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Degenerative full thickness rotator cuff tears

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CHAPTER 4

Tear size, muscle atrophy and fatty infiltration do not increase within a year of conservative treatment of degenerative rotator cuff tears.

A secondary analysis of a randomized controlled trial.

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Submitted

ABSTRACT

Background: Case series reporting results of conservative treatment of degenerative rotator cuff tears report success rates of approximately 75%. Although this would stimulate a conservative approach to such tears, concern exists over tear progression over time. This might impair cuff reparability if conservative treatment fails. The goal of this study was to compare the changes in tear size, muscle atrophy and fatty infiltration after one year in patients randomized for conservative treatment or surgical repair.

Methods: We performed a secondary analysis of a randomized controlled clinical trial in patients with an MRI-proven degenerative full-thickness rotator cuff tear, randomized into a conservative and a surgical repair group. Patients were included between January 2009 and December 2012. MRI was performed before and one year after inclusion. Changes in Warner, Goutallier and Patte scores, the tangent sign and the amount of retraction were compared between the three groups (intact repairs, retears and conservatively treated patients).

Results: At 12 months follow-up there were 5 patients with intact repairs, 14 patients with a re-tear and 22 patients who received conservative treatment. No significant changes in tear size, muscle atrophy or fatty infiltration of the rotator cuff were observed in the three study groups one year after inclusion.

Conclusion: This study provides evidence that in patients with a full-thickness rotator cuff tear conservative treatment can be performed during at least one year without jeopardizing cuff reparability.

INTRODUCTION

In recent literature, controversy remains on the choice of treatment for degenerative rotator cuff tear. Comparable good outcomes are reported for both conservative and surgical treatment of rotator cuff tears at short-term follow-up.¹⁻¹⁰ Three recent randomized controlled trials comparing surgical with conservative treatment failed to show clinically relevant differences between these two treatment modalities in long term follow up.¹¹⁻¹³

An important aspect in the debate on treatment modalities is progression of tear size, atrophy and fatty infiltration. In caring for patients, many individuals ask if they will be 'worse off' trying a conservative approach. In multiple case series, tear size progression is found in approximately 50% of conservatively treated patients.¹⁴⁻¹⁶ At present there are no prognostic factors that will predict increase in tear size atrophy or fatty infiltration in surgical or in conservative treated patients.

We undertook a secondary analysis of a randomized controlled trial to compare radiological outcome in patients treated surgically or conservatively for a degenerative rotator cuff tear.¹⁷ The clinical outcome of this group of patients was published previously.¹³ The goal of this study was to measure changes in tear size, muscle atrophy and fatty infiltration after one year in all patients.

METHODS

A secondary analysis of a randomized controlled trial conducted at one university hospital and two regional hospitals was performed. Institutional Review Board approval was obtained for this randomized controlled trial (registration number M08.062126). The trial is registered in the Netherlands Trial Registry (NTR TC 2343).

PATIENT SELECTION

Inclusion of patients with a degenerative full-thickness rotator cuff tear was done from January 2009 until December 2012. Exclusion criteria were traumatic onset of complaints, previous surgical treatment of the shoulder, frozen shoulder, radiological and symptomatic osteoarthritis of the glenohumoral or acromioclavicular joint, arthritis/rheumatoid arthritis, diabetes mellitus, cognitive disorders, neurological disease affecting function of the upper extremity and language barriers impairing participation. Written informed consent was obtained from all patients. Randomization to either surgical or conservative treatment was done using 100 prefilled opaque sealed envelopes. As described in the discussion, the inclusion of patients for this trial was difficult. We eventually had to terminate the inclusion prematurely, resulting in an unequal number of participants in the conservative and surgical groups. Due to the surgical vs. conservative therapy set-up, patients and outcome assessors could not be blinded for type of treatment. For this study 92 patients suspected of a degenerative rotator cuff rupture were screened with MRI. Twenty-seven of these patients did not meet the inclusion criteria, six patients declined to participate, and three other patients were excluded for other reasons. The trial thus included 56 patients, 25 of whom were treated surgically and 31 conservatively. Nine patients in the conservatively treated group were lost to follow-up at one year (discontinued intervention (n=3), no MRI at follow-up due to claustrophobia (n=3), moved (n=2), died (n=1)). In the surgical group six patients were lost to follow-up (no MRI at follow-up due to claustrophobia (n=1), moved (n=1), no rotator cuff repair performed due to an intact rotator cuff (false positive MRI) (n=2), or irreparable rotator cuff tear (n=2)). A patient flow diagram is included as Figure 1. Available for this secondary analysis were 41 patients. At one year a MRI was performed, three groups were created: patients with an intact repair (5), patients with a retear (14) and conservatively treated patients (22).

INTERVENTIONS

SURGERY GROUP

Surgery was performed by two qualified and experienced surgeons (JvR, CTK). An anterolateral mini-open approach was used. Subacromial decompression was performed in all cases. Repair of the rotator cuff was performed after debridement of the greater tuberosity. Side-to-side repair (n=6) and augmented repair using bone anchors (n=14) were performed depending on the shape and size of the rupture. A standardized postoperative rehabilitation protocol was used.¹⁷

CONSERVATIVE GROUP

Conservative treatment consisted of subacromial steroid infiltration, physical therapy and analgesic medication. The number of subacromial infiltrations was limited to a maximum of three. Further conservative treatment options consisted of analgesic medication with non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol and/ or tramadol. Patients were referred to a physical therapist. A standardized physical therapy protocol for the conservative treatment of rotator cuff tears was used.¹⁷

OUTCOME ASSESSMENT

Assessment of the rotator cuff with MRI was performed at inclusion and one year after the start of the intervention, i.e. surgical repair or the first subacromial injection. Preoperative and postoperative MRIs were compared to assess whether the rotator cuff was intact following repair. Changes in tear size, fatty infiltration and muscle atrophy were measured. Two musculoskeletal radiologists (RD, RW) analyzed all the MRIs. At inclusion, MRI analysis was performed to measure tear size, muscle atrophy and fatty infiltration. Location of the tear, size and retraction were determined.

The Patte score, which assesses the degree of tendon retraction in the frontal plane on MRI, was used to describe the amount of retraction of the supraspinatus.¹⁸ Full-thickness tears with little tendon retraction were assessed as grade 1, tendon retraction to the level of the humeral head as grade 2, and tendon retraction to the level of the glenoid as grade 3. Retraction was also described in millimeters. This was measured from the insertion site on the footprint to the lateral end of the tendon in a coronal plane.

Muscle atrophy was measured using the Warner classification in the oblique sagittal plane on MRI.¹⁹ A line is drawn from the inferior tip of the scapula to the scapular spine and from the scapular spine to the coracoid process. The line from the scapular spine to the coracoid process is referred to as the tangent sign.²⁰ If the muscle is convex above the line, there is no atrophy. If the muscle contour is even with the line, there is mild atrophy. If the contour of the muscle is concave below the line (a positive tangent sign), moderate atrophy is present. If there is barely any muscle visible, severe atrophy exists.¹⁹

Fatty infiltration of the supraspinatus muscle was graded according to the Goutallier classification (Grade 0, no fatty infiltration; Grade 1, some fatty streaking of the supraspinatus; Grade 2, less fat than muscle; Grade 3, equal amounts of fat and muscle; Grade 4, more fat than muscle).²¹

STATISTICAL ANALYSIS

Baseline and follow-up characteristics are presented as proportions or means (\pm SD). Differences in baseline characteristics between the three groups were tested using Chi-square tests in case of categorical variables and Kruskal-Wallis tests in case of ratio variables. The interobserver agreement was determined for each classification system by Cohen's Kappa measures. Agreement was considered excellent between 0.81 and 1.0, high between 0.61 and 0.80, moderate between 0.41 and 0.60, fair between 0.21 and 0.40, and poor if 0.20 or less.²² For the continuous variable millimeters retraction, Pearson correlation coefficients between the values of the two observers were calculated. A p-value < 0.05 was considered statistically significant. Statistical analyses were performed with IBM SPSS Statistics version 20.

RESULTS

At baseline no significant differences in demographic data (sex, side, dominance, age and complaints in months) were found between the three groups. (Table I) Mean age of patients in the group with an intact repair was 62.2 years, in the group of patients with a failed repair 62.5 years, and in conservatively treated patients 60.4 years.

Table I: Baseline patient characteristics

	Intact repairs (n=5)	Retears (n=14)	Conservative (n=22)
Sex (% men)	60.0	57.1	63.3
Side (% R)	60.0	42.9	63.6
Dominance (% R)	100	71.4	81.8
Age in years (mean (SD))	62.2 (4.0)	62.5 (7.4)	60.4 (7.2)
Complaints in months (median (range))	12 (4-60)	14 (3-120)	12 (1-120)
Distribution of rotator cuff tears			
supraspinatus	5	14	19
supraspinatus +infrapinatus	0	0	1
supraspinatus +subscapularis	0	0	2

Data presented as mean.

Table II describes the radiological baseline and outcome values of the three groups. In the conservative group no significant changes in any MRI parameters (tear size, atrophy, fatty infiltration) were found one year after start of treatment. In one patient increase in tear size to a multiple tendon tear was observed (supraspinatus and subscapularis). In the intact rotator cuff repair group tear size was reduced to zero, but successful repair had no effect on atrophy or fatty infiltration. In the patient group with retears, no change in tear size, atrophy or fatty infiltration was found at one year compared to baseline.

Table II: Radiological outcome measures at baseline and one year post-treatment.

	Intact repairs		Retears		Conservative	
	baseline	follow-up	baseline	follow-up	baseline	follow-up
Warner	1.8 (0.8)	1.5 (0.6) p=0.56	1.5 (0.5)	1.9 (0.8) p=0.18	1.6 (1.1)	1.4 (0.8) p=0.16
Tangent sign*	0 (0)	0 (0) p=1.00	13.3	15.3 p=0.32	22.2	50 p=1.0
Goutallier	0.8 (1.3)	0.8 (0.8) p=1.00	0.6 (0.7)	0.4 (0.5) p=0.56	1.0 (1.5)	0.8 (1.2) p=0.32
Retraction**	18.2 (10.7)	Intact	24.8 (13)	23.3 (17.7) p=0.75	24.5 (13.9)	26 (10.6) p=0.87
Patte	1.6 (0.9)	Intact	1.9 (0.6)	1.8 (1.0) p=0.74	1.9 (0.7)	2.1 (0.6) p=0.32

Data presented as mean (SD).

* Percentage of patients with muscle below tangent line (positive tangent sign).

** Significant difference in improvement between intact repairs vs. retears and intact repairs vs. conservative treatment; no significant differences between retears and conservative treatment.

INTEROBSERVER RELIABILITY

Cohen's Kappa values for the different classifications are presented in Table III. For retraction of the torn rotator cuff, measured in millimeters, a pre-treatment Pearson correlation coefficient of 0.99 was found, post-treatment 0.98. Interobserver agreement for the Warner classification system is high to excellent, for the Goutallier classification high, for the tangent sign moderate to high, and for Patte score excellent.

Table III: Cohen's Kappa values for the classification pre- and post-treatment.

	Pre-treatment	Post-treatment
Warner	0.73	0.91
Goutallier	0.77	0.68
Tangent line	0.52	0.72
Patte	0.86	0.83

DISCUSSION

Goal of this study was to measure short term differences in tear size, atrophy and fatty infiltration in degenerative rotator cuff tears treated surgically or conservative. As clinicians and patients may consider if they are 'worse off' trying a conservative approach, as first step in the treatment of degenerative rotator cuff tears, this is a relevant question. We found no increase in tear size, atrophy or fatty infiltration in conservatively and surgically treated patients.

These findings do not support the hypothesis that early rotator cuff repair should be performed to prevent increase in tear size, further atrophy or fatty infiltration. It should be noticed that conservative treatment is not successful in all patients. Moosmayer reported 12 (24%) patients with disappointing results after conservative treatment for a rotator cuff tear.¹² In nine of these 12 patients surgery was performed within two years of inclusion. In a multicenter prospective cohort study, Kuhn et al. reported the effectiveness of conservative treatment in 422 patients.³ During a two-year follow-up, 26% (n=82) of patients decided to have surgery; most patients made this decision within three months. According to our results, within this short term no increase in tear size, which would influence cuff reparability, is to be expected. It should be noticed that no conclusions can be drawn of this study for the long term results effect on the rotator cuff of conservatively treated patients.

In a retrospective analysis Melis et al. described development of moderate supraspinatus fatty infiltration at an average of three years and severe fatty infiltration at an average of five years following start of complaints.²³ In a prospective cohort of 118 patients with an asymptomatic full-thickness rotator cuff tear, Keener et al. report tear progression in 61% of patients.¹⁴ Median time to tear increase was 2.3 years. In multiple case series, tear size progression is found in approximately 50% of conservatively treated patients.¹⁴⁻¹⁶ In most patients, tear progression was associated clinically with an increase in complaints.^{12,14,24} Asymptomatic increase in tear size without aggravation of symptoms is found in 5-22% of patients treated conservatively for a full-thickness rotator cuff tear.^{12,24,25} These findings do not support the hypothesis that early rotator cuff repair should be performed to prevent increase in tear size, further atrophy or fatty infiltration. They do support the practice of conservative treatment as first step of treatment for patients in this age group or older. When combining our results with these studies, the "window" for a safe decision to switch from conservative treatment to surgical repair might be one to two years after diagnosis. It should be stressed

that at this moment long term results regarding the efficacy of conservative treatment for degenerative rotator cuff tears are lacking.

No significant difference in MRI parameters of atrophy and fatty infiltration were observed in this study between patients with an intact repair and a retear. One might expect an improvement of the degenerative changes in successful rotator cuff repair, yet our results are in line with previously published studies. In animal studies no decrease of fatty infiltration was found following rotator cuff repair.^{26,27} In a study by Gladstone et al. surgical repair did not improve degenerative changes of the rotator cuff.²⁸ Thomazou et al. found 10% improvement in atrophy in half of the patients with intact rotator cuff repair.²⁹ Gerber et al. also reported further development of degenerative changes despite successful surgical repair.³⁰ A recent study suggests that surgery itself induces extensive injury to the rotator cuff muscle.³¹ This might explain why no improvement is found in patients with an intact repair compared to patients with a retear.

STRENGTH AND LIMITATIONS

The interobserver quality in this study for the different classification systems is high-to-excellent; a moderate-to-high quality was observed only for the tangent sign. This suggests high image quality and reliable assessment of MRI. Only patients with degenerative tears were included in this study. As the origin of traumatic tears differ from degenerative tears this might have implications for the development of degenerative muscle changes. Therefore, these patients were not included in this trial.

A limitation of this study is the limited amount of participants. Most patients already undergoing conservative treatment by their general practitioner or physical therapists were unwilling to participate in the randomized controlled trial. Therefore inclusion had to be terminated prematurely. Another limitation was the percentage of patients lost to follow-up. 26% of patients were lost to follow up for various reasons, one of them not willing to undergo a second MRI due to claustrophobia.

CONCLUSION

The results of this study show no increase in tear size, atrophy or fatty infiltration within a year following conservative treatment, successful (intact) rotator cuff repair or failed (retear) rotator cuff repair for a degenerative rotator cuff tear. This extends the “window” for conservative treatment, and it can be advised to initiate treatment conservatively. However, no long term conclusions for the efficacy of conservative treatment can be drawn.

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