

Calcific Tendinitis of the Rotator Cuff

A Randomized Controlled Trial of Ultrasound-Guided Needling and Lavage Versus Subacromial Corticosteroids

Pieter Bas de Witte,^{*†} MD, BSc, Jasmijn W. Selten,[†] MD, BSc, Ana Navas,[‡] MD, Jochem Nagels,[†] MD, Cornelis P.J. Visser,[§] MD, PhD, Rob G.H.H. Nelissen,[†] MD, PhD, and Monique Reijnen,[‡] MD, PhD
Investigation performed at Leiden University Medical Center, Leiden, the Netherlands

Background: Calcific tendinitis of the rotator cuff (RCCT) is frequently diagnosed in patients with shoulder pain, but there is no consensus on its treatment.

Purpose: To compare 2 regularly applied RCCT treatments: ultrasound (US)-guided needling and lavage (barbotage) combined with a US-guided corticosteroid injection in the subacromial bursa (subacromial bursa injection [SAI]) (group 1) versus an isolated SAI (group 2).

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Patients were randomly assigned to the 2 groups. Shoulder function was assessed before treatment and at regular follow-up intervals (6 weeks and 3, 6, and 12 months) using the Constant shoulder score (CS, primary outcome), the Western Ontario Rotator Cuff Index (WORC), and the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH). Additionally, calcification location, size, and Gärtner classification were assessed on radiographs. Results were analyzed using the *t* test, linear regression, and a mixed model for repeated measures.

Results: This study included 48 patients (25 female, 52.1%; mean age, 52.0 ± 7.3 years; 23 patients in group 1) with a mean baseline CS of 68.7 ± 11.9. No patients were lost to follow-up. Four patients in group 1 and 11 in group 2 (*P* = .06) had an additional barbotage procedure or surgery during the follow-up period because of persisting symptoms and no resorption. At 1-year follow-up, the mean CS in group 1 was 86.0 (95% CI, 80.3-91.6) versus 73.9 (95% CI, 67.7-80.1) in group 2 (*P* = .005). The mean calcification size decreased by 11.6 ± 6.4 mm in group 1 and 5.1 ± 5.7 mm in group 2 (*P* = .001). There was total resorption in 13 patients in group 1 and 6 patients in group 2 (*P* = .07). With regression analyses, correcting for baseline CS and Gärtner type, the mean treatment effect was 20.5 points (*P* = .05) in favor of barbotage. Follow-up scores were significantly influenced by baseline scores. Results for the DASH and WORC were similar.

Conclusion: On average, there was improvement at 1-year follow-up in both treatment groups, but clinical and radiographic results were significantly better in the barbotage group.

Keywords: rotator cuff; calcific tendinitis; treatment; randomized controlled trial; needling; barbotage

*Address correspondence to Pieter Bas de Witte, MD, BSc, Department of Orthopaedics, Leiden University Medical Center, Postzone J11R, Postbus 9600, 2300 RC Leiden, the Netherlands (e-mail: p.b.de_witte@lumc.nl).

[†]Department of Orthopaedics, Leiden University Medical Center, Leiden, the Netherlands.

[‡]Department of Radiology, Leiden University Medical Center, Leiden, the Netherlands.

[§]Department of Orthopaedics, Rijnland Hospital, Leiderdorp, the Netherlands.

Clinical trial registration number (Netherlands Trial Register): NTR2282.

One or more of the authors has declared the following potential conflict of interest or source of funding: This study is part of a larger project funded by ZonMw, the Netherlands Organisation for Health Research and Development (NOW) (grant number 40-00703-98-8564), and the Dutch Arthritis Association (grant number 09-1-303).

Calcific tendinitis of the rotator cuff (RCCT) is a frequently diagnosed condition, generally affecting people between the ages of 30 and 50 years and with a reported prevalence of 6.8% to 54% in patients with shoulder pain.^{17,46,50,51} Although it is allegedly a self-limiting disease with low-grade pain, symptoms can be severe and long lasting.^{17,25,50} There is no consensus on the preferred treatment for these cases. The current study is the first double-blinded randomized controlled trial comparing ultrasound (US)-guided needling and lavage (barbotage) in combination with a US-guided injection with corticosteroids and bupivacaine in the subacromial bursa (subacromial bursa injection [SAI]) versus an isolated US-guided SAI.

In RCCT, there are calcific deposits in 1 or more rotator cuff tendons. Its cause is unclear, but 3 stages have been described: (1) a formative stage (precalcific), (2) a resting phase (calcific), and (3) a final resorptive phase

(postcalcific).⁵⁰ Symptoms generally worsen in the last phase, in the form of pain in the deltoid region, with typical worsening of pain at night or after activities and variable functional impairment.^{11,13,16,46,49,51} Because of the self-limiting character of RCCT, treatment is preferably nonoperative, including physical therapy and nonsteroidal anti-inflammatory drugs (NSAIDs).^{11,33,37,50,51} In patients with severe or persisting symptoms, more invasive therapy is indicated. Numerous treatments have been reported: subacromial corticosteroid injections, US shock therapy (lithotripsy or extracorporeal shockwave therapy [ESWT]), needling and lavage (barbotage), acetic acid iontophoresis, and surgical techniques.¹¹ However, as there is a lack of high-level evidence studies comparing these modalities, the preferred treatment for RCCT remains a subject of debate.

Barbotage and SAI are among the most frequently applied treatments of RCCT.^{4,13,16,21,22,32,49} In fact, SAIs are relatively easy to perform, have a low complication risk, have low costs, and are easily available. Barbotage treatment is more invasive, needs more skills and equipment, is time consuming, and can be painful during and after intervention but is reported to give better results than SAI in retrospective studies.^{11,49} However, there are no trials, to our knowledge, that have compared these two treatments directly.

Our primary objective was to compare clinical and radiographic outcomes of treatment with (1) US-guided barbotage combined with a US-guided SAI versus (2) an isolated US-guided SAI in patients diagnosed with symptomatic RCCT who were nonresponsive to nonoperative treatment. We hypothesized that barbotage would lead to superior clinical and radiographic outcomes at 1 year after intervention.

MATERIALS AND METHODS

The current study was a multicenter, double-blinded randomized controlled trial with parallel groups and equal (1:1) simple randomization, conducted at Leiden University Medical Center (LUMC), Leiden, the Netherlands, and in cooperation with Rijnland Hospital, Leiderdorp, the Netherlands. Consecutive patients were included between March 2010 and December 2011. All stages of the study were approved by both institutional medical ethics review boards, and all participating patients signed informed consent forms.

Study Population

The source population consisted of patients referred to the orthopaedics department of either one of the 2 participating hospitals for treatment of nontraumatic shoulder complaints (>3 months). Inclusion criteria were pain in the deltoid region; worsening of symptoms with activities above shoulder level; positive Hawkins, empty can, and Yocum test results; and calcifications >3 mm in size on

standard anteroposterior (AP) radiographs. All patients qualified for more intensive treatment on account of no clinical and radiographic improvements after a minimum of 3 months with nonoperative treatment. Exclusion criteria were the following: age <18 or >65 years; radiographic or clinical signs of resorption (defined as a change in shape and density of the calcification and/or the presence of calcific deposits in the bursa, in combination with a recent period of increased pain); comorbidities in the affected shoulder with clinical, radiographic, and ultrasound evaluation; limited passive external rotation in 90° of abduction, suggestive of frozen shoulder syndrome; >1 SAI in the 3 months before inclusion; and history of fracture, surgery, or barbotage in the affected shoulder. Eligible patients were referred to the coordinating investigator (P.B.dW.) for further evaluation and inclusion.

Blinding and Intervention

Baseline demographics and clinical parameters were obtained by the coordinating investigator at the orthopaedics outpatient clinic of LUMC 1 hour before the planned study intervention. Standard shoulder radiographs were obtained (AP external rotation, AP internal rotation, and axial view). Each consecutive patient fulfilling the clinical and radiographic eligibility criteria received a sealed, personal randomization envelope. The randomization code, obtained from the randomizer function in Excel 2003 software (Microsoft, Redmond, Washington), was generated and stored by an independent local data manager.

Next, US-guided examination of the shoulder was performed to check for comorbidities and to localize the calcific deposits. After these investigations, with eligibility criteria still fulfilled, the patient-specific randomization code was revealed to assign the patient to either US-guided barbotage in combination with SAI (group 1) or only a US-guided SAI (group 2). All patients and the coordinating investigator, who was absent during the entire intervention, were blinded to treatment.

In each patient, 1 of 2 experienced musculoskeletal radiologists (A.N., M.R.) performed the entire US-guided procedure. After sterile preparation, patients received a local anesthetic injection in the skin (lidocaine 1%) and SAI using a 21-gauge needle. For the SAI, the needle was positioned in the subacromial bursa with US guidance 1 to 2 cm caudolateral to the acromion. Next, 5 mL of bupivacaine (5 mg/mL; Actavis group, Hafnarfjordur, Iceland) and 1 mL of Depo-Medrol (40 mg/mL; Pfizer, New York, New York) were injected. In group 1, in addition to the SAI, US-guided needling was performed using a 55-mm 18-gauge needle. The needle was introduced into the calcific deposit. Using a syringe with saline solution (room temperature), the calcification was flushed. After lavage, repeated perforation of the deposit was performed. Group 2 received only the SAI.

An identical postintervention pain suppression protocol was applied in both groups: 100 mg celecoxib 2 times a day for 3 days, with supplementary paracetamol (1000 mg, 4 times a day). Celecoxib was replaced with 50 mg tramadol 3 times a day in patients with contraindications for NSAIDs. Patients were instructed to cool the shoulder

¹¹References 1-3, 5, 7, 8, 10, 12, 13, 19, 49.

with an icepack when experiencing pain in the days after the intervention. In case of persisting symptoms, patients were treated with additional oral pain medication or physical therapy. In case of persisting symptoms and no radiographic signs of resorption >6 months after the index procedure, patients were scheduled for barbotage (ie, a second barbotage in group 1 patients) or surgery, depending on the preference and experience of the referring orthopaedic surgeon. The patients and the coordinating investigator remained blinded to the study intervention.

Follow-up

All patients had regular follow-up visits with the coordinating investigator before the intervention and at 6 weeks, 3 months, 6 months, and 1 year after the intervention. Standard radiographs of the shoulder were obtained immediately before treatment and at 1-year follow-up. At each visit, the Constant shoulder score (CS),¹⁴ the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH),¹⁸ and the Western Ontario Rotator Cuff Index (WORC)³¹ were used for clinical assessment. A 0- to 10-cm visual analog scale (VAS)³⁵ for pain at rest and during arm motion was administered directly after the intervention.

For the evaluation of calcific deposits on the radiographs, the Gärtner classification was used.²³ Deposits with a sharp border and a dense structure are type I calcifications, type II calcifications either have a sharp border and an inhomogeneous structure or a cloudy border and a homogeneous structure, and type III calcifications have a cloudy outline and are transparent in structure. The sizes of all calcification deposits (in mm) were measured, and the number of deposits and affected tendons were determined. In case of multiple calcifications, the characteristics of the largest calcification were used in statistical analyses.

Sample Size Calculation

As a primary outcome measure, the CS was applied for sample size calculation. We defined a difference of 10.0 points in the CS at 1 year after treatment as clinically relevant. Using a standard deviation of 9.0 based on previous studies, the standardized difference was 1.1. Combined with a desired power of 0.9 and a level of significance of .05, this led to a sample size of 40 using the Altman nomogram. Accounting for a potential dropout rate of 20%, we included 48 patients.

Statistical Analysis

Demographics and study data were entered into a local database. Continuous data were presented using means and standard deviations or medians and ranges, where appropriate.

The VAS pain scores directly after the intervention in both groups were compared with the unpaired Student *t* test. We compared the CS at 1-year follow-up between groups with unpaired Student *t* tests for total scores and difference-to-baseline scores. Difference-to-baseline scores were also assessed stratified for baseline Gärtner type. Additionally, linear regression analysis was performed

with the CS at 1 year as a dependent variable, taking into account the treatment group, baseline CS, and baseline Gärtner type. Similar analyses were used for the WORC and DASH. Resorption rates (proportions of patients with either a decrease in Gärtner type, calcification size, or total resorption) and proportions of patients in both groups undergoing a barbotage procedure or surgery during follow-up because of persisting symptoms were compared using Fisher exact tests.

To investigate how the postintervention course (repeated measures) was influenced by treatment, baseline Gärtner type, and baseline clinical scores, mixed models were constructed with a random effect for each patient. The WORC, CS, and DASH were each applied as a dependent variable, and follow-up moment, baseline clinical scores, baseline Gärtner classification, and the interaction terms between follow-up moment and treatment method as well as baseline Gärtner type and treatment method were applied as independent variables.

All follow-up analyses were performed according to the intention-to-treat principle. As a sensitivity analysis, the follow-up data were also assessed using a per-protocol analysis. PASW SPSS 20.0 software (IBM Inc, Armonk, New York) was used for statistical analyses, and *P* values <.05 were interpreted as statistically significant.

RESULTS

Baseline Characteristics

During the inclusion period, a total of 88 patients were potentially suitable for study participation. Of these, 40 did not meet all eligibility criteria (Figure 1). The final study group of 48 patients comprised 25 (52.1%) female patients. Mean age was 52.0 ± 7.3 years. Baseline characteristics appeared similar for group 1 (*n* = 23) and group 2 (*n* = 25), except for slightly lower baseline clinical scores and Gärtner types in group 2 (Table 1).

Baseline Radiographs and US-Guided Procedure

Thirty (62.5%) patients had a single calcific deposit, and in 18 (37.5%) patients, there were 2 or more calcifications. Baseline radiographs demonstrated that the mean calcification size was 14.2 mm. In 20 (41.7%) patients, the largest calcification was a Gärtner type I (Table 2). There were no statistically significant correlations between baseline Gärtner type or calcification size with either one of the baseline clinical scores (see Appendix Table S1, available in the online version of this article at <http://ajsm.sagepub.com/supplemental>).

Preintervention ultrasound evaluation demonstrated signs of a partial-thickness rotator cuff tear in 3 patients: supraspinatus tear in 1, infraspinatus tear in 1, and a combined supraspinatus and infraspinatus tear in 1 patient. There were no full-thickness rotator cuff tears. With regard to barbotage treatment in group 1, there was perforation in all 23 patients, aspiration in 11 (47.8%), and fragmentation in 14 (60.9%). Four (17.4%) patients had no aspiration or fragmentation.

TABLE 1
Demographics and Baseline Characteristics^a

Baseline Characteristics	All Patients (N = 48)	Group 1: Barbotage + SAI (n = 23)	Group 2: SAI (n = 25)
Age, y	52.0 ± 7.3	53.7 ± 7.3	50.4 ± 7.2
Sex, male/female, n	23/25	11/12	12/13
BMI	25.7 ± 3.3	27.0 ± 3.2	24.7 ± 3.0
Affected side, right/left, n	35/13	16/7	19/6
Dominant side affected, yes/no, n	31/17	15/8	16/9
Baseline clinical score			
WORC	45.3 ± 19.7	49.6 ± 20.3	41.6 ± 18.7
DASH	36.4 ± 17.3	32.6 ± 18.5	40.1 ± 15.7
CS	68.7 ± 11.9	71.6 ± 12.3	66.0 ± 11.2
VAS (at rest)	40.0 ± 24.3	33.4 ± 23.2	46.0 ± 24.2
VAS (motion)	49.2 ± 21.5	42.5 ± 23.6	55.3 ± 17.7

^aValues are shown as mean ± standard deviation unless otherwise indicated. BMI, body mass index; CS, Constant shoulder score; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; SAI, subacromial bursa injection; VAS, visual analog score for pain (100 = severe pain); WORC, Western Ontario Rotator Cuff Index.

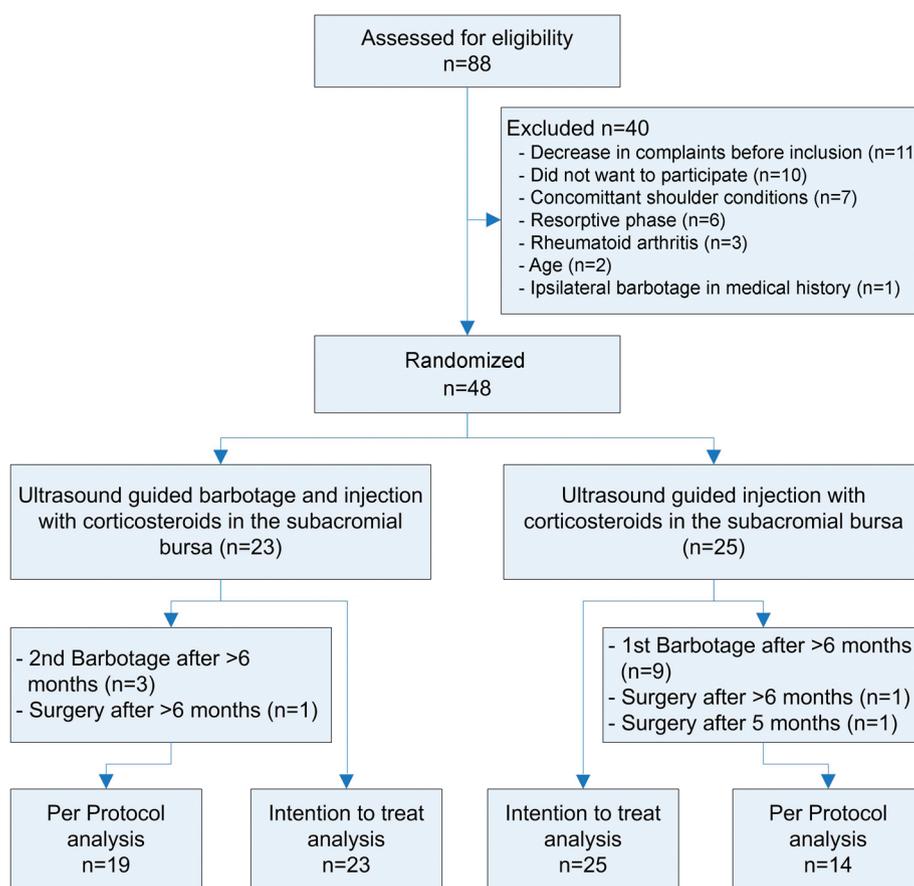


Figure 1. Study flowchart.

Directly after intervention, mean VAS pain scores were 22.1 ± 20.8 at rest and 23.6 ± 22.0 for motion in group 1 and 19.6 ± 24.2 at rest and 25.0 ± 23.9 for motion in group 2. Resulting mean differences were not significant: 2.5 (95% confidence interval [CI], -11.3 to 16.3) for rest and -1.4 (95% CI, -15.3 to 12.6) for motion.

Complications and Additional Treatment

Overall, there were no serious adverse events or complications. Two patients developed frozen shoulder syndrome after barbotage, but symptoms declined during the study follow-up period.

TABLE 2
Baseline Findings With Radiographic Evaluation^a

	All Patients (N = 48)	Group 1: Barbotage + SAI (n = 23)	Group 2: SAI (n = 25)
No. of calcifications			
1	30 (62.5)	18 (78.3)	12 (48.0)
2	15 (31.3)	5 (21.7)	10 (40.0)
>2	3 (6.3)	0 (0)	3 (12.0)
More than 1 tendon involved	7 (14.6)	3 (13.0)	4 (16.0)
Affected tendon(s)			
Supraspinatus	36 (75.0)	17 (73.9)	19 (76.0)
Infraspinatus	16 (33.3)	7 (30.4)	9 (36.0)
Subscapularis	4 (8.3)	1 (4.3)	3 (12.0)
Teres minor	0 (0)	0 (0)	0 (0)
Gärtner calcification classification			
Type I	20 (41.7)	11 (47.8)	9 (36.0)
Type II	22 (45.8)	9 (39.1)	13 (52.0)
Type III	6 (12.5)	3 (13.0)	3 (12.0)
Calcification size, mean ± SD, mm	14.2 ± 5.5	14.6 ± 4.7	19.9 ± 6.1

^aValues are shown as n (%) unless otherwise indicated. For calcification classification and size, numbers are based on the observations of the largest calcific deposit in each patient. SAI, subacromial bursa injection.

No patients were lost to follow-up. Two patients were unable to attend the last follow-up visit (CS and radiographs) but completed the 1-year WORC and DASH. Additionally, 15 patients underwent either a barbotage procedure (second procedure in the case of group 1 patients) or shoulder surgery during follow-up because of no clinical and radiographic improvements: 4 (3 barbotage, 1 surgery) in group 1 and 11 (9 barbotage, 2 surgery) in group 2 ($P = .06$) (Figure 1). This was within 6 months in 1 patient. For the group 1 (barbotage) patients, all 4 had Gärtner type I calcifications, and there was successful aspiration and/or fragmentation in 3 (75%) during the first barbotage procedure. For the 11 group 2 patients, there were 4 type I calcifications, 6 type II, and 1 type III.

Follow-up Radiographs and Clinical Characteristics

After 1 year, at final follow-up, there was resorption (partial or total) in 22 (95.7%) of the patients in group 1 (barbotage) and 17 patients (73.9%) in group 2 ($P = .10$). There was total elimination of the calcifications in 13 (56.5%) patients in group 1 and in 6 (26.1%) patients in group 2 ($P = .07$). The mean calcification size decreased by 11.6 ± 6.4 mm in group 1 and by 5.1 ± 5.7 mm in group 2 ($P = .001$).

There was a statistically significant improvement in the CS of 14.3 in group 1 (95% CI, 8.7-20.0) and 7.2 in group 2 (95% CI, 1.0-13.4) compared with the pretreatment scores. There were also significant improvements for the WORC and DASH in both groups, without statistically significant differences between both groups (Table 3). Stratified for baseline Gärtner type, there was more clinical improvement (CS) in patients with a higher Gärtner type in group 1 versus a lower clinical improvement with a higher Gärtner type in group 2. Clinical improvement was similar for type I calcifications, but statistically significant differences between groups were found for type III calcifications in particular, with superior results for group 1 (Figure 2). Results

for the WORC and DASH were similar, albeit to a lesser extent (see Appendix Figure S1A and S1B, available online).

In regression analysis accounting for baseline clinical score, baseline Gärtner type, and the interaction between treatment method and baseline Gärtner type, the CS at 1-year follow-up was significantly influenced by the baseline CS with an effect size of 0.45 (95% CI, 0.11-0.79), meaning that 10 points higher in the baseline CS leads to an average additional 4.5 points at 1-year follow-up. The mean treatment effect was 20.5 points (95% CI, -0.09 to 41.1) in favor of barbotage. For the DASH and WORC, baseline scores had a significant effect on the final follow-up scores, as did applied treatment for the WORC (Table 4). There were no significant effects for baseline Gärtner classification and its interaction term with treatment.

The course of clinical scores (repeated measures) is displayed in Figure 3. For all clinical scores and both groups, there was an average improvement at 6 weeks, followed by recurrent symptoms at 3 months. After 3 months, all scores showed an improvement in group 1 versus a further decline in scores in group 2. After 6 months, there was improvement in both groups. In mixed-model analyses, the mean overall effect of barbotage on the final CS was 17.9 points (95% CI, 2.0-33.7). Considering the pretreatment condition of the patients, the baseline CS added a 0.71-point (95% CI, 0.46-0.95) improvement for each pretreatment point. For the follow-up periods of 6 weeks and 3 months, there was a significant interaction effect with treatment: 10.8 (95% CI, 2.0-19.6) and 15.0 (95% CI, 6.1-23.8) points in favor of barbotage. There were no significant effects of Gärtner classification and its interaction term with treatment method in this model. Similar results were found for the WORC, with an overall treatment effect of 33.1 points (95% CI, 8.1-58.0) in favor of barbotage and a baseline WORC effect of 0.78 points (95% CI, 0.56-1.0). Similar patterns were found for the DASH but with only a significant effect for baseline scores: 0.94 (95% CI,

TABLE 3
Mean Final Clinical Scores and Mean Improvement During Follow-up^a

Clinical Score, 1-Year Follow-up	Group 1: Barbotage + SAI	Group 2: SAI Mean	Difference	
			Mean	P Value
CS				
Total score	86.0 (80.3 to 91.6)	73.9 (67.7 to 80.1)	12.1 (3.9 to 20.2)	.005
Improvement	14.3 (8.7 to 20.0)	7.2 (1.0 to 13.4)	7.1 (-1.0 to 15.3)	.08
WORC				
Total score	69.7 (57.6 to 81.8)	55.7 (45.0 to 66.5)	14.0 (-1.7 to 29.7)	.08
Improvement	20.5 (9.6 to 31.3)	15.8 (6.2 to 25.4)	4.7 (-9.3 to 18.7)	.51
DASH				
Total score	19.6 (9.5 to 29.8)	30.3 (20.3 to 40.4)	-10.7 (-24.6 to 3.2)	.12
Improvement	-10.4 (-19.3 to -3.2)	-11.3 (-19.3 to -3.2)	0.9 (-10.5 to 12.3)	.88

^aValues are shown as mean (95% confidence interval). CS, Constant shoulder score; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; SAI, subacromial bursa injection; WORC, Western Ontario Rotator Cuff Index.

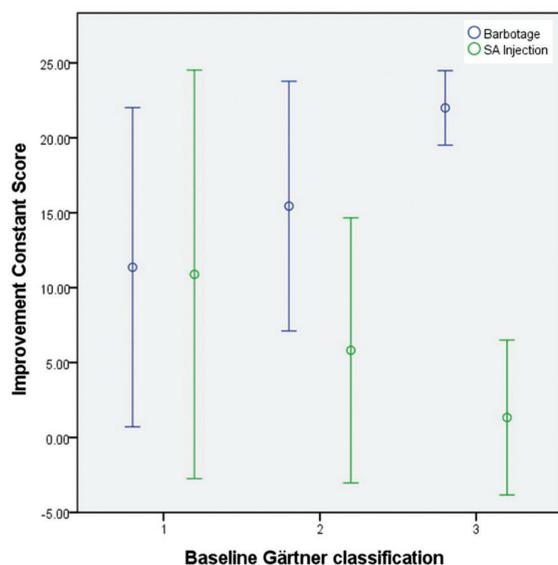


Figure 2. Improvement in the Constant shoulder score at 1-year follow-up in both treatment groups, stratified for baseline Gärtner classification.

0.7-1.2). Estimated clinical outcomes (CS) for an average RCCT patient group at 6 weeks, 3 months, 6 months, and 1 year for both groups based on the mixed model are displayed in Appendix Table S2.

Per-Protocol Analysis

Analyzing only patients who did not undergo barbotage or surgery at follow-up led to similar results as the intention-to-treat analyses. For the *t* tests comparing total scores at final follow-up, the WORC scores and CS were significantly higher in the barbotage group. There were no significant differences in the improvement scores between both treatment groups (see Appendix Table S3). The mean decrease in calcification size was significantly larger in the barbotage

TABLE 4
Influence of Baseline Scores and Treatment Method on Final Clinical Scores^a

	Effect	95% CI (All Patients)	P Value
CS			
Baseline score	0.45	0.11 to 0.79	.01
Treatment method	10.2	-0.09 to 41.1	.05
WORC			
Baseline score	0.76	0.39 to 1.13	<.001
Treatment method	38.2	0.93 to 75.4	.05
DASH			
Baseline score	0.93	0.54 to 1.32	<.001
Treatment method	-5.6	-43.7 to 32.5	.77

^aFor the CS, WORC, and DASH, there was a significant effect of baseline score on the clinical score at 1-year follow-up in linear regression analysis, accounting for baseline Gärtner type and the interaction between treatment and baseline Gärtner type. For all scores, there was a positive and clinically relevant effect of barbotage treatment on the final score. This was significant for the WORC. CS, Constant shoulder score; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; WORC, Western Ontario Rotator Cuff Index.

group. In the linear regression analyses, effects of baseline scores were significant for the WORC, DASH, and CS (see Appendix Table S4). There were no significant effects for treatment. In the mixed-model analyses, barbotage had a positive effect on outcome for all scores and with statistical significance for the WORC: 36.1 (95% CI, 10.1-62.1). Again, effects of all baseline scores on the final outcome were significant: 0.78 (95% CI, 0.56-1.01) per baseline point for the WORC, 0.72 (95% CI, 0.47-0.96) for the CS, and 0.95 (95% CI, 0.70-1.20) for the DASH.

DISCUSSION

The results of this study show that at 1 year after intervention, both US-guided barbotage with SAI and an isolated

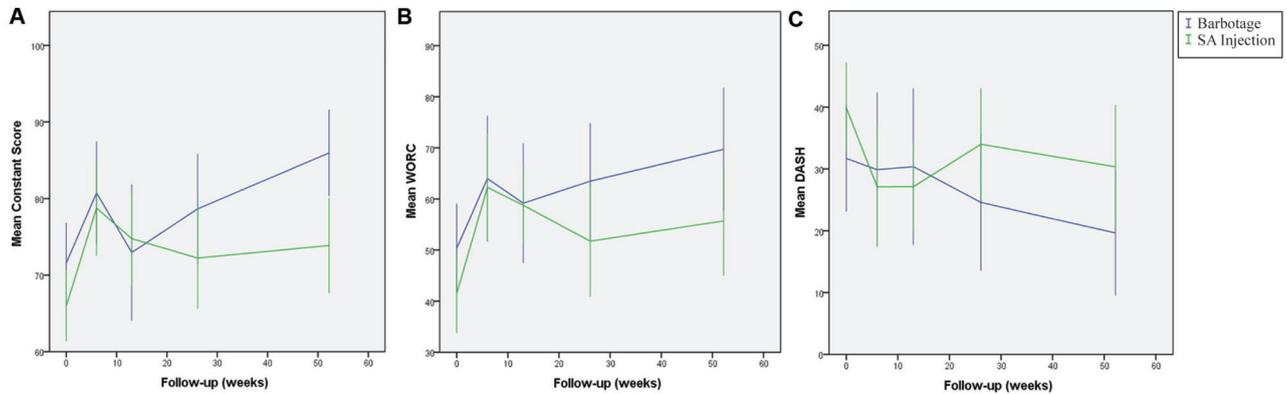


Figure 3. Clinical course expressed in the mean (A) Constant shoulder score, (B) Western Ontario Rotator Cuff (WORC) Index, and (C) Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire with 95% confidence intervals, after treatment of calcific tendinitis with either barbotage (group 1) or an ultrasound-guided injection with corticosteroids in the subacromial bursa (group 2).

SAI lead to an improvement in clinical and radiographic status in patients with symptomatic RCCT that is nonresponsive to conservative treatment. However, results of barbotage were significantly better in terms of more resorption and higher clinical scores at follow-up.

Although SAI, whether or not with US guidance, is a frequently applied nonoperative treatment for RCCT,³⁴ we found no studies assessing its effectiveness specifically in patients with RCCT. It is a widely available low-cost method, is relatively easy to perform, and has a low complication risk. Arroll and Goodyear-Smith⁴ reported in a meta-analysis on painful shoulders that US-guided corticosteroid injections proved to be 3.1 times more effective compared with placebo and 1.4 times more effective than oral NSAIDs, with a duration of benefit of up to 9 months. In our study, patients treated with a US-guided SAI had statistically significant and clinically relevant short-term improvement, but symptoms recurred after 6 weeks and worsened until 6 months after treatment. After 1 year of follow-up, there was clinical and/or radiographic improvement in some patients. This might be caused by, for example, the US-guided treatment, regular follow-up visits, or natural course of RCCT.^{49,50}

Barbotage is also a relatively noninvasive and widely available treatment that is often applied when more conservative methods fail. It is generally more painful than SAI but moderately to well tolerated. In our study, we found similar VAS pain scores directly after intervention in both groups. In the barbotage group, there was a significant and relevant average improvement of clinical and radiographic status at 1 year of follow-up. There are other reports with good midterm and long-term results of barbotage,^{13,16,21,29,38,39,42,47} but few compared with other treatments, and to our knowledge, there are no randomized controlled trials with barbotage. In a nonrandomized study, Serafini et al⁴⁹ reported significantly better short-term results of barbotage (n = 219) compared with a control group (n = 68). However, after 1 year of follow-up, there were no more significant differences between the two groups. The control group consisted of nonrandomly

selected patients who refused to undergo barbotage for unreported reasons. Many patients in this group were lost to follow-up (26% in the first 3 months), and it was not reported whether patients in the control group received any treatment during follow-up. Another point of discussion is the absence of calcification classifications in this study.⁹ As type III calcifications are reported to have a higher possibility of spontaneous recovery,^{6,46} an analysis of clinical outcome in 2 nonrandomized treatment groups without taking into account calcification types is prone to confounding and not reliable.

Barbotage was introduced in 1937 and was generally performed under radiographic guidance in the first decades.^{13,41} A more modern alternative is barbotage under US guidance, which is radiation free and enables easier localization of calcifications; US-guided injections in the subacromial bursa; and visualization of the rotator cuff, bursa, and biceps tendon and possible comorbidities in these structures.²⁰ Specifically in older patients, RCCT and rotator cuff tears can coexist, and both need different treatment approaches.³⁰ There is no consensus on the size and number of needles needed for optimal outcome. Some authors prefer small needles and a limited number of punctures to prevent excessive tendon damage,^{1,33,49} whereas others report multiple punctures^{1,21} or larger needles¹³ to stimulate continuing resorption after treatment. The alleged benefit of using 2 different needles for irrigation and aspiration has not been verified, and also on this subject, agreement has not yet been attained.^{1,16,49}

Our results demonstrated a similar pattern in both randomized groups until 3 months of follow-up: there was on average clinical improvement at 6 weeks, followed by recurring symptoms at 3 months. This temporary recurrence of symptoms around 3 months has been reported earlier for barbotage.¹⁶ It is plausible that both groups have short-term improvement, followed by recurring symptoms, because of a temporary effect of the administered subacromial corticosteroids. In the SAI group, there was a further worsening of symptoms after the recurrence at 3 months, followed by some improvement after 6 months. In contrast,

there was continuous clinical improvement after 3 months in the barbotage group to near healthy levels at 1 year.

Our radiographic results show similar outcomes in favor of barbotage. There was complete or partial resorption in 17 (68.0%) patients in the SAI group. In the barbotage group, there was resorption in 22 (95.7%) patients at 1 year after treatment, with complete resorption in 17 (56.6%), comparable with results in previous studies.^{16,21,42} Confirming our radiographic and clinical results, it has been reported that patients with radiographic improvement report better clinical results at follow-up.³³ Furthermore, patients with a baseline Gärtner type II or III calcification had better clinical results of barbotage in our study, whereas clinical results were similar for all types in the SAI group. This supports the findings of Farin et al,²¹ who reported that results of barbotage are better in patients with ill-defined calcifications (eg, Gärtner type II or III) and that these type of calcifications can be resistant to more conservative treatments.

With regard to the alternatives for barbotage and SAI, specifically, ESWT is a technique that is frequently reported. Indeed, ESWT seems to be a low-risk and low-cost procedure, but generally multiple procedures with special equipment are required. Good results have been reported but mostly with short-term follow-up and comparisons with placebo.^{15,19,26,27,36,53} Few studies with more than 6 months' follow-up compare ESWT to other treatments.^{8,43,44} Cho et al¹¹ reported that radiographic success rates for ESWT range between 15% to 70%, for barbotage between 28% and 76%, and for surgery around 72%. However, surgery for RCCT must be regarded as a last resort.²⁸ Reported clinical results are good,^{45,48,52} but complications (5.8%-9.5%), including infections and rotator cuff tears, exist, and surgical treatment is accompanied by a longer hospital stay.⁵⁴ Studies comparing surgery with other treatments are scarce. Our results show that barbotage, easily available and with a low complication risk, leads to good clinical and radiographic results. Also, as there are few randomized controlled trials comparing RCCT treatments, barbotage is now one of the few RCCT treatments with a proven efficacy in a high level of evidence study.

There are some limitations that need to be taken into account when interpreting our results. First, patient blinding was difficult. Patients in group 1 received a longer and somewhat more invasive treatment than those in group 2, which can be more painful during and after the procedure. As a result, there is a chance that some patients might have been able to make a distinction between the 2 therapies. However, measures were taken, such as applying US guidance in both groups and the same number of syringes that were visible to patients, to make recognition of the treatment method less plausible. And after all, patients in both groups indicated similar amounts of pain directly after the intervention. Second, depending on the treating radiologist, 1 or 2 needles were used for flushing with barbotage. However, no difference in resorption rates or clinical results was found. Third, our follow-up period was 1 year. Previous publications and analyses of our data suggest that

a decrease in symptoms and resolution of calcifications can take longer.^{24,40,44,49,55} Nevertheless, the majority of barbotage patients in our study already had good or excellent results at 1 year, and we were able to find significant and clinically relevant differences with SAI over the studied period of time. Future research is needed to further investigate which patients benefit most from barbotage and in whom more conservative, or in contrast, repeated barbotage or, for example, surgery is most beneficial.

This is the first study comparing the clinical and radiographic results of barbotage (combined with corticosteroid SAI) and corticosteroid SAI for the treatment of RCCT in a double-blinded randomized controlled trial. We conclude that both treatments give clinical improvement in patients with RCCT who fail more conservative treatments. Nevertheless, the results of barbotage in combination with SAI are superior to those of SAI alone, specifically in case of type II or III Gärtner calcifications. We therefore recommend the use of barbotage in patients with persisting symptoms of RCCT and no signs of spontaneous resorption over time.

ACKNOWLEDGMENT

The authors acknowledge Dr Erik van Zwet (Department of Medical Statistics, LUMC, Leiden, the Netherlands) for his help in the statistical analyses for this study and also the colleagues and secretaries of the Departments of Orthopaedics and Radiology of LUMC for their help in the logistics and planning of the patients.

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