

Rotator Cuff Calcific Tendinopathy: Randomized Comparison of US-guided Percutaneous Treatments by Using One or Two Needles¹

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Purpose:

To determine whether the use of one or two needles influences procedure performance and patient outcomes for ultrasonography (US)-guided percutaneous irrigation of calcific tendinopathy.

Materials and Methods:

Institutional review board approval and written informed patient consent were obtained. From February 2012 to December 2014, 211 patients (77 men and 134 women; mean age, 41.6 years \pm 11.6; range, 24–69 years) with painful calcific tendinopathy diagnosed at US were prospectively enrolled and randomized. Operators subjectively graded calcifications as hard, soft, or fluid according to their appearance at US. US-guided percutaneous irrigation of calcific tendinopathy (local anesthesia, needle lavage, intrabursal steroid injection) was performed in 100 patients by using the single-needle procedure and in 111 patients by using the double-needle procedure. Calcium dissolution was subjectively scored (easy = 1; intermediate = 2; difficult = 3). Procedure duration was recorded. Clinical evaluation was performed by using the Constant score up to 1 year after the procedure. The occurrence of postprocedural bursitis was recorded. Mann-Whitney *U*, χ^2 , and analysis of variance statistics were used.

Results:

No difference in procedure duration was seen overall ($P = .060$). Procedure duration was shorter with the double-needle procedure in hard calcifications ($P < .001$) and with the single-needle procedure in fluid calcifications ($P = .024$). Ease of calcium dissolution was not different between single- and double-needle procedures, both overall and when considering calcification appearance ($P > .089$). No clinical differences were found (Constant scores for single-needle group: baseline, 55 ± 7 ; 1 month, 69 ± 7 ; 3 month, 90 ± 5 ; 1 year, 92 ± 4 ; double-needle group: 57 ± 6 ; 71 ± 9 ; 89 ± 7 ; 92 ± 4 , respectively; $P = .241$). In the single-needle group, nine of 100 cases (9%) of postprocedural bursitis were seen, whereas four of 111 cases (3.6%) were seen in the double-needle group ($P = .180$).

Conclusion:

The only difference between using the single- or double-needle procedure when performing US-guided percutaneous irrigation of calcific tendinopathy is procedure duration in hard and fluid calcifications. Clinical outcomes are similar up to 1 year.

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Rotator cuff calcific tendinopathy is a common condition, reported to occur in up to 20% of painful shoulders (1,2). Intratendinous calcifications may be caused by the deposition of calcium on a fibrocartilaginous metaplasia induced by low oxygen tension, even though this theory is not completely demonstrated (3). Calcific tendinopathy is more frequent in women in their 40s and 50s and its association with work or physical activity is still unclear (4,5). Symptoms may vary from low-grade, subacute pain that worsens during the night to intense, highly disabling pain resistant to high doses of oral anti-inflammatory drugs and painkillers (6,7).

No consensus exists on how to treat calcific tendinopathy. Extracorporeal shockwave therapy and surgery can be used. However, ultrasonography (US)-guided percutaneous irrigation of calcific tendinopathy is widely performed throughout the world; it currently represents the first-line treatment for this condition (8,9) because it is quick, inexpensive, minimally invasive, and has a low complication rate (10,11). Slightly different approaches have been reported (2,12–19), all making use of a fluid (local anesthetic or saline solution)

to dissolve calcific deposits before aspiration. The main difference among procedures is the use of one needle (11,13,15–17,20–26) or two needles (2,5,12,18,19,27,28) to inject fluid and remove calcium, mainly based on authors' personal preference or on the idea that two needles may cause more damage to tendons than one. To date, to our knowledge, a direct comparison between the use of one or two needles has never been performed.

Thus, the purpose of our study was to determine whether the use of one or two needles influences procedure performance and patient outcomes for US-guided percutaneous irrigation of calcific tendinopathy.

Materials and Methods

Study Population

Our study had local ethics committee approval and all patients provided written informed consent. Patients were accrued from February 2012 to December 2014. Out of 263 subjects screened to undergo US-guided percutaneous irrigation of calcific tendinopathy, we excluded patients with ipsilateral concomitant rotator cuff tear ($n = 11$) and those previously treated with extracorporeal shockwave therapy, physical therapy, or local steroid injection ($n = 34$). The remaining 218 patients included 80 men and 138 women (mean age \pm standard deviation, 41.6 years \pm 11.7; range, 24–69 years) who

were prospectively randomized into two groups. Randomization sequence was calculated by using the random function in Excel (Microsoft, Redmond, Wash). One hundred eleven patients underwent US-guided percutaneous treatment of calcific tendinopathy by using two needles to inject saline and drain dissolved calcium, whereas 107 patients underwent the same treatment by using a single needle. Patients were not blinded to their group assignment. Demographic data are provided in Table 1. A flowchart of the study is presented in Figure 1.

The Constant score (29) was used for clinical assessment, which was performed by one of two musculoskeletal radiologists (F.L. and L.M.S., with 11 years and 10 years of experience in clinical evaluation of the shoulder, musculoskeletal US, and US-guided musculoskeletal interventions, respectively). The Constant score consists of two subjective measurements (pain and its relation to activities of daily living, up to 35 points) and two objective measurements (strength and range of motion as assessed by a physician, for the remaining 65 points). The sum of the two scores ranges from zero (total impairment) to 100 (normal shoulder). The criteria used to assess Constant score are reported in Table 2. Patients' right- or left-hand dominance was also recorded.

Pretreatment US Evaluation

After clinical evaluation, to define the exact location and consistency of the

Advances in Knowledge

- There was no significant difference ($P = .241$) in short- and long-term clinical outcomes between single- and double-needle US-guided percutaneous irrigation of calcific tendinopathy.
- There was no significant difference ($P = .180$) in occurrence of postprocedural bursitis between single- and double-needle US-guided percutaneous irrigation of calcific tendinopathy.
- No difference in procedure duration was seen overall ($P = .060$) between the single- and double-needle approaches; however, procedure duration was shorter by using two needles in hard calcifications ($P < .001$) and by using one needle in fluid calcifications ($P = .024$).

Implications for Patient Care

- Patients with rotator cuff calcific tendinopathy can be treated by using single- and double-needle US-guided percutaneous irrigation of calcific tendinopathy with comparable clinical outcomes up to 1 year and comparable incidence of postprocedural bursitis.
- Because of shorter procedure duration, the double-needle approach may be preferred in patients with hard calcifications, whereas the single-needle approach may be preferred in patients with fluid calcifications.

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Conflicts of interest are listed at the end of this article.

Table 1

Demographics and Clinical Characteristics at Baseline

Parameter	Patients Treated with One Needle	Patients Treated with Two Needles	P Value
No. of patients	100	111	...
Sex			.773
M	38	39	...
F	62	72	...
Age (y)*			.341
Overall	40.9 ± 11.4 (24–68)	42.2 ± 11.8 (26–69)	...
Men	39.7 ± 12.0 (26–66) [†]	41.2 ± 12.3 (26–68) [‡]	...
Women	41.6 ± 11.2 (24–68) [†]	42.8 ± 11.6 (26–29) [‡]	...
Affected shoulder			.146
Left	64	59	...
Right	36	52	...
Hand dominance			.139
Left	11	22	...
Right	86	89	...
Tendon			.352
Supraspinatus	84	86	...
Infraspinatus	8	11	...
Subscapularis	7	14	...
Teres minor	1	0	...
Calcification appearance			.802
Hard	30	38	...
Soft	61	64	...
Fluid	9	9	...
Bursitis	98	103	.146

Note.—Unless otherwise stated, data are number of patients. Data of patients treated using one needle do not include seven patients who were excluded from the study due to fluid leakage in the subacromial bursa and in the surrounding tissues during the procedure.

* Data are means ± standard deviation, with ranges in parentheses.

[†] No significant age differences were seen between men and women in the group of patients treated with one needle ($P = .309$; Mann Whitney U test).

[‡] No significant age differences were seen between men and women in the group of patients treated with two needles ($P = .393$; Mann Whitney U test).

calcified tendon, a US examination of the affected shoulder was performed by using MyLab Twice or MyLab70XvG (Esaote, Genova, Italy) with a 6–13-MHz probe (Esaote) or RS80A Prestige (Samsung Medical, Seoul, Korea) with a 3–12-MHz probe (Samsung Medical). The examination was performed according to the guidelines issued by the European Society of Musculoskeletal Radiology (30,31). The tendon and shoulder affected by the calcium deposit in each patient were recorded, and the US appearance of the calcium deposit was rated as follows: (a) hard, when presenting with a hyperechoic rim and acoustic shadowing; (b) soft, when presenting with homogeneous hyperechoic appearance without acoustic shadowing; and (c) fluid, when

presenting with a thin peripheral hyperechoic rim and hypo-anechoic core. All US examinations and US-guided procedures were performed by one of two operators (F.L. and L.M.S.).

US-guided Procedure

After thorough cleaning of the skin and US probe, local anesthetic (maximum of 200 mg of 2% mepivacaine chloridrate without adrenaline, Carbocaina; Aspen Pharmacare, Milan, Italy) was injected under direct US guidance into the subcutaneous tissues, the subacromial-subdeltoid bursa, and around the calcification. For patients treated with the double-needle procedure, two 16-gauge needles were inserted inside the calcification under continuous US monitoring.

The calcification was then washed with a 20-mL syringe of saline (NaCl 0.9%) heated at 42°C (107°F) (T 5045 Convection Oven; Heraeus, Hanau, Germany). This step was repeated several times until the fluid flush was completely free of visible calcium (1,5). For patients treated with the single-needle procedure, one 18-gauge needle was inserted within the calcification under continuous US monitoring. The calcification was then washed with a 10-mL syringe of heated saline, and successive propulsions and aspiration were performed with a syringe plunger (17). Extracted calcium was identified by a cloudy appearance within the saline and by the deposition of whitish material in the lowest portion of the syringe. This step was repeated several times, using new saline solution when needed, until no further amount of calcium could be extracted (17). In cases of needle obstruction, a 9-cm long, 21-gauge spinal needle (Terumo Europe, Leuven, Belgium) was used to restore needle patency without the need to extract or replace the treating needle(s) (9,32). The number of procedures in which needle obstruction occurred was recorded. After the washing phase was completed (Fig 2), the two needles were extracted from the tendon. Last, 1 mL of triamcinolone acetate (40 mg/mL Kenacort; Bristol-Myers Squibb, Rome, Italy) was injected in the subacromial-subdeltoid bursa under direct US guidance.

Procedure duration (from first needle insertion to steroid injection) was recorded. Ease of calcium dissolution was subjectively scored by the operator as previously reported (5) as easy, when initial calcium extraction required only a few slight compressions on the plunger, encountering almost no resistance; intermediate, when extraction required some compressions on the plunger, encountering some resistance; or difficult, when extraction required several intense compressions on the plunger, encountering high resistance, in conjunction with slight movement of the needles to help calcium removal.

A thorough US examination of the shoulder was performed after the procedure to detect potential immediate complications, such as complete

Figure 1

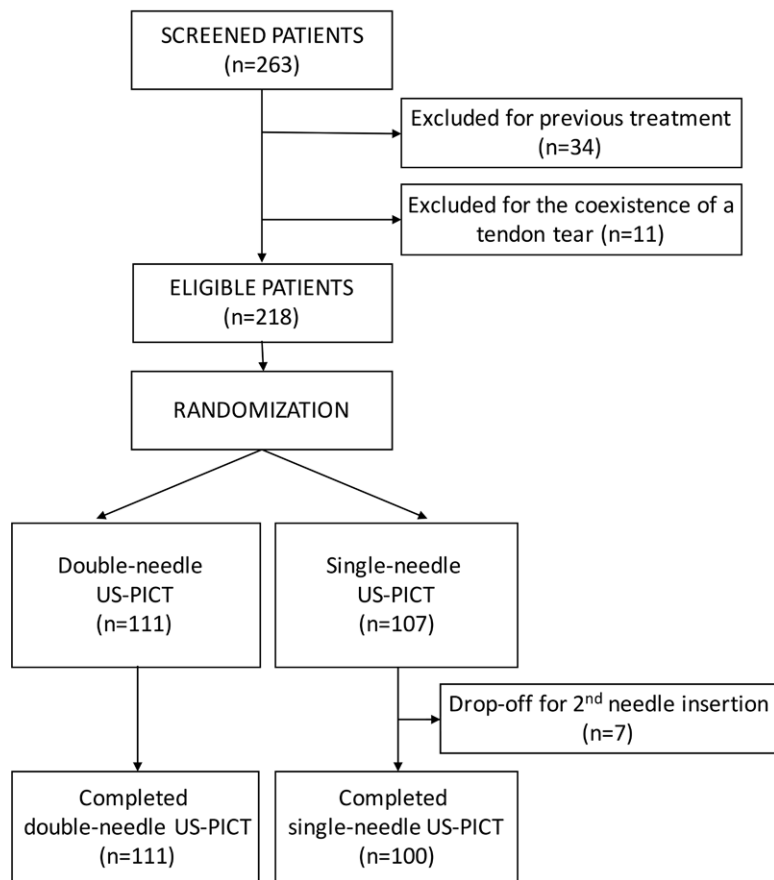


Figure 1: Flowchart of study population. *US-P ICT* = ultrasonography-guided percutaneous irrigation of calcific tendinopathy.

tendon rupture or abnormal bleeding. The occurrence of postprocedural vagal reactions was recorded.

Care after Procedure

After the procedure, each patient was observed for about 30 minutes and then discharged from the department. The routine protocol did not include any medication administration after patient discharge, but we suggested applying ice to the treated shoulder up to 6 hours after the procedure.

Follow-up

All patients underwent clinical follow-up and were evaluated by using the Constant score at 1 month and 3 months and by using the Constant score as well as follow-up with US at 1 year. The number of patients evaluated at

different follow-up time points is shown in Table 3. Those patients who experienced recurrence of their initial pain or discomfort underwent an additional US examination outside the routine follow-up protocol. In these patients, the presence of postprocedural bursitis was diagnosed with US as distension larger than 2 mm of the subacromial-subdeltoid bursa (10,32). US was also used to depict the presence of residual calcific deposits for potential retreatment. When bursitis was diagnosed, an additional US-guided intrabursal injection of 1 mL of triamcinolone acetonide was performed.

Statistical Analysis

Based on previous literature, the sample size was calculated a priori, taking into account values of Constant score

Table 2

Criteria Used to Assess the Constant Score

Criteria	Points
Pain	
Severe	0
Moderate	5
Mild	10
None	15
Activity level (check all that apply)	
Unaffected sleep	2
Full recreation/sport	4
Full work	8
Arm positioning	
Up to waist	2
Up to xiphoid	4
Up to neck	6
Up to top of head	8
Above head	10
Strength of abduction (pounds)	
0	0
1–3	2
4–6	5
7–9	8
10–12	11
13–15	14
15–18	17
19–21	20
22–24	23
>24	25
Forward flexion (degrees)	
31–60	2
61–90	4
91–120	6
121–150	8
151–180	10
Lateral elevation (degrees)	
31–60	2
61–90	4
91–120	6
121–150	8
151–180	10
External rotation	
Hand behind head, elbow forward	2
Hand behind head, elbow back	4
Hand behind top of the head, elbow forward	6
Hand behind top of the head, elbow back	8
Full elevation	10
Internal rotation	
Lateral thigh	0
Buttock	2
Lumbosacral junction	4
Waist (L3)	6
T12 vertebra	8
Interscapular (T7)	10

Note.—Unless otherwise stated, patients were asked to select one answer per item pertaining to the previous 4 weeks.

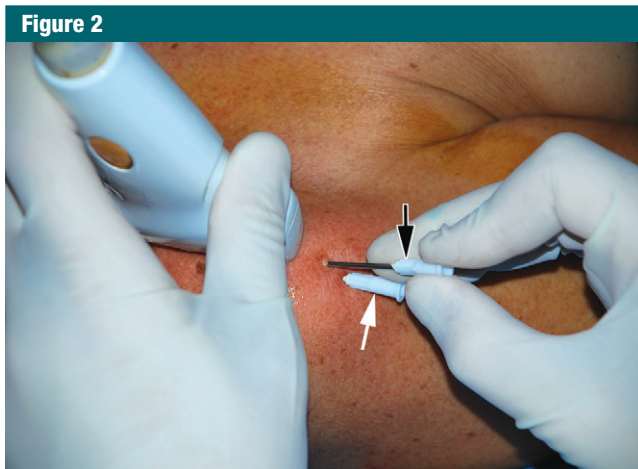


Figure 2: Photograph shows positioning of needles in a 56-year old woman treated with double-needle procedure. Needles are inserted from lateral side of shoulder. However, entrance position can be varied according to most convenient access to calcification. The more caudal needle (white arrow) should be inserted first to avoid image disturbance by the more cranial needle (black arrow). Needles should be inserted on same coronal plane, so they can be visualized together with a single scan during the procedure. When single-needle procedure is used, approach is the same but only the more caudal needle (white arrow) is used.

Table 3

Follow-up of 211 Patients with Rotator Cuff Calcific Tendinitis Who Underwent US-guided Percutaneous Treatment by Using Single- or Double-Needle Procedure

Population	Evaluated by Using Constant Score at 1 Mo	Evaluated by Using Constant Score at 3 Mo	Evaluated by Using Constant Score and US at 1 Y
No. of patients treated with one needle	100	96	90
No. of patients treated with two needles	111	105	100

before and after treatment, and hypothesizing an effect size of 0.35, with $\alpha = .05$, power = 0.80, and allocation of 1:1. Thus, we calculated a sample of 102 patients per group. Sample size was calculated by using G*Power software (version 3.1; Heinrich Heine Universität, Dusseldorf, Germany) (33). Procedure duration in patients treated with two needles was compared with that of patients treated with one needle by using the Mann-Whitney *U* test. Ease of calcium dissolution and failure rate of the procedure in patients treated with two needles were compared with those of patients treated with one needle by using the χ^2 test (34). The

Constant score of patients treated with two needles was compared with that of patients treated with one needle at baseline, 1 month, 3 months, and 1 year after the procedure. Normality of distributions was checked with the Kolmogorov-Smirnov test. A mixed-effect analysis of variance repeated measure model was applied with four levels for the within-subjects factor (time) and with two levels for the between-subjects factor (group). After testing the sphericity with the Mauchly test, the Greenhouse-Geisser correction was applied. The number of cases of post-procedural bursitis in patients treated with two needles was compared

with that of patients treated with one needle by using the χ^2 test. Statistical analyses were performed with SPSS software (version 23; SPSS, Chicago, Ill). For overall comparisons, *P* value less than .05 was considered indicative of a statistically significant difference; for multiple paired comparisons, the Bonferroni correction was applied.

Results

In seven of 107 patients (6.5%) treated with one needle who had a hard calcification, we detected leakage of fluid in the subacromial bursa and in the surrounding tissues after a few compressions on the syringe plunger. In these patients, a second needle was used and the procedure was conveniently completed. However, these patients were considered to have treatment failure and were excluded from the study. The results reported here are related to the remaining 100 patients treated with one needle. Thus, our final study group included 211 patients (77 men and 134 women; mean age, 41.6 years \pm 11.6; range, 24–69 years). Demographic data, frequency of affected tendons, right- or left-hand dominance, affected shoulder, and presence of bursitis at preliminary US of both groups of patients are provided in Table 1.

Procedure Duration and Calcium Dissolution

No significant difference in terms of overall procedure duration ($P = .060$) was seen in patients treated with two needles compared with patients treated with one needle. However, subgroup analysis demonstrated that procedure duration was shorter by using two needles in hard calcifications ($P < .001$) and by using one needle in fluid calcifications ($P = .024$).

Ease of calcium dissolution was not significantly different between patients treated with two needles compared with those treated with one needle, both overall and when performing subgroup analysis ($P > .089$).

Full data of procedure duration and ease of calcium dissolution is given in Table 4.

Table 4
Procedure Duration and Ease of Calcium Dissolution Scores in 211 Patients

Parameter	Hard Calcifications	Soft Calcifications	Fluid Calcifications	Overall
Procedure duration (sec)*				
Patients treated with one needle	554 (528–578)	455 (410–500)	400(351–402)	487(413–530)
Patients treated with two needles	479 (452–513)	458 (409–498)	418 (401–423)	461 (420–499)
<i>P</i> value [†]	<.001	.908	.024	.060
Ease of calcium dissolution[‡]				
Patients treated with one needle				
Easy	...	7/61 (12)	8/9 (89)	15/100 (15)
Intermediate	16/30 (53)	44/61 (72)	1/9 (11)	61/100 (61)
Difficult	14/30 (47)	10/61 (16)	...	24/100 (24)
Patients treated with two needles				
Easy	1/38 (3)	14/64 (22)	7/9 (78)	22/111 (20)
Intermediate	28/38 (74)	45/64 (70)	2/9 (12)	75/111 (67)
Difficult	9/38 (23)	5/64 (8)	...	14/111 (13)
<i>P</i> value [§]	.106	.140	.527	.089

* Data are medians, with ranges between the 25th–175th percentiles in parentheses.

[†] Mann-Whitney *U* test.

[‡] Data are the number of cases, with percentages in parentheses.

[§] χ^2 test.

Treatment Results and Follow-up

The seven patients we decided to treat with two needles after failure of the single-needle procedure were considered to have treatment failure. Thus, we had seven of 107 treatment failures (6.5%) in the group of patients treated with one needle and no failures in those patients treated with two needles ($P < .001$). Needle obstruction occurred in 15 of 100 shoulders (15%) treated with one needle and in four of 111 shoulders (3.6%) treated with two needles ($P = .030$). In all cases, needle patency was properly restored by using a 9-cm long, 21-gauge spinal needle, as reported above. In three cases treated with one needle, needle obstruction occurred more than once during the same procedure.

At the end of the treatment, all calcifications were mostly washed and only a thin peripheral calcific rim could be depicted at US (see Fig 3). All procedures were free from any immediate complications except for mild vagal reactions occurring in three of 111 patients (2.7%)

treated with two needles and in four of 100 patients (4%; $P = .888$) treated with one needle. No patients reported severe postprocedural pain requiring an observation period longer than 30 minutes.

Regarding Constant score, we observed no overall significant difference between patients treated with single- and double-needle procedures ($P = .241$). Full data are reported in Table 5.

Out of the scheduled time points, we performed 13 evaluations in patients who presented with pain in the treated shoulder. The patients comprised five men and eight women (mean age, 47.1 years \pm 4.7). In 12 of 13 evaluations (92.3%), subacromial bursitis was depicted at US within 49 days \pm 23 (median, 53 days; range, 23–67 days) after the treatment. Four of 111 cases (3.6%) were observed in patients treated with two needles, while nine of 100 (9%) of them were observed in patients treated with one needle ($P = .180$). In the remaining patient complaining of pain, who was treated with two needles, we observed glenohumeral joint effusion

with no sign of bursitis (Fig 4). In all returning patients, US images depicted tiny calcific spots where the original calcification was treated, but we determined there was no need for retreatment. All these patients received an US-guided steroid injection in the subacromial bursa (for those patients diagnosed with bursitis) or in the joint space (for the patient diagnosed with joint effusion). After the injection, all patients fully recovered from pain.

At 1-year follow-up US, we found no tendon tears at the site of the removed calcification. No residual or new calcifications were seen.

Discussion

Our main findings indicate that no significant difference exists between single- and double-needle US-guided percutaneous irrigation of calcific tendinopathy in terms of short- and long-term clinical outcomes, occurrence of postprocedural bursitis, ease of calcium dissolution, and overall procedure duration. However, procedure duration was shorter by using two needles in hard calcifications and by using one needle in fluid calcifications.

Calcific tendinopathy is common in rotator cuff tendons. The condition occurs mainly in the supraspinatus, although other tendons in the body can be similarly affected. Calcific tendinopathy is thought to be caused by poor oxygen supply within a tendon, although other theories have also been proposed. This condition implies the deposition of hydroxyapatite, calcium salts, collagen matrix, and cellular debris to form large, nodular deposits within tendons. Of note, no inflammatory cells are usually encountered. The conglomerate nature of the deposit allows for a relatively easy dissolution using simple saline solution. The disease has a well-known evolution into four stages: precalcific, calcific, resorptive, and postcalcific. In the resorptive stage, vascular invasion, increase of phagocytic cells, and edema can be seen, resulting in remarkable local pain. The stage of calcific tendinopathy is usually related to the consistency of the deposit: soft

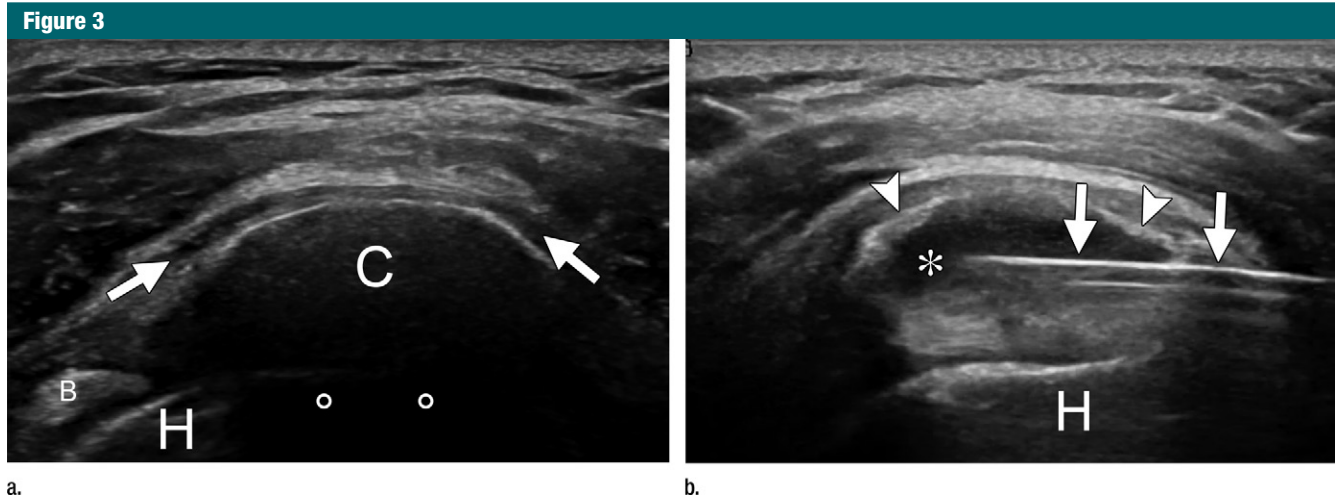


Figure 3: US images show supraspinatus calcification in a 29-year-old woman. **(a)** Calcific deposit (*C*) can be clearly seen with moderate acoustic shadowing (circles). Subacromial bursitis (arrows) can be seen. **(b)** End of treatment. Most calcific material was removed from calcification (*) with single-needle procedure. Only a thin calcific wall (arrowheads) was left. Needle (arrows) is still inside calcification. *B* = biceps tendon, *H* = humeral head.

during the precalcific stage, hard during the calcific stage, and fluid during the early resorptive phase. Symptoms may range from low-grade discomfort to unbearable pain affecting activities of daily living. When symptomatic, calcific tendinopathy can be treated with different approaches. Oral nonsteroidal anti-inflammatory drugs may be used to control low-grade symptoms, whereas extracorporeal shockwave therapy, surgery, or image-guided procedures can be used in advanced cases (35–37).

Since its first description by Bradley et al in 1995 (15), US-guided percutaneous irrigation of calcific tendinopathy has been reported in several studies with slight variations among them (12,13). The main and most debated differences are the number and the size of needles used to dissolve deposits and aspirate calcium. More than half of authors used one needle (11,13,15–17,20–26), whereas others preferred to use two needles (2,5,12,18,19,27,28). Of note, the mechanism of calcium removal when using one or two needles is conceptually different. With one needle, successive propulsions and aspiration with the syringe plunger are performed and calcium is collected on the bottom of the same syringe that is used to inject fluid. With two needles, the purpose is to create a continuous flow of saline solution that is injected through

Table 5

Constant Score Evaluation of 211 Patients				
Population	Constant Score at Baseline	Constant Score at 1 Mo	Constant Score at 3 Mo	Constant Score at 1 Y
No. of patients treated with one needle	55 ± 7	69 ± 7	90 ± 5	92 ± 4
No. of patients treated with two needles	57 ± 6	71 ± 9	89 ± 7	92 ± 4

Note.—Data are means ± standard deviation.

a needle and expressed out from the other. Remarkable variations in terms of needle caliber have also been reported, ranging between 16-gauge and 25-gauge needles. Some authors have postulated that using two larger needles might be “potentially harmful to the tendon” (15,17,38). However, although this hypothesis seems to be theoretically reasonable, the direct relationship between larger needle caliber and occurrence of tendon tears has never been reported, neither in the short nor in the long term (2,25,37,39). This is consistent with what we found in our series, in which no tendon tears were seen at 1-year follow-up US in patients treated with one or two needles.

Regarding needles and syringes, we chose to use different sizes between one- and two-needle procedures. We acknowledge that forces exerted on

calcifications with needles and syringes of different size are not equal; thus, this may be viewed as a limitation. However, 16-gauge needles were already used in conjunction with 20-mL syringes (2,5,28); similarly, 10-mL syringes were also used (26). Some authors used 20–22-gauge needles (15,17,21,25,26). However, we chose to use an 18-gauge needle as a good compromise between 20-gauge and 16-gauge needles, because in our clinical experience (unpublished data), 20–22-gauge needles frequently get obstructed and remarkably increase procedure duration. We acknowledge that our results apply only to the double-needle procedure performed with a 16-gauge needle versus the single-needle procedure performed with an 18-gauge needle, which may be regarded as a further limitation. The use of a different combination of needle

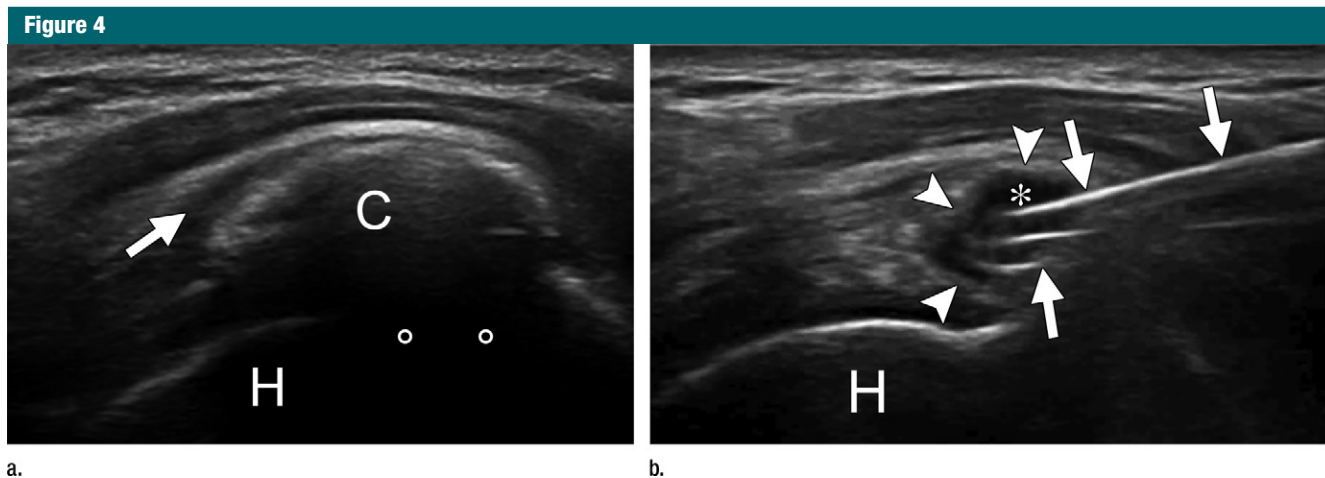


Figure 4: US images show supraspinatus calcification in a 37-year-old man. **(a)** Calcific deposit (*C*) can be clearly seen with moderate acoustic shadowing (circles). Subacromial bursitis (arrow) can be seen. **(b)** End of treatment. Most calcific material was removed from calcification (*) with double-needle procedure. Only a thin calcific wall (arrowheads) was left. Needles (arrows) are still inside calcification. *H* = humeral head.

sizes and numbers may lead to different results. Last, the use of an 18-gauge needle may also have influenced the higher rate of needle obstruction in patients treated with the single-needle procedure.

No significant difference exists in terms of clinical outcome up to 1 year, because both procedures allowed for prompt and long-lasting improvement of Constant score. Based on that finding and because procedure duration was shorter with two needles in patients with harder calcifications and with one needle in patients with fluid calcifications, we suggest that patients with hard calcifications are treated with two needles and patients with fluid calcifications are treated with one needle. However, the absolute time difference is not that high, thus tempering the importance of this result.

In terms of shorter duration, the superiority of the two-needle procedure when treating patients with hard calcifications may have different explanations. First, hard calcifications are usually very compact; thus, the insertion of two large-bore needles may help to fragment the deposition and to facilitate its dissolution. Then, when using a single needle, high pressure can be needed to allow for calcium dissolution. Thus, if not controlled by

a second needle, pressure may cause the disruption of calcific peripheral rim, possibly spreading saline and calcium mixture in the bursa and the surrounding tissues. Of note, this calcium spreading occurred in seven patients with hard calcifications treated with one needle, who were considered to have treatment failure and were therefore excluded from data analysis, because calcium spreading may represent a confounding factor for clinical outcome. Although this topic was not assessed in this article, in clinical practice we prefer to avoid calcium spreading around tendons, because calcific bursitis is a known source of pain in patients with calcific tendinopathy. Overall, we speculate that patients with hard calcifications may be preferably treated using two needles to avoid leakage. Last, a spinal needle to restore needle patency in case of obstruction should be used very carefully and under continuous US monitoring to avoid interruption of peripheral rim and subsequent leakage of saline and calcium.

Regarding procedure duration, our results with the double-needle procedure are comparable to a previous study using warm saline solution (5) and in a previous study performed with room temperature saline (2). Single-needle

procedure duration in the present series is also comparable with results previously reported by del Cura et al (15).

Although not statistically significant, the number of cases of postprocedural bursitis was almost double in the group treated with one needle. Because the rate of bursitis is comparable to that in previous literature (40), we speculate that lack of statistical significance may be due to a relatively low prevalence of this minor complication. However, this cannot be derived from present data and further studies may be needed to address this issue.

Some limitations of our study should be taken into account. First, two different operators performed the procedure, which may have in some way influenced the subjective scoring of ease of calcium dissolution. This score was previously reported (5) but reproducibility could not be tested. However, both radiologists were trained at the same institution to treat patients with calcific tendinitis of the rotator cuff in the same way. Second, patients and operators were not blinded to the number of needles used. Third, we did not measure the amount of calcium extracted during each procedure. This measurement might have been of value, as we could understand whether one method or the other

allows for improved calcium removal. However, this information may be not relevant, because results are not different between both groups.

To conclude, US-guided percutaneous irrigation of calcific tendinopathy can be performed with one or two needles to obtain similar results in terms of short- and long-term clinical outcomes, occurrence of postprocedural bursitis, ease of calcium dissolution, and overall procedure duration. Patients with hard calcifications treated with two needles and those with fluid calcifications treated with one needle may benefit from a shorter treatment duration.

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