

Smoking and morphology of calcific deposits affect the outcome of needle aspiration of calcific deposits (NACD) for calcific tendinitis of the rotator cuff



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ABSTRACT

Introduction: Although NACD has proven to be an effective minimal invasive treatment for calcific tendinitis of the rotator cuff, little is known about the factors associated with treatment failure or the need for multiple procedures.

Methods: Patients with symptomatic calcific tendinitis who were treated by NACD were evaluated in a retrospective cohort study. Demographic details, medical history, sonographic and radiographic findings were collected from patient files. Failure of NACD was defined as the persistence of symptoms after a follow-up of at least six months. NACD procedures performed within six months after a previous NACD procedure were considered repeated procedures. Multivariate logistic regression analysis was used to determine factors associated with treatment failure and multiple procedures.

Results: 431 patients (277 female; mean age 51.4 ± 9.9 years) were included. Smoking (adjusted odds ratio (AOR): 1.7, 95% CI 1.0–2.7, $p = 0.04$) was significantly associated with failure of NACD. Patients with Gärtner and Heyer (GH) type I calcific deposits were more likely to need multiple NACD procedures (AOR: 3.4, 95% CI 1.6–7.5, $p < 0.01$) compared to patients with type III calcific deposits. Partial thickness rotator cuff tears were of no influence on the outcome of NACD or the number of treatments necessary.

Conclusion: Smoking almost doubled the chance of failure of NACD and the presence of GH type I calcific deposits significantly increased the chance of multiple procedures. Partial thickness rotator cuff tears did not seem to affect the outcome of NACD. Based on the findings in this study, the importance of quitting smoking should be emphasized prior to NACD and partial thickness rotator cuff tears should not be a reason to withhold patients NACD.

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1. Introduction

Calcific tendinitis of the rotator cuff (CTRC) is a common cause of shoulder complaints with a prevalence of 8 to 20% in asymptomatic adults and up to 54% in patients with shoulder complaints [1–5]. Several theories regarding the pathophysiology of CTRC, such as ischemia and degeneration of the rotator cuff, have been suggested [6–11]. Currently, the most accredited theory is the multiphasic theory proposed by Uhthoff et al., he state that CTRC is caused by an active process of cell-mediated calcification of the rotator cuff

tendons which is generally followed by spontaneous phagocytic resorption [12–14]. Despite the fact that CTRC is a self-limiting disease, treatment of this condition is indicated as the spontaneous resorption of calcific deposits may take years. CTRC is preferably treated conservatively, e.g., non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy and/or subacromial steroid injections, with reported success rates ranging from 70–90% [3,15–17]. When conservative treatment fails, ultrasound-guided needle aspiration of calcific deposits (NACD) is often performed. NACD has proven to be effective in 70–75% of patients [2,18,19]. Previous research suggests that the success rate of NACD depends on the radiographic morphology of the calcific deposits [20]. However, little is known about other variables that can predict the outcome of NACD.

Besides pain and functional outcome, the effectiveness of NACD could also be assessed in terms of the number of NACD procedures

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needed to obtain permanent results. Although up to 45% of patients will require multiple NACD procedures [21], no studies investigating factors associated with multiple procedures have been conducted, to the authors knowledge.

Therefore, the purpose of this study was to define factors associated with successful treatment and factors associated with the need for multiple NACD procedures.

2. Methods

2.1. Study design

A retrospective cohort study was conducted to evaluate the outcome of NACD of patients treated between January 2010 and June 2013. Data on the outcome of NACD were obtained from routine treatment evaluation, therefore, approval by a medical ethics review board was not deemed necessary.

2.2. Study population

The study population consisted of patients referred to the department of radiology by either orthopedic surgeons or general practitioners for the treatment of symptomatic CTFC. The radiology department is well experienced in performing NACD procedures, performing over 300 procedures every year. Prior to the NACD procedure, all patients were screened by the radiologist performing the NACD procedure to confirm that NACD was indicated. Criteria for a NACD procedure as applied by the radiologists were:

1. Clinical symptoms of calcific tendinitis:
 - Pain in the shoulder region:
 - Pain worsened by elevation of the arm above the shoulder level
 - Pain worse at night
 - Pain worse by lying on the shoulder
 - Stiffness of the shoulder
 - Weakness of the shoulder
2. Presence of calcific deposits was confirmed on radiographs and/or ultrasound examination
3. Absence of other causes for shoulder complaints (e.g., frozen shoulder, subacromial bursitis).

All patients that underwent NACD were registered by the radiologist performing the NACD procedure. Inclusion criteria were checked by the researcher (BO) before entering patients in the study database. Only the treatment of the first shoulder was analyzed in patients who underwent bilateral treatment ($n = 32$).

2.3. Technical procedure

NACD procedures were performed by a well-experienced musculoskeletal radiologist in an ultrasound room, using the Logic E9 Ultrasound system (GE Healthcare). Patients were treated in supine position. After sterile preparation, the skin and subcutaneous tissue were anesthetized by local injection of lidocaine 1%. Thereafter ultrasound-guided NACD was performed using a 20 or 21 gauge needle. After maneuvering the needle into the calcific deposit, the deposits was infiltrated with lidocaine 1%, fragmented and removed by aspiration. The lavage was continued until no visible calcium could be aspirated. After completing the aspiration, the subacromial bursa was infiltrated with 4 ml bupivacaine (2.5 mg/ml) and 1 ml kenacort (40 mg/ml). Patients were advised to use the treated arm within pain limits and to avoid heavy duties in the first six weeks; no specific rehabilitation program

Demographic details
Gender
Age
Medical history
Duration of symptoms
Bilateral occurrence
Previous SAI therapy
Pre-treatment pain score
Sonographic findings
Subacromial bursitis
Partial rotator cuff tears
Radiographic findings
Gärtner and Heyer classification
Tendon healing influencing factors
Smoking
Diabetes Mellitus

Fig. 1. Overview of factors investigated in this study. SAI: subacromial injection.

was prescribed. Furthermore, they were advised to use paracetamol 1000 mg to a maximum of four times a day in case of pain in the first days following the NACD procedure.

2.4. Repeated procedures

In case of persisting symptoms, patients were scheduled for another NACD procedure. Criteria for a repeated NACD procedure were clinical symptoms of calcific tendinitis, calcific deposits on ultrasound examination and absence of another cause for shoulder complaints (e.g., frozen shoulder, subacromial bursitis). A minimal term of six weeks between the first and second NACD procedure or the second and third NACD procedure was applied.

2.5. Data collection and outcome measures

An overview of the prognostic factors evaluated in this study is presented in Fig. 1. As a standard, medical history, duration of symptoms, unilateral or bilateral occurrence, previous subacromial injection (SAI) therapy and specifically, tendon healing influencing factors, such as smoking and diabetes mellitus were registered. Smoking was defined as smoking on a daily basis for the minimum duration of one year. Prior to the NACD procedure, patients were asked to indicate their pain score on an 11-point numeric rating scale (NRS).

The primary endpoint in this study was successful treatment. Successful treatment was defined as complete relief of symptoms six months after the last NACD procedure measured by a dichotomous outcome (free/not free of symptoms). Persistence of symptoms six months after the last NACD procedure or requiring an alternative treatment (e.g. surgical removal of calcific deposits) within six months after the last NACD procedure was considered as failure of NACD. NACD procedures performed within six months of a previous NACD procedure were considered repeated treatments.

To assess the outcome at six months post-treatment, patients were approached by telephone by an independent researcher (BO) who was not involved in the NACD procedure(s). Patients were asked whether they were free of symptoms or not and whether they had needed any alternative treatments in the six months following the last NACD procedure.

2.6. Radiographic assessment

According to the classification described by Gärtner and Heyer, calcific deposits were categorized into three different types of cal-

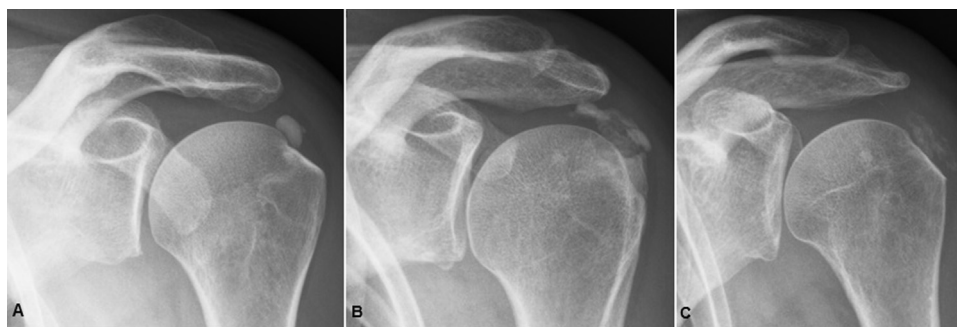


Fig. 2. Gärtner and Heyer classification of calcific deposits. (A) type I calcific deposit: dense with a well-defined border; (B) type II calcific deposit: dense with a indistinct border or transparent with a well-defined border; (C) type III calcific deposit: transparent with a indistinct border.

cific deposits [11]. Type I deposits are dense with well-defined borders, type II deposits dense with indistinct borders or transparent with well-defined borders and type III deposits transparent with indistinct borders (Fig. 2). The radiographic assessment consisted of a standardized anteroposterior (AP) X-ray. These X-rays were analyzed by an independent researcher (BO). Because of logistic considerations, not all patients underwent radiographic assessment prior to NACD. In total 289 patients (67%) were radiographically assessed prior to the NACD procedure. Patients who were assessed radiographically were comparable to those who were not assessed with regards to the evaluated prognostic factors ($p > 0.10$).

2.7. Sonographic assessment

Besides the presence of calcific deposits, findings on ultrasound examination of particular interest for the purpose of this study were subacromial bursitis and partial rotator cuff tears. Subacromial bursitis was diagnosed when the bursa was thickened and/or there was evidence of fluid in the subacromial bursa. Partial rotator cuff tears (PRCT) were diagnosed in case of tears that did not cover the complete thickness of the tendon and communicated with either the subacromial bursa or glenohumeral joint. The presence of rotator cuff tears was verified during the NACD procedure. In case of a partial rotator cuff tear, the fluid used for the lavage will leak into the subdeltoid subacromial bursa (in case of a bursal sided partial tear) or in the direction of the glenohumeral joint (in case of an articular sided partial tear) during the NACD procedure; in case of a full thickness tear, the fluid used for the lavage will leak into both the subdeltoid subacromial bursa and in the direction of the glenohumeral joint. The sonographic assessments of the rotator cuff were performed following a standardized method by an experienced musculoskeletal radiologist.

2.8. Statistical analysis

Visual inspection of histograms was used to determine whether continuous variables followed a normal distribution. Demographic and clinical characteristics were described as continuous or categorical variables as appropriate.

Patients were grouped based on whether they were or were not free of symptoms at six months post-treatment and based on whether they received a single NACD procedure or multiple (>1) procedures. To determine whether factors differed between the groups (free of symptoms vs. not free of symptoms and single procedure vs. multiple procedures) independent t-tests (parametric) and χ^2 test (non-parametric) were used. Factors that differed significantly between the groups ($p < 0.10$) were included for multivariate logistic regression analysis. Irrespective of the outcome of the univariate analysis, the factors gender and age were added to the multivariate logistic regression analysis.

Table 1
Baseline characteristics ($n = 431$).

Demographic details	
Male (%)	154 (36)
Female (%)	277 (64)
Age (\pm SD)	51.4 (\pm 9.9)
Medical history	
Duration of symptoms (\pm SD)	2.4 (\pm 2.4)
Bilateral occurrence (%)	32 (7)
Previous SAI therapy (%)*	90 (48)
Pre-treatment NRS score (\pm SD)	7.5 (\pm 1.6)
Sonographic findings	
Subacromial bursitis (%)	14
Partial rotator cuff tears (%)	16
Full thickness rotator cuff tears (%)	1
Radiographic findings**	
G&H type I (%)	40
G&H type II (%)	40
G&H type III (%)	20
Tendon healing influencing factors	
Smoking (%)	26
Diabetes Mellitus (%)	7

*Based on data from 188 patients. **Based on data from 289 patients. Values are presented as mean \pm standard deviation or number (%) unless otherwise indicated. NRS: numeric rating scale.

Stepwise backwards binary logistic regression was performed to determine factors associated with treatment failure or multiple treatments. A significance level of $p < 0.05$ was used to define factors that significantly increased the probability of failure of NACD or multiple treatments. Additionally, in-depth analyses were performed in order to define factors associated with the type of calcific deposit. The factors associated with the type of calcific deposit were determined using the same procedure as described above.

In order to avoid the influence of missing data, data of patients without any missing values were initially analyzed to determine model fit. After logistic regression was completed, the model was applied on the entire population to obtain definitive adjusted odds ratios (AOR). All statistical analyses were performed using the statistical package SPSS version 20.0 (IBM, Armonk, NY, USA).

3. Results

Table 1 lists the baseline characteristics of the 431 patients. At six months post-treatment, 317 (74%) patients reported to be free of symptoms. Two or more NACD procedures were performed in 143 (33%) patients. Of the 114 (26%) patients with failure of the NACD procedure, 57 (13%) patients underwent surgery.

3.1. Factors associated with failure of treatment

The results of the univariate analysis are presented in Table 2. Patients in the failure group were significantly younger ($p = 0.02$)

Table 2
Univariate analysis for failure of NACD and multiple procedures.

	Outcome of NACD			Number of NACD procedures		
	Successful	Failure	<i>p</i>	Single procedure	Multiple procedures	<i>p</i>
Male (%)	75	25	0.69	70	30	0.28
Female (%)	73	27		65	35	
Age (±SD)	52.1 (±10.1)	49.4 (±9.1)	0.02	51.9 (±10.4)	50.2 (±8.7)	0.09
Smoking (%)	23	35	0.02	28	23	0.31
Diabetes Mellitus (%)	8	5	0.35	7	7	0.88
Duration of symptoms (±SD)	2.4 (±2.4)	2.5 (±2.6)	0.79	2.2 (±2.2)	2.7 (±2.9)	0.27
Bilateral occurrence (%)	7	10	0.29	7	8	0.88
Previous SAI therapy (%)	46	51	0.44	49	45	0.58
Pre-treatment NRS score (±SD)	7.5 (±1.6)	7.5 (±1.3)	0.76	7.4 (±1.7)	7.7 (±1.2)	0.02
Subacromial bursitis (%)	15	11	0.22	14	13	0.79
Partial rotator cuff tears (%)	16	18	0.66	17	15	0.73
G&H type I (%)	39	42		34	50	
G&H type II (%)	41	36	0.79	41	39	0.01
G&H type III (%)	20	22		25	11	

Values are presented as mean ± standard deviation (SD) or number (%) unless otherwise indicated. NRS: numeric rating scale, G&H: Gärtner & Heyer classification, SAI: subacromial injection.

Table 3
Summary of binary logistic regression analysis predicting failure of NACD and the need for multiple NACD procedures.

Factor	<i>p</i>	AOR	95% CI
Factors predicting failure of NACD			
Smoking	0.04	1.7	1.0–2.7
Factors predicting the need for multiple NACD procedures			
Age	0.26	1.0	1.0–1.1
Pre-treatment NRS score	0.07	1.3	1.0–1.6
Type I calcific deposits ^a	<0.01	3.4	1.6–7.5

AOR: adjusted odds ratio. 95% CI: 95% confidence interval. NRS: numeric rating score.

^a Based on Gärtner and Heyer classification.

and more often smokers ($p = 0.02$). Presence of subacromial bursitis or partial rotator cuff tears on sonographic examination, or the type of calcific deposit on radiographic assessment were of no influence on failure of NACD ($p > 0.05$).

Multivariate logistic regression analysis showed that only smoking (AOR 1.7, 95% CI 1.0–2.7, $p = 0.04$) was significantly associated with failure of treatment at six months post NACD (Table 3).

3.2. Factors associated with multiple treatments

As illustrated in Table 2, patients in the multiple treatment group reported higher NRS scores pre-treatment ($p = 0.02$). Type I calcific deposits were seen significantly more often among patients in the multiple treatment group, type III calcific deposits were seen significantly less often ($p = 0.01$). Presence of partial rotator cuff tears or subacromial bursitis were of no influence on the number of NACD procedures ($p > 0.05$).

In the multivariate logistic regression analysis only the type of calcific deposit was significantly associated with multiple procedures: type I calcific deposits give an AOR of 3.4 (95% CI 1.6–7.5, $p < 0.01$) for the need for a second NACD procedure compared to type III calcific deposits. No significant association was found between the pre-treatment NRS score and the need for multiple procedures ($p = 0.07$; 95% CI 1.0–1.6) (Table 3).

4. Discussion

The current study demonstrated that smoking significantly increased the chance of failure of NACD and that Gärtner and Heyer type I calcific deposits increased the chance of multiple procedures. Furthermore, in this series partial rotator cuff tears did not affect the outcome of NACD.

4.1. Factors associated with failure of treatment

First of all, results of this study demonstrate that smoking almost doubles the chance of failure of NACD. No such results have been published in literature to our knowledge. One could hypothesize that smoking compromises the vascular supply to rotator cuff tendons and smoking, therefore, might impede recovery of tendon tissue. This hypothesis is supported by a cadaveric study by Kane et al. who reported that the presence of advanced microscopic rotator cuff pathology was more than twice as likely in patients with a history of smoking [22]. However, associations between rotator cuff tendinopathy and smoking have never been reported. In fact, according to a population-based study by Rechart et al. [23], smoking is not associated with chronic rotator cuff tendinitis. Additionally, little is known about the influence of smoking on the outcome of treatment of rotator cuff tendinopathies. In contrast, smoking is associated with less improvement of pain and worse functional results postoperatively in patients who underwent rotator cuff repair [24–26]. Based on the findings in this study, the importance of quitting smoking should also be emphasized in patients with CTRC prior to NACD.

A second important and clinically relevant finding of this study is that partial rotator cuff tears were of no effect on the outcome of NACD. Although rotator cuff tears have been reported in up to 25% of patients with CTRC [27], no studies investigating the influence of partial rotator cuff tears on the outcome of NACD have been conducted to our knowledge. The larger studies investigating the outcome of NACD all excluded patients with partial rotator cuff tears, therefore it is unknown whether the presence of a partial rotator cuff tear affects the outcome of NACD or whether treatment of CTRC should be altered in case of a concomitant partial rotator cuff tear [12,28–30]. Based on the current study, NACD for CTRC can be performed successfully in presence of a concomitant partial rotator cuff tear and partial rotator cuff tears should therefore not be regarded as a contraindication for NACD.

4.2. Factors associated with multiple treatments

The morphology (based on the Gärtner and Heyer classification) of the calcific deposits was significantly associated with the number of NACD procedures needed; the odds for multiple treatments in patients with type I deposits were over 3 times higher compared to patient with type III deposits. In the current study plain radiographs were used to classify the calcific deposits. According to Farin

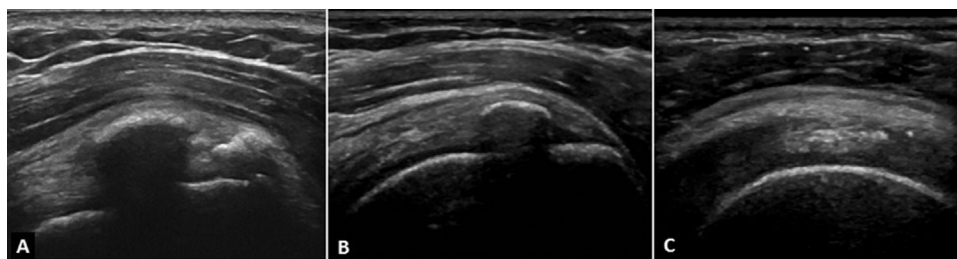


Fig. 3. Sonographic findings of calcific deposits as described by Farin et al.. (A) A hyperechoic focus with a well-defined shadow; (B) a hyperechoic focus with a faint shadow; and (C) a hyperechoic focus with no shadow.

Table 4

The association between smoking and the type of calcific deposit.

	G&H classification		
	Type I	Type II	Type III
Non-smokers	43%	37%	20%
Smokers	29%	51%	20%

G&H classification: Gärtner and Heyer classification.

et al., classification of the calcific deposits is preferably based on plain radiographs, as classification of calcific deposits with ultrasound does not correlate well with the phase of calcification [31]. With regard to the ultrasound findings of CTFC, three types of calcifications can be found: (1) a hyperechoic focus with a well-defined shadow; (2) a hyperechoic focus with a faint shadow; and (3) a hyperechoic focus with no shadow (Fig. 3). Although type 1 calcifications usually present with an acoustic shadow on ultrasound, no significant correlation was found between type 3 calcifications and calcifications without an acoustic shadow. Therefore the use of plain radiographs is advised for classification of calcific deposits [31].

Associations between the consistency or the morphology of the calcific deposit and the number of NACD procedures necessary have never been investigated before. As type III calcific deposits are already in the resorptive phase, the calcific deposit is more fluid-like and therefore easier to aspirate. This is in contrast to type I calcific deposits, which are more solid and which makes it harder to aspirate the calcium. Literature is inconclusive about the association between the ability to aspirate calcium during the procedure and the effectiveness of NACD [32,33]. We hypothesize that NACD in type I calcific deposits initiates the resorption of calcific deposits, whereas in type III calcific deposits the resorptive phase is shortened by removing the calcium. As, after initiating the resorption in type I calcific deposits, the body itself is not always capable of eliminating all of the calcium, patients will stay in a prolonged resorptive phase and will therefore need a second NACD procedure more often. This hypothesis is supported by the finding of Gärtner et al. [11], who reported a decreased rate of resolution of calcific deposits in type I calcific deposits after NACD. As managing patient expectations is becoming increasingly important, this information might be useful in informing patients about what to expect prior to the NACD procedure.

In order to define factors associated with the type of calcific deposit, additional in-depth analyses were performed. Remarkably, only smoking was significantly associated with the type of calcific deposit ($p=0.024$). As presented in Table 4, type I calcifications were less common and type II calcifications were more common amongst smokers. Assuming that type I calcifications give an increased chance for multiple procedures, one could hypothesize that multiple procedures are less often needed amongst smokers. However, logistic regression analysis of factors predicting the need for multiple procedures showed that smoking was of no influence on the amount of necessary NACD procedures. As the

effects of smoking on calcific tendinitis have never been described before, it is uncertain whether this finding is an incidental finding or that smoking influences the course of the disease and thereby the type of calcific deposit found in the tendon. To gain more insight into the effects of smoking on calcific tendinitis, more longitudinal studies are needed.

4.3. Limitations

To our knowledge, the current study is one of the largest cohort studies on the outcome of NACD. However, given the retrospective character of this study, there are some methodological issues. First of all, because the information on patients being symptom-free or not at six months post-treatment was collected retrospectively, there is a substantial variability in the time between the six months post-treatment term and the moment of the actual obtaining of these data (recall bias). However, the percentage of patients that reported to be free of symptom at six months post-treatment did not differ substantially from percentages mentioned in literature (70–75%) [2,9,10]. Secondly, the radiographic assessment prior to the NACD procedure could not be performed in one third of the patients. However, patients who did and did not undergo the radiographic assessment were comparable for all of the evaluated prognostic factors in this study. Furthermore, in-depth analysis revealed no differences between the statistic model without and the model with missing values. We therefore assume that the influence of these missing values on the outcome is limited. Finally, as the current study was designed to identify factors associated with persisting symptoms, all symptoms of CTFC six months after the last NACD procedure were regarded persisting symptoms. Persisting symptoms that were considered tolerable by patients were also regarded persisting symptoms. In order to gain more insight in what factors contribute to complete relief of symptoms or tolerable persisting symptoms following NACD, future research using quality of life questionnaires or functional shoulder scores is needed.

5. Conclusions

Smoking almost doubled the chance of failure of NACD and Gärtner and Heyer type I calcific deposits increased the chance of multiple procedures. Partial rotator cuff tears did not affect the outcome of NACD and should therefore not be considered a contraindication for NACD.

Conflicts of interest

None.

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