High-Energy Extracorporeal Shock-Wave Therapy for Treating Chronic Calcific Tendinitis of the Shoulder

A Systematic Review

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Background: Calcific and noncalcific tendinitis of the shoulder can be unresponsive to conventional therapies. Extracorporeal shock-wave therapy (ESWT) has been suggested as an alternative treatment.

Purpose: To assess the efficacy of ESWT in patients with calcific and noncalcific tendinitis.

Data Sources: MEDLINE, Cochrane Central Register of Controlled Trials, EMBASE, Web of Science, and Google Scholar were searched up to 1 November 2013.

Study Selection: Randomized, controlled trials (RCTs) comparing high-energy versus low-energy ESWT or placebo for treatment of calcific or noncalcific tendinitis of the shoulder. Outcome measures included pain (visual analogue scale score), functional assessment (Constant–Murley score), and resolution of calcifications.

Data Extraction: Three independent reviewers abstracted data and determined eligibility and quality by consensus.

Data Synthesis: Twenty-eight RCTs met the inclusion criteria. Studies were heterogeneous. Twenty RCTs compared ESWT energy levels and placebo and consistently showed that high-energy ESWT was significantly better than placebo in decreasing pain and improving function and resorption of calcifications in calcific tendinitis. No significant difference was found between ESWT and placebo in treatment of noncalcific tendinitis.

Limitation: The number of RCTs was small, and the studies were heterogeneous.

Conclusion: High-energy ESWT is effective for improving pain and shoulder function in chronic calcific shoulder tendinitis and can result in complete resolution of calcifications. This therapy may be underutilized for a condition that can be difficult to manage.

Primary Funding Source: None.

Ann Intern Med. 2014;160:542-549. www.annals.org
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Rotator cuff tendinitis is one of the most common causes of shoulder pain. The term *noncalcific tendinitis* refers to rotator cuff tendinitis without calcium deposits. The term *calcific tendinitis* indicates the presence of calcium deposits in the rotator cuff tendons, most commonly in the supraspinatus tendon near its insertion site (1).

The prevalence of calcium deposits has been reported as 2% to 20% of asymptomatic shoulders, 6.8% of patients with shoulder pain, and up to 17% of patients with chronic periarthritis (2–4). The calcifications are most commonly classified into 3 types, according to the Gärtner criteria; type 3 is characterized by the highest frequency of spontaneous resorption (5). Although calcium deposits cannot be readily identified by history or clinical examination, they may be identified by plain radiography or sonography, with ultrasonography being somewhat more sensitive (6, 7). Magnetic resonance imaging is not needed to diagnose calcific tendinitis.

Conventional therapies used in general practice include rest, ice, nonsteroidal anti-inflammatory drugs, physical therapy, and subacromial corticosteroid injections, although strong evidence to support the efficacy of any of these treatment modalities is lacking (3, 8). Treatment-resistant cases, which are more common with calcific tendinitis, may require surgery, such as arthroscopic debridement of calcifications or subacromial decompression (1).

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Extracorporeal shock-wave therapy (ESWT) has been suggested as an alternative treatment for refractory shoulder pain due to calcific or noncalcific tendinitis and may be an alternative to expensive and risky surgical interventions. This modality uses sound waves of high or low energy that impart rapid fluctuations of pressure to tissues. The degree of energy imparted to the tissues is measured as energy flux density (EFD). There are many manufacturers of ESWT devices. Shock waves are delivered transcutaneously in an office setting with or without local anesthesia for 10 to 30 minutes.

The use of ESWT has gained popularity in many countries worldwide for treating numerous musculoskeletal disorders (9, 10), although it is less common in the United States. Initially used for lithotripsy to treat nephrolithiasis, the application of shock waves to soft-tissue structures has demonstrated promising results in treating such conditions as tendinitis, plantar fasciitis, nonunion long-bone fractures, and avascular necrosis of the femoral head (9–11). In the United States, ESWT devices have been approved by the U.S. Food and Drug Administration for the treatment of lateral epicondylitis and plantar fasciitis refractory to conventional conservative therapies (9–13).

Although ESWT may provide a nonsurgical alternative to treating multiple soft-tissue conditions, its appropri-

ate use, dosage, and efficacy are still uncertain. Many randomized, controlled trials (RCTs) examining the effects of ESWT on calcific and noncalcific tendinitis showed disparate results regarding resolution of pain and effect on shoulder mobility.

To provide evidence-based conclusions about the efficacy of ESWT for calcific and noncalcific tendinitis of the shoulder, we aimed to address the following key questions.

1. In patients with rotator cuff tendinitis, what are the benefits and harms of ESWT compared with placebo?

2. In patients with rotator cuff tendinitis, what are the benefits and harms of different energy levels of ESWT?

3. How do outcomes differ among subgroups of patients with calcific versus noncalcific tendinitis treated with ESWT?

4. In patients with rotator cuff tendinitis, what are the benefits and harms of ESWT compared with other treatment modalities?

METHODS

Data Sources and Searches

We searched MEDLINE, the Cochrane Central Register of Controlled Trials, EMBASE, Web of Science, and Google Scholar from inception to 1 November 2013 by using the following search terms: *shoulder joint, shoulder pain, tendinitis, tendonitis, tendinosis, tendinopathy, calcific tendinitis, calcinosis, bursitis, extracorporeal shock wave therapy, extracorporeal shock-wave therapy, extracorporeal shock-wave therapy,* and *lithotripsy*. We also hand-searched review articles, manuscripts, and medical journal supplements for additional references. We placed no restrictions on language and translated relevant non–English-language articles.

Study Selection

Three independent reviewers screened abstracts and the full text of articles and determined eligibility by consensus. We included all RCTs in humans that studied treatment of calcific or noncalcific tendinitis of the shoulder and compared different energy levels of ESWT against each other or placebo or weighed ESWT against other treatments. We included studies that reported clinical, radiologic, or sonographic outcomes. Outcomes of interest included shoulder pain and function measurements and evaluation of calcification resolution (for calcific tendinitis trials only). We excluded nonrandomized comparative studies, single-cohort studies, and case reports.

Data Extraction and Quality Assessment

After an a priori training exercise, 3 reviewers independently evaluated the included trials and recorded data on a standardized form. Data on participants' demographic characteristics, treatment characteristics, outcomes, adverse events, and study design were obtained. We also recorded information on study quality indicators, including randomization, allocation concealment, blinding, and intention-to-treat analysis and assessed the risk of bias (14).

Energy Levels

Shock-wave therapy is usually classified as high, medium, or low energy, according to the EFD administered. Although there is no consensus on the threshold values, a commonly used grouping defines EFD less than 0.08 mJ/mm^2 as low energy, 0.08 to less than 0.28 mJ/mm^2 as medium energy, and 0.28 mJ/mm^2 to 0.6 mJ/mm^2 as high energy (15–17). Once a given EFD is selected, it is applied in pulses to the affected area. The number of pulses per dose typically ranges from 1000 to 3000, and several doses may be given in a course of treatment.

The EFD applied to patients varied among the trials in our study. Owing to a paucity of studies comparing different energy levels with each other or with placebo, we categorized the trials as high-energy ESWT (EFD $\geq$0.28 mJ/mm^2) or low-energy ESWT (EFD $<$0.28 mJ/mm^2).

Outcome Measurements

The included trials evaluated pain predominantly by using a visual analogue scale pain score: a grading tool for subjective measurement of pain, typically ranging from 0 or 1 (no pain) to 10 (worst pain). Shoulder function was most frequently evaluated by using the Constant score (or Constant–Murley score), a standardized tool that assesses clinical shoulder function by using a 100-point scale (on which 0 is the worst score) to evaluate subjective and objective variables (18). The subjective variables evaluate perception of pain and ability to perform normal tasks of daily living, and the objective variables assess the active range of motion and shoulder power (18). Other reported shoulder function measurement instruments were range of motion, the Shoulder Pain and Disability Index, and the function subscale of the UCLA Shoulder Rating Scale. Resolution of calcification resolution was evaluated only in calcific tendinitis trials and was measured radiographically or sonographically.

Role of the Funding Source

The study did not receive external funding.

RESULTS

Trial Selection

Our literature search yielded 376 articles (**Appendix Figure**, available at www.annals.org). After we screened the titles and abstracts and removed duplicates, 38 articles were considered potentially relevant. Seven articles were excluded after full-text review because they described 6 nonrandomized comparative studies and thus did not meet our inclusion criteria (19–25). In total, we included 28 RCTs that reported results in 31 publications. Of the 28 RCTs used in our analysis, 20 compared different ESWT energy levels with placebo (26–45) and 8 (in 11 publications) compared ESWT with other treatment modalities (46–56).

Trial Characteristics

Appendix Tables 1 and **2** (available at www.annals.org) show the characteristics of the included trials. Overall, there were 1745 participants, with a mean age of 51 years (range, 47 to 56 years), and the average proportion of women was 58% (range, 39% to 76%). The minimum duration of symptoms ranged from 3 to 12 months. Except for 2 trials from Taiwan (37, 51), all studies were conducted in Europe. Among trials that compared different ESWT energy levels with placebo, 16 (in 15 publications) evaluated calcific tendinitis (26–40), and 4 (in 5 publications) evaluated noncalcific tendinitis (41–45).

Quality of Included Trials

The quality of trials varied in several respects and was generally low (**Appendix Tables 3** and **4**, available at www.annals.org). All trials reported a parallel-group design. The sample sizes ranged from 20 to 144 participants. Trial duration ranged from 3 to 12 months. Only 6 trials were double-blinded; the rest were either single-blinded (15 trials) or did not report blinding (7 trials). Withdrawal rates ranged from 0% to 33%, with 3 trials reporting a withdrawal rate of more than 20% (27, 29, 30). Intention-to-treat analysis was reported in 14 trials. No trial reported only on resolution of calcifications without accompanying clinical outcomes.

Possible Sources of Heterogeneity and Bias

The trials had numerous sources of heterogeneity and bias, precluding formal meta-analysis. Diverse ESWT regimens and devices were used. Overall, 14 ESWT devices were used in the 28 trials, with the Modulith SLK (Storz Medical, Tägerwilen, Switzerland) and Minilith SL1 (Storz Medical) reported most frequently. The EFD varied from 0.06 mJ/mm^2 to 0.55 mJ/mm^2; the number of pulses from 1000 to 3000; and the number of sessions from 1 to 5, with intervals between administered shock waves ranging from 1 to 6 weeks.

In 13 studies, ESWT was preceded by local anesthesia (26, 27, 31, 36–39, 41, 42, 44, 45, 52, 54); intravenous analgesia was administered in 2 studies (28, 30); and in 1 study an anesthetic patch was applied (35). Rescue oral analgesics, such as acetaminophen or various nonsteroidal anti-inflammatory drugs, were prescribed in 6 trials (30, 32, 35, 39, 40, 45). Only 1 study reported industry sponsorship (45).

Calcific Tendinitis Trials

High- and Low-Energy ESWT Versus Placebo

Seven calcific tendinitis trials evaluated ESWT versus placebo (20, 27, 30, 32, 34, 37, 38) (**Appendix Table 1**). All 7 trials reported on pain and function; 5 trials reported on resolution of calcification.

Compared with placebo, high-energy ESWT seemed to improve shoulder pain, function, and calcifications, whereas low-energy ESWT seemed to improve only function. In all studies, ESWT reduced shoulder pain or improved function significantly better than placebo (**Figure 1**). High-energy ESWT was statistically significantly better than placebo for both pain and function. The results for low-energy ESWT favored ESWT only for function, whereas results for pain were inconclusive. The reduction in calcification was significantly greater after high-energy ESWT than after placebo treatment (20, 27, 30, 32, 34); results for low-energy ESWT were inconclusive.

High-Energy Versus Low-Energy ESWT

Eight calcific tendinitis trials compared high-energy ESWT with low-energy ESWT (26, 27, 30–33, 35, 39) (**Figure 2**). Five of the trials reported on pain (27, 30, 32, 33, 39), and all 8 reported on function and resolution of calcifications. For pain outcomes, the available studies did not demonstrate superiority of high-energy over low-energy ESWT. However, high-energy ESWT improved shoulder function significantly more than low-energy ESWT (26, 30, 33, 35). High-energy ESWT seemed to be more efficient than low-energy ESWT in resolving shoulder calcium deposits. Of note, there was a trend toward a relative benefit of high-energy over low-energy ESWT for pain, but the fewer number of trials limited the power of this analysis.

Noncalcific Tendinitis Trials

Evidence suggesting a benefit of ESWT in noncalcific tendinitis was inconclusive. Three trials compared low-energy ESWT with placebo (41, 43, 45) (**Appendix Table 1**). Only 1 trial showed a significant improvement with ESWT (45), whereas 2 found no difference in pain and functional outcomes (41, 43) (**Figure 1**).

Only 1 trial of noncalcific tendinitis compared high- versus low-energy ESWT (44). It showed no difference between the groups with respect to pain or functional outcomes (**Figure 2**).

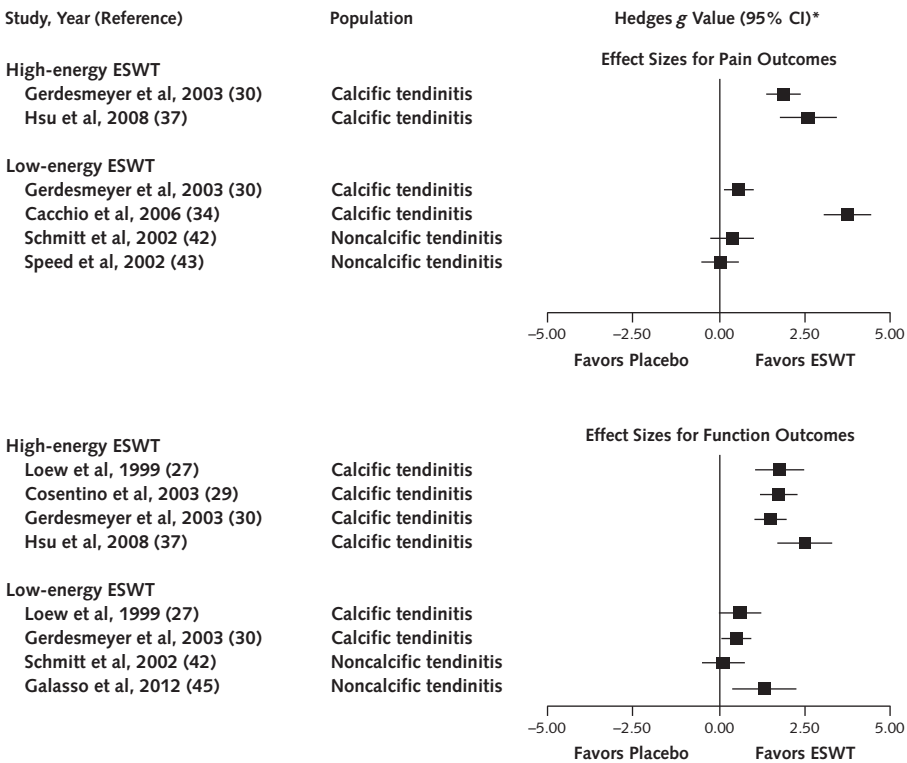
Comparison of ESWT Regimens in EFD Categories

Three studies compared low-energy ESWT regimens (EFD $<$0.28 mJ/mm^2) (28, 36, 40), and 1 compared 1 versus 2 doses of high-energy ESWT (27). Consistent with the other trials, these showed benefits of high-energy, but not low-energy, ESWT in terms of shoulder pain and function (40) and suggested that the effect is dose-dependent (27, 28, 36).

ESWT Versus Other Treatment Modalities

We found very few comparisons of ESWT with other treatment modalities in the literature (**Appendix Table 2**). Extracorporeal shock-wave therapy seemed to be as effective as exercise or radiation therapy and more effective than transcutaneous electric nerve stimulation (46–51). Limited evidence indicated that the results of ESWT in treating calcific tendinitis could be enhanced by the addition of needling (52), fluoroscopic focusing of the shock waves on calcium deposits (53–55), and placing the shoulder in the hyperextended internal rotation position (56).

Figure 1. **Effect sizes for pain and function in trials comparing ESWT with placebo.**



ESWT = extracorporeal shock-wave therapy.
* The Hedges *g* value is the standardized mean difference corrected for small sample sizes.

Safety

Most studies reported on adverse events (**Table** and **Appendix Table 5** [available at www.annals.org]). The most commonly reported adverse events related to ESWT were petechiae, small bruises and hematomas, local erythema, and acute pain. Patients who received high- or medium-energy ESWT reported more adverse events than those who received low-energy ESWT or placebo. No serious adverse events occurred in any of the included studies.

DISCUSSION

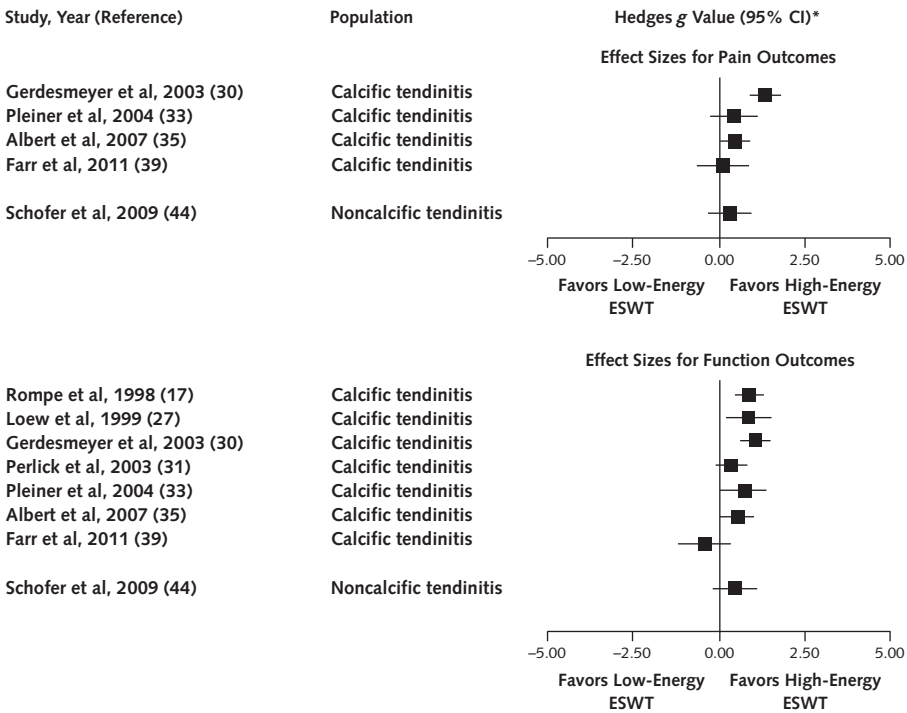
Our systematic review showed that high-energy ESWT (EFD $\geq$0.28 mJ/mm^2) was effective for the treatment of calcific tendinitis of the shoulder in terms of reducing pain, improving function, and inducing resorption of calcifications. We also found that although lower-energy ESWT (EFD $<$0.28 mJ/mm^2) was not as effective as high-energy ESWT, it did improve shoulder function in patients with calcific tendinitis. Conversely, ESWT did not seem to be effective in treating noncalcific tendinitis, regardless of energy dose.

The methodological quality of most of the included studies was low, indicating a high risk of bias. Only 6 trials reported proper double-blinding, and only 3 trials could be considered high-quality RCTs (30, 34, 40). The findings from only the higher-quality RCTs or from the trials reporting proper double-blinding did not alter the conclusions of our review.

The reviewed evidence suggested that ESWT was a safe treatment. Adverse effects of ESWT were dose-dependent and generally limited to a temporary increase in pain and local reactions, such as swelling, erythema, and petechiae or small hematomas; no serious adverse events were reported. To decrease pain during and immediately after the treatment, local anesthesia or oral analgesia was used in many studies; intravenous analgesia was used in 2 studies (28, 30). In separate analyses, the use of or type of analgesia changed neither outcomes nor our conclusions.

The safety and efficacy of ESWT, coupled with its noninvasiveness, may offer an alternative to surgery. A nonrandomized study not included in our review compared ESWT with surgery (24). It reported equivalence of high-energy ESWT and surgery in patients with nonhomogenous calcium deposits, although surgery seemed to be superior to ESWT for homogenous deposits. Further studies are required to better understand the relative efficacy of these treatments and outline patient subsets for which ESWT might be as effective as surgery and thus preferable, owing to its noninvasive nature.

Figure 2. **Effect sizes for pain and function in trials comparing high-energy ESWT with low-energy ESWT.**



ESWT = extracorporeal shock-wave therapy.
* The Hedges *g* value is the standardized mean difference corrected for small sample sizes.

The exact biological effect of shock waves on soft tissues is unknown. Neovascularization, tissue regeneration, and hyperstimulation analgesia are some of the proposed mechanisms suspected to play a role in tissue healing; they are theorized to occur as the consequences of a complex cascade of molecular events induced by direct tissue trauma from shock waves (9–11). Shock waves have been suggested to cause fragmentation and cavitation within calcifications, leading to disorganization and disintegration of the deposits into the adjacent subacromial bursa and resorption by local inflammatory response (57).

Numerous prospective case series, cohort studies, and clinical trials have examined the efficacy of ESWT in shoulder tendinitis. Several reviews summarizing this evidence have been published (8, 58–61). These reviews attempted to address overly broad research questions and included case series and cohort studies along with RCTs (58). They were also focused toward a small subset of clinicians who were already using or might be willing to consider this procedure. Our systematic review answers a more structured research question, synthesizing evidence from only RCTs in both calcific and noncalcific tendinitis and tries to introduce this treatment to a broader audience.

A meta-analysis published in 2009 evaluating only calcific tendinitis trials concluded that ESWT was effective and that the effect was dose-dependent, with high-energy interventions providing better results than low-energy (62). A recent meta-analysis of 4 calcific tendinitis trials reported reduction in pain and improvement in shoulder function and calcification resorption (63). The results of our research corroborated these earlier findings.

We encountered numerous challenges in summarizing and interpreting this body of evidence, and our study has limitations. First, the treatment application differed greatly among the studies. The EFD, number of pulses, number of sessions, and intervals between administered shock waves varied widely. Different shock-wave devices were also used. The heterogeneous nature of the included trials and general paucity of similar trials were the main reasons that we could not perform a meta-analysis of these studies.

Second, the trials were small and far too heterogeneous to reasonably estimate the rates of calcification resorption. It was also unclear whether resorption resulted in improved clinical prognosis. In most trials, patients in the placebo group showed no resolution of calcification, whereas 21% to 100% of patients who received ESWT had complete resorption. Of note, 2 trials reported calcification resolution among placebo recipients (27, 30). This may be explained by possible differences in patient populations in these studies. For example, if a relatively greater proportion of patients with type 2 versus type 1 calcifications according to the Gärtner classification were included, the probability of spontaneous resorption of calcifications in the

control group would be higher (5). One of the studies that did not report the type of calcifications might have included patients with type 3 calcifications, which have an 85% probability of spontaneous resorption (29). Furthermore, our conclusions regarding resolution of calcifications may only be applicable to type 1 and 2 calcium deposits because most calcific tendinitis trials excluded patients with type 3 deposits.

Third, there are no universally accepted EFD cut-off values, and some of the included studies used different cut-off values and thus classified their energy levels into categories that differed from ours. Finally, study grouping by EFD levels did not take into account the frequency of shock waves delivered or total cumulative dose administered, both of which may have an effect on clinical outcomes. Evidence evaluating these factors was sparse (21, 27, 28), which limited our ability to gauge their influence. More studies investigating various ESWT modalities and the treatment aggregate effects are needed to pinpoint the optimal therapeutic regimen for the procedure.

In conclusion, high-energy ESWT (EFD $\geq$0.28 mJ/mm^2) is effective for improving pain and shoulder function in chronic calcific tendinitis of the shoulder and can result in complete resolution of calcification. In patients with calcific tendinitis, ESWT at a lower energy density (EFD $<$0.28 mJ/mm^2) is not as effective as high-energy ESWT but may still have therapeutic value in improving shoulder function. Regardless of energy dose, ESWT does not seem to be effective in treating noncalcific tendinitis.

Extracorporeal shock-wave therapy is emerging as an innovative treatment for musculoskeletal disorders. As our

Table. **Adverse Events Reported in Studies Comparing Different ESWT Energy Levels and Placebo**

Study, Year (Reference)	Total Patients, *n*	Adverse Events			
		Type	Affected Patients, *n (%)*		
			High- or Medium-Energy ESWT Group	Low-Energy ESWT Group	Placebo Group
Calcific tendinitis					
Rompe et al, 1998 (26)	100	Hematomas	Unknown	Unknown	NA*
Loew et al, 1999 (27)	195	Hematomas	Unknown	ND	ND
Seil et al, 1999 (28)†	50		ND	ND	NA*
Cosentino et al, 2003 (29)	70	Any adverse events	0	NA*	0
Gerdesmeyer et al, 2003 (30)	144	Petechiae, hematomas, and small bruises or local erythema	36 (75)	32 (67)	8 (17)
		Pain during or after treatment	36 (75)	27 (56)	25 (52)
		Patients requiring intravenous analgesia for severe pain	8 (17)	2 (4)	1 (2)
Perlick et al, 2003 (31)	80	Petechiae, hematomas, and small bruises or local erythema	40 (100)	15 (38)	NA*
		Pain during or after treatment	3 (8)	2 (5)	
		Acute bursitis subacromialis	4 (10)	2 (5)	
Peters et al, 2004 (32)	90	Hematomas	6 (19)	2 (7)	0
		Pain during or after treatment	31 (100)	30 (100)	0
		Considerable pain requiring a short interruption of shock-wave application	6 (19)	0	0
Pleiner et al, 2004 (33)	43	Any adverse events	0	ND	NA*
Cacchio et al, 2006 (34)	90	Hematomas	NA*	3 (7)	0
Albert et al, 2007 (35)	80	Petechiae, hematomas, and small bruises or local erythema	15 (38)	0	NA*
		Panic attack	0	1 (2.5)	
Sabeti et al, 2007 (36)†	50	Strong pain that led to exclusion from the study	0	2 (8)	NA*
Hsu et al, 2008 (37)	46	Local erythema	3 (9)	NA*	ND
Hearnden et al, 2009 (38)	20	Petechiae, hematomas, and small bruises or local erythema	7 (62)	NA*	ND
		Pain during or after treatment	9 (82)		ND
Farr et al, 2011 (39)	30	Any adverse events	0	0	NA*
Ioppolo et al, 2012 (40)†	46	Any adverse events	0	0	NA*
Noncalcific tendinitis					
Schmitt et al, 2001 (41) and 2002 (42)	39	Any adverse events	NA*	0	0
Speed et al, 2002 (43)	74	Pain during or after treatment that led to exclusion from the study	NA*	1 (3)	1 (3)
Schofer et al, 2009 (44)	40	Pain during or after treatment	0	1 (5)	NA*
Galasso et al, 2012 (45)	20	Pain during or after treatment	NA*	3 (27)	1 (11)

ESWT = extracorporeal shock-wave therapy; NA = not applicable; ND = no data.
* The trial did not evaluate this treatment.
† These studies compared low-energy (<0.08 mJ/mm^2) with medium-energy ESWT (0.08–0.27 mJ/mm^2) or 2 different levels of medium-energy ESWT.

understanding of its physiologic effects advance and more controlled homogeneous studies are conducted to further define the most effective dosing parameters and administration technique, ESWT may be a promising approach to treating chronic soft-tissue disorders.

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Disclosures: None. Forms can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M13-1982.

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Administrative, technical, or logistic support: R.R. Bannuru, E. Vaysbrot.
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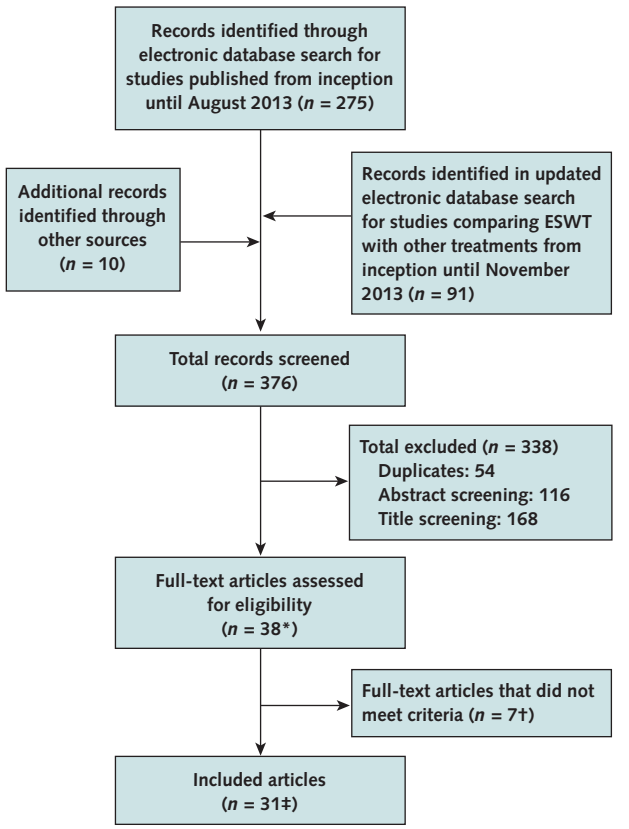
Appendix Figure. **Summary of evidence search and selection.**



ESWT = extracorporeal shock-wave therapy.
* 38 articles describing 34 studies.
† 7 articles describing 6 studies.
‡ 31 articles describing 28 studies.

Appendix Table 1. Characteristics of Studies Comparing Different ESWT Energy Levels and Placebo

Study, Year (Reference), Country	ESWT	Patients, *n*	Gärtner Calcification Category	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Notes
Calcific tendinitis											
Rompe et al, 1998 (26), Germany	HE: 0.28 mJ/mm^2, 1500 pulses, 1 dose	50	1 and 2	48	56	12	6	Experimental device integrating an electromagnetic shock-wave generator and a mobile fluoroscopy unit (Siemens, Erlangen, Germany)	Yes	10 patients in HE group and 6 patients in LE group received additional therapy with NSAIDs, infiltration with local anesthetics, or corticosteroids	All patients also received physical therapy for 3 d after ESWT
	LE: 0.06 mJ/mm^2, 1500 pulses, 1 dose	50									
Loew et al, 1999 (27), Germany	HE: 0.30 mJ/mm^2, 2000 pulses, 1 or 2 doses	40	1 and 2	ND	ND	12	3	MFL 5000 (Philips, Hamburg, Germany)	Yes	ND	
	LE: 0.10 mJ/mm^2, 2000 pulses, 1 dose	20									
	No treatment	20									
Loew et al, 1999 (27), Germany*	HE: 0.30 mJ/mm^2, 2000 pulses, 1 dose	56	1 and 2	ND	ND	12	6	Compact (Dornier MedTech, Wessling, Germany)	Yes	ND	
	HE: 0.30 mJ/mm^2, 2000 pulses, 2 doses	59									
Seil et al, 1999 (28), Germany	LE: >0.12 mJ/mm^2, 5000 pulses, 1 dose†	25	ND	ND	ND	ND	6	ND	No	Intravenous analgesia in the "high-dose" group	Two different treatment protocols with a similar total amount of applied energy were compared
	LE: 0.04–0.12 mJ/mm^2, 5000 pulses, 3 doses	25									
Cosentino et al, 2003 (29), Italy	HE: 0.28 mJ/mm^2, 1200 pulses, 4 doses every 4–7 d	35	ND	52	61	10	6	Orthima (Direx, Wiesbaden, Germany)	No	No	
	Placebo: 0 mJ/mm^2, 1200 pulses, 4 doses every 4–7 d	35									
Gerdesmeyer et al, 2003 (30), Germany and Austria	HE: 0.32 mJ/mm^2, 1500 pulses, 2 doses, 2 wk apart	48	1 (71%) and 2 (29%)	50	60	6	12	Shock-wave equipment by Dornier MedTech, Wessling, Germany	No	Analgesia or sedation was given intravenously during treatment (8 patients in the HE group and 2 patients in the LE group); rescue therapy consisted of acetaminophen, 2 g/d for up to 14 d after the last treatment, and acetaminophen, 2 g/wk thereafter	Patients also received 10 physiotherapy sessions after the intervention (exercise, massage, and manual therapy)
	LE: 0.08 mJ/mm^2, 6000 pulses, 2 doses, 2 wk apart	48	1 (63%) and 2 (37%)								
	Placebo: 0 mJ/mm^2, 1500 pulses, 2 doses, 2 wk apart	48	1 (67%) and 2 (33%)								
Perlick et al, 2003 (31), Germany	HE: 0.42 mJ/mm^2, 2000 pulses, 2 doses, 3 wk apart	40	1 and 2	48	55	12	12	Lithostar lithotripter (Siemens)	Yes	ND	
	LE: 0.23 mJ/mm^2, 2000 pulses, 2 doses, 3 wk apart	40									

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Appendix Table 1—**Continued**

Study, Year (Reference), Country	ESWT	Patients, *n*	Gärtner Calcification Category	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Notes
Peters et al, 2004 (32), Germany	HE: 0.44 mJ/mm^2, 1500 pulses, up to 5 doses, 6 wk apart‡	31	1 and 2	52	61	6	6	Minilith (Storz Medical, Tägerwilen, Switzerland)	No	At the beginning of the study, patients required anti-inflammatory treatments; NSAID intake during and after the study was not reported	
	LE: 0.15 mJ/mm^2, 1500 pulses, up to 5 doses, 6 wk apart‡	30									
	Placebo: 0 mJ/mm^2, 1500 pulses, up to 5 doses, 6 wk apart	29									
Pleiner et al, 2004 (33), Austria	HE: 0.28 mJ/mm^2, 2000 pulses, 2 doses, 2 wk apart	23	ND	52	72	6	7	Orthospec (Medispec, Montgomery Village, Maryland)	No	Concomitant drug therapy was not standardized; patients refrained from intake of painkillers on the day of follow-up visits	ESWT was focused on the area of maximum pain, not on calcium deposits (clinical focusing)
	LE: <0.07 mJ/mm^2, 2000 pulses, 2 doses, 2 wk apart	20									
Cacchio et al, 2006 (34), Italy	LE: 0.10 mJ/mm^2, 2500 pulses, 4 doses weekly	45	1 (24%) and 2 (76%)	56	39	6	6	Physio Shock Wave Therapy (Elettronica Pagani, Paderno Dugnano, Italy)	No	No	Used radial shock-wave therapy (radially emitted, unfocused, low-energy waves)
	Placebo: 0.10 mJ/mm^2, 25 pulses, 4 doses weekly ("less active similar therapy")	45	1 (29%) and 2 (71%)								
Albert et al, 2007 (35), France	HE: 0.45 mJ/mm^2, 2500 pulses, 2 doses, 2 wk apart	40	Type A or B, as defined by the French Arthroscopy Association	47	76	3	3	Modulith SLK (Storz Medical, Tägerwilen, Switzerland)	No§	1 h before each session, 100 mg of ketoprofen and 2 capsules of a paracetamol–dextropropoxyphene combination (400 mg/30 mg per capsule) was given; after each session, patients were prescribed analgesic and anti-inflammatory drugs if they experienced severe pain	
	LE: 0.02–0.06 mJ/mm^2, 2500 pulses, 2 doses, 2 wk apart	40									
Sabeti et al, 2007 (36), Austria	LE: 0.2 mJ/mm^2, 2000 pulses, 2 weekly sessions, fluoroscopically focused at the calcific deposit‖	25	ND	51	68	6	3	Modulith SLK (Storz Medical)	Yes ("middle-energy" group only)	ND	

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Appendix Table 1—**Continued**

Study, Year (Reference), Country	ESWT	Patients, *n*	Gärtner Calcification Category	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Notes
	LE: 0.08 mJ/mm^2, 1000 pulses, 3 weekly sessions, fluoroscopically focused at the calcific deposit	25									
Hsu et al, 2008 (37), Taiwan	HE: 0.55 mJ/mm^2, 1000 pulses, 2 doses, 2 wk apart	33	1 (67%) 2 (33%)	56	51	6	12	OrthoWave (MTS, Konstanz, Germany)	Yes	ND	
	Placebo: 0 mJ/mm^2, 0 pulses, 2 doses 2 wk apart	13	1 and 2 (% unknown)								
Hearnden et al, 2009 (38), United Kingdom	HE: 0.28 mJ/mm^2, 2000 pulses, number of doses is unclear	11	1 and 2	ND	ND	12	6	ND	Yes	ND	Very little information provided on outcomes
	Placebo: 0.03 mJ/mm^2, 20 pulses, number of doses is unclear	9									
Farr et al, 2011 (39), Austria	HE: 0.30 mJ/mm^2, 3200 pulses, 1 dose, fluoroscopically focused at the calcific deposit	15	ND	49	47	6	3	Modulith SLK (Storz Medical)	Yes	For minor pain symptoms, NSAIDs at standard dosages were recommended (mefenamic acid, 500 mg up to 3 times/d)	
	LE: 0.20 mJ/mm^2, 1600 pulses, 2 doses, weekly, fluoroscopically focused at the calcific deposit	15									
Ioppolo et al, 2012 (40), Italy	LE: 0.20 mJ/mm^2, 2400 pulses, 4 weekly doses	23	1 (22%) and 2 (78%)	54	67	6	12	Modulith SLK (Storz Medical)	No	Dexibuprofen, 400 mg 1 h before treatment	
	LE: 0.10 mJ/mm^2, 2400 pulses, 4 weekly doses	23	1 (26%) and 2 (74%)								
Noncalcific tendinitis											
Schmitt et al, 2001 (41) and 2002 (42), Germany	LE: 0.11 mJ/mm^2, 2000 pulses, 3 doses weekly¶	20	NA	52	50	6	3	Minilith SL1v (Storz Medical)	Yes	ND	
	Placebo: 0 mJ/mm^2, 2000 pulses, 3 doses weekly	19									
Speed et al, 2002 (43), England	LE: 0.12 mJ/mm^2, 1500 pulses, 3 doses, 4 wk apart	34	NA	52	58	3	6	Sonocur Plus Unit (Siemens, Munich, Germany)	No	No	
	Placebo: 0.04 mJ/mm^2, 1500 pulses, 3 doses, 4 wk apart	40									

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Appendix Table 1—**Continued**

Study, Year (Reference), Country	ESWT	Patients, *n*	Gärtner Calcification Category	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Notes
Schofer et al, 2009 (44), Germany	HE: 0.35 mJ/mm^2, 2000 pulses, 3 doses weekly**	20	NA	53	53	6	12	Minilith SL1 (Storz Medical)	Yes	ND	
	LE: 0.11 mJ/mm^2, 2000 pulses, 3 doses weekly¶	20									
Galasso et al, 2012 (45), Italy	LE: 0.068 mJ/mm^2, 3000 pulses, 2 doses weekly	11	NA	51	45	4	3	Modulith SLK (Storz Medical)	Yes	Acetaminophen, 1000 mg/d after treatment and during follow-up in case of pain; patients observed a pain medication-free interval 3 d before each evaluation	
	Placebo: 0 mJ/mm^2, 3000 pulses, 2 doses weekly	9									

ESWT = extracorporeal shock-wave therapy; HE = high energy; LE = low energy; ND = no data; NSAID = nonsteroidal anti-inflammatory drug.
* This was a separate 6-mo study that compared 1 vs. 2 sessions of high-energy ESWT.
† An ESWT energy level >0.12 mJ/mm^2 was classified as "high energy."
‡ Total energy flux density as measured by the manufacturer by using a fiberoptic hydrophone.
§ A patch with 25 mg of lidocaine and 25 mg of prilocaine was used.
‖ An ESWT energy level of 0.2 mJ/mm^2 was classified as "middle-energy."
¶ 0.11 mJ/mm^2 measured with a membrane hydrophone, which is equivalent to 0.33 mJ/mm^2 measured with a fiberoptic hydrophone.
** 0.35 mJ/mm^2 measured with a membrane hydrophone, which is equivalent to 0.78 mJ/mm^2 measured with a fiberoptic hydrophone.

Appendix Table 2. Characteristics of Studies Comparing ESWT With Other Active Treatments or Applied to Different Shoulder Sites

Study, Year (Reference), Country	Treatment	Patients, *n*	Calcification Status	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Study Conclusions	Notes
ESWT vs. exercise												
Engebretsen et al, 2009 (46) and 2011 (47), Norway	ESWT: pressure 2.5–4.0 Bar, frequency 8–12 Hz, 2000 pulses, 1 dose weekly for 4–6 wk	52	Not discussed	48	50	3	12	DolorClast (Electro Medical Systems, Nyon, Switzerland)	No	Allowed (drug treatments for pain, including NSAIDs)	Supervised exercise was more effective than ESWT in the short term (18 wk) for shoulder pain and disability index; no significant long-term difference between the groups (12 mo); concomitant drug use at 18 wk and 12 mo did not statistically significantly differ	Patients with rotator cuff rupture were included if they met the rest of the inclusion criteria
	Supervised exercise: two 45-min sessions weekly, up to 12 wk	52										
ESWT vs. radiation therapy												
Gross et al, 2001 (48), Germany	ESWT: 0.1 mJ/mm^2, 2000 pulses, 1 dose weekly for 3 wk	30*	Not discussed	ND	ND	ND	3	Minilith SL1 (Storz Medical, Tägerwilen, Switzerland)	ND	ND	No statistically significant differences between treatments	
	Low-dose radiation therapy: 6 × 0.5 Gy delivered to the ICRU reference point (1 fraction/d) with cobalt-60 gamma rays											
Gross et al, 2002, (49); Haake et al, 2001 (50), Germany	ESWT: 0.11 mJ/mm^2, 2000 pulses, 1 dose weekly for 3 wk†	16	Noncalcific tendinitis	53	50	6	3	Minilith (Storz Medical)	No	ND	No statistically significant differences between treatments	
	X-ray stimulation radiation therapy: 6 × 0.5 Gy delivered to the ICRU reference point (1 fraction/d) with cobalt-60 gamma rays	14										
ESWT vs. TENS												
Pan et al, 2003 (51), Taiwan	ESWT: 0.26–0.32 mJ/mm^2 (adjusted to patients' tolerance), 2000 pulses, 2 doses 2 wk apart	32	Calcific tendinitis	57	65	6	3	Orthospec (Medispec, Montgomery Village, Maryland)	No	ND	ESWT was more effective than TENS for pain, Constant score, and calcification resolution outcomes	
	TENS with Neurosan50 (Hüttinger Medizintechnik, Umkirch, Germany): 0.5-ms pulse width, 10-ms interval length, 95 Hz for 20 min; 3 times/wk for 4 wk	28										

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Appendix Table 2—**Continued**

Study, Year (Reference), Country	Treatment	Patients, *n*	Calcification Status	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Study Conclusions	Notes
ESWT vs. ultrasonography-guided needling followed by ESWT												
Krasny et al, 2005 (52), Austria	ESWT: 0.36 mJ/mm^2, 2500 pulses, 1 dose	40	Calcific tendinitis	48	51	12	5	Epos Flouro (Dornier MedTech, Wessling, Germany)	Yes	ND	Ultrasonography-guided needling plus high-energy ESWT was more effective than ESWT alone, with significantly higher rates of calcification resorption, better clinical results (Constant score), and reduction in the need for surgery	
	Ultrasonography-guided needling, followed by ESWT: 0.36 mJ/mm^2, 2500 pulses, 1 dose	40										
ESWT with exact focusing at the calcific deposit vs. conventional ESWT												
Haake et al, 2002 (53) and 2001 (54), Germany	ESWT: 0.35 mJ/mm^2, 2000 pulses, 2 weekly doses, focused on the insertion of the supraspinatus tendon (tuberculum majus)‡	24	Calcific tendinitis	50	70	6	12	Storz Minilith SL1 (Storz Medical)	Yes	ND	Focusing on the calcification rather than on tuberculum majus is significantly more effective for pain and Constant score outcomes; calcification resorption rate did not significantly differ between the groups	
	ESWT: 0.35 mJ/mm^2, 2000 pulses, 2 weekly doses, fluoroscopically focused at the calcific deposit‡	25										
Sabeti-Aschraf et al, 2005 (55), Austria	ESWT: 0.08 mJ/mm^2, 1000 pulses, 4 Hz, 3 weekly doses, focused on the point of maximum tenderness through palpation and patients' feedback	25	Calcific tendinitis	53	56	6	3	Modulith SLK (Storz Medical)	No	ND	Guided, 3-dimensional, computer-assisted ESWT had significantly better results than the feedback-guided ESWT for pain, Constant score, and calcification resolution outcomes	
	ESWT: 0.08 mJ/mm^2, 1000 pulses, 4 Hz, 3 weekly doses, focused on calcium deposits via a radiographically guided, 3-dimensional, computer-assisted device (Lithotrack system [Storz Medical])	25										

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Appendix Table 2—**Continued**

Study, Year (Reference), Country	Treatment	Patients, *n*	Calcification Status	Mean Age, *y*	Female, %	Minimum Duration of Symptoms, *mo*	Longest Follow-up, *mo*	ESWT Device	Local Anesthesia	Other Analgesics	Study Conclusions	Notes
ESWT in different shoulder positions												
Tornese et al, 2011 (56), Italy	ESWT: 0.22 mJ/mm^2, 1800 pulses, 3 weekly doses, shoulder in the neutral position ESWT: 0.22 mJ/mm^2, 1800 pulses, 3 weekly doses, shoulder in the hyperextended internal rotation position	17 18	Calcific tendinitis; type 1 and 2 by Gärtner classification	53	60	ND	3	Epos Ultra (Dornier MedTech)	No	ND	Shoulders positioned in hyperextension showed significantly better outcomes for calcifications resolution and the strength subscale of Constant score; no significant differences between changes in Constant total score and pain, activities of daily living, and range-of-motion subscales	Patients also performed self-assisted stretching of the posterior capsule of the shoulder and Codman pendulum exercises

ESWT = extracorporeal shock-wave therapy; ICRU = International Commission on Radiation Units and Measurements; ND = no data; NSAID = nonsteroidal anti-inflammatory drug; TENS = transcutaneous electric nerve stimulation.

* Total number of patients; number of patients in each treatment group was not provided.

† 0.11 mJ/mm^2 measured with a membrane hydrophone, which is equivalent to 0.33 mJ/mm^2 measured with a fiberoptic hydrophone.

‡ 0.35 mJ/mm^2 measured with a membrane hydrophone, which is equivalent to 0.78 mJ/mm^2 measured with a fiberoptic hydrophone.

Appendix Table 3. Quality of Included Studies Comparing Different ESWT Energy Levels and Placebo

Study, Year (Reference)	Allocation Sequence Adequately Generated	Allocation Concealed	Blinding	ITT Analysis	Total Withdrawals, %	Groups Similar at Baseline
Calcific tendinitis						
Rompe et al, 1998 (26)	Unknown	Unknown	Unknown	Yes	0	Yes
Loew et al, 1999 (27)*	Unknown	Unknown	Unknown	Yes	0	Unknown
Loew et al, 1999 (27)†	Unknown	Unknown	Unknown	No	21	Unknown
Seil et al, 1999 (28)	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Cosentino et al, 2003 (29)	Unknown	Unknown	Single (patient)	No	23	Unknown
Gerdesmeyer et al, 2003 (30)*	Yes	Yes	Double	Yes	33	Yes
Perlick et al, 2003 (31)	Unknown	Unknown	Unknown	Yes	0	Unknown
Peters et al, 2004 (32)*	Yes	Unknown	Double	Yes	3	Unknown
Pleiner et al, 2004 (33)	Unknown	Unknown	Double	Yes	10	Yes
Cacchio et al, 2006 (34)	Yes	Yes	Single (outcome assessor)	Yes	6	Yes
Albert et al, 2007 (35)	Yes	Unknown	Single (patient)	Yes	2	Yes
Sabeti et al, 2007 (36)	Unknown	Unknown	Single (outcome assessor)	No	12	Unknown
Hsu et al, 2008 (37)	Yes	Unknown	Unknown	Yes	0	Yes
Hearnden et al, 2009 (38)	Yes	Yes	Single (patient)	Unknown	Unknown	Unknown
Farr et al, 2011 (39)	Unknown	Unknown	Single (outcome assessor)	No	3	Yes
Ioppolo et al, 2012 (40)	Yes	Yes	Single (outcome assessor)	Yes	10	Yes
Noncalcific tendinitis						
Schmitt et al, 2001 (41) and 2002 (42)	Yes	Yes	Double	No	2	Yes
Speed et al, 2002 (43)	Unknown	Unknown	Double	Yes	9	Yes
Schofer et al, 2009 (44)	Yes	Yes	Single (outcome assessor)	No	3	Yes
Galasso et al, 2012 (45)	Yes	Unknown	Single (patient)	Yes	0	Yes

ESWT = extracorporeal shock-wave therapy; ITT = intention to treat.
* High-energy ESWT, low-energy ESWT, and placebo were compared.
† This was a separate 6-mo study that compared 1 vs. 2 sessions of high-energy ESWT.

Appendix Table 4. Quality of Included Studies Comparing ESWT With Other Treatment Modalities

Study, Year (Reference)	Allocation Sequence Adequately Generated	Allocation Concealed	Blinding	ITT Analysis	Total Withdrawals, %	Groups Similar at Baseline
Engebretsen et al, 2009 (46) and 2011 (47)	Yes	Unknown	Single (outcome assessor)	No	4	Yes
Gross et al, 2001 (48)	Unknown	Unknown	Single (outcome assessor)	Unknown	Unknown	Unknown
Gross et al, 2002 (49); Haake et al, 2001 (50)	Yes	Unknown	Single (outcome assessor)	Unknown	20	Unknown
Pan et al, 2003 (51)	Unknown	Unknown	Single (outcome assessor; only for calcification resolution)	Yes	2	Yes
Krasny et al, 2005 (52)	Yes	Unknown	Single (outcome assessor)	Unknown	Unknown	Unknown
Haake et al, 2002 (53) and 2001 (54)	Yes	Yes	Double	Yes	0	Unknown
Sabeti-Aschraf et al, 2005 (55)	Unknown	Unknown	Single (patient)	Unknown	Unknown	Unknown
Tornese et al, 2011 (56)	Yes	Unknown	Unknown	Yes	0	Unknown

ESWT = extracorporeal shock-wave therapy; ITT = intention to treat.

Appendix Table 5. **Adverse Events Reported in Studies Comparing ESWT and Other Treatments**

Study, Year (Reference)	Total Patients, *n*	Adverse Events	ESWT		Comparator	
			Technique	Patients Affected, *n (%)*	Technique	Patients Affected, *n (%)*
Engebretsen et al, 2009 (46) and 2011 (47)	104	Pain increase	ESWT	2 (3.8)	Exercise	1 (1.9)
Gross et al, 2001 (48)	30	Any adverse events	ESWT	ND	Radiation therapy	ND
Gross et al, 2002 (49); Haake et al, 2001 (50)	30	Pain Skin irritation	ESWT	1 (6.3) 1 (6.3)	Radiation therapy	0
Pan et al, 2003 (51)	60	Pain Cardiac palpitations and anxiety	ESWT	5 (15.6) 1 (3.1)	TENS	1 (3.6)*
Krasny et al, 2005 (52)	80	Hematoma, petechiae, and local swelling	ESWT	ND†	Needling plus ESWT	ND†
Haake et al, 2002 (53) and 2001 (54)	49	Any adverse events	ESWT focused on the insertion of the supraspinatus tendon	0	ESWT focused at the calcific deposit	0
Sabeti-Aschraf et al, 2005 (55)	50	Any adverse events	ESWT focused on the point of maximum tenderness	0	ESWT focused at the calcific deposit	0
Tornese et al, 2011 (56)	35	Any adverse events	ESWT with shoulder in the neutral position	ND	ESWT with shoulder in the hyperextended internal rotation position	ND

ESWT = extracorporeal shock-wave therapy; ND = no data; TENS = transcutaneous electric nerve stimulation.
* Caused withdrawal from the study.
† The number of events was not provided.