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Operative versus conservative treatment of small, nontraumatic supraspinatus tears in patients older than 55 years: over 5-year follow-up of a randomized controlled trial

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Background: Nontraumatic rotator cuff tear is a common shoulder problem that can be treated either conservatively or operatively. In the previous publications of the 1- and 2-year results of this trial, we found no significant between-group clinical differences. The aim of this study was to investigate the differences in mid-term clinical and radiologic outcomes in patients older than 55 years.

Materials and methods: One hundred eighty shoulders with symptomatic, nontraumatic supraspinatus tears were randomly assigned to 1 of the 3 cumulatively designed treatment groups: physiotherapy (group 1); acromioplasty and physiotherapy (group 2); and rotator cuff repair, acromioplasty, and physiotherapy (group 3). The change in the Constant score was the primary outcome measure. The secondary outcome measures were the change in the visual analog scale score for pain and patient satisfaction. Radiologic analysis included evaluation of glenohumeral osteoarthritis (OA) and rotator cuff tear arthropathy (CTA).

Results: A total of 150 shoulders (mean age, 71 years) were available for analysis after a mean follow-up period of 6.2 years. The mean sagittal tear size of the supraspinatus tendon tear at baseline was 10 mm in all groups ($P = .33$). During follow-up, 8 shoulders in group 1 and 2 shoulders in group 2 crossed over to rotator cuff repair. The mean baseline Constant score was 57.1, 58.2, and 58.7 in groups 1, 2, and 3, respectively ($P = .85$). There were no significant differences ($P = .84$) in the mean change in the Constant score: 18.5 in group 1, 17.9 in group 2, and 20.0 in group 3. There were no statistically significant differences in the change in the visual analog scale pain score ($P = .74$) and patient satisfaction ($P = .83$). At follow-up, there were no statistically significant differences in the mean progression of glenohumeral OA ($P = .538$) or CTA ($P = .485$) among the groups. However, the mean progression of glenohumeral OA from baseline to follow-up was statistically significant in the trial population ($P = .0045$).

Conclusions: On the basis of this study, operative treatment is no better than conservative treatment regarding small, nontraumatic, single-tendon supraspinatus tears in patients older than 55 years. Operative treatment does not protect against degeneration of the glenohumeral joint or CTA. Conservative treatment is a reasonable option for the primary initial treatment of these tears.

The Ethics Committee of the Hospital District of South-West Finland approved this study (ETMK 106/180/2007), and the study protocol was registered at ClinicalTrials.gov (NCT01116518).

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Level of evidence: Level II; Randomized Controlled Trial; Treatment Study
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Keywords: Rotator cuff tear; conservative treatment; rotator cuff repair; Constant score; VAS pain score; patient satisfaction; radiographic analysis; randomized controlled trial

A nontraumatic rotator cuff tear may be regarded as a consequence of tendon degeneration, with a prevalence of up to 30% in the population older than 60 years.[41] The awareness of this condition, as well as its association with shoulder pain and disability, and medical, technologic, diagnostic, and therapeutic advancements have all plausibly increased the number of arthroscopic rotator cuff reconstructions worldwide.[6,29]

Despite the recognized trend in the treatment paradigm, nontraumatic rotator cuff tears may also be successfully treated nonoperatively.[2,18] In fact, there is no significant difference in short-term clinical outcomes between operative and nonoperative treatment modalities.[19,31] Nevertheless, there is a valid concern that tears may enlarge in time and, on the basis of a mechanical rationale, predispose conservatively treated patients in particular to further symptoms, glenohumeral joint degeneration, and early rotator cuff tear arthropathy (CTA).[5,11,13,15,27,32,42] However, there is a lack of evidence that operative treatment would prevent this potentially deplorable end result.

The purpose of this trial was to investigate the difference in mid-term clinical and radiologic outcomes between (1) physiotherapy only; (2) acromioplasty and physiotherapy; and (3) rotator cuff repair, acromioplasty, and physiotherapy in the treatment of symptomatic, nontraumatic rotator cuff tears. Our hypothesis was that surgical repair of rotator cuff tears would give superior clinical and radiologic results compared with other treatment modalities.

Materials and methods

Design

This randomized, controlled superiority trial consisted of 3 cumulatively designed parallel treatment arms. The trial was conducted between October 2007 and December 2012 at 3 hospitals in Finland: Kuopio University Hospital, Tampere Hatanpää Hospital, and Turku University Hospital.

Participants

The participants were sequentially recruited among patients referred to undergo surgical intervention for rotator cuff tears in 1 of the 3 participating hospitals. Patients older than 55 years who had symptoms relating to degenerative cuff tear (pain in abduction and at rest) and met the trial criteria (Table I) were invited to participate. Patients underwent a shoulder magnetic resonance imaging (MRI) investigation, and those with an isolated full-thickness supraspinatus tear were asked to participate in the trial. Each patient gave written informed consent. A flowchart of the trial is shown in Figure 1.

The trial interventions were explained to the patients in detail, and it was pointed out that all 3 interventions have been found to be effective and that the treatment results have not differed in studies so far. Patients were informed that they could consider crossing over to rotator cuff repair in case of treatment failure, that is, if adequate relief of symptoms was not achieved by 6 months after the allocated intervention.

Randomization and blinding

After the consent process, the study nurse randomized the patients into 1 of the 3 treatment groups using sequentially numbered, opaque, sealed envelopes. The randomization was stratified according to participating hospital into 3 blocks. After randomization, the patient and the treating physician were openly informed of the treatment group. The radiologists were blinded to clinical patient data. The treatment started within 1 month after randomization.

Interventions

Physiotherapy (group 1)

A physiotherapist specializing in shoulder rehabilitation gave the patient written information and guided the patient on how to perform a standardized training exercise protocol at home. The first 6 weeks of the exercise protocol aimed at improving glenohumeral motion and active scapular retraction, after which static and dynamic exercises to improve scapular and glenohumeral muscle function were gradually increased until 12 weeks. Thereafter, the patient increased resistance and strength training up to 6 months. In addition to receiving written instructions, the patient was referred to undergo 10 sessions of physiotherapy at an outpatient health care facility where his or her progress was monitored.

Acromioplasty and physiotherapy (group 2)

All operations (groups 2 and 3) were performed arthroscopically in a standardized manner by 4 experienced shoulder surgeons. In group 2, subacromial débridement and arthroscopic acromioplasty were carried out by smoothing the inferior surface of the acromion in the posterior-to-anterior direction. Biceps tenotomy was performed if the long head of the biceps tendon was frayed or unstable. Acromioclavicular (AC) resection was also performed if palpation of the AC joint elicited pain preoperatively and severe radiographic osteoarthritic changes were present in the AC joint. The postoperative rehabilitation protocol was the same as that in group 1.

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Table I Inclusion and exclusion criteria

Inclusion criteria
Subject age > 55 yr
Atraumatic, symptomatic, isolated full-thickness supraspinatus tendon tear documented with MRI
Full range of motion of shoulder
Written informed consent by participating subject
Exclusion criteria
History of trauma relating to onset of symptoms
Tear involving whole supraspinatus tendon and/or combined tear of 2-3 tendons (ie, supraspinatus with infraspinatus or subscapularis tendon tear)
Stiffness of glenohumeral joint: passive external rotation < 30° and/or elevation < 120°
Glenohumeral osteoarthritis with osteophytes visible on radiographs
Systematic glucocorticosteroid or antimetabolite medication
Malignant, hematologic, endocrine, metabolic, rheumatoid, or gastrointestinal disease
History of alcoholism, drug abuse, or psychological or emotional problems likely to jeopardize informed consent
Previous surgery on same shoulder

MRI, magnetic resonance imaging.

Rotator cuff repair, acromioplasty, and physiotherapy (group 3)

The supraspinatus tendon was repaired anatomically with standard titanium bone anchors and nonabsorbable sutures (Corkscrew FT II [Arthrex, Naples, FL, USA] or Twinfix [Smith & Nephew, Andover, MA, USA]) according to surgeon preference. In cases of a tear size $\leq$ 10 mm, a single-row technique was used, whereas for larger tears, the repair was performed in a double-row fashion. Subacromial débridement, acromioplasty, and where appropriate, biceps tenotomy and AC resection were performed as in group 2. Postoperatively, the arm was immobilized in a sling for 3 weeks, after which passive mobilization was commenced. Active shoulder motion was allowed after 6 weeks, and thereafter, the rehabilitation protocol was the same as that in group 1.

Outcome measures

The change in the absolute Constant score was used as the primary outcome measure. The Constant score was recorded no later than 1 month before the intervention and again at 3, 6, 12, 24, and 60 months after the baseline assessment by an independent study nurse or physiotherapist. Patients whose change in score exceeded the previously reported minimal clinically important difference (MCID)[20] were regarded as responders.

The secondary outcome measures were the visual analog scale (VAS) score for pain and subjective satisfaction with treatment outcome. A repeated radiograph was obtained 5 years after baseline. A musculoskeletal radiologist analyzed the radiographic images for signs of glenohumeral osteoarthritis (OA) according to Samilson and Prieto[36] or CTA according to Hamada et al.[9]

Sample size calculation and statistical analysis

The power calculations were based on the assumed changes in the Constant score. On the basis of previous registry data from Turku University Hospital, the mean score at baseline was assumed to be 50 (standard deviation, 10). The score in the best treatment group at follow-up was assumed to be 70 and in the worst treatment group, 60. The correlation between the measurements during follow-up was assumed to be 0.40-0.50 (standard deviation, 20). On analysis-of-variance testing with $\alpha = .05$ and power = 85%, we expected the findings to be statistically significant if the number of subjects per group was 51. The dropout rate was assumed to be 15%; thus, the number of subjects per group was 60.

Outcomes were analyzed on an intention-to-treat basis. The main outcomes were analyzed with analysis of covariance controlling for baseline values. The distributions of continuous variables were investigated with the Shapiro-Wilk test of normality. Differences between categorical variables were calculated with the Pearson χ^2 test. The numeric values of the VAS pain score were log transformed to attain normality. Post hoc pair-wise comparisons were adjusted for multiplicity using a simulation-based method, yielding corrected P values and 95% confidence intervals (CIs). Model fit was verified using Pearson residuals.

Results

Patient characteristics

A total of 150 shoulders (51 in group 1, 50 in group 2, and 49 in group 3) were available for analysis at a mean of 6.2 years after baseline (dropout rate, 17%). There were no significant differences in patient demographic characteristics among the groups. Detailed patient characteristics and intraoperative findings are presented in Tables II and III, respectively.

Constant score, VAS pain score, and patient satisfaction

No treatment-related complications occurred in any group. The mean Constant score at baseline was 57.1 (95% CI, 53.1-61.1) in group 1, 58.2 (95% CI, 54.1-62.2) in group 2,

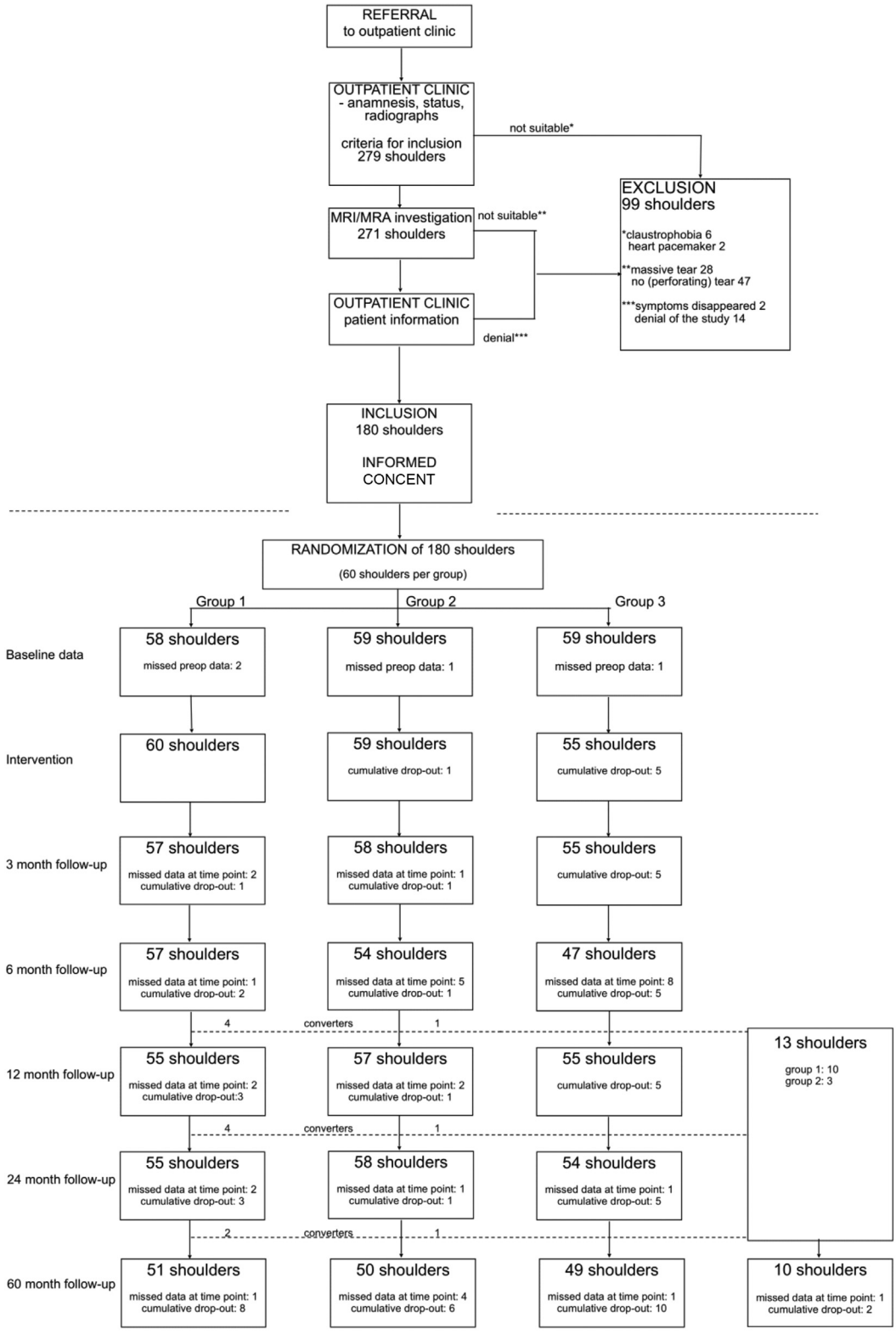

Figure 1 Flowchart of inclusion process. Group 1 underwent physiotherapy; group 2, acromioplasty and physiotherapy; and group 3, rotator cuff repair, acromioplasty, and physiotherapy. *MRI*, magnetic resonance imaging; *MRA*, magnetic resonance arthrography; *preop*, preoperative.

Table II Patient demographic characteristics

	Group 1	Group 2	Group 3
n	51	50	49
Sex			
Female	29	24	22
Male	22	26	27
Mean age at follow-up (range), yr	70 (61-83)	71 (61-79)	71 (60-86)
Mean length of follow-up (SD; range), yr	6.1 (1.12; 4.4-8.5)	6.2 (1.12; 4.9-8.6)	6.2 (1.15; 5.0-8.5)
Affected side			
Right	39	30	33
Left	12	20	16
Working status at baseline			
Working	13	10	21
Sick leave	5	1	1
Retired	31	34	26
Mean duration of symptoms before intervention (SD) mo	19 (12.1)	20 (12.2)	20 (12.3)
Smoking (% within group)	10 (20)	4 (8)	7 (14)
Prior corticosteroid injection (% within group)	37 (73)	28 (56)	28 (57)

SD, standard deviation.
Group 1 underwent physiotherapy; group 2, acromioplasty and physiotherapy; and group 3, rotator cuff repair, acromioplasty, and physiotherapy.

Table III Intraoperative findings

	Group 2 (n = 50)	Group 3 (n = 49)	*P* value
Tear size in operation, mm*	12.7 ± 7.4	14.9 ± 9.3	.20
Acromioclavicular resection, %†	12	16	.74
Biceps tenotomy, %†	50	43	.61
Operation time, min‡	36 ± 11	69 ± 22	<.0001

Group 2 underwent acromioplasty and physiotherapy; and group 3, rotator cuff repair, acromioplasty, and physiotherapy.
* Assessed by *t* test.
† Assessed by χ^2 test (assumptions hold).
‡ Assessed by Wilcoxon rank sum test.

and 58.7 (95% CI, 54.7-62.8) in group 3 ($P = .85$). The mean Constant score at follow-up was 75.6 (95% CI, 71.5-79.8), 76.3 (95% CI, 72.0-80.5), and 78.7 (95% CI, 74.4-83.0), respectively ($P = .5761$). The mean change in the Constant score at follow-up was 18.5 (95% CI, 13.6-23.4), 17.9 (95% CI, 13.0-22.9), and 20.0 (95% CI, 15.0-24.9), respectively ($P = .84$) (Fig. 2). The mean VAS pain score at baseline was 2.92 (95% CI, 2.19-3.65) in group 1, 2.62 (95% CI, 1.89-3.35) in group 2, and 2.47 (95% CI, 1.73-3.21) in group 3 ($P = .6902$); at follow-up, it was 1.43 (95% CI, 0.98-1.88), 0.63 (95% CI, 0.18-1.08), and 0.62 (95% CI, 0.16-1.08), respectively ($P = .0194$). There were no statistically significant differences in the change in the VAS pain scores among the groups (−1.5 in group 1, −2.0 in group 2, and −1.9 in group 3; $P = .74$) (Fig. 3). The binary method for evaluation of satisfaction showed high satisfaction in all 3 groups (88% in group 1, 92% in group 2, and 92% in group 3; $P = .83$). During follow-up, 8 shoulders in group 1 and 2 shoulders in group 2 crossed over to rotator cuff repair. Data on the crossover cases are presented in Table IV. There was no statistically significant difference in the proportion of responders among the treatment groups ($P = .7089$). A summary of the clinical results is presented in Table V.

Preoperative MRI findings

The mean sagittal size of the supraspinatus tendon tear at baseline was 10.1 mm (95% CI, 8.6-11.6 mm) in group 1, 9.6 mm (95% CI, 8.1-11.1 mm) in group 2, and 8.5 mm (95% CI, 7.0-10.0 mm) in group 3 ($P = .33$).

Radiographic analysis

Preoperatively, there was no or mild radiographic OA (Samilson-Prieto grade 0-1) in 36 (97%), 31 (89%), and 33 shoulders (89%) and moderate or severe OA (Samilson-

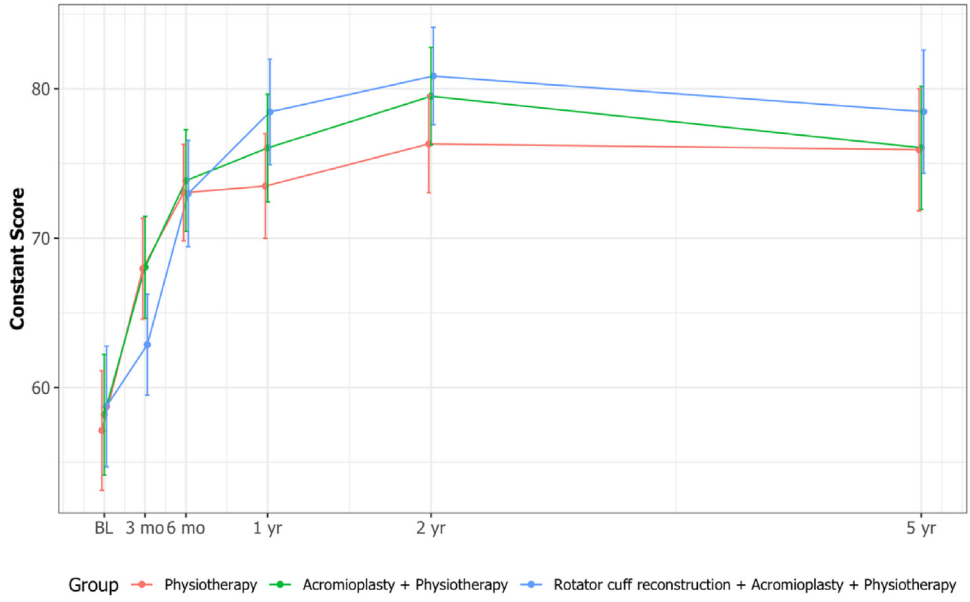

Figure 2 Behavior of Constant score. *BL*, baseline.

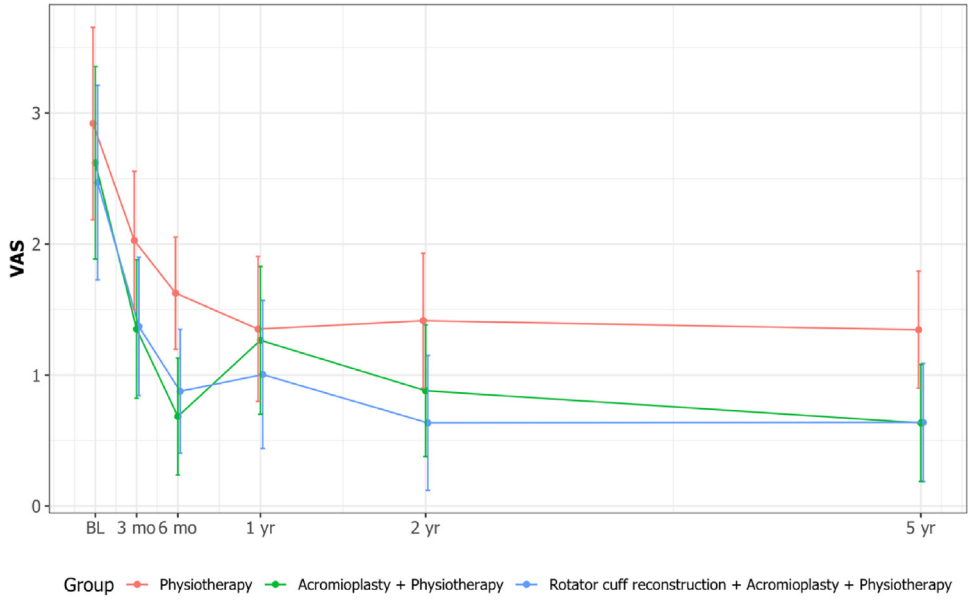

Figure 3 Behavior of visual analog scale *(VAS)* pain score. *BL*, baseline.

Prieto grade 2-3) in 1 (3%), 4 (11%), and 4 shoulders (11%) in groups 1, 2, and 3, respectively ($P = .352$). At follow-up, moderate or severe OA was detected in 7 (19%), 14 (40%), and 13 shoulders (35%) in groups 1, 2, and 3, respectively ($P = .124$). Despite nonsignificant between-group differences, we found a statistically significant mean progression of 0.33 steps in Samilson-Prieto grading from baseline to follow-up in the trial population ($P = .0045$).

The humeral head was radiographically centered in a craniocaudal manner in 30 (81%), 30 (88%), and 34 shoulders (92%) preoperatively and 26 (59%), 23 (56%), and 24 shoulders (62%) at follow-up in groups 1, 2, and 3, respectively ($P = .0003$). There were no statistically significant between-group differences in radiographic Hamada classification (Table VI). There was a mild but statistically significant negative correlation between the radiographic

Table IV Data of 10 crossover cases at final follow-up

	Group 1	Group 2
Shoulders, n (%)	8 (16)	2 (4)
Mean Constant score at baseline (SD)	55.6 (13.7)	45.0 (11.3)
Mean time of reoperation (SD), mo	20.5 (17.4)	15.0 (8.3)
Mean Constant score before reoperation (SD)	63.6 (9.7)	40.5 (9.2)
Mean VAS pain score at follow-up (SD)	0.3 (0.5)	1.2 (1.2)
Mean Constant score at follow-up (SD)	78.9 (2.9)	68.0 (0)
Satisfied patients, %	100	100

SD, standard deviation; *VAS*, visual analog scale.
Group 1 underwent physiotherapy; and group 2, acromioplasty and physiotherapy.

Table V Clinical outcomes at follow-up adjusted for baseline measurements with 95% CIs and between-group *P* values

	Group 1	Group 2	Group 3	*P* value
Mean change in VAS pain score (95% CI)*	−1.55 (−2.35 to −0.75)	−1.99 (−2.79 to −1.19)	−1.85 (−2.66 to −1.04)	.7375
Mean change in Constant score (95% CI)*	18.5 (13.6-23.4)	17.9 (13.0-22.9)	20.0 (15.0-24.9)	.8421
Working status at follow-up†				
Working	5	4	3	
Sick leave	0	0	0	
Retired	45	46	45	.9292
Responder rate, %‡,§	68.0	71.4	75.5	.7089
Mean satisfaction with treatment outcome, %†	88.2	92.0	91.8	.8272

VAS, visual analog scale; *CI*, confidence interval.
Group 1 underwent physiotherapy; group 2, acromioplasty and physiotherapy; and group 3, rotator cuff repair, acromioplasty, and physiotherapy.
* Assessed by *F* test (analysis of variance).
† Assessed by Fisher exact test (χ^2 assumptions do not hold).
‡ Assessed by χ^2 test (assumptions hold).
§ Percentage of patients with follow-up Constant score of 10 points (ie, minimal clinically significant difference) or higher than at baseline.

Hamada classification and Constant score at follow-up ($r = -0.27$, $P = .0026$).

Discussion

The main finding of this study is that there were no clinically or statistically significant differences in the outcomes among the 3 studied interventions after 5 years of follow-up in patients older than 55 years with small, symptomatic, nontraumatic supraspinatus tears. In contrast to our hypothesis, surgical repair of supraspinatus tears did not result in a significantly better change in the Constant score or VAS pain score compared with acromioplasty or conservative treatment. Patient satisfaction was high and essentially similar among the 3 study groups.

The findings of our trial indicate a slight progression of glenohumeral joint wear in patients with degenerative supraspinatus tear. However, there were no significant between-group differences in radiographic OA or CTA changes, and our findings imply that the degeneration and eccentricity of the glenohumeral joint cannot be prevented with a supraspinatus repair. We assume the unstoppable joint degeneration is a pervasive process affecting all parts of the joint despite the given treatment.

MCID and responder analyses are common approaches to evaluate the clinical significance of the treatment effect. The MCID for the Constant score in operatively treated rotator cuff tears has been described earlier,[20] as has the MCID for the VAS pain score in patients with rotator cuff disease.[39] Responder analyses have known weaknesses, such as the arbitrary nature of the definition of a response, that is, What is the threshold for a responder and a nonresponder?[37,38] Few randomized controlled trials of interventions for chronic low-back pain have reported responder analyses.[10] This tool has also been used in 1 randomized controlled trial in shoulder impingement patients.[28] We used the previously described 10-point MCID limit[20] as a threshold in determining the number of responders in each treatment group. There were more responders in the operative groups than in the nonoperative group, although this difference was not statistically significant.

Table VI Radiographic Hamada classification

	Baseline Hamada classification				Follow-up Hamada classification			
	1	2	3	4	1	2	3	4
Group 1, %	81	19	0	0	62	38	0	0
Group 2, %	88	12	0	0	64	28	8	0
Group 3, %	92	8	0	0	71	21	6	3
*	.3962				.1933			

Group 1 underwent physiotherapy; group 2, acromioplasty and physiotherapy; and group 3, rotator cuff repair, acromioplasty, and physiotherapy.
* Fisher exact test.

There is no robust evidence of the benefit of physiotherapy for treating nontraumatic rotator cuff tears. Moreover, it is likely that the effect of transitory training diminishes with time. Therefore, it can be argued that the mid-term natural course of degenerative supraspinatus tears is favorable.[7] However, there is an obvious placebo effect related to all medical treatment modalities,[3] and it may be that the patients cope better after receiving physiotherapy than they would if just left untreated altogether.[1,40] Similarly, there may be an even stronger placebo effect in surgical treatment,[12] seen as a non–statistically significant difference in clinical scores in favor of the operative treatment groups in our trial. However, the placebo effect is reported to diminish with time, and it is uncertain whether it can last for >2 years.[17]

Moosmayer et al[24-26] randomized 103 small- and medium-sized rotator cuff tears to mini-open repair or physiotherapy; both traumatic and nontraumatic tears were included. They published 1-, 5-, and 10-year results and found a statistically significant between-group difference at 1-year follow-up, with better results in the operative treatment group; at 10 years, this difference further increased. In a study by Lambers Heerspink et al,[21] 56 patients with degenerative full-thickness rotator cuff tears were randomized to conservative treatment or rotator cuff repair. No statistically significant difference in the Constant score was found between the treatment groups at 1-year follow-up. A limitation of this study was the small group size owing to difficulties with patient recruitment. Two systematic reviews and meta-analyses including the 1-year results of our trial cohort, as well as the 2 aforementioned studies by Moosmayer et al and Lambers Heerspink et al, have been published recently.[30,35] Both studies found a statistically significant difference in the Constant score of 5.6 in favor of rotator cuff repair. This difference is below the reported MCID.[20] The same 3 randomized controlled trials comparing operative and conservative treatment of rotator cuff tears were included in a Cochrane systematic review.[14] This review concluded that operative treatment may not provide any benefit over conservative treatment of symptomatic full-thickness rotator cuff tears. Ranebo et al[31] recently published a randomized study in which 58 trauma-related rotator cuff tears were randomized to conservative treatment or rotator cuff repair. So far, this is the only study that has included purely traumatic rotator cuff tears. At 1-year follow-up, no statistically significant difference in the Constant score was found between the treatment groups. Longer follow-up and the results of ongoing studies are needed to evaluate the optimal treatment for trauma-related rotator cuff tears.[34] In the latest randomized trial comparing nonsurgical and surgical treatments for rotator cuff disease, Cederqvist et al[4] reported that surgery yielded superior improvement in pain and function in patients with full-thickness rotator cuff tears at 2-year follow-up. This study also included larger rotator cuff tears comprising not only the supraspinatus tendon. However, the mean change in the Constant score between the groups was below the reported MCID for rotator cuff tear patients.[20]

One strength of our study is a good follow-up rate of 83%. The cases of dropout partly comprised deceased patients, and some patients were not available because of migration to another district. Radiologic analysis in addition to clinical outcome measures is also a strength of this study. At 5-year follow-up, we had fewer cases of crossover compared with the Norwegian study.[26] Nevertheless, conservative therapy failed in 8 shoulders (16%), and these crossed over to surgical repair.

Our trial has some limitations. First, owing to the trial setup, blinding was not possible and both the patients and the medical staff knew the allocated treatment modality; this may have affected the outcomes. Second, the supraspinatus tendon insertion area is very small, as described by Mochizuki et al,[23] and the supraspinatus and infraspinatus tendon insertions overlap. Accordingly, some larger tears likely had extension to the infraspinatus tendon. Third, without repeated MRI, we cannot draw conclusions on mid-term rotator cuff integrity. In a previously published article, we reported the 2-year MRI results of the same cohort.[19] Fourth, plain radiography is a crude method to evaluate degeneration or centricity of the glenohumeral joint. Measurement of the acromiohumeral distance, for example, is dependent on the individual anatomy and quality and projection of the radiographs. The reliability of the acromiohumeral distance measurement using radiographs has been reported to be poor.[22] To ascertain the best possible

interpretation, the images were assessed by an independent musculoskeletal radiologist. Missing preoperative radiographs were a result of the inclusion criteria, requiring only MRI examination. Fifth, the Constant score may be criticized for being a mix of both patient- and physiotherapist-reported measures.[16] However, it is endorsed by the European Society for Surgery of the Shoulder and the Elbow, and it is reportedly a suitable outcome measurement for patients with rotator cuff tears.[8,33]

Conclusion

On the basis of the results of this study, a conservative treatment strategy is supported in the treatment of small, single-tendon, nontraumatic supraspinatus tears in patients older than 55 years. The mid-term outcome is essentially similarly favorable in all studied treatment groups. Furthermore, the initial operative treatment does not seem to prevent the subtle progression of OA or CTA in these patients. The possible progression of glenohumeral wear warrants further follow-up and is a potential concern especially when treating younger patients.

Disclaimers

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