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Surgery and physiotherapy were both successful in the treatment of small, acute, traumatic rotator cuff tears: a prospective randomized trial

Mats C. Ranebo, MD[a,b,*], Hanna C. Björnsson Hallgren, MD, PhD[c], Theresa Holmgren, PT, PhD[c,d], Lars E. Adolfsson, MD, PhD[b,c]

[a]*Department of Orthopedics, Kalmar County Hospital, Kalmar, Sweden*
[b]*Department of Clinical and Experimental Medicine, Faculty of Health Sciences, Linköping University, Linköping, Sweden*
[c]*Department of Orthopedics, Linköping University Hospital, Linköping, Sweden*
[d]*Department of Medical and Health Science, Division of Physiotherapy, Linköping University, Linköping, Sweden*

Background: Previous randomized trials on cuff repair have included mainly degenerative tears, but studies on acute traumatic tears are lacking. We aimed to compare early surgical repair with nonoperative treatment for traumatic supraspinatus tears.
Methods: We did a 2-center randomized controlled trial of patients with small rotator cuff tears mainly involving supraspinatus, comparing surgical repair (n = 32) and physiotherapy (n = 26). The primary outcome was a group difference in the Constant-Murley score at 12-month follow-up. Secondary outcomes were differences in the Western Ontario Rotator Cuff index, pain (Numerical Rating Scale 0-10), and Euro quality-of-life-visual analog scale. We used magnetic resonance imaging to assess retear rate, tear progression, fatty infiltration, and atrophy.
Results: The mean age was 59.7 years (range, 44-77 years), median sagittal tear size was 9.7 mm (range, 4-21 mm), and baseline characteristics were well balanced between the 2 groups. The repair group had a median Constant-Murley of 83 (25 quartile range [QR]) and the physiotherapy group 78 (QR, 22) at 12 months, with the between-group difference in medians of 4.5 (−5 to 9, 95% confidence interval; $P = .68$). The corresponding values for the Western Ontario Rotator Cuff index were 91% (QR, 24) vs. 86% (QR, 24), with the between-group difference of 5.0 (−4 to 9, 95% confidence interval; $P = .62$). There was no difference in Numerical Rating Scale or in Euro quality-of-life-visual analog scale. Retear was found in 6.5% of repaired patients and tear progression >5 mm in 29.2% of unrepaired patients.
Conclusions: We found no significant differences in clinical outcomes between cuff repair and nonoperative treatment at 12-month follow-up. Approximately one third of unrepaired patients had a tear enlargement of more than 5 mm.

The trial had Regional Ethics Committee approval (Dnr 2013/330-31) and was registered with ClinicalTrials.gov (NCT02059473).

*Reprint requests: Mats C. Ranebo, MD, Department of Orthopedics, Kalmar County Hospital, 391 85 Kalmar, Sweden.
E-mail address: mats.ranebo@regionkalmar.se (M.C. Ranebo).

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Rotator cuff repair is a commonly performed surgical procedure.[8] Shoulder pain and function after repair or physiotherapy without repair of small- to medium-sized cuff tears have been investigated in a few prospective randomized studies.[28,29,32,39,41] These studies have shown no difference[28,29] or slightly better outcome with repair,[32,39,41] but differences have been below or on thresholds for clinical importance. The majority of studies have included only degenerative nontraumatic tears.[29,32,43] Moosmayer et al[41] included both traumatic and nontraumatic tears, but only 39% of the patients had sustained an adequate trauma.

The degenerative rotator cuff tendon has been shown to have features that may have an impact on healing and treatment results. Several studies have shown cellular and vascular changes indicative of tissue degeneration,[2,18,35,37] and a multitude of systemic risk factors seem to influence the occurrence of degenerative cuff tears.[44,48] The retear rate after rotator cuff repair is also potentially high, reportedly with a large variation from 11%[31] to 94%.[13] Many factors may thus affect the results after repair of degenerative tears. The conditions regarding traumatic rotator cuff tears in patients with a previously healthy shoulder may be different due to better healing conditions, potentially allowing a good result for repaired tendons. There are however no prospective randomized studies published focusing exclusively on this category of patients, and the benefits of cuff repair in comparison with physiotherapy without repair are not known.

The overall aim of this randomized controlled trial was to compare physiotherapy only with surgical repair and physiotherapy in patients with acute traumatic rotator cuff tears. Secondary aims were to assess the healing rate in repaired shoulders and tear progression in unrepaired shoulders after 12-month follow-up.

Methods

Study design and setting

We did a 2-center prospective randomized trial comparing parallel groups of rotator cuff repair and physiotherapy without repair for acute traumatic rotator cuff tears. One university hospital and one county hospital took part in patient recruitment, which was undertaken from January 2014 to June 2017.

Patient selection

Recruitment base was patients seeking at the emergency departments in the catchment area for each hospital. We also screened referrals to the participating orthopedic departments of patients suspected to have a traumatic rotator cuff tear. Eligible cases were patients without previous shoulder complaints seeking help for pain and/or decreased elevation after a shoulder trauma. Shoulder trauma was defined as any fall, impact, sudden pulling, or sudden stretching involving the symptomatic shoulder. Inclusion criteria were shoulder pain, decreased elevation after trauma, and magnetic resonance imaging (MRI) showing a full-thickness cuff tear, not exceeding the 2 most superior segments out of a 12-segment division of a sagittal MRI image of the humeral head (Fig. 1). This method was used to ascertain that the tear included mainly the supraspinatus, instead of relying on tendon nomenclature or tear measurement. Exclusion criteria were a delay of more than 3 months between trauma and operation, previous shoulder complaints, glenohumeral osteoarthritis, symptomatic acromioclavicular joint-arthritis, shoulder fracture or dislocation, previous shoulder operations, systemic joint disease, malignancy, fibromyalgia, shoulder instability, frozen shoulder, neurological disease affecting arm function, inability to understand Swedish, drug abuse, and cognitive impairment. We obtained written informed consent from all participants.

Randomization

One computer-generated and open randomization list with a 1:1 ratio was made by one of the authors not participating in patient recruitment. We used sequentially numbered, opaque, and sealed envelopes containing the randomization result. Each envelope was sequentially opened by the recruiting physician according to number on envelope, after patient acceptance of participation.

Interventions

Repair group

Operations were performed by 5 shoulder surgeons, all well experienced with the technique and with more than 10 years of practice as orthopedic subspecialists in shoulder surgery. Patients were operated as an outpatient procedure under general anesthesia, complemented with an interscalene brachial plexus block, as soon as practically possible after the traumatic event. An arthroscopically assisted mini-open approach was used in all cases to minimize the effects of learning curves or inexperience with arthroscopic cuff repair.[16] Several studies have not shown any substantial differences in results or complications between arthroscopic and mini-open repair.[6,49] A routine diagnostic arthroscopy was performed in all patients to confirm a

full-thickness cuff tear, and to rule out other relevant concomitant pathologies. An arthroscopic bursectomy with a small acromioplasty was performed in 18 cases according to surgeon preference. For the repair, a small sagittal superolateral skin incision, just lateral to the acromion, was used in conjunction with a deltoid split in the white line separating the anterior and middle portions of the deltoid. After footprint preparation and mobilization of the tear, where the most appropriate way of reducing the tendon was assessed, metallic suture anchors were inserted in the greater tuberosity. Anchors used were Fast-in RC (DePuy-Synthes Mitek Sports Medicine, Raynham, MA, USA) and Super QUICKANCHOR Plus (DePuy-Synthes Mitek Sports Medicine), both loaded with Orthocord. In the tendon, mattress sutures or Mason-Allen sutures were used according to surgeon preference. In 1 case, osteosutures were used in conjunction with an anchor. In 5 cases, a biceps tenodesis was performed. AC-joint resections were not performed. After irrigation the wound was closed in layers. In the postoperative period, a sling was used for 4 weeks.

Nonoperative group

The treatment regime consisted of active training, guided by 1 of 4 physiotherapists (2 in each center), each with more than 10 years of experience as subspecialists in shoulder physiotherapy. No immobilization was used in the nonoperative group.

Rehabilitation program

The rehabilitation program for the 2 groups was equal and consisted of 3 phases. Patients having undergone surgical repair started the program 4 weeks after surgery because of restrictions of immobilization with the arm in a sling. The first training session for the nonoperative group was scheduled as soon as possible after the inclusion.

Each phase contained several recommended exercises from which the physiotherapist could choose, with respect to restrictions. The physiotherapist decided when the patient was ready to move on to the next phase, considering aspects of quality of motion and pain.

Phase 1 included standardized information about the condition and exercises aimed at promoting good posture and stabilization of the scapula.[20,27] Initially, range of motion exercises that unload the rotator cuff were used, such as the wall slide and supported active flexion on a table using a ball[14] and active assisted exercises in elevation, abduction, and external rotation.[27] Phase 2 contained active unloaded exercises in elevation, external, and internal rotation as well as isometric strengthening exercises.[20,27] Phase 3 included dynamic strengthening exercises for the rotator cuff and scapula stabilizers according to a previously published exercise program.[20]

Supervised physiotherapy sessions were held weekly for the first 4 weeks and then every other week over the next 12 weeks (a total of 10 visits). In between these sessions patients performed home exercises, and a maximum of 3-4 exercises were recommended. In a subset of patients (n = 34), adherence was recorded in an exercise diary.

Outcome assessment

Background variables recorded at inclusion included age, sex, arm dominance, profession (including manual or nonmanual labor), trauma mechanism, smoking, hypertension, diabetes, use of painkillers, flexion, abduction, and external and internal rotation. We also recorded scores for the Western Ontario Rotator Cuff index (WORC)[26] and Hospital Anxiety and Depression score.[52] Anxiety and depression have been shown to affect results after cuff surgery,[7] and Hospital Anxiety and Depression score results in 1 numeric value for anxiety (0-21 points) and 1 for depression (0-21 points).[52] A value of 8 or more in one of the subscales has been suggested as a cutoff of either anxiety or depression.[3]

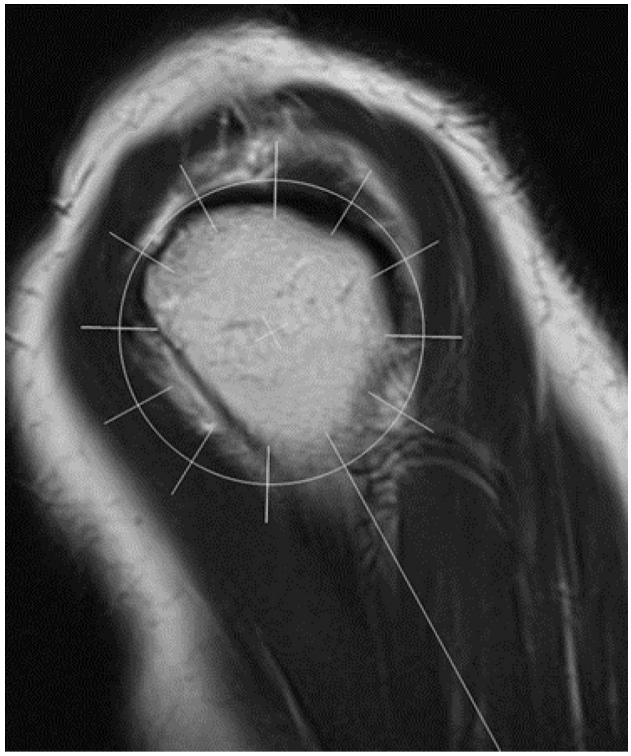

Figure 1 Sagittal oblique MRI image with Cuff clock. For inclusion, the tear could not exceed the 2 most superior sectors. *MRI*, magnetic resonance imaging.

We performed follow-up assessment at 3, 6, and 12 months by 2 independent physiotherapists, who were not involved in the recruitment, training, or handling of the patients. The zero time point, used for calculating assessment date, was the start of the intervention, that is, the date of the operation or the date for the first visit to a physiotherapist in the nonoperative group. Patients were instructed to wear clothing covering the scar to have the outcome assessor blinded to treatment allocation as far as possible. We did no evaluation of whether this blinding was successful.

Outcome measures

The primary outcome measure was pain and function as assessed with the Constant-Murley score (C-M)[9] at 1 year. We used a validated digital myometer (Mecmesin Myometer, Mecmesin, Slinford, UK)[23] to measure strength at 90° of elevation in the scapular plane. If the patient was unable to reach 90°, strength was considered to be zero. The proportion of patients having a

Constant score of 70 or more (satisfactory) and 80 or more (good or excellent) at follow-up was calculated and interpreted according to a published valuation scale of the C-M score.[10,17]

Secondary outcome measures were WORC,[26] pain registered with Numerical Rating Scale 0-10 (NRS),[36] and MRI characteristics regarding healing, tear progression, atrophy, and fatty infiltration at 1 year. We also used the Euro quality-of-life-visual analog scale 0-100 mm for the assessment of quality of life. NRS registers pain as a numerical value from 0 to 10, where 10 indicates worst pain imaginable, and patients were instructed to assign an NRS value for rest, activity, and at night, as experienced during the last week.

Radiographic assessment

All patients had an x-ray performed as a normal procedure after shoulder trauma, and to rule out fracture, dislocation, cuff tear arthropathy, and glenohumeral osteoarthritis. MRI was performed according to the standard protocol used in each hospital. The doctor responsible for inclusion checked the images for full-thickness tear of the superior rotator cuff according to inclusion criteria. To divide a sagittal MRI image of the humeral head in 12 sectors, we used a custom-made application from Sectra (called Cuff clock, Fig. 1) in the digital picture archiving and communication system workstation (Sectra AB, Linköping, Sweden). During the study, and at the end of the study, all MRI images (including a second look at inclusion images) were independently assessed by 3 of the authors and discrepancies were solved through consensus discussion.

We used the Sugaya score for MRI assessment of healing in repaired shoulders.[47] This score has 5 categories and we defined retear as Sugaya types 4 and 5. We measured tear size in millimeters in the coronal oblique plane from the tendon edge to the middle of the footprint and in the sagittal oblique plane from the posterior tendon edge to the anterior tendon edge or, if the anterior tendinous supraspinatus portion was avulsed, to the posterior border of the biceps tendon or bicipital groove. Tear progression was defined as an increase of >5 mm in either coronal oblique or sagittal oblique planes, when comparing MRI at baseline with MRI at 1 year. For the assessment of atrophy, we used the tangent sign as described by Zanetti et al,[51] using the most lateral T1 sagittal oblique images where the scapular spine is in contact with the scapular body. We classified fatty infiltration of the muscle bellies of supraspinatus and infraspinatus in stages 0-4 as described for computed tomography by Goutallier et al[15] and for MRI by Fuchs et al.[12]

Sample size

Sample size calculation drew assumptions from a previous trial regarding timing of repair for acute traumatic cuff tears,[5] where the difference in C-M score between patients with healed repairs and patients with retear was 18 points (73 vs. 55) with standard deviations of 21 and 20. With a power of 80% and a significance level of 5% the required sample size would be 42. Considering that the minimal clinically important difference for C-M score has been suggested to be between 10 and 17[21,30] for rotator cuff tear and subacromial pain, as well as potential losses to follow-up, we aimed at including at least 56 patients.

Statistical analysis

All patients were analyzed according to the intention-to-treat principle, which in this study means that results for the patient who crossed over from physiotherapy to the operative repair group were analyzed in the physiotherapy group. Continuous data were checked for parametric distribution with the Kolmogorov-Smirnov test and Shapiro-Wilk test, as well as visual inspection of histograms and normal quantile-quantile plots. In case of nonparametric distribution, we used the median value and interquartile range as primary descriptive statistics measures, but for the 12-month results additional information of the mean values is provided as well. We used the Mann-Whitney *U*-test or the independent *t*-test when comparing continuous variables and the chi-squared test or Fischer's test for categorical variables.

We tested our null hypothesis (no difference in primary and secondary outcome measures between the 2 groups at 12 months) with the Mann-Whitney *U*-test. We calculated effect sizes with the standardized test statistic/$\sqrt{N}$. The 95% confidence intervals (CIs) for the difference between medians were calculated according to Armitage et al,[1] using Excel (Microsoft, Redmond, WA, USA). All other analyses were performed with SPSS 24.0 (IBM, Armonk, NY, USA). We did no imputation for missing values, and correction for multiple comparisons was not considered necessary. We considered P values <.05 as statistically significant and used 2-sided tests.

Results

Fifty-eight patients with the mean age 59.7 years (range, 44-77 years) met the inclusion criteria and were randomized to either surgical repair (n = 32) or physiotherapy without repair (n = 26). All patients had a complete 12-month follow-up, except 3 patients who did all the clinical scores but refused MRI at this time point, and 1 patient who had missing data for WORC and NRS at 12 months. A flowchart of the inclusion process is shown in Fig. 2. Patient characteristics at enrollment are shown in Table I, and the 2 groups were comparable regarding all measured baseline variables. The median sagittal tear size for the whole group was 9.7 mm (range, 4-21 mm). The tear sizes in categories are shown in Fig. 3, with 53.4% having a sagittal tear size of <10 mm, 39.7% 10-20 mm, and 6.9% 21 mm. The median sagittal tear sizes were 10 mm for the repair group and 8.7 for the physiotherapy group (Table I). Most patients (90%) in each group attended 6-9 visits or more to physiotherapist. Of the 34 patients in whom an exercise diary was used, 32 completed their diary and had missed fewer than 15 days of exercises out of 84. There were no differences regarding visits to physiotherapist or training adherence between the groups.

Clinical results

The median values and between-group median differences for all outcome scores and subdomains at 12 months are

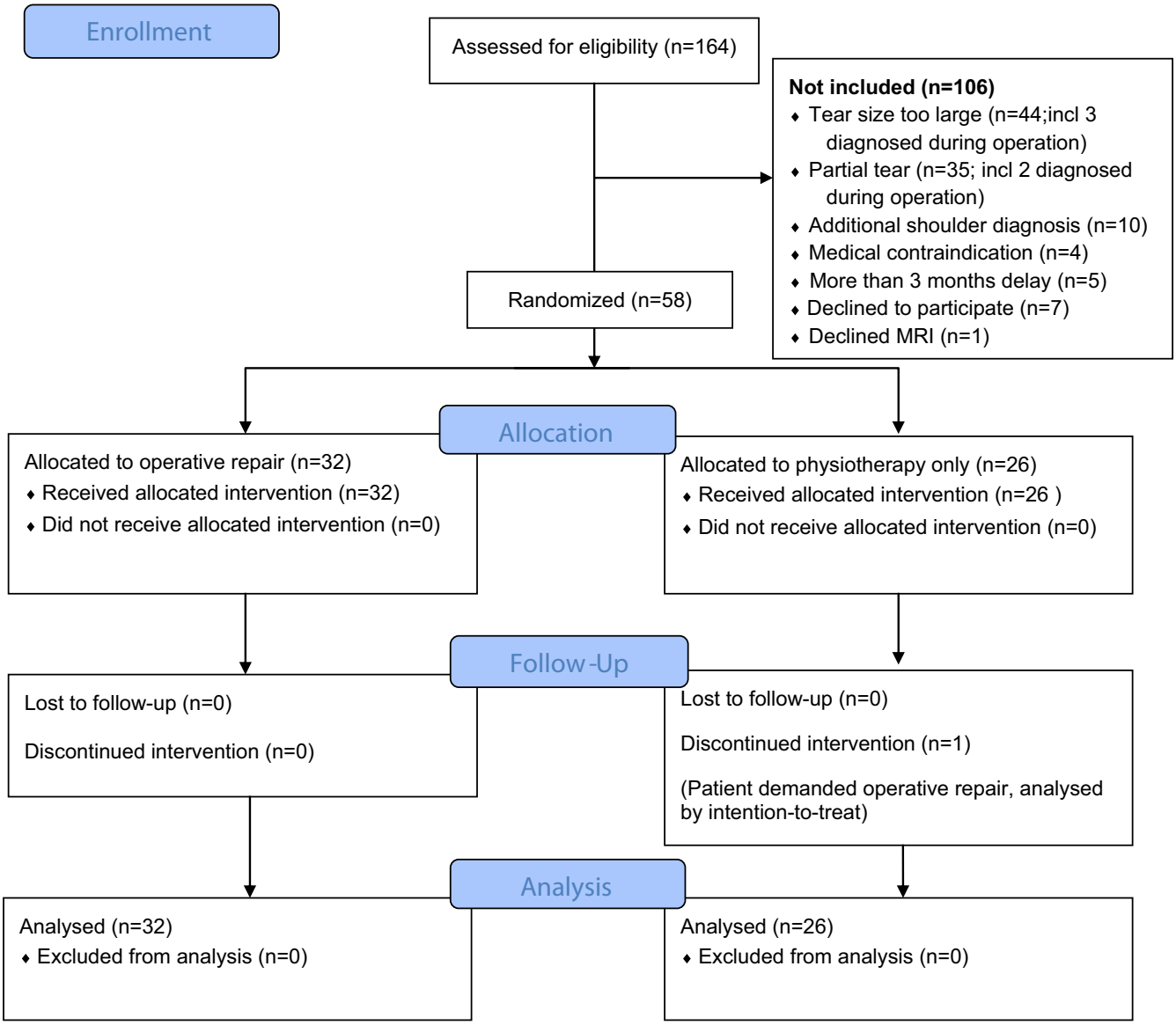

Figure 2 Flowchart of the inclusion process. *MRI*, magnetic resonance imaging.

shown in Table II. The median C-M score at 12-month follow-up in the operative repair group was 83 (quartile range [QR], 25) and in the physiotherapy group 78 (QR, 22). The between-group difference in medians of 4.5 (−5 to 9, 95% CI) was not significant ($P = .68$).

The proportion of patients having a C-M score of 70 or more was 68.8% in the operative repair group and 69.2% in the physiotherapy group ($P = .97$). The corresponding values for the C-M score of 80 or more were 59.4% and 46.2% ($P = .43$).

The repair group had the 12-month median WORC of 91% (QR, 24) and the physiotherapy group 86% (QR, 24), a nonsignificant between-group difference of 5.0 (−4 to 9, 95% CI; $P = .62$). We did not find significant differences between the 2 treatment groups regarding the other secondary outcome measures pain NRS and Euro quality-of-life-visual analog scale at 12-month follow-up (Table II).

The median scores (with 95% CI) of all outcome variables at 3, 6, and 12 months are shown in Fig. 4. The difference in C-M score between the 2 groups at 3 months was significant ($P = .004$) in favor of the physiotherapy group, but differences between the other outcome measures were not significant at 3 months nor in any outcome score at 6 months.

Morphological results

An increase in tear size above 5 mm in at least 1 plane was found in 7 of 24 (29.2%) of unrepaired patients

Table I Patient characteristics at enrollment

Variables	Cuff repair (n = 32)	Physiotherapy (n = 26)	*P* value
Age, mean (min-max)	58 (44-77)	62 (46-77)	.12
Sex, male, n (%)	18 (56)	14 (54)	.86
Dominant side, n (%)	15 (47)	17 (65)	.16
Manual labor, n (%)	17 (53)	8 (31)	.09
Current smokers, n (%)	2 (6)	0 (0)	.30
Hypertensive medication, n (%)	7 (22)	6 (23)	1.00
Diabetes mellitus, n (%)	0 (0)	1 (4)	.45
Time to intervention, d (min-max)	58 (21-98)	53 (12-83)	.42
Flexion, median° (min-max)	90 (30-180)	90 (40-180)	.93
Abduction, median° (min-max)	85 (30-180)	65 (30-180)	.67
External rotation, median° (min-max)	60 (30-80)	70 (45-90)	.06
Internal rotation, median (min-max)*	5 (3-6)	4 (2-6)	.66
Sagittal tear size, median (min-max)	10.0 (5-21)	8.7 (4-15)	.15
Coronal tear size, median (min-max)	9.1 (4-24)	10.2 (3-20)	.89
Pain, NRS 0-10, median (QR)			
Activity	8 (3)	8 (1)	.68
Rest	4 (6)	3 (4)	.19
At night	7 (4)	5 (5)	.16
HAD-score total points, median (QR)	5 (3)	5 (5)	.85
HAD-score anxiety	3 (3)	4 (3)	.64
HAD-score depression	1 (1)	1 (2)	.81
WORC total %, mean (SD)	36 (14)	39 (16)	.44
Physical symptoms	49 (16)	51 (13)	.65
Sport/recreation	27 (16)	27 (17)	.97
Work	21 (12)	24 (19)	.95
Lifestyle	39 (23)	40 (24)	.96
Emotions	53 (16)	60 (19)	.14

NRS, Numerical Rating Scale; *QR*, quartile range; *HAD*, Hospital Anxiety and Depression scale; *WORC*, Western Ontario Rotator Cuff index; *SD*, standard deviation.

* 1 = Thigh, 2 = Gluteus, 3 = Lumbosacral level, 4 = Lumbar process 3, 5 = Thoracic process 12, 6 = Thoracic process 7.

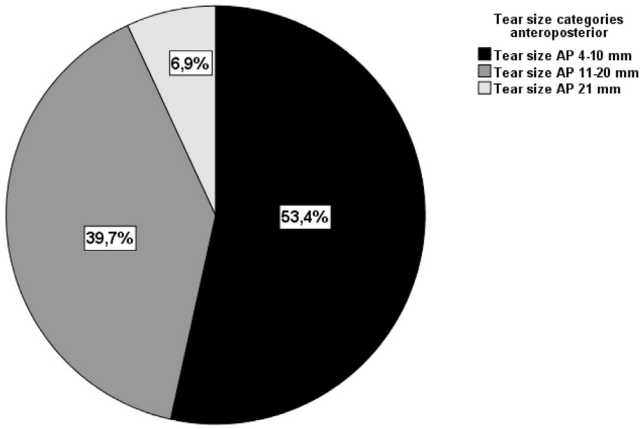

Figure 3 Pie chart of the sagittal tear size in categories for the whole cohort at inclusion. *AP*, anteroposterior.

with an MRI at 12 months (Table III). Of the 24 patients, 8 (33%) had developed fatty infiltration to a grade 1 and 4 patients (16.7%) had developed a tangent sign. Of 31 (6.5%) repaired patients with MRI, 2 patients had a retear (Sugaya 4 or 5), giving a healing rate of 93.5%.

Complications and unexpected events

Two patients had a postoperative wound infection. In 1 case (a 68-year-old man), an infection was diagnosed at 5 weeks after the operation and an open revision was performed, where 1 loose anchor was removed and 1 anchor was left in situ along with osteosutures performed at the index operation. This infection resolved after antibiotic treatment, the 12-month MRI showed a healed tendon, and at 12-month follow-up, the C-M score was 89.

The other infection was in a 64-year-old woman randomized to physiotherapy without repair but who insisted on crossing over to repair at 6 months. The patient was diagnosed with infection 2.5 months after this operation. The infection was treated with 4 revisions and prolonged antibiotic treatment but had not completely resolved at the end of the study period. The tendon appeared healed both at revision operations and follow-up MRI, and the C-M score was 74 at follow-up.

Table II Twelve-month results for primary and secondary outcome scores for each group, including between-group differences and effect sizes

Variable	Cuff repair (n = 32)		Physiotherapy (n = 26)		Between-group difference				
	Median ± QR (min-max)	Mean ± SD	Median ± QR (min-max)	Mean ± SD	Mean difference (95% CI)	*P* value*	Median difference (95% CI)	*P* value†	Effect size
C-M score, points	83 ± 25 (43-96)	77 ± 15	78 ± 22 (44-96)	76 ± 15	1.5 (−6.3 to 9.4)	.70	4.5 (−5 to 9)	.68	0.05
Pain	15 ± 5 (10-15)	13 ± 2	13 ± 5 (5-15)	12 ± 3	1.4 (−0.3 to 3.0)	.10	2.5 (0 to 5)	.14	0.19
ADL	19 ± 8 (9-20)	17 ± 4	18 ± 6 (9-20)	17 ± 3	0.6 (−0.3 to 1.5)	.21	1.0 (−1 to 2)	.41	0.11
Int rotation	8 ± 2 (2-10)	7.3 ± 2	8 ± 3 (4-10)	7.5 ± 2	−0.2 (−1.2 to 0.8)	.65	0.0 (−2 to 0)	.73	−0.05
Ext rotation	10 ± 0 (2-10)	8.9 ± 2	10 ± 2 (6-10)	9.2 ± 2	−0.3 (−1.3 to 0.8)	.60	0.0 (0 to 0)	.90	0.02
Flexion	10 ± 2 (6-10)	8.8 ± 2	10 ± 2 (6-10)	8.9 ± 2	0.0 (−0.9 to 0.8)	.94	0.0 (0 to 0)	.91	0.02
Abduction	10 ± 2 (4-10)	8.8 ± 2	10 ± 4 (2-10)	8.5 ± 2	0.3 (−0.8 to 1.4)	.61	0.0 (0 to 0)	.60	0.07
Strength	13 ± 7 (4-25)	14 ± 6	12 ± 6 (4-25)	13 ± 6	0.4 (−2.7 to 3.4)	.82	1.0 (−1 to 4)	.51	0.09
WORC, %‡	91 ± 24 (52-99)	85 ± 13	86 ± 24 (44-100)	84 ± 14	1.8 (−5.4 to 9.0)	.62	5.0 (−4 to 9)	.62	0.07
Phys symptoms	91 ± 14 (68-99)	88 ± 9	93 ± 13 (57-99)	87 ± 13	1.5 (−4.5 to 7.5)	.62	−2.5 (−4 to 4)	.94	−0.01
Sports/leisure	84 ± 27 (26-99)	79 ± 20	93 ± 13 (57-99)	74 ± 20	4.6 (−6.0 to 15.3)	.39	3.3 (−5 to 14)	.33	0.12
Work	87 ± 39 (41-99)	78 ± 21	84 ± 32 (31-100)	78 ± 21	−0.5 (−11.5 to 10.6)	.93	3.5 (−9 to 8)	.88	−0.02
Life style	95 ± 12 (63-100)	92 ± 9	95 ± 16 (44-100)	89 ± 13	2.9 (−2.9 to 8.7)	.33	0.3 (−2 to 4)	.68	0.06
Emotions	96 ± 13 (13-100)	89 ± 18	92 ± 16 (31-100)	89 ± 14	0.3 (−8.4 to 9.1)	.94	4.0 (−2 to 6)	.54	0.08
Pain NRS, 0-10‡									
Activity	1 ± 2 (0-5)	1.3 ± 1.3	1 ± 2 (0-7)	1.8 ± 1.6	−0.6 (−1.4 to 0.2)	.13	0.0 (−1 to 0)	.10	−0.22
At rest	0 ± 1 (0-3)	0.5 ± 0.8	0 ± 1 (0-5)	0.8 ± 1.4	−0.3 (−0.9 to 0.3)	.29	0.0 (0 to 0)	.68	−0.06
At night	0 ± 1 (0-4)	0.6 ± 1.0	0 ± 2 (0-8)	1.3 ± 2.2	−0.7 (−1.7 to 0.2)	.13	0.0 (−1 to 0)	.22	−0.16
EQ-VAS, mm‡	84 ± 18 (50-100)	84 ± 12	85 ± 13 (50-100)	82 ± 13	1.7 (−4.8 to 8.3)	.60	0.0 (−5 to 7)	.76	0.04

CM, Constant Murley score; *ADL*, Activities of Daily Living; *WORC*, Western Ontario Rotator Cuff index; *NRS*, Numerical Rating Scale for pain 1-10; *EQ-VAS*, Euro Qol-Visual analog scale for quality-of-life 0-100 mm; *QR*, quartile range; *SD*, standard deviation; *CI*, confidence interval.

* Independent *t*-test.

† Mann-Whitney *U*-test.

‡ One case had missing values for WORC, Pain NRS, and EQ-VAS.

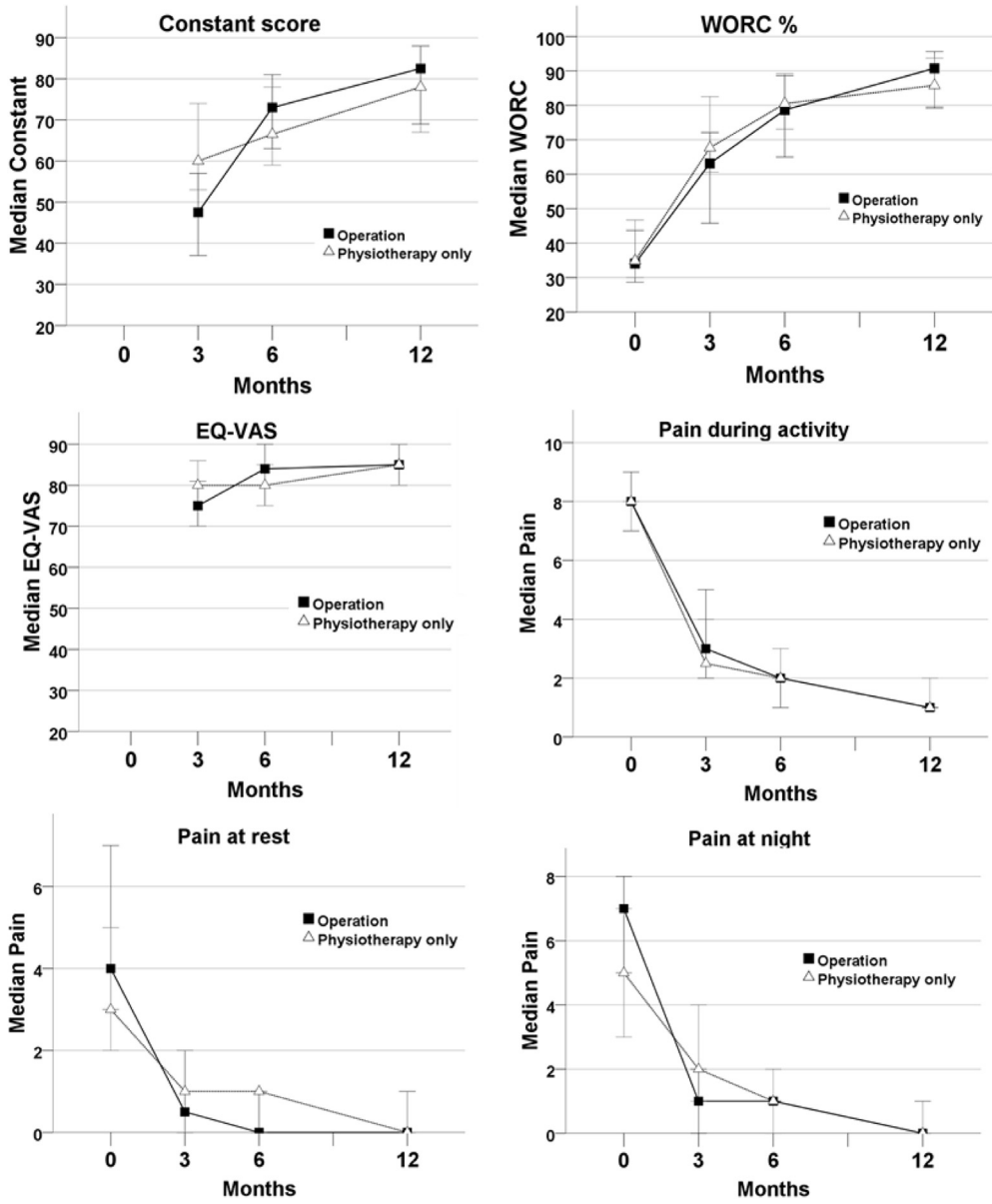

Figure 4 Line graphs showing outcome scores at all follow-up points. Error bars indicate 95% confidence intervals. Missing data: Constant score, 1 patient at 6 months; WORC, 1 patient at 6 months, 1 patient at 12 months; EQ-VAS, 2 patients at 3 months, 1 at 6 months, and 1 at 12 months; Pain NRS, 2 patients at 3 months, 1 patient at 6 months, and 1 patient at 12 months. *WORC*, Western Ontario Rotator Cuff index; *EQ-VAS*, Euro quality-of-life-visual analog scale; *NRS*, Numerical Rating Scale.

One 49-year-old man with manual labor had an extensive amount of scar tissue over the otherwise completely healed tendon, resulting in impaired abduction. Because it was not tolerated by the patient, a resection of scar tissue was performed just after the end of the study period. Cultures from this operation were negative for bacterial growth. The 12-month C-M score was 57.

One 66-year-old woman randomized to physiotherapy without repair sustained a complicated femur fracture 1.5 months after the start of the intervention. She denied having a new injury to her study shoulder and performed her shoulder exercises and rehabilitation as instructed. At 12-month follow-up, the C-M score was 88.

Discussion

This study shows that 1 year after an acute traumatic and small full-thickness rotator cuff tear, treated with either operative repair or physiotherapy without repair, the results as measured with C-M score and WORC can be considered good or satisfactory in a majority of patients. Operative

Table III MRI findings at 12 months after cuff repair or physiotherapy without repair

Variables	Cuff repair (n = 31)	Physiotherapy (n = 24)	*P* value
Sagittal tear size, median (min-max)	0 (0-30.0)	11.3 (0-22.2)*	<.001
Coronal tear size, median (min-max)	0 (0-25.3)	13 (0-32.5)*	<.001
Tear progression >5 mm, n (%)†		7 (29.2)	
Tear progression >10 mm, n (%)†		2 (8.3)	
Retears (Sugaya 4-5), n (%)	2 (6.5)		
Tangent sign, n (%)	2 (6.5)	4 (16.7)	.39
Fatty infiltration, n (%)			
Grade 1	6 (19.4)	8 (33)	.35
Grade 2-4	0	0	

Sugaya, retear classification grade 1-5 according to Sugaya et al[47]; *Tangent sign*, atrophy of supraspinatus[51]; *Fatty infiltration*, according to Goutallier grade 0-4.[15]

* Analyzed by intention-to-treat, and the minimum value of 0 at 12-month follow-up in the physiotherapy group represents the only cross-over patient.

† An increase in tear size from baseline to 12-month follow-up in the mediolateral or anteroposterior plane.

repair resulted in slightly higher C-M and WORC scores, but the differences were neither clinically nor statistically significant. There were also no significant differences in pain or quality of life between the 2 groups. Twenty-nine percent of unrepaired tears had increased in tear size >5 mm during the observation period.

This is, to our knowledge, the first prospective randomized study focusing exclusively on trauma-related cuff tears. Moosmayer et al[39,41] compared mini-open repair to physiotherapy in a study of 103 patients, 40 (39%) of whom had had a significant trauma. At 1-year follow-up,[41] the repair group had 10 points higher mean C-M score than the physiotherapy group (76.8 vs. 66.8), a difference that may be interpreted as clinically significant,[30] but at 5-year follow-up, the difference had diminished to only 5.3 points.[39] The C-M scores of median 83 points in the repair group and 78 points in the nonrepair group at 1 year in our study are comparable with the results of Moosmayer et al, although we found a nonsignificant between-group difference of only 5 points, mainly due to better results in the physiotherapy group. One possible explanation is that our cohort contained a larger proportion of very small tears (Fig. 3). Another possibility is that patients without previous shoulder complaints and a traumatic tear may have better compensatory conditions, giving better results in the nonrepair group. A third possibility is differences between our rehabilitation program and the one used in the study by Moosmayer et al.

Kukkonen et al[28] compared physiotherapy only vs. acromioplasty vs. arthroscopic cuff repair, in patients with nontraumatic tears and a mean tear size of <10 mm. They found mean C-M scores of 74, 77, and 78 at 1 year and hence no significant between-group differences.[28] Even though our patients had a traumatic tear, something which has been suggested to strengthen the indication for operative repair,[33] the level of Constant score and the lack of superiority in favor of repair are similar as for the degenerative tears in Kukkonen's study.

Lambers Heerspink et al[32] in their trial of repair vs. physiotherapy for nontraumatic cuff tears could not find any significant difference between treatment groups. They however reported a high retear rate (73.7%) and a subgroup analysis showed a significant difference in favor of healed repair.[32]

Odak et al[43] randomized 25 patients to acromioplasty and mini-open repair and 17 patients to acromioplasty without repair. At 12 months, the repair group had a mean C-M score of 76.4 vs. 65.3 for the nonrepair group, a difference of 11.1 points, which was not significant ($P = .06$).

The results of the present study are based on tears with a median 9.7 mm in the sagittal plane, and 53.9% of patients having tears smaller than 10 mm. Caution in extrapolating these results to larger tears is warranted and cannot give guidance for the treatment of tears involving substantial parts of infraspinatus or subscapularis. Hinsley et al[19] performed a cross-sectional study of 464 persons examined with ultrasound and clinical scores and tried to find a tear size above which pain is more likely to be present, and suggested a cutoff value for tear size >25 mm. The majority of patients taking part in the present study, and other comparative randomized trials,[28,32,41] have had tear sizes well below this suggested threshold.

It is possible that as the acute pain subsides, compensatory mechanisms in patients with smaller tears will suffice to make results equal to those of a repaired and healed tendon in a 12-month perspective. One cause for concern however is the documented tendency for progression of tear size shown in numerous studies.[24,34,42,45,46] It is not known whether tear progression is caused by poor healing conditions in tendons affected by degeneration or if it has mechanical reasons that may apply also to healthy but torn tendons. It is also important to note that we do not know whether the tears in our cohort of previously symptom-free shoulders were completely nondegenerative or not. Some of them may in fact represent acute-on-chronic tears.

The 2 groups were equally good regarding clinical scores, but the rate of tear enlargement (29.2%) of more than 5 mm after 1 year in the nonoperative group may be a matter of concern. Although representing a small increase in tear size in most cases, it is a finding that is in accordance with several studies showing increasing tear size in rotator cuff tears treated without repair.[24,34,42,45,46] A small increase is unlikely to be of clinical significance in a 1-year perspective but may indicate a tendency for progression that could have long-term implications. It is also worth noting that a previous study found a mean difference in tear size of 5.4 mm comparing symptomatic and asymptomatic shoulders.[50] Atrophy and low-grade fatty infiltration were also observed at follow-up, especially in the physiotherapy group and in patients with a retear.

The results in the nonoperative group in the present study may also be due to the physiotherapy program, which was based on previously published studies of specific shoulder exercises.[4,20] If physiotherapy without repair is used in clinical practice, the reported association between pain development and tear progression in the long term may be of relevance.[24]

We found a retear rate (full-thickness retear Sugaya 4 and 5) of 6.5%, which is lower than in previous studies. Moosmayer et al[41] had a rate of 8% full-thickness retear after 1 year and Kukkonen et al[29] 31% at 2-year follow-up. We cannot ascertain if this lower retear rate is due to the small tear sizes, the short follow-up, or a better healing capacity in traumatic as compared with degenerative tears.

Of 32 operated patients in the present study, 2 had an infection, which is a higher incidence than in previous studies, which did not report any infections.[28,32,41,43] The infection rate was also higher than in the UKUFF-study[6] and in a large cohort of arthroscopically repaired patients.[22] Because the patients with infection came from different groups (one being a cross-over patient), infection is unlikely to have affected the conclusions of the present study.

A limitation of this study is the small sample size, which is mainly attributed to difficulty in finding patients with previously symptom-free shoulders. Also a substantial part of the screened patients had a tear that was either partial thickness or involved a large part of subscapularis, a pattern of tendon involvement after trauma that has been recognized in other studies.[33] The small sample size may increase the risk of a type II error, even though it is questionable if the differences and effect sizes found in this study would be of any clinical significance, had they been statistically significant.

The 12-month follow-up in this study is shorter than the 24-month follow-up often advocated for assessing short- to medium-term results after shoulder surgery. Khatri et al[25] did a meta-analysis of 57 randomized trials regarding various treatments for patients with rotator cuff tears and showed that these patients improve (as measured with Constant score) regardless of treatment and that this improvement occurs mainly during the first year and that a 24-month follow-up adds very little of value. Considerably longer follow-up may be more relevant considering the documented tendency of progression of cuff tears.[38,45]

Considering the results from the present study and to some extent supported by other randomized trials,[28,29,39,41] small cuff tears may be treated nonoperatively in a short-term perspective. Most clinicians agree that there are indications to repair a full-thickness rotator cuff tear, especially for medium-sized and larger tears.[11] The remaining question is: which patients gain substantially from a repair? Considering a previous study, with long-term follow-up of unrepaired full-thickness tears showing tear progression in 87% and cuff tear arthropathy in 74% after more than 20 years,[45] the follow-up in future studies should be long enough for tear progression to develop. A recently published 10-year follow-up of a randomized study showed superior results for repair compared with nonoperative treatment, with the unrepaired group having tear progression and deteriorating results.[40] Further studies, incorporating different tear sizes and tear configurations as well as patient-specific factors, such as age and activity level, are needed to define proper indications for an early repair.

Conclusions

Patients with previously symptom-free shoulders and a traumatic rotator cuff tear with a median sagittal tear size of approximately 1 cm have good results after 12 months either with or without rotator cuff repair. The healing rate was high after repair of traumatic cuff tears. Unrepaired tears increased in tear size in a 12-month perspective, but the increase was small and no significant fatty infiltration was observed.

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