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What happens to patients when we do not repair their cuff tears? Five-year rotator cuff quality-of-life index outcomes following nonoperative treatment of patients with full-thickness rotator cuff tears

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Background: The purpose of this study was to examine 5-year outcomes in a prospective cohort of patients previously enrolled in a nonoperative rotator cuff tear treatment program.

Methods: Patients with chronic (>3 months), full-thickness rotator cuff tears (demonstrated on imaging) who were referred to 1 of 2 senior shoulder surgeons were enrolled in the study between October 2008 and September 2010. They participated in a comprehensive, nonoperative, home-based treatment program. After 3 months, the outcome in these patients was defined as "successful" or "failed." Patients in the successful group were essentially asymptomatic and did not require surgery. Patients in the failed group were symptomatic and consented to undergo surgical repair. All patients were followed up at 1 year, 2 years, and 5 or more years.

Results: At 5 or more years, all patients were contacted for follow-up; the response rate was 84%. Approximately 75% of patients remained successfully treated with nonoperative treatment at 5 years and reported a mean rotator cuff quality-of-life index score of 83 of 100 (SD, 16). Furthermore, between 2 and 5 years, only 3 patients who had previously been defined as having a successful outcome became more symptomatic and underwent surgical rotator cuff repair. Those in whom nonoperative treatment had failed and who underwent surgical repair had a mean rotator cuff quality-of-life index score of 89 (SD, 11) at 5-year follow-up. The operative and nonoperative groups at 5-year follow-up were not significantly different ($P = .11$).

This study was approved by the Conjoint Health Research Ethics Board, Faculty of Medicine, University of Calgary (study ID E-21979).

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Conclusion: Nonoperative treatment is an effective and lasting option for many patients with a chronic, full-thickness rotator cuff tear. While some clinicians may argue that nonoperative treatment delays inevitable surgical repair, our study shows that patients can do very well over time.
Level of evidence: Level II; Prospective Cohort Design; Treatment Study

Keywords: Shoulder; rotator cuff; nonoperative treatment; surgery; outcome; quality of life

Rotator cuff tears are an age-related finding on diagnostic imaging.[10] Pathology that causes pain and disability in one patient's shoulder may not cause symptoms in another individual. The variability in rotator cuff symptoms and treatment is extensive and thus poses a conundrum for clinicians, surgeons, and researchers.

An abundance of literature supports surgical repair as a primary and long-lasting treatment option, while seemingly just as much literature supports conservative management.[2,4-9] This is likely because some patients will get better with nonoperative management whereas some will not. We have previously published the results of a prospective cohort of patients who underwent a structured and supervised course of nonoperative treatment for chronic, full-thickness rotator cuff tears with very favorable outcomes. Follow-up to 2 years has previously been reported.[1] Seventy-five percent of patients in this cohort were successfully treated with a comprehensive, nonoperative treatment program and did not require surgery. Clinical factors were identified that helped predict the outcome of nonoperative treatment versus which patients would more likely benefit from surgical repair.

Of concern, however, was that nonoperative management might not yield a long-lasting successful result. Therefore, the purpose of this study was to examine 5-year outcomes of patients previously enrolled in our nonoperative rotator cuff study.

Materials and methods

Patients with chronic (>3 months), full-thickness rotator cuff tears (demonstrated on ultrasound or magnetic resonance imaging) who were referred consecutively to 1 of 2 senior shoulder surgeons were enrolled in this prospective cohort study between October 2008 and September 2010.

The inclusion criteria were as follows:

- Age of 40 to 85 years
- Full-thickness tear of supraspinatus or infraspinatus, confirmed on ultrasound or magnetic resonance imaging
- Symptomatic for a minimum of 3 months

The exclusion criteria were as follows:

- Already exhausted nonoperative treatment: minimum of 3 months of stretching and strengthening with the use of analgesics, anti-inflammatories, and/or modalities; with or without injections
- Full-thickness tear of subscapularis and/or teres minor
- Concomitant pathology of the affected shoulder (eg, instability, high-riding humeral head indicating cuff tear arthropathy, or osteoarthritis)
- Substantial cervical spine pathology and/or radiculopathy
- Elite athlete
- Acute injury (symptoms for <3 months)
- Substantial medical issues precluding surgery
- Secondary-gain issues (ie, workers' compensation or litigation)
- Unable or unwilling to complete study outcomes
- Unable or unwilling to provide informed consent

Patients participated in a comprehensive, nonoperative, home-based treatment program. Under supervision of a physiotherapist and sports medicine physician, patients undertook stretching and strengthening exercises, supplemented on an individual basis with anti-inflammatory and/or corticosteroid pain control. After 3 months, patients met with the surgeon and their outcome was defined as "successful" or "failed." A patient was defined as having a successful outcome if surgery was no longer deemed an appropriate treatment option by both the patient and the surgeon because the patient had improved considerably and was predominantly asymptomatic. In contrast, nonoperative management was deemed to have failed if the patient elected to undergo surgery because he or she had not improved and remained symptomatic. The definitions of "success" and "failure" were a joint classification by the patient and surgeon. All patients were followed up at 1 and 2 years (the results were previously reported[1]).

For 5-year follow-up, all patients were contacted by the research coordinator using all available contact information, including home phone, work phone, and cell phone numbers and E-mail addresses. After 3 contact attempts by the research coordinator, the surgeon then attempted to contact any patient who had not responded. If there was no response following the contact attempt by the surgeon (4 attempts in total), the patient was considered lost to follow-up. Responsive patients were asked whether they had sought treatment (specifically surgery) and were asked to complete the rotator cuff quality-of-life index (RC-QOL) questionnaire.[3]

The patients were grouped according to the outcome of the original nonoperative treatment protocol: successful (no surgery) or failed (surgery). Group means and standard deviations were calculated for the RC-QOL scores. The significance level was set at $P = .05$.

Results

A total of 116 patients were originally screened prospectively, of whom 104 met the inclusion criteria and provided informed consent for participation (Fig. 1). Of the 104

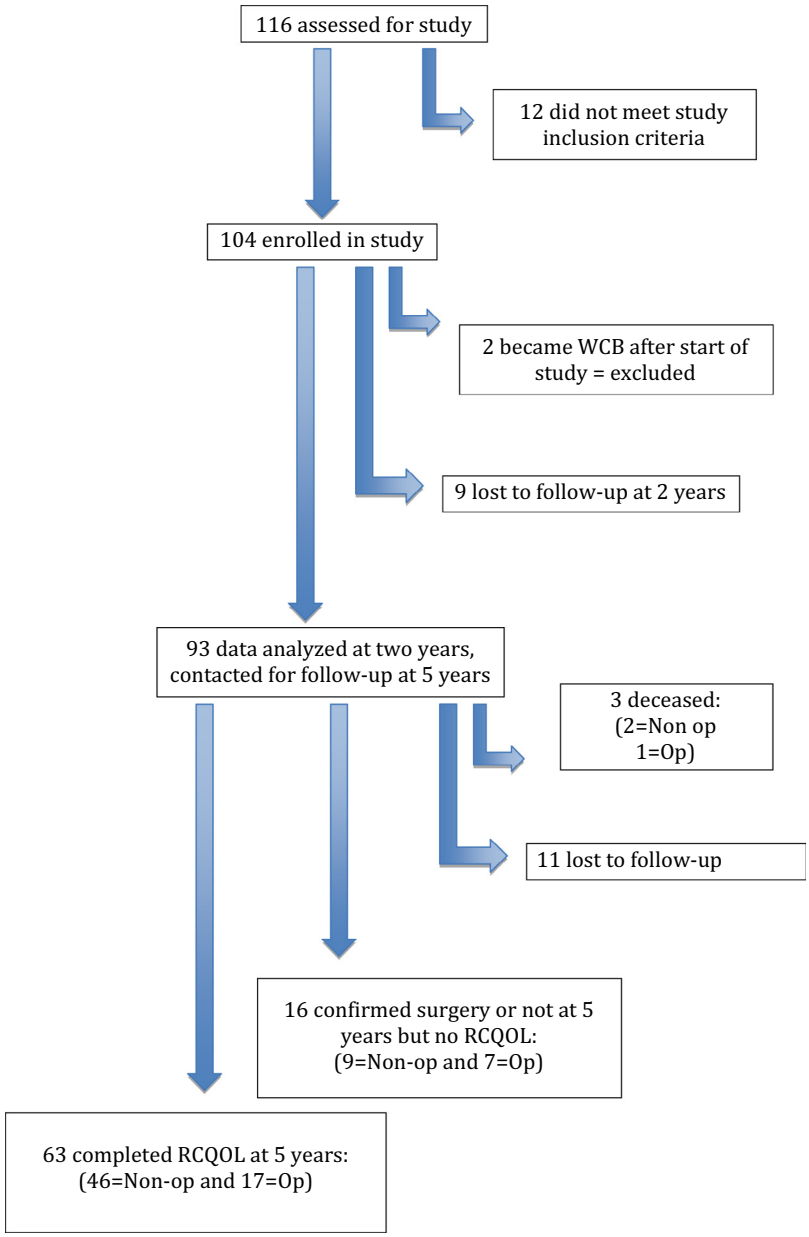

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) diagram. *WCB*, workers compensation; *Non op*, nonoperative; *Op*, operative; *RCQOL*, rotator cuff quality-of-life index.

patients enrolled, 2 subsequently applied for workers' compensation while 9 were lost to follow-up and had insufficient data for 2-year analysis. Thus, 93 patients from the original cohort were analyzed. Demographic data are provided in Table I.

At 5 or more years, all 93 patients were again contacted for follow-up. Of these patients, 3 were reported to have died since the last follow-up time point (2 in the successful group and 1 in the failed group originally). Sixty-three patients completed the RC-QOL questionnaire at a minimum of 5 years. Of the remaining 30 patients, 16 confirmed whether or not they underwent surgery between the 2- and 5-year follow-up periods but were unwilling to complete the RC-QOL questionnaire again. We were unable to contact 11 patients to determine whether they had undergone surgery or not since the 2-year follow-up or to collect the RC-QOL score; thus, these patients were considered lost to follow-up.

Between the 2- and 5-year follow-up periods, only 3 of 64 patients who had previously been defined as having a successful outcome became more symptomatic and underwent surgical rotator cuff repair. Of these 3 patients, 2 experienced a gradual worsening over time whereas 1 was doing very well until an errant golf swing significantly exacerbated his symptoms. The remaining 46 patients in the

Table I Demographic data of all patients at enrollment (n = 93)

	Data
Age, yr	60 ± 9.3 (40-85)
Tear size, mm	15.90 ± 7.62 (4-40)
Forward-elevation ROM, °	154 ± 22 (65-180)
Duration of symptoms, mo	28 ± 39 (3-180)
Baseline RC-QOL score	44.6 ± 21.1 (0-84)
Sex	
Male	54 (58%)
Female	39 (42%)
Onset	
Traumatic	46 (49%)
Insidious	47 (51%)
Dominant side involved	
Yes	67 (72%)
No	26 (28%)
External rotation strength	
Full	34 (37%)
Less than full	59 (63%)
Smoking status	
Smoker	15 (16%)
Nonsmoker	78 (84%)

ROM, range of motion; *RC-QOL*, rotator cuff quality-of-life index.
Data are presented mean ± standard deviation (range) or number of patients.

Table II RC-QOL scores of successful versus failed patients at each reported study time point

	Mean RC-QOL score (out of 100)	
Time point	Successful group	Failed group*
Baseline	49 (SD, 22)	33 (SD, 15)
3 mo	82 (SD, 12)	38 (SD, 21)
2 yr	80 (SD, 18)	78 (SD, 23)
≥5 yr	83 (SD, 16)	89 (SD, 11)

RC-QOL, rotator cuff quality-of-life index; *SD*, standard deviation.
* Failed 3-month nonoperative treatment program and went on to undergo surgery.

nonoperative successful group had a mean RC-QOL score of 83 of 100 (SD, 16).

Those patients in whom nonoperative treatment failed and who underwent surgical repair had a mean RC-QOL score of 89 (SD, 11) at 5-year follow-up (Table II). The operative and nonoperative groups at 5-year follow-up were not significantly different ($P = .11$).

Discussion

Despite the extensive controversy in the current orthopedic literature surrounding the optimal treatment of chronic, full-thickness rotator cuff tears, the results of this study show that nonoperative management is a reasonable treatment option that can provide lasting relief over the medium term. It would be our inference that successfully treated patients are relatively asymptomatic and most often remain that way over time. The results demonstrate durability over time. It should be emphasized that those patients in whom nonsurgical treatment failed, independent of the timeline, ended up with a similar outcome to those in whom failure occurred early. Therefore, we recommend following up non–surgically treated patients regularly (annually) to ensure that those in whom deterioration occurs are identified and operated on if necessary. The fear that many tears may generally become more symptomatic over time is unfounded based on this study. We do recognize that the results of this study are essentially self-reported and do not indicate whether a tear increased in size or whether strength or range of motion decreased. However, if patients reported satisfactory scores on the RC-QOL questionnaire at follow-up, it would be reasonable to presume that their level of symptoms had remained manageable and that, even if their tear had increased in size, it had not significantly affected their shoulder function.

The results also show that at 5 years, operative and nonoperative outcomes are not significantly different from each other. This finding is supported by several recent studies in the orthopedic literature.[7,8]

Limitations

The response rate at 5-year follow-up was 84%, which is acceptable. To determine whether the patients who fully responded differed in any way from the partial responders and those lost to follow-up, we compared their baseline characteristics. Patients were classified into the 3 following groups: (1) patients who completed the RC-QOL questionnaire at 5 years, (2) patients in whom surgery or no surgery was confirmed but who did not complete the RC-QOL questionnaire at 5 years, or (3) patients lost to follow-up. The baseline data showed no differences between the 3 groups (Table III). Therefore, we feel confident that those who responded were representative of the whole group and that those who were lost to follow-up likely did not differ significantly from the rest of the cohort.

Additional limitations of this study include that we did not physically examine the shoulders (range of motion, strength, or imaging) at the 5-year time point, so while we understand the patient's self-reported outcome, we do not know the physical state of the shoulder. We are planning to address this limitation when we perform 10-year follow-up, when we will measure the range of motion and strength of the shoulder and perform repeat imaging. Furthermore, we are unable to reliably report whether patients sought additional treatment (with the exception of surgery) outside of our center during the 5-year study duration. We will attempt to gather these data to report at the 10-year follow-up time point. This cohort of patients continues to be followed up, and our group will analyze the 10-year outcomes.

Table III Loss–to–follow-up comparison (baseline data of patients grouped by 5-year follow-up response)

Baseline data	RC-QOL questionnaire completed at 5 yr (n = 63)	Confirmed surgery or not at 5 yr (n = 16)	LTF at 5 yr (n = 11)
Age, yr			
Mean	61	55	61
SD	8.7	9.9	8.7
Sex, n			
Male	37	8	4
Female	26	8	7
Tear size, mm			
Mean	17.5	12.9	12.9
SD	8.6	4.9	4.1
Smoking status, n			
Nonsmoker	54	11	10
Smoker	9	5	1
FE ROM, °			
Mean	155	151	153
SD	21.8	28.6	20.4
Full ER strength, n			
Yes	23	5	2
No	40	11	9
Dominant side, n			
Not involved	17	5	3
Involved	46	11	8
Onset, n			
Insidious	32	9	6
Acute	31	7	5
Baseline RC-QOL score (out of 100)			
Mean	47.1	41.8	42.5
SD	21.0	23.4	22.3

LTF, lost to follow-up; *RC-QOL*, rotator cuff quality-of-life index; *SD*, standard deviation; *FE*, forward elevation; *ROM*, range of motion; *ER*, external rotation.

Conclusion

Nonoperative treatment is an effective and lasting option for many patients with a chronic, full-thickness rotator cuff tear. Patients who subsequently ended up requiring surgical repair had similar outcomes to those who underwent surgery early in the study, as well as those in whom nonoperative treatment was successful. While some clinicians may argue that nonoperative treatment delays inevitable surgical repair, our study shows that patients can do very well over time, no matter whether treated operatively or nonoperatively.

Disclaimer

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