation/ (556038)

14 (shockwave$ or shock wave$).tw. (13099)

15 hesw.tw. (73)

16 ((extracorporeal or radial) adj shock$).tw. (7611)

17 or/13-16 (567797)

18 12 and 17 (849)

19 random$.tw. (1312577)

20 factorial$.tw. (33026)

21 crossover$.tw. (66509)

22 cross over.tw. (29264)

23 cross-over.tw. (29264)

24 placebo$.tw. (275824)

25 (doubl$ adj blind$).tw. (190416)

26 (singl$ adj blind$).tw. (21300)

27 assign$.tw. (340342)

28 allocat$.tw. (128622)

29 volunteer$.tw. (233888)

30 crossover procedure/ (55878)

31 double blind procedure/ (151040)

32 randomized controlled trial/ (506798)

33 single blind procedure/ (31640)

34 or/19-23 (1378960)

35 18 and 34 (155)

36 limit 35 to em=197401-201818 (154)

Appendix 4. ClinicalTrials.gov search strategy

Database: clinicaltrials.gov/ 3 May 2018

Search strategy: Shock wave AND shoulder (6)

Appendix 5. WHO International Clinical Trials Registry Platform (ICTRP)

Database: apps.who.int/trialsearch/default.aspx 3 May 2018

Search strategy: Shock wave AND shoulder (16)

WHAT'S NEW

Date	Event	Description
30 July 2014	Amended	CMSG ID C173-R

HISTORY

Protocol first published: Issue 1, 2011
Review first published: Issue 3, 2020

Date	Event	Description
14 November 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

RB, RJ and a previous author, Juliana Roos (JR) drafted the protocol (Buchbinder 2011).

SJS and JD were responsible for performing the searches, selecting trials, performing risk of bias assessment, data extraction, analysing the data and interpreting the results of the review, and writing the first draft of the review.

RJ and RB were responsible for checking the quality of the review, performing the risk of bias assessment, performing the GRADE assessment and 'Summary of findings' tables, interpretation of results and editing of the final manuscript.

DECLARATIONS OF INTEREST

RB has authored two randomised controlled trials; one of ESWT for heel pain and one for lateral elbow pain (Buchbinder 2002; Staples 2008), as well as a Cochrane systematic review of ESWT for lateral elbow pain (Buchbinder 2005). RB has received royalties from Wolters Kluwer Health for writing a chapter on plantar fasciitis in UpToDate. She is also the Co-ordinating Editor of Cochrane Musculoskeletal, but is not involved in editorial decisions regarding this review. She is a recipient of a National Health and Medical Research Council (NHMRC) Cochrane Collaboration Round 7 Funding Program Grant, which supports the activities of Cochrane Musculoskeletal - Australia and Cochrane Australia, but the funders do not participate in the conduct of reviews.

JD has been employed by Alfred Health from January 2016 to present as a Hospital Medical Officer (HMO).

RJ is the Managing Editor of Cochrane Musculoskeletal, but is not involved in editorial decisions regarding this review. She is a recipient of an NHMRC (Australia) Cochrane Collaboration Round 7 Funding Program Grant, which supports the Cochrane Musculoskeletal Australian Editorial base, but the funders do not participate in the conduct of this review.

SJS: none known.

SOURCES OF SUPPORT

Internal sources

- Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Australia.

  In kind support
- Cabrini Institute, Cabrini Hospital, Malvern, Victoria, Australia.

  In kind support

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We changed the major outcomes to be included in the summary of findings tables after publication of the protocol, from six (participant-reported pain relief of 30% or greater; mean pain score, or mean change in pain score on VAS or NRS; disability or function (various scales); composite endpoints measuring 'success' of treatment such as participants feeling no further symptoms; participant withdrawals due to adverse events; number of participants experiencing any adverse event) to seven, by the addition of quality of life. As no studies reported the outcome "pain relief of 30% or greater" we instead used the outcome "Pain relief of 50% or greater", as one study reported the latter.

We specified three months as our main time point as it was thought clinically likely to allow enough time for a treatment effect to occur.

We specified sham as our main comparator (i.e. presented in 'Summary of findings' table) as it was most likely to demonstrate a treatment benefit independent of a placebo effect (e.g. if comparing to a no-treatment control).

We specified that we would perform a subgroup analysis comparing people aged older than 65 years with those aged 65 years or younger, but as there was no identifiable rationale for this analysis we did not perform this analysis.

We specified, post hoc, that we would perform sensitivity analyses on the presence of adequate allocation concealment and participant blinding to assess the possible effects of selection and detection biases on pain and function and assessed the effect of including trials with a unit of analysis issue due to bilateral treatment in some participants in a sensitivity analysis.

The text word "Radiofrequency" was removed from the search strategy, as it was made redundant by the broader search term "Radiation, non-ionizing" and no relevant studies were lost upon its removal.

INDEX TERMS

Medical Subject Headings (MeSH)

*Rotator Cuff; Calcinosis [*therapy]; Exercise Therapy; Extracorporeal Shockwave Therapy [adverse effects] [*methods]; Glucocorticoids [administration & dosage]; Hyaluronic Acid [administration & dosage]; Muscular Diseases [*therapy]; Patient Dropouts [statistics & numerical data]; Randomized Controlled Trials as Topic; Shoulder Pain [therapy]; Transcutaneous Electric Nerve Stimulation; Viscosupplements [administration & dosage]

MeSH check words

Humans; Middle Aged