Comparing Ultrasound-Guided Needling Combined With a Subacromial Corticosteroid Injection Versus High-Energy Extracorporeal Shockwave Therapy for Calcific Tendinitis of the Rotator Cuff: A Randomized Controlled Trial

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Purpose: To compare clinical and radiographic outcomes after treatment with standardized high-energy extracorporeal shock wave therapy (ESWT) and ultrasound-guided needling (UGN) in patients with symptomatic calcific tendinitis of the rotator cuff who were nonresponsive to conservative treatment. **Methods:** The study was designed as a randomized controlled trial. The ESWT group received ESWT (2000 pulses, energy flux density 0.35 mJ/mm^2) in 4 sessions with 1-week intervals. UGN was combined with a corticosteroid ultrasound-guided subacromial bursa injection. Shoulder function was assessed at standardized follow-up intervals (6 weeks and 3, 6, and 12 months) using the Constant Murley Score (CMS), the Disabilities of the Arm, Shoulder, and Hand questionnaire, and visual analog scale for pain and satisfaction. The size, location, and morphology of the deposits were evaluated on radiographs. The a priori sample size calculation computed that 44 participants randomized in each treatment group was required to achieve a power of 80%. **Results:** Eighty-two patients were treated (56 female, 65%; mean age 52.1 ± 9 years) with a mean baseline CMS of 66.8 ± 12 and mean calcification size of 15.1 ± 4.7 mm. One patient was lost to follow-up. At 1-year follow-up, the UGN group showed similar results as the ESWT group with regard to the change from baseline CMS (20.9 vs 15.7; $P = .23$), Disabilities of the Arm, Shoulder, and Hand questionnaire (−20.1 vs −20.7; $P = .78$), and visual analog scale for pain (−3.9 and −2.6; $P = .12$). The mean calcification size decreased by 13 ± 3.9 mm in the UGN group and 6.7 ± 8.2 mm in the ESWT group ($<P = .001$). In total, 22% of the UGN and 41% of the ESWT patients received an additional treatment during follow-up because of persistent symptoms. **Conclusions:** This RCT compares the clinical and radiographic results of UGN and high-energy ESWT in the treatment of calcific tendinitis of the rotator cuff. Both techniques are successful in improving function and pain, with high satisfaction rates after 1-year follow-up. However, UGN is more effective in eliminating the calcific deposit, and the amount of additional treatments was greater in the ESWT group. **Level of evidence:** II, randomized controlled trial.

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Calcific tendinitis of the rotator cuff is a common cause of pain in the shoulder. The condition is characterized by the deposition of calcium carbonate hydroxyapatite crystals in the rotator cuff tendons. The prevalence of calcific tendinitis in either the general population (2.7%-7.8%) or in a population with a painful shoulder (8%-40%) is high.[1] In calcific tendinitis of the rotator cuff, the supraspinatus tendon is most frequently affected. Typically, individuals with calcific tendinitis are aged between 30 and 60 years, with women affected 1.5 times more than men.[1] Patients experience activity-related pain in the deltoid region, a decrease in active range of motion, as well as pain at night with variable functional impairment. Although it is considered to be a self-limiting disease with spontaneous improvement over time, symptoms can be severe and long-lasting.[2-4] The exact etiology remains unclear, but the most widely accepted theory is by Uhthoff and Sarkar,[5] who describe an active, cell-mediated reactive process that is divided in 3 distinct stages: the precalcific, calcific (with a formative and resorptive phase) and postcalcific stage. Symptoms generally worsen during the resorptive phase. The patients in this phase have the greatest chance of nonoperative recovery.[6] Primary treatment consists of nonsteroidal anti-inflammatory drugs, physiotherapy, and a subacromial corticosteroid injection (SAI) when indicated.[6-8] When primary treatment fails, more invasive techniques are available.[9] Extracorporeal shockwave therapy (ESWT) and ultrasound-guided needling (UGN) are among the most frequently applied treatments in refractory cases and can be considered as alternatives for a surgical intervention.[10,11] These treatments are minimally invasive, inexpensive, relatively easy to perform, with low complication rates, and have shown promising results in previous studies.[9,12-16] However, previous systematic reviews also concluded that there is a lack of level 1 evidence comparing UGN with ESWT.[8,13]

The primary objective of this study was to compare clinical and radiographic outcomes after treatment with standardized high-energy ESWT and UGN in patients with symptomatic calcific tendinitis of the rotator cuff who were nonresponsive to conservative treatment. Our hypothesis was that UGN would be superior in terms of clinical and radiographic outcome after 1-year follow-up.

Methods

The study was designed as a single-center, randomized controlled trial with parallel groups. Patients were included between May 2014 and December 2017. The study was registered in the Dutch clinical trial registration (NL4304/NTR4448) and approved by both the medical ethics review committee (METC, number NL44205.094.13) and the institutional review board (number 2013.26; Spaarne Gasthuis, Hoofddorp, the Netherlands). Informed consent forms were signed by all participating patients.

Study Population

The population consisted of patients referred to the outpatient orthopaedic clinic with clinical signs of nontraumatic anterograde-lateral shoulder pain when the arm was elevated. The medical history was taken and a clinical examination of the shoulder was performed. Standardized shoulder radiographs (anteroposterior, outlet-, axial-, and acromioclavicular view) and an ultrasound examination of the rotator cuff were obtained.

Inclusion criteria for participation in this study were age >18 years, clinical sign of subacromial pain syndrome, standardized radiographs showing a calcific deposit with a diameter of at least 5 mm in size, morphologic type I and type II deposits corresponding to the classification of Gärtner[17] (type I, sharply outlined and densely structured; type II, sharply outlined and inhomogeneous or homogenous with no defined border), symptoms for more than 4 months, a completed and unsuccessful nonsurgical treatment program including nonsteroidal anti-inflammatory drugs, physiotherapy (centric and eccentric rotator cuff strengthening exercises in combination with scapular stabilization), and at least 1 SAI with a corticosteroid. Exclusion criteria were the following: ultrasonic signs of a partial or full rotator cuff tendon, clinical or radiographic signs of a resorption phase as defined as a recent period of increased pain in combination with a morphologic type III deposit (cloudy and transparent in structure) on radiographs, calcific deposits in multiple tendons of the rotator cuff, osteoarthritis of the glenohumeral or acromioclavicular joint, adhesive capsulitis, previous shoulder surgery, ESWT or UGN to the affected shoulder, instability of the shoulder, rheumatoid arthritis, neurologic disorders or dysfunction of the upper limb, and the inability to give informed consent.

Inclusion and Randomization

Eligible patients were provided with written and oral information about the trial and had at least 1 week to consider participation. Patients who were willing to participate were referred to the coordinating investigator (J.L.) for further evaluation and inclusion. A research nurse allocated the patients to 1 of 2 treatment groups using the computer-generated block randomization function (10 patients per block) in Research Manager (Nova Business Software, Zwolle, the Netherlands). Treatment was scheduled within 4 weeks.

ESWT: Technique and Study Protocol

High-energy shockwave therapy is a technique in which monophasic pressure pulses with high peak pressure are distributed to the calcific deposit and the surrounding soft tissues through, in this study, a piezoelectric mechanism. The shockwave group was treated with 4 sessions of high-energy ESWT with a 1-week interval. Each session consisted of 2000 piezoelectric pressure pulses, focused on the calcific deposit, at a frequency of 4 Hz with a total energy flux density of 0.351 mJ/mm^2 resulting in a total energy amount of 2808 mJ. Two identical extracorporeal shockwave sources were used in this study, the Piezowave2 system (Richard Wolf GmbH, Knittlingen, Germany). The calcific deposit was localized by ultrasound with the patient positioned in a supine position. Patients initially received a small amount of low-energy pulse to get used to the sensation after which the actual therapeutic dose was administered. After treatment, the visual analog score (VAS) for pain was registered and when necessary the shoulder was cooled with ice packs. The high-energy ESWT treatment was performed at 2 nearby physiotherapy clinics by 2 specialized shoulder physiotherapists (R.B. and E.V.) with extensive experience in shockwave treatment.

UGN: Technique and Study Protocol

In UGN, ultrasound is used to allow a radiation free, 3-dimensional localization and assessment of the calcific deposit. Assisted by real-time ultrasonic guidance the deposit is then punctured and irrigated with a needle to break it down. This procedure effectively removes part of the calcific deposit and promotes further reabsorption of the calcific material. In this study a double-needle technique was used with repeated perforation of the deposit and subsequent aspiration and lavage. Patients were treated with a single UGN procedure, performed in an outpatient clinical setting by 1 orthopaedic shoulder surgeon (A.v.N.) assisted by an experienced ultrasonographer. The patient was positioned in a supine position and the size and location of the calcific deposit was confirmed and marked by ultrasound imaging. After sterile preparation, patients received a local anesthetic injection of the skin and subcutaneous tissue with 5 cc of lidocaine HCL 10 mg/mL (Braun, Melsungen, Germany). The ultrasound transducer was kept focused on the calcific deposit and the deposit was punctured multiple times with a 40-mm 17-gauge needle. A second 40-mm 17-gauge needle was introduced from a different angle and lavage and aspiration of the deposit with a saline solution was performed. After the UGN procedure, one of the needles was introduced in the subacromial bursa under ultrasonic guidance and a mixture of 4 cc of bupivacaine HCL 0.5% (Pfizer Inc., New York, NY) and 1 cc Depo-Medrol 40 mg/mL (Pfizer Inc.) was injected. The sterile drapes were removed and the puncture site was sealed with an island dressing. The VAS for pain during treatment was registered after treatment.

Postprocedure Care

After treatment, both groups followed a standardized physical therapy program including active and passive exercise mobilization techniques. Oral analgesics were administered for a maximum of 7 days postintervention when necessary. The medication was only prescribed once. We have not systematically monitored the use of additional over-the-counter analgesics. In case of persistent or refractory symptoms within the 1-year follow-up period, additional treatment options were discussed with the patients. In case of full resorption but persistent pain despite analgesics, a subacromial bursa infiltration was considered. In case of no- or partial resorption, (redo) UGN or an arthroscopic bursectomy with intraoperative needling was considered.

Clinical and Radiographic Evaluations

Both treatment groups had regular follow-up visits with the coordinating investigator before the intervention and at 6 weeks, 3 months, 6 months, and 1 year after treatment. At each visit, the Constant Murley Score (CMS)[18] and the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH)[19] were used for clinical assessment. A VAS for average pain during the last week and VAS for satisfaction was registered at each follow-up visit. At 6 months and 1 year, the patients' reported change in symptoms were screened using a 7-point Likert scale. The size, morphology, and amount of resorption of the calcific deposit (complete, less than 50%, more than 50%, none) were assessed using standard shoulder radiographs obtained at baseline and after 6 weeks and 6 months. The length of the deposit was measured in terms of the maximum size of the longest axis in any direction. The radiographs were analyzed by an independent physician, blinded for the allocated treatment.

Sample Size

In this superiority study the 0- to 100-point CMS was used as primary outcome measure. A difference of 12 points was defined as the minimal clinical important difference between the treatment groups. With an assumed standard deviation of 20 points we computed that a sample size of 44 participants randomized in each treatment group, would achieve a power of 80% to detect a 12-point difference. The statistical level of significance was set at .05.

Statistical Analysis

Statistical analyses were performed using of SPSS version 24.0 (IBM Corp., Armonk, NY). Continuous data are presented as means with standard deviations or

95% confidence intervals, and categorical variables as frequencies with accompanying proportions. Primary analysis was performed according to the intention-to-treat principle. Change from baseline was calculated for the CMS, DASH, and VAS. Differences between the treatment groups were analyzed by use of Student *t* tests as well as multivariate linear regression analyses, adjusted for potential confounders (sex, age, body mass

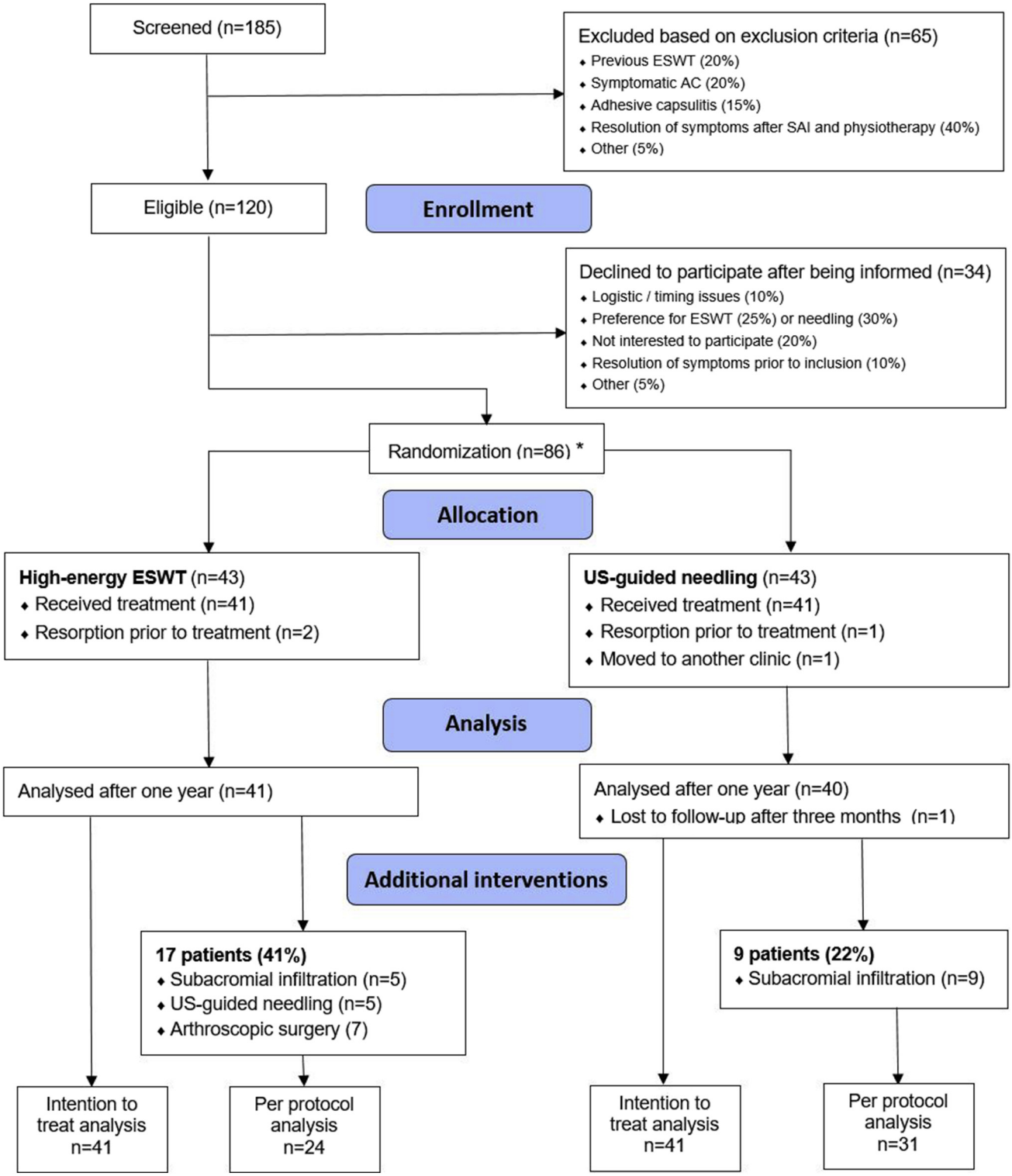

Fig 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart. (*) The a priori sample size calculation computed that 44 participants randomized in each treatment group, was required to achieve a power of 80%. (AC, Acromioclavicular joint; ESWT, Extracorporeal shockwave therapy; SAI, Subacromial infiltration; US, ultrasound.)

index, duration of complaints, baseline, Gärtner) at all follow-up moments. In addition, a mixed-model repeated-measures analysis of covariance was used to assess treatment effect during the follow-up period of 12 months. Adjustment for potential confounders (sex, age, body mass index, duration of complaints, baseline, Gärtner) was performed and interaction between treatment and follow-up was assessed. Secondary ordinal variables were analyzed by use of Mann–Whitney U tests, for categorical variables χ^2 tests were used. The level of statistical significance was set at $P < .05$ for all tests. Due to an imbalance of the occurrence of additional treatments between the 2 groups (22% vs 41%), 2 sensitivity analyses were performed: a per-protocol and last observation carried forward protocol. In the last observation carried forward protocol,[20] additional treatment was considered an endpoint, and results of the last follow-up before initiation of the additional treatment were carried forward to avoid overestimation of the treatment effect.

Table 1. Demographics and Baseline Data

	ESWT (n = 41)	UGN (n = 41)
	Mean (SD)	Mean (SD)
Sex, n (%)		
Male	14 (34)	15 (37)
Female	27 (66)	26 (63)
Age, mean (SD)	51.6 (9.4)	52.7 (8.7)
BMI, mean (SD)	25.6 (4.3)	25.6 (3.4)
Duration of complaints, y, mean (SD)	3.4 (3.0)	3.0 (3.0)
Location, n (%)		
Supraspinatus	35 (85)	36 (88)
Infraspinatus	4 (10)	3 (7)
Subscapularis	2 (5)	2 (5)
Size deposit, mm, mean (SD)	15.5 (5.8)	15.8 (4.5)
Gärtner, n (%)		
Type I	13 (32)	21 (68)
Type II	28 (51)	20 (49)
CMS, mean (SD)	67.7 (12.2)	66.4 (12.7)
DASH, mean (SD)	38.7 (16.0)	35.2 (15.8)
VAS pain, mean (SD)	5.8 (1.8)	6.0 (1.5)

BMI, body mass index; CMS, Constant Murley Score; DASH, Disability of Arm, Shoulder, and Hand Score; ESWT, extracorporeal shockwave therapy; SD, standard deviation; UGN, ultrasound-guided needling; VAS, visual analog scale.

Results

Baseline Characteristics

Between May 2014 and December 2017, a total of 185 patients were screened for participation in the study. A CONSORT study flowchart is provided in Figure 1. Sixty-five patients were not found to be eligible for participation because they did not meet the inclusion criteria and 120 patients were invited for the study. After being invited, 34 patients (28%) were not willing to participate and 86 patients were randomized. Before treatment, 1 patient switched to another clinic for treatment and 3 patients improved in such a manner that no further treatment was indicated. The final study group consisted of 82 patients, of whom 56 (65%) were female with a mean age of 52.1 ± 9.1 years. The mean duration of symptoms was 3.2 ± 3.0 years, and the supraspinatus was the most frequently (85%) affected tendon. Demographics and baseline clinical characteristics were similar for both groups except for the distribution of the Gärtner types, as is shown in Table 1.

Interventions

During intervention the mean VAS scores were 6.2 ± 1.2 in the ESWT group and 4.5 ± 2.4 in the UGN group. This score was significantly lower in the UGN group ($P < .001$). The consistency of the calcific deposits during UGN was categorized as solid in 54%, soft in 20%, and mixed in 26% of the cases.

Clinical Outcome Measures

Table 2 shows the change from baseline scores and total scores for the 3 clinical outcome measures. A significant interaction between follow-up and treatment was observed for the change from baseline scores from the CMS ($P < .01$), DASH ($P = .03$) and VAS ($P < .01$). For both the CMS (Fig 2A) and the DASH (Fig 2B), a statistically significant and clinical relevant improvement was observed after 1 year, without significant differences between the treatment groups. Six weeks after treatment, the DASH score for the UGN group was significantly worse than the ESWT group ($P = .046$). When looking at the average pain over the week, measured on a 0- to 10-point VAS score, the UGN group improved by 3.9 points and the ESWT group improved by 2.6 points, which was not significantly different after adjusting for confounding factors ($P = .12$) (Table 2 and Fig 2C). The mean satisfaction scores after year were 7.6 ± 2.2 for the ESWT group and 7.0 ± 2.8 for the UGN group ($P = .30$). Patient-reported change in symptoms is reported in Table 3. Sixty-seven percent of the ESWT patients and 78% of the UGN patients reported either an improvement or strong improvement in symptoms after 1-year follow-up. Results of both types of sensitivity analyses (per protocol and last observation carried forward) of the CMS, DASH, and VAS at all follow-up moments were similar to those of the primary analyses (Appendix Tables 1 and 2, available at www.arthroscopyjournal.org).

Radiographic Outcome

The radiographic results were superior in the UGN group ($P < .001$), as shown in Figure 3 and Table 4. UGN resulted in full resorption of the calcific deposit in 27 cases (68%) with a mean size of 1.8 ± 3.4 mm after 6 months, implying a mean reduction of 14.2 ± 4.1

Table 2. CFB Scores for the CMS, DASH, and VAS Pain (ITT)

	ESWT	UGN	Crude	Multivariate	
	Mean (95% CI)	Mean (95% CI)	*P* Value	B-coefficient (95% CI)	*P* Value
CMS (CFB)					
6 wk	7.6 (3.5; 11.7)	5.1 (0.8; 9.4)	.40	4.1 (−1.8; 10.0)	.17
3 mo	9.9 (5.4; 14.4)	7.0 (2.4; 11.7)	.37	3.3 (−3.1; 9.8)	.31
6 mo	13.3 (7.8; 18.8)	12.4 (7.1; 17.6)	.80	1.9 (−5.6; 9.3)	.62
1 y	15.7 (10.1; 21.3)	20.9 (16.9; 24.8)	.13	−3.6 (−9.5; 2.3)	.23
DASH (CFB)					
6 wk	−12.3 (−17.2; −7.4)	−5.0 (−9.9; −0.2)	.04	−6.8 (−13.4; −0.14)	.046
3 mo	−13.2 (−19.3; −7.1)	−6.4 (−12.4; −0.4)	.11	−6.2 (−14.0; 1.5)	.11
6 mo	−17.6 (−24.1; −11.1)	−13.6 (−18.5; −8.7)	.32	−3.2 (−10.8; 4.4)	.41
1 y	−20.7 (−27.2; −14.2)	−20.1 (−25.4; −14.8)	.87	1.1 (−6.5; 8.6)	.78
VAS pain (CFB)					
6 wk	−1.6 (−2.3; −0.9)	−0.9 (−1.7; 0.03)	.19	−1.1 (−2.1; −0.1)	.03
3 mo	−1.7 (−2.6; −0.7)	−1.1 (−2.1; −0.1)	.41	−1.0 (−2.2; 0.1)	.08
6 mo	−2.3 (−3.3; −1.3)	−2.9 (−3.6; −2.2)	.28	0.3 (−0.8; 1.4)	.62
1 y	−2.6 (−3.7; −1.6)	−3.9 (−4.6; −3.1)	.05	0.9 (−0.2, 2.0)	.12

NOTE.Mean difference between treatment groups, adjusted for potential confounders where required (sex, age, BMI, duration of complaints, baseline, Gärtner).

BMI, body mass index; CFB, change from baseline; CMS, Constant Murley Score; DASH, Disability of Arm, Shoulder, and Hand Score; ESWT, extracorporeal shockwave therapy; ITT, intention to treat; SD, standard deviation; UGN, ultrasound-guided needling; VAS, visual analog scale.

mm. In the ESWT group full resorption was observed in 14 cases (34%). With a mean size of 8.6 ± 8.3 mm after 6 months, a reduction in size of 7.1 ± 8.7 mm was measured.

Complications and Additional Interventions

Overall, there were no serious adverse events. Respectively, 1 (ESWT) and 2 (UGN) patients developed a frozen shoulder. Symptoms resolved during the study follow-up. One (ESWT) versus 5 (UGN) patients returned to the outpatient clinic in the first 2 months with severe symptoms of subacromial bursitis, which resolved after a SAI. One patient was lost to follow-up after the 12 weeks visit. In total, 26 patients received an additional treatment due to persistent pain and symptoms (Fig 1): 9 patients (22%) in the UGN group and 17 (41%) in the ESWT group ($P = .058$). In the UGN group, the additional interventions primarily consisted of an SAI to treat an acute bursitis in the first few weeks after treatment (5 patients) or persistent pain after 6 months despite full resorption on radiographs. In the ESWT group, 5 patients received an additional SAI (full resorption), 5 a UGN procedure, and 7 an arthroscopic bursectomy and intraoperative needling procedure. The secondary UGN and surgical procedures were performed after a minimal follow-up of 6 months (range 6-15 months).

Post-hoc Sample Size Analysis

A post-hoc power-analyses with the actual standard deviation found in this study after 1 year (standard deviation = 13.4) showed that 21 patients per group would have been sufficient to show a statistically significant and clinically relevant difference of 12 points in the CMS score. With 82 treated patients, a 97% power with a β error of 3% was achieved.

Discussion

The most important finding of this study is that both treatment techniques show clinically relevant improvements in terms of shoulder function and pain after 1-year follow-up. UGN was more effective in eradicating the calcific deposit, and there were more requests for additional interventions in the high-energy ESWT group. This study therefore only provides partial evidence to support our hypothesis.

The effectiveness of UGN has been studied in 2 previous randomized controlled trials. de Witte et al.[13] compared UGN with an ultrasound-guided SAI in their RCT containing 48 patients. They concluded that UGN is superior to a SAI in terms of functional and radiographic results after 1-year follow-up without between-group differences after 5-year follow-up. Kim et al.[12] analyzed 54 patients in their RCT comparing UGN with high-energy ESWT. Although both treatment techniques improved clinical outcomes, the results for UGN were superior in terms of functional outcome, pain, and resorption. However, in this study the ESWT protocol consisted of high-energy shockwaves focused, without ultrasound guidance, at the point of maximum tenderness. In a single blinded RCT, Sabeti-Aschraf et al.[21] already showed that the outcome of ESWT is superior when focusing on the calcific deposit as opposed to the point of maximum tenderness. We therefore believe that this was not a best-level of evidence shockwave protocol.[22] The ESWT protocol in the present study consisted of ultrasound-guided

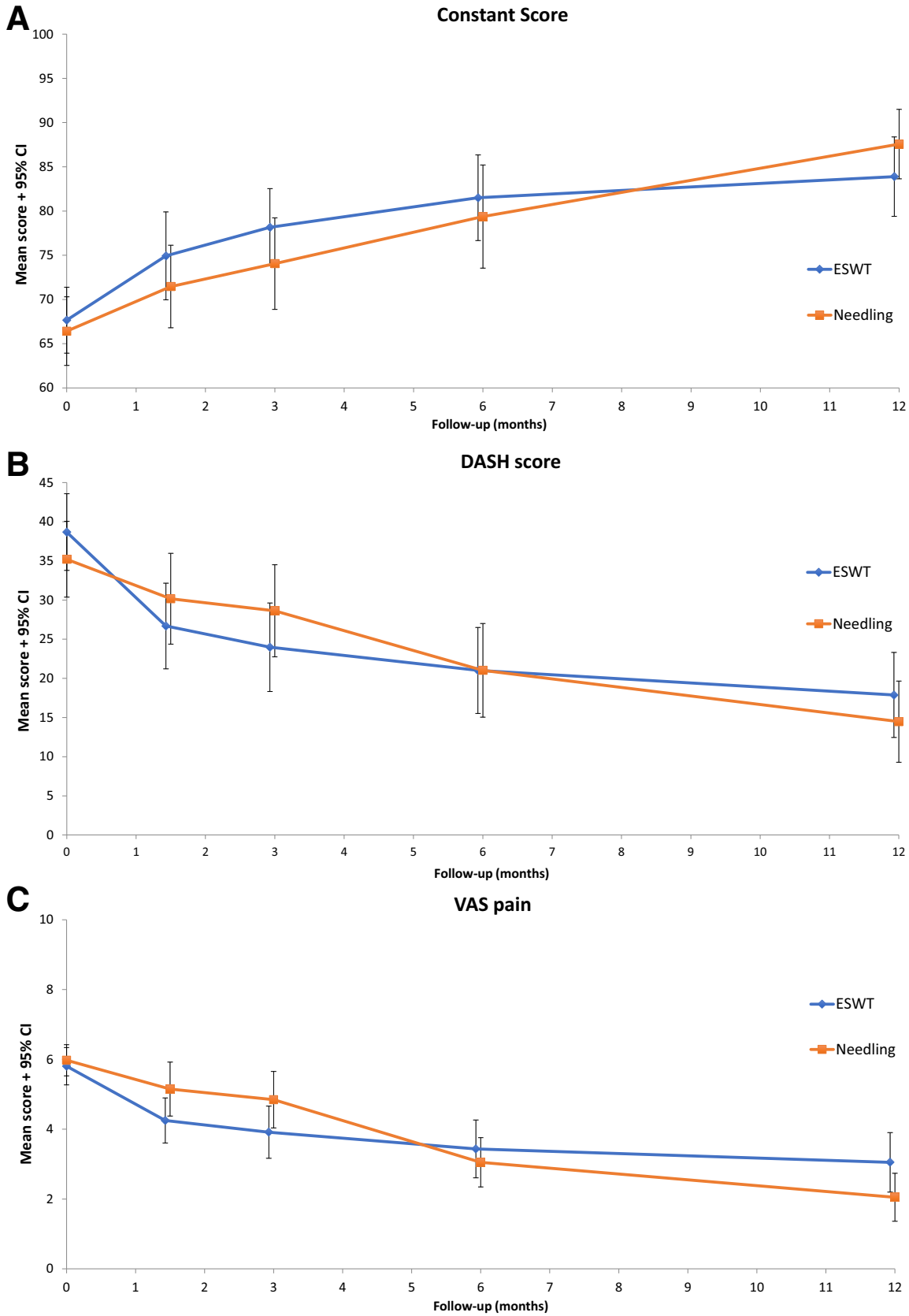

Fig 2. Development of the mean Constant Murley Score (A), DASH (B), and VAS pain score (C) after treatment with ESWT and UGN. (CI, confidence interval; DASH, Disability of Arm, Shoulder, and Hand Score; ESWT, Extracorporeal shockwave therapy; UGN, ultrasound-guided needling; VAS, visual analog scale.)

Table 3. Patient-Reported Change in Symptoms After 1-Year Follow-Up

	(Strong) Decline	Neutral	(Strong) Improvement
ESWT, n (%)	3 (8)	10 (26)	26 (67)
UGN, n (%)	1 (3)	8 (20)	31 (78)

NOTE. $P = .25$ (Mann–Whitney U test).
ESWT, extracorporeal shockwave therapy; UGN, ultrasound-guided needling.

Table 4. Resorption of Calcific Deposits After 6 Months Follow-Up

	No Change	<50%	>50%	Full Resorption
ESWT patients (%)	17 (42)	6 (15)	4 (10)	14 (34)
UGN patients (%)	0 (–)	1 (3)	12 (30)	27 (68)

NOTE. $P < .001$ (Mann–Whitney U test).
ESWT, extracorporeal shockwave therapy; UGN- ultrasound-guided needling.

shockwaves focused on the calcific deposit. The energy flux density was based on data from a meta-analysis containing 15 high-energy ESWT RCTs.[9]

The clinical results show that both treatment options provide a clinically relevant improvement in functional outcome and pain. A minimal clinically important difference (MCID) for the CMS was not known when the study protocol was conducted. In 2013, Kukkonen et al.[23] concluded that the MCID for patients undergoing rotator cuff surgery is 10.4 and a recent systematic review estimated the MCID for the CMS to be 8.3 based on 10 studies.[24] Accounting for this, it took patients between 3 and 5 months to reach this MCID level. For the UGN group, the pain and DASH scores stabilized at 6 to 12 weeks follow-up, after which further improvement was seen between 3-month and 1-year follow-up. This might be attributed to the temporary treatment effect of the subacromial corticosteroids, which declines after 6 weeks while the natural healing response of the tendon has not been completed yet.[13,25]

The radiographic results are in favor of UGN, with near full resorption in most of the patients. Despite the fact that the radiographic results of the ESWT group were less successful, this did not result in a statistically significant difference in clinical outcome. Previous studies have reported good clinical outcome without full removal of the calcific deposit and the beneficial inflammatory response after ESWT might also contribute.[21,26] However, Chou et al.[27] concluded that there is a strong relationship between subsidence of symptoms and remission of the calcification. It must be noted that most additional interventions were in patients with none or only partial (<50%) resorption of the calcific deposit. No differences in clinical outcome were found between Gärtner type I and II calcifications. Previous authors suggested that UGN might be more efficient in the more ill-defined Gärtner type II and type III deposits.[13,28] In this study, Gärtner type III deposits were excluded since they have the greatest chance of resorption and natural resolution of symptoms without (minimal) invasive therapies.[3,6,17] Long-term data on the natural history of calcific tendinitis vary greatly. Gärtner et al.[17] reported an 85% chance of natural resolution after 3 years for type III deposits, as opposed to 33% for type I and II deposits. In his classic study, Bosworth[3] reported that 6.4% off calcific lesions showed spontaneous resorption.

The effectiveness and safety of high-energy shockwave therapy has been studied extensively in previous randomized controlled trials and has been shown to be superior when compared with low-energy,[14,21,29] sham treatment, and placebo.[14,30,31] In both treatment groups, a percentage of patients experienced persistent

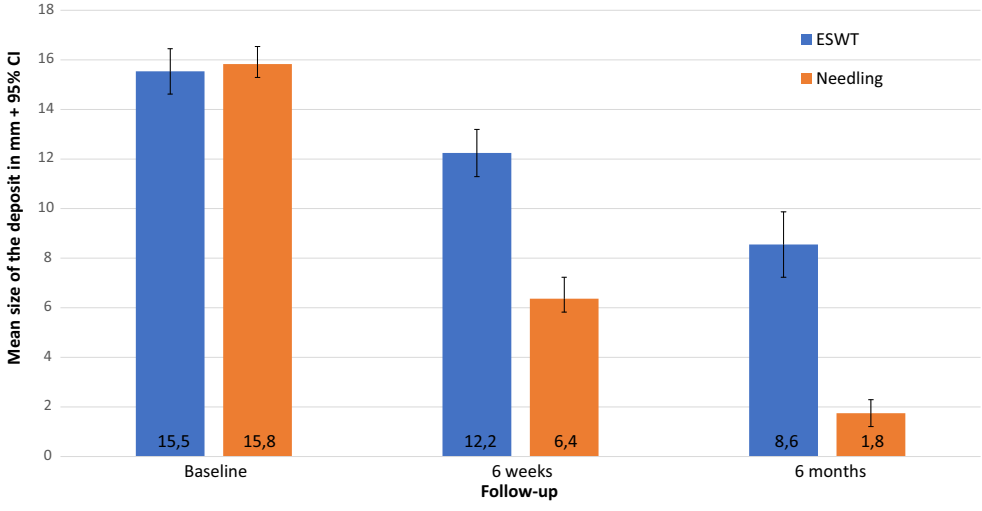

Fig 3. Change in size of calcific deposits. (CI, confidence interval; Extracorporeal shockwave therapy.)

pain and prolonged symptoms with or without radiographic change in size of the calcific deposit. Although not statistically significant, the absolute amount of patients was greater in the ESWT group and the applied treatment techniques more invasive. It must be noted that the study protocol did not contain an objective cut-off point in terms of CMS, DASH, or pain scores indicating when the treatment would be unsuccessful and an additional intervention would be required. There were no re-needling procedures or conversions to surgery in the UGN group. Previous studies reported a re-needling rate of between 10% and 45% and a conversion to arthroscopy in 6% and 17% of the cases.[13,32] The incidence of acute bursitis, necessitating a corticosteroid subacromial bursa injection, was slightly greater than previously reported.[10,15] Despite the fact that aspiration and lavage of the calcific material was performed these bursitis symptoms are probably caused by a reactive inflammatory response due to residual calcific minerals in the bursal tissue. The necessity of a corticosteroid SAI following UGN was questioned in a recent RCT comparing steroids with saline. However, pain and function were significantly lower in the corticosteroid group in the short term without long term disadvantageous effects.[33] A double-needle technique was used in our UGN protocol and although a single-needle technique is also known to be effective,[13] 2 needles can create a continuous in- and outflow of saline to remove calcific minerals and control the pressure inside the calcification during injection.

Limitations

The results of this study must be interpreted in light of several limitations. First, the presence of a third, observational, control group would have made the study results stronger. We attempted to compensate for this fact by including only patients with prolonged symptoms (mean period of 3 years) who did not respond to a strict nonoperative treatment protocol and exclude patients that had a high chance of natural resolution of symptoms. Our opinion was that patients would not have been willing to participate if there was a one-third chance they would have to continue with their conservative therapy. A second limitation is that blinding of patients was not possible due to the differences in technique and treatment protocol. Third, the substantial amount of additional interventions and variety in techniques might have caused a source of bias on the part of the provider. However, when correcting for this confounder in the sensitivity analysis, no differences in outcome were found. Fourth, the study population was slightly smaller than anticipated in the sample size analysis. However, due to a more homogeneous study population (with smaller standard deviation), the post-hoc sample size analysis revealed that the study was adequately powered (97%) with a minimal beta-error (3%) to show a significant clinically relevant difference. Finally, the follow-up of 1 year might have been short since recovery from calcific tendinitis sometimes takes longer. However, patients eventually ask for a treatment option in which their prolonged symptoms will resolve in an acceptable amount of time. The natural history of the condition will also play a more predominant role as the follow-up period exceeds the conventional one-year period.[34-36]

Conclusions

This RCT compares the clinical and radiographic results of UGN and high-energy ESWT in the treatment of calcific tendinitis of the rotator cuff. Both techniques are successful in improving function and pain with high satisfaction rates after 1-year follow-up. However, UGN is more effective in eliminating the calcific deposit, and the amount of additional treatments was greater in the ESWT group.

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Appendix Table 1. Sensitivity Analysis—Last Observation Carried Forward (LOCF)

	ESTW (n = 41)	UGN (n = 41)	Crude	Multivariate	
	Mean (95% CI)	Mean (95% CI)	*P* Value	β Coefficient (95% CI)	*P* Value
CMS (CFB LOCF)					
6 wk	7.6 (3.5; 11.7)	5.1 (0.8; 9.4)	.40	4.1 (−1.8; 10.0)	.17
3 mo	9.0 (4.2; 13.7)	7.0 (2.4; 11.6)	.56	2.3 (−4.4; 9.0)	.50
6 mo	11.1 (5.4; 16.8)	11.0 (5.6; 16.3)	.97	1.2 (−6.7; 9.1)	.76
1 y	11.6 (5.9; 17.3)	14.7 (9.0; 14.3)	.44	−1.6 (−9.6; 6.3)	.68
DASH (CFB LOCF)					
6 wk	−12.3 (−17.2; −7.4)	−5.0 (−9.9; −0.2)	.04	−11.3 (−20.2; −2.4)	.01
3 mo	−12.8 (−18.8; −6.9)	−6.4 (−12.4; −0.4)	.13	−6.1 (−15.7; 3.4)	.20
6 mo	−16.1 (−22.7; -9.5)	−11.8 (−16.8; −6.8)	.30	0.3 (−7.6; 8.2)	.94
1 y	−17.8 (−24.0; −11.6)	−14.9 (−20.4; −9.4)	.49	1.9 (−5.9; 9.8)	.62
VAS pain (CFB LOCF)					
6 wk	−1.7 (−2.4; −0.9)	−0.8 (−1.7; −0.1)	.13	−1.2 (−6.1; 2.4)	.02
3 mo	−1.7 (−2.7; −0.8)	−1.1 (−2.0; −0.1)	.34	−0.9 (−2.0; 0.3)	.13
6 mo	−2.2 (−3.2; −2.2)	−2.4 (−3.2; −1.5)	.80	−0.04 (−1.3; 1.2)	.95
1 y	−2.4 (−3.4; −1.3)	−3.1 (−4.1; −2.2)	.26	0.6 (−0.8; 1.9)	.40

NOTE.In this analysis, the additional treatment was considered an endpoint, and results of the last follow-up before initiation of the additional treatment were carried forward to avoid overestimation of the treatment effect.

Mean difference between treatment groups is shown, adjusted for potential confounders where required (sex, age, BMI, duration of complaints, baseline, and/or Gärtner).

BMI, body mass index; CFB, change from baseline; CI, confidence interval; CMS, Constant Murley score; DASH, Disability of Arm, Shoulder, and Hand Score; ESWT, extracorporeal shockwave therapy; UGN, ultrasound-guided needling; VAS, visual analog score.

Appendix Table 2. Sensitivity Analysis—Per-Protocol (PP) Analysis

	ESTW (n = 24)	UGN (n = 31)	Crude	Multivariate	
	Mean (95% CI)	Mean (95% CI)	*P* Value	β Coefficient (95% CI)	*P* Value
CMS (CFB PP)					
6 wk	10.9 (5.1; 16.7)	6.3 (1.0; 11.5)	.23	5.6 (−1.6; 12.8)	.13
3 mo	13.1 (7.2; 19.1)	11.0 (6.0; 16.0)	.57	0.4 (−6.1; 6.9)	.91
6 mo	18.3 (10.9; 25.8)	17.1 (12.2; 21.9)	.77	0.0 (−7.0; 7.1)	.99
1 y	19.9 (11.8; 26.3)	22.0 (17.6; 26.4)	.46	−3.8 (−10.2; 2.5)	.23
DASH (CFB PP)					
6 wk	−16.1 (−23.4; −8.7)	−4.4 (−10.0; 1.1)	**.01**	−11.3 (−20.2; −2.4)	**.01**
3 mo	−19.5 (−27.8; −11.2)	−8.4 (−15.5; −1.2)	**.04**	−6.1 (−15.7; 3.4)	.20
6 mo	−24.1 (−33.2; −15.0)	−16.8 (−21.9; −11.6)	.16	−0.3 (−7.6; 8.1)	.94
1 y	−26.2 (−34.5; −17.9)	−20.9 (−26.3; −15.5)	.28	1.9 (−5.9; 9.8)	.62
VAS pain (CFB PP)					
6 wk	−2.1 (−3.1; −1.1)	−1.1 (−2.2; 0.1)	.18	−1.3 (−2.6; −0.03)	**.046**
3 mo	−2.5 (−3.9; −1.1)	−1.6 (−2.6; −0.5)	.29	−1.0 (−2.3; 0.4)	.15
6 mo	−3.3 (−5.6; −1.9)	−3.4 (−4.1; −2.8)	.79	0.1 (−0.9; 1.3)	.70
1 y	−3.5 (−4.8; −2.2)	−4.1 (−5.0; −3.3)	.38	0.6 (−0.5; 1.8)	.28

NOTE.In this analysis only the cases were included who were compliant with the study protocol and did not receive additional treatments.

Mean difference between treatment groups adjusted for potential confounders where required (sex, age, BMI, duration of complaints, baseline and/or Gärtner).

Bold values indicate statistically significant.

BMI, body mass index; CFB, change from baseline; CI, confidence interval; CMS, Constant Murley score; DASH, Disability of Arm, Shoulder, and Hand Score; ESWT, extracorporeal shockwave therapy; UGN, ultrasound-guided needling; VAS, visual analog score.