

Clinical outcome after ultrasound-guided needling in the treatment of chronic calcifying rotator cuff tendinopathy

Abstract

Introduction: Chronic calcifying rotator cuff tendinopathy is a common painful condition and one of the causes of subacromial pain syndrome. Ultrasound-guided needling has proven to be a successful minimally invasive treatment modality. The study aim is functional and patient reported outcome after needling in a cohort of patients with calcifying tendinopathy with a follow-up of 4 years.

Materials and methods: Between September 2010 and March 2011 a total of 65 patients were prospectively enrolled. Clinical evaluations were performed at baseline and at 8 weeks, 1 and 4 years after treatment. Pain and function were analyzed by the Shoulder Pain and Disability Index (SPADI) questionnaire and patient satisfaction and effectiveness was reported at final follow-up.

Results: The mean change from baseline SPADI score after four years was 47.9 (95%CI 57.7; - 38.8, $p < 0.001$) points. Fifteen patients (28%) were treated again with needling or surgery due to unresolved pain. A significant difference in patient reported effectiveness after four years was found between the two groups ($p = 0.01$) in favor of single treatment.

Conclusion: US-guided needling provides clinical improvement in patients with calcifying tendinopathy (70%) after four years and a high percentage of patients is satisfied (73%).

Level of evidence: IV

Keywords: Shoulder, Rotator cuff, Chronic, Calcific, Tendinopathy, Treatment, Minimally invasive, Ultrasound guided needling

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Introduction

Calcifying rotator cuff tendinopathy is a common painful condition and is one of the causes of subacromial pain syndrome (SAPS). The estimated prevalence ranges from 2.7% to 27% in the general population^{1,2} and 6.8% to 42% in patients with shoulder pain.^{3,4} Individuals aged between 30 and 60 years are most susceptible to develop calcifying tendinopathy, with women affected 1.5 times more often than men.³⁻⁵

The precise etiology of calcifying tendinopathy is still unclear. It is hypothesized that metaplasia of tendinocytes in an active biological environment as a reactive process to a disbalance in workload and load-capacity of the shoulder plays a role in the formation of calcific deposits in the tendons.^{6,7} In calcifying tendinopathy, three overall stages can be distinguished: precalcific, calcific and postcalcific.⁷ The essential calcific stage can also be divided in three separate phases: formative, resting and resorptive. Due to this cyclic behaviour, spontaneous resorption and reconstitution of the tendon may occur.^{1,8}

The pillars in the conservative treatment of calcifying tendinopathy are nonsteroidal anti-inflammatory drugs, physiotherapy and prudent use of subacromial corticosteroid injections (SAI). These non-operative therapies are effective in approximately 70% of individuals with calcifying tendinopathy.⁹ Ultrasound (US) guided needling and extracorporeal shockwave therapy (ESWT) have been proven to be successful minimally invasive treatment modalities when conservative treatment fails (Figure 1 & 2).^{10,11} Nevertheless, failure of these nonsurgical therapies may necessitate surgical treatment in some cases.¹²

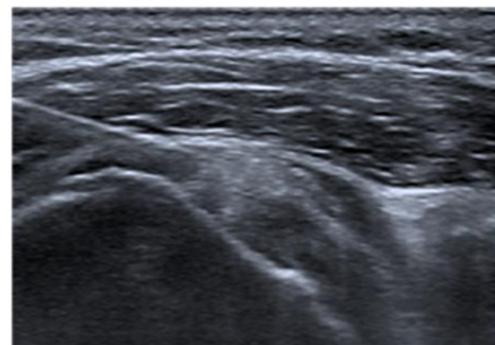


Figure 1 Before US-guided needling.

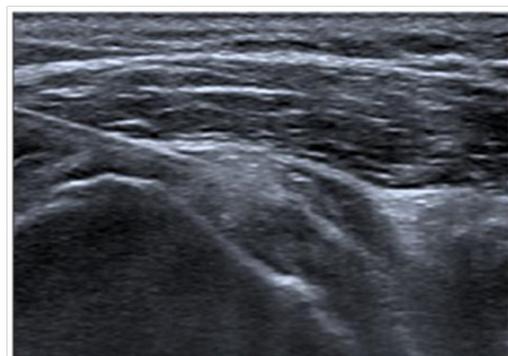


Figure 2 After US-guided needling.

There are only a few studies in which the clinical outcome of US-guided needling in calcifying tendinopathy in the long-term is described¹³⁻¹⁶ and none of these investigate patient reported effectiveness and satisfaction. The aim of this study was therefore to assess the functional and patient reported outcome and the necessity of arthroscopic surgery after US-guided needling in a prospective cohort of patients with chronic calcifying tendinopathy with a mean follow-up of 4 years.

Materials & methods

The Institutional Research Board of the primary investigators hospital approved this study. Between September 2010 and March 2011, patients who underwent US-guided needling for calcifying tendinopathy of the rotator cuff were prospectively enrolled in this study. Patients diagnosed with a unilateral calcific deposit in the rotator cuff of at least 5 mm in diameter, confirmed on conventional radiographs, not responding to conservative treatment with subacromial steroid injections and physiotherapy were included. There was a minimal time frame of three months or more between the subacromial steroid injection and the US-guided needling procedure. The purpose was to treat a group of patients with chronic complaints not responding to full conservative treatment, i.e. physiotherapy and NSAIDs and subacromial infiltration. When a patient did not undergo these three modalities as treatment options US-guided needling should not be considered as a matter of fact. Patients with other shoulder disease, such as rotator cuff tears, adhesive capsulitis, osteoarthritis, fractures, glenohumeral dislocations infection or any previous treatment with surgery, ESWT or needling of the affected shoulder were excluded.

US-guided needling procedure

All US-guided needling procedures were performed by an experienced radiologist with a single needle technique without lavage or aspiration. This is common because the goal of fragmenting the calcific depot ensures surface increase and helps the tendon to remove the calcification itself.^{14,17,18} The procedure was performed by sterile technique and surgical gloves. First, a diagnostic US examination in the sitting position was performed to evaluate the location and size of the calcific deposits and the integrity of the rotator cuff in the affected shoulder. The skin was then cleaned with a 10% iodine solution and antiseptically draped. After administration of local anesthesia (10cc, 2% lidocaine), the calcific deposit was punctured 10-15 times with a hyperdermic needle under real-time monitoring with US (Figure 3 & 4). There is no evident preference for the used technique,¹¹ single-needling is used in about 50% of recent studies, hence a prevailing technique.¹⁹ The final step in the procedure was an injection of a bupivacaine 0.5% kenacort 10 mg/ml (7:3) mixture into the subacromial space under US guidance.

Clinical evaluations were performed at baseline and at 8 weeks, 12 months and 4 years after treatment. Radiologic evaluation was performed at baseline and 8 weeks after the procedure with a shoulder radiograph in anteroposterior, external and internal rotation, and a supraspinatus outlet view to assess the technical result after needling. If the deposit was reduced less than 50% after two months and pain persisted, patients were considered for a second needling treatment. The calcifications were classified on the anteroposterior view according to Molé²⁰ and the length of the calcific deposit was estimated by using the 'caliper' tool (IMPAX 6.5.2 Client, Agfa Healthcare, Belgium) in the anteroposterior view.

Age, gender, affected side, mean duration of symptoms prior to treatment, relevant medical history, morphologic classification

and size of the deposit and type of previous conservative treatment were recorded at baseline. Pain and function were analyzed with the Shoulder Pain and Disability Index (SPADI) questionnaire²¹ before the index procedure and at 8 weeks, 12 months and 4 year after the intervention. The 12 months and 4 year follow-up was done by telephone and online questionnaires. Patients that had undergone an arthroscopic procedure were recorded as failure and excluded from the needling group. Patient satisfaction and patient reported effectiveness was investigated at final follow-up by means of a two question likert-scale questionnaire. Additional treatments after the needling procedure were recorded and a risk analysis was performed to screen for prognostic factors that could predict for a negative outcome.



Figure 3



Figure 4

Statistical analysis

Depending on the distribution of the variables, Student's t-tests or the nonparametric Mann-Whitney U-tests were performed to compare continuous baseline characteristics, calcific deposit size, patient satisfaction and SPADI scores between the initial success and failure group. Categorical variables were analyzed by use of Chi2-tests. Linear mixed model analysis for repeated measurements was performed for the SPADI Change from Baseline (CFB) as dependent variable to identify differences between the success and failure group, controlling for age and sex. The level of statistical significance was set at $p < 0.05$. Post hoc pairwise comparisons for each follow-up assessment were performed with adjusted significance levels

(Bonferroni, $\alpha < 0.17$). Statistical analyses were performed by use of IBM SPSS statistical package (version 21.0; SPSS, Chicago, Illinois).

Results

A total of 65 consecutive patients were treated by US-guided needling. Eleven patients were excluded because they were not, or only partially, treated with a conservative therapy. Baseline characteristics are summarized in Table 1. The group consisted of 32 females, the mean age was 54 years (range 39-83 years) and the right side was affected in 33 cases. Median time from onset to the procedure was 34 months (range 1-120 months). The calcific deposits

were categorized according to Molé: 16 type A, 17 type B and 21 type C. Average deposit size was 15.9 ± 6.8 mm. The mean SPADI score at baseline was 74.9 ± 25.7 points. After two months the overall mean SPADI score changed by -28.4 (95%CI -38.3 ; -15.3 $p < 0.001$) points and the average deposit size was reduced to 7.4 mm. One year after the needling procedure the overall SPADI score was reduced by 37.0 (95%CI -46.3 ; -28.4 , $p < 0.001$) points. Between the two month and one year interval fifteen patients (28%) were treated a second time of which four patient (7%) eventually underwent arthroscopic surgery. No immediate or delayed complications were encountered during the needling procedures.

Table 1 Demographics

Baseline Characteristics	All Patients (N = 54)	Single Treatment (N = 36)	Re-Needling / Surgery (N = 18)	p
Age, mean (range)	53.8 (39 – 83)	54.4 (39-83)	52.8 (40-68)	0.57
Sex, male / female, = n (%)	22 (41) / 32 (59)	14 (39) / 22 (61)	11 (61) / 7 (39)	0.07
Involved shoulder, right / left	33 (61) / 21 (39)	21 (58) / 15 (32)	9 (50) / 9 (50)	0.49
Duration of symptoms, median (range)	34.0 (1-120)	26.9 (1-84)	48.33 (1-120)	0.02
Morphologic classification, = n (%)				
Type A	16 (30)	10 (28)	6 (33)	0.88
Type B	17 (32)	12 (33)	5 (28)	
Type C	21 (39)	14 (39)	7 (39)	
SPADI, mean (SD)	74.9 (25.7)	76.3 (23.2)	72.9 (30.5)	0.58
Deposit size (mm), mean (SD)	15.9 (6.8)	16.1 (7.7)	15.4 (7.7)	0.7

N: Number; mm: Millimeter; p: < 0.05 ; SD: Standard Deviation; SPADI: Shoulder pain and Disability Index; %: Percentage

Table 2 Functional, radiological and patient reported results after US-guided needling and comparison between the single treatment and re-treatment group

	All Needling Patients	Single Treatment	Re-needling	p*	Surgery
2 months after procedure, N	54	39	15		
CFB SPADI, mean (95% CI)	-28.4 (-38.3;-15.3)	-36.6 (-52.2;-23.2)	-6.3 (-24.5;13.2)	0.01	
Deposit size (mm), mean (SD)	7.4 (7.9)	5.3 (6.5)	12.3 (9.0)	<0.01	
*after second procedure	*6.1 (6.4)		*8.6 (6.8)		
1 year after procedure, N	50	39	11		4
CFB SPADI, mean (95% CI)	-37.0 (-46.3;-28.4)	-38.8 (-50.4;-26.7)	-31.0 (-46.7;-13.3)	0.32	-17.8 (-34.4;0.55)
4 year after procedure, N	37	27	10		8
CFB SPADI, mean (95% CI)	-47.9 (-57.7;-38.8)	-52.6 (-61.9;-43.5)	-35.3 (-53.3;-18.4)	0.08	-39.8 (-61.2;-18.4)
Patient satisfaction, N (%)					
Very satisfied	14 (38)	11 (40)	3 (30)		-
Satisfied	13 (35)	9 (33)	4 (40)		2 (25)
Neutral	5 (13)	5 (19)	-		1 (12.5)
Unsatisfied	4 (11)	2 (8)	2 (20)		4 (50)
Very unsatisfied	1 (3)	-	1 (10)	0.38	1 (12.5)
Patient-reported effectiveness, N (%)					
Strong improvement	14 (38)	11 (41)	3 (30)		-
Improved	12 (32)	11 (41)	1 (10)		3 (37.5)
Unchanged	10 (27)	5 (18)	5 (50)		2 (25)
Worse	1 (3)	-	1 (10)		4 (50)
Much worse	0 (0)	-	-	0.01	1 (12.5)

CFB: Change from Baseline; CI: Confidence Interval; N: number; mm: millimeter; SD: Standard Deviation; SPADI: Shoulder Pain and Disability Index; %: Percentage;

*: Comparison between the Single Treatment and the re-treatment Group, $p = < 0.05$.

After a mean follow-up of four years, 45 patients (83%) were available for follow-up. Nine patients were not available; four patients refused to participate and we were unable to contact five patients in spite of numerous attempts in a three month time period. Another four patients (7%, 18% in total) were treated by arthroscopic surgery and were therefore excluded. The mean change from baseline SPADI score after four years in the needling patients was -47.9 (95%CI -57.7 ; -38.8 , $p < 0.001$) points. Overall, 38% of the patients were very satisfied, 35% were satisfied, 13% remained neutral and 14% were not satisfied with the outcome of the procedure. Furthermore, 38% of the patients reported a strongly improved shoulder function, 32% an improved function, 27% an unchanged function and 3% a decline in function.

Comparison single treatment vs. re-treatment

Between group differences are summarized in Table 1 & 2. With regard to the demographics there was a significant difference in duration of symptoms (26.9 vs. 48.3 months) in favor of the single treatment group. The mean deposit size after two months decreased significantly to 5.3 ± 6.5 mm in the single treatment group and to 12.3 ± 9.0 mm in the re-treatment group ($p < 0.01$). As expected this also resulted in a significant difference in change from baseline SPADI score: mean -36.6 for the single treatment group and -6.3 for the re-needling group ($p < 0.01$). Significant between group effect was observed for the SPADI during the follow-up period ($p = 0.04$). Both groups showed clinical score improvements after one year and

four years. The mean change from baseline SPADI score after four years was -52.6 (95%CI -61.9; -43.5) points in the single treatment group and 35.3 (95%CI -53.3; -18.4) points in the re-treatment group respectively ($p = 0.08$). With regard to patient reported effectiveness and satisfaction a significant difference in patient reported effectiveness four years after treatment was found between the two groups ($p = 0.01$) in favor of the single treatment group. No patient reported satisfaction difference was found between the two groups ($p=0.38$). Overall eight patients (18%) were treated with an arthroscopic acromioplasty and bursectomy according to the technique described by Neer. The post-operative rehabilitation protocol consisted of an immediate passive and active physiotherapy program. All surgically treated patients were available for follow-up after 4 years. The change from baseline SPADI score was -39.8 (95% CI -61.2;-18.4).

Discussion

This study shows that four years after treatment with US-guided needling a significant improvement in shoulder function was achieved in patients with chronic calcifying tendinopathy of the rotator cuff. In this study the SPADI score was used to evaluate the results of the needling procedure. This is a validated, self-administered questionnaire designed to measure the effect of the shoulder pathology on the functional status and pain levels.²¹ The SPADI score ranges from 0 to 130 whereas a score of 0 represents the best possible score. This patient reported outcome measure has been previously used in needling studies: Del Cura et al. reported a post-treatment SPADI score of 14.7 after 1 year²² and Aina et al. described a decrease in SPADI score from 39.2 to 28.6 after a median of 53 days.

The purpose of US-guided needling is to reduce the pressure and to remove the calcific deposit. Partial removal of calcific deposits is known to enable decompression of calcium-containing cavities and to promote spontaneous resorption of calcium.^{14,23-25} There is still no evidence-based consensus about the size and number of needles used in the needling procedure to achieve optimal outcome.¹⁷ Some authors prefer a single needle to prevent damage to the surrounding tendon tissue, whereas others describe a two needle-technique to promote resorption and to create a continuous flow of fluid in which the calcific deposits are dissolved. The potential advantages of lavage and aspiration have been mentioned by different authors^{26,22,16} but has never been proven in clinical studies. Zhu et al.²⁷ showed that there is no significant difference in patient reported outcome between needling with or without aspirating the calcific deposits.²⁷ The needling procedure was completed by infiltrating the subacromial bursa with a corticosteroid in order to reduce the inflammatory response that is induced by the needling. The short term result of this infiltration is a reduction in pain and subsequent improvement of function which may partly explain the improved SPADI score after two months. The expected effect of this infiltration is however not long-lasting as confirmed by Witte et al.¹⁷ They reported higher clinical outcome score after 1 year with needling in combination with a SAI compared to SAI alone.

Extracorporeal shockwave therapy and US-guided needling may be considered if patients do not respond to a conservative therapy. The success rates of high-energy ESWT in clinical and radiologic examination have been reported to range between 78% and 91%.^{28,11,29} US-guided needling success rates range between 68% and 92%.^{10,14,18} The main advantages of needling are visualization of the deposit location in various directions, real-time monitoring during needle placement, confirmation of procedure success, no radiation exposure

and decreased risk of injury to adjacent structures.¹⁴ In previous studies, the percentage of additional treatment ranges from 11% to 50%¹⁰ and our results are similar to the 28.6% failure rate that Yoo et al. reported.²⁸ Bursitis, a mild vagal response and bursal thickening are known and reported complications of needling.¹⁰ No immediate or delayed complications were recorded during this study.

In a recent study, Lanza et al.³⁰ state an improvement in pain of 55% after 11 months in US-guided percutaneous irrigation in rotator cuff calcific tendinopathy. 10% (minor) complication rate, no existing evidence in favour of using a specific size/number of needles, no routinely imaging follow-up and structural uniformity (Constant Score) to assess outcomes with 1-year minimum follow-up are their key points. This manuscript shows similarity because our reported pain improvement is higher, but this is after four year follow-up. Also, a complication rate of 10% is approximately equal. No preference in used needle size or number and the absence of routinely imaging follow-up is in accordance with this manuscript.

There are several limitations to this study. The first limitation is the absence of a control group. Considering the self-limiting nature of calcifying tendinopathy, a direct comparison with an untreated control group would provide beneficial evidence on what the benefit is of US-guided needling in comparison to the natural course of the disease. However the percentage of spontaneous resorption of the calcific deposits is variable and has been reported by Bosworth et al to be 9.3% after 3 years and 27% after ten years.¹ Serafini et al. compared 219 US-guided needling patients to 68 patients who refused a needling procedure and stated that there was no significant difference after ten year follow-up between the two groups with an equal excellent clinical outcome.¹⁶ Secondly, this study used a single needle US-guided technique without inspiration of saline and lavage as opposed to using multiple or larger needles. There is no consensus on the size and number of needles needed for optimal outcome and different studies have investigated the alleged benefit of inspiration and lavage but also on this subject, no agreement has been attained.^{26,22,16} Thirdly, the final follow-up consisted of a clinical assessment and no radiographs were made after four years. Due to this fact this study does not provide data on any recurrence of calcific deposits. Finally, our study was not powered to find a pre-set difference in SPADI outcome after four years, therefore the cohort of 54 patients might have been too small.

Conclusion

This study analyses the clinical and patient-reported satisfaction and effectiveness of US-guided needling after four years in patients with calcifying tendinopathy of the rotator cuff. We conclude that US-guided needling provides clinical improvements after 2 months, 1 year and 4 years in patients with rotator cuff calcifying tendinopathy and that a high percentage of patients is satisfied (73%) and report a significant improvement in function (70%). The initial needling treatment was successful in 67% of patients and success was correlated with a significant decrease in deposit size after two months. Overall, 15% of the needling patients necessitated arthroscopic surgery. We therefore recommend the use of US-guided needling in patients with calcifying tendinopathy who do not respond to conservative treatment.

Acknowledgments

None.

Conflicts of interest

None.

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