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Factors Associated with Choice for Surgery in Newly Symptomatic Degenerative Rotator Cuff Tears: A Prospective Cohort Evaluation

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Abstract

Background—The patient related factors for the perceived need for surgery for degenerative rotator cuff tears are not known. The purpose of this study is to examine patient and tear-specific factors leading to surgery in newly painful degenerative rotator cuff tears.

Methods—Asymptomatic, degenerative rotator cuff tears were followed prospectively to identify the onset of pain and tear enlargement. Newly painful tears were continually monitored with a focus on identifying patient-specific (age, occupation, activity level) and tear-specific (tear type and size, tear progression, ASES score, muscle degeneration) factors that are associated with surgical intervention.

Results—Forty-eight of 169 newly painful shoulders were eventually managed surgically. Factors associated with surgical treatment included younger age (p=0.0004), pain development earlier in surveillance (p=0.0002), a greater increase in pain (p=0.0001) and decline in ASES score (p<0.0001) and a history of contralateral shoulder surgery (p=0.0006).

Eighty-five of the 169 tears (50%) enlarged either prior to or within 2 years of pain development. Neither the severity of muscle degeneration, occupational status, hand dominance, Shoulder Activity Score, nor changes in RAND-12 mental or physical scales differed between groups. The severity of muscle degeneration, occupational status, hand dominance, Shoulder Activity Score or changes in RAND-12 mental or physical scales differed between groups.

Discussion—For newly painful rotator cuff tears, patient specific factors such as younger age and prior surgery on the contralateral shoulder are more predictive of future surgery than tear-specific factors or changes in tear size over time.

Level of Evidence—Level II – prospective cohort

Keywords

rotator cuff tear; degenerative; predictor; surgery; prospective; operative treatment

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Introduction

Degenerative rotator cuff disease is the most common cause of shoulder pain in middle-aged and older patients. The incidence of rotator cuff tears has been strongly linked to advancing age in multiple studies [17, 21, 24, 27]. For the majority of patients these tears are asymptomatic. Despite an increasing knowledge of the natural history of tear progression for degenerative rotator cuff tears, the factors associated with the onset of pain are not completely known. Previous studies have shown that predictors of failure for nonoperative treatment for painful rotator cuff tears are less dependent on tear characteristics and may be more reflective of a patient's subjective expectations of the likelihood for success with nonoperative treatment [6–8].

Previous research has suggested that between 70–75% of painful rotator cuff tears will respond favorably to nonoperative treatment [14, 15, 18]. In the available literature, it is unclear as to which patient or tear related factors may predict success with nonoperative treatment. Although there are risks of tear enlargement and progression of muscle fatty degeneration over time with nonoperative treatment, it is generally recommended to avoid surgery for rotator cuff tears that respond favorably to conservative treatment. This is especially relevant for smaller tears with minimal muscle changes that are at lower risk for becoming irreparable in the short-term. Previous studies have shown that tear enlargement is a risk factor for pain development in shoulders followed longitudinally with asymptomatic rotator cuff tears [13, 19]. In these newly painful shoulders, fundamental unanswered questions are the relevant natural history of these tears once they become painful and identification of risk factors associated with the need or decision for surgical intervention.

The purpose of this study is to report the patient-related and tear-specific factors that are associated with a patient's decision for choosing operative treatment for a newly symptomatic tear in a cohort of patients with asymptomatic tears that were followed prospectively.

Methods

IRB approval was obtained prior to and maintained throughout this study (IRB#201103230). This study is a retrospective review of prospective, longitudinally collected data. Subjects included patients with an asymptomatic rotator cuff tear identified with shoulder ultrasound while undergoing treatment for painful rotator cuff disease in the contralateral shoulder. Inclusion criteria included: 1) bilateral shoulder ultrasonography investigating unilateral shoulder pain, 2) painful rotator disease in the non-study shoulder, 3) documentation of rotator cuff integrity in the asymptomatic study shoulder (full-thickness, partial-thickness and control (no tear)), 4) verified as asymptomatic at enrollment in the asymptomatic shoulder, 5) no history of trauma to either shoulder and remained free of trauma throughout the study follow-up, 6) a minimum 2 year follow-up from enrollment (unless pain developed prior to 2 years). Exclusion criteria included: 1) any past or current pain in the asymptomatic shoulder, 2) continuous use of narcotic or nonsteroidal anti-inflammatory medication from 3 months before to enrollment, 3) history of trauma in the asymptomatic shoulder, 4) inflammatory arthritis, 5) radiographic osteoarthritis in the asymptomatic shoulder, 6) upper

extremity weight bearing demands, 7) isolated subscapularis tears in the asymptomatic shoulder.

Study Protocol

Subjects underwent an enrollment and subsequent yearly surveillance examinations consisting of shoulder ultrasound, radiographs, physical examination and assessment of shoulder pain. Additionally, patients were instructed to contact the study coordinator if they developed shoulder pain at any time between study visits, at which time, they would return for repeat clinical examination with a treating physician. Demographic data was collected including age, sex, hand dominance and retrospective assessment of work status (working or retired) and occupational demand classified as “sedentary”, “labor” and “in between”. All physical examinations were performed by trained research staff (research nurse and/or research study coordinator). Questionnaires were completed consisting of a numeric pain scale (0–10), components of the American Shoulder and Elbow Surgeon (ASES) Score at each visit and the RAND-12 physical and mental component scores (where scores are normalized to have a mean of 50 and a standard deviation of 10 in the normal 1998 US population). The Shoulder Activity Score [2] was collected at the first non-missing study visit as this information was not collected in the original cohort at baseline.

New shoulder pain was defined by any of the following criteria: 1) shoulder pain >=3 on a 10 point scale lasting for 6 weeks or longer, 2) pain requiring formal consultation with a physician who administered pain medication or treatment 3) night pain affecting sleep. Patients were retained in the study after the development of shoulder pain or the recognition of tear enlargement until the point of surgery (if applicable).

Shoulder ultrasonography was performed by one of four experienced radiologists according to previously described protocol [22, 23]. The maximum anteroposterior dimension of the tear was measured in transverse views (perpendicular to the long axis of the cuff) and designated as the tear width. The maximum degree of retraction was measured in longitudinal views (parallel to the long axis of the cuff) and designated as tear length. Tear dimensions are provided for full tears that are not massive in size. Tear progression was defined as tear enlargement of conversion to a more severe tear type (partial to full-thickness or control to partial or full-thickness defect). Partial and full-thickness tears were considered enlarged if the tear size increased 5 mm or greater in any dimension compared to baseline. A partial-thickness tear was also considered enlarged if it converted to a full-thickness defect regardless of tear size compared to baseline.

The target group for this study were individuals that developed pain in their previously asymptomatic shoulder during longitudinal follow-up. Individual subject’s records were reviewed to determine the type of treatment previously rendered to the contralateral (nonstudy) shoulder. This information included whether surgery was performed or not and the type of surgery performed with surgical date. For the purposes of this study, we only considered surgery in the contralateral shoulder to be significant if it was related to cuff disease (rotator cuff repair, subacromial decompression/bursectomy, tendon transfer or reverse shoulder arthroplasty). We also determined the timing of surgery (when applicable) in relation to the development of pain in the study shoulder.

When pain developed in the study shoulder, subjects were evaluated according to the study protocol and offered examination by a treating orthopedic surgeon specializing in shoulder and elbow surgery. Upon completion of examination, each subject was offered either conservative treatment or surgery based on patient preferences. It was the practice of each treating surgeon to recommend a course of conservative treatment and continued surveillance according to study protocol; however, this was not mandated. Subjects electing nonsurgical treatment completed a questionnaire outlining their response to treatment and pain level 6 months after identification and evaluation of shoulder pain. Conservative treatment consisted of either surveillance alone or physical therapy with optional corticosteroid injection based on shoulder pain level and patient preference. The decision for eventual surgery was left to the discretion of the subject and was based primarily on the presence of residual symptoms. Study protocol continued for all subjects until the point of surgery.

Statistical Analysis

Categorical variables are reported as the number of patients (percent of group). Continuous data that are normally distributed are reported as mean and standard deviation (SD). Median and interquartile range (IQR; defined as the 75^{th} minus the 25^{th} percentile) are reported for data that are not normally distributed. The same size with missing data is reported when less than the entire cohort provided data.

To account for different durations of follow-up from study enrollment, univariable Cox proportional hazards regression was used to determine if covariates (i.e., patient related and tear specific factors) are associated with the probability that a patient will undergo operative treatment during surveillance. Surveillance is defined as the length of follow-up from study enrollment (in the nonoperative group) or the time between study enrollment and surgery (in the operative group). Patients who did not undergo surgery were statistically censored at the time of the final study follow-up visit. Unless otherwise indicated, covariates were included in the Cox regression model as ordered variables. The proportional hazards assumption was confirmed with a non-significant interaction between each covariate and surveillance time. Due to sample size limitations, we are not able to assess the combined effects of covariates.

Results

The study database was formally initiated in 2005 and remains active for eligible subjects. The subjects from this cohort were enrolled during two separate recruitment periods spaced approximately 4 years apart from the clinical practices of three attending surgeons. A total of 395 subjects were enrolled from the initial 2 recruiting cycles, including 73 control subjects (no cuff tear on ultrasound at baseline). A total of 322 subjects had a minimum of 2 years of follow-up from enrollment or developed pain prior to the 2 year time point.

A total of 173 subjects developed pain during surveillance. Of the 173, three of these were excluded due to traumatic onset of pain and one subject was excluded because the timing and nature of their shoulder surgery was unclear due to missing records. Four additional subjects were excluded from the analysis that underwent surgery due to tear enlargement but did not met the defined criteria for new pain development. Of the 169 eligible newly painful

shoulders, the median time to pain development was 2.6 years. From study enrollment, the median length of follow-up in the nonoperative group was 6.4 (range 0.5 to 13.1) years and the median time to surgery in the operative group was 4.3 (range 0.5 to 13.5) years.

Demographics

Of the 169 newly painful shoulders, 48 shoulders underwent surgery at a median of 1.5 (range 0 to 9.1) years after pain onset and 121 shoulders maintained a nonoperative course with a median of 2.9 (range 0 to 9.2) years of follow-up after pain onset. There was no difference in gender (Table 1), 41% female in the nonoperative vs 42% in the operative group (p=0.94). Subjects that underwent operative treatment developed pain at a significantly younger age (mean 60.6 years) than those that maintained a nonoperative course (mean 65.9 years, p=0.0004, Table 2). Subjects that underwent surgery developed pain earlier in the course of surveillance than the nonoperative group (median 1.9 vs 3.0 years, p=0.0002). Shoulders that underwent operative treatment had a greater increase in pain (pain numeric pain scale, p=0.0001) and a greater decline in ASES scores (p<0.0001) than those that maintained a nonoperative course. There was no difference in the change in RAND-12 mental component (p=0.06) and physical component (p=0.15) scores between groups.

A total of 113 subjects had a history of cuff based surgery in the contralateral (nonstudy) shoulder, 107 of which occurred prior to surgery or pain development in the study shoulder. There was a significantly higher proportion of shoulders in the operative cohort that previously underwent surgery in the contralateral shoulder (88%) compared to shoulders that maintained a nonoperative course (54%, p=0.0005, Table 1).

Activity level

We found no difference in the proportion of subjects that were retired at study enrollment between shoulders managed operatively and those that maintained a nonoperative course (p=0.34, Table 1)). Likewise, there was no difference in the work demand classification between groups (p=0.29). There was no difference in the proportion of shoulders that involved the dominant extremity (p=0.14) nor the Shoulder Activity Score between shoulders managed operatively (median 10.0) versus the nonoperative group (median 9.0, p=0.25).

Tear characteristics

When examining tear types in the study shoulder, there was no significant difference noted in the tear type on ultrasound prior to pain development between shoulders that underwent surgery and those that maintained a nonoperative course (p=0.13, Table 2). However, subgroup analysis showed that there was a greater percentage of partial tears (40%) in the operative group compared to those managed nonoperatively (22%, p= 0.046). Among full-thickness tears, there were no differences between groups in the median tear width (11.0mm operative vs 13.0mm nonoperative, p=0.52) and median tear length (12.0mm vs 13.0mm, p=0.51). There was no difference between groups with regards to the proportion of tears with disruption of the anterior cable attachment (p=0.22).

During the course of surveillance, 85 of 169 (50%) of shoulders demonstrated tear enlargement either prior to or within 2 years (27 months) of pain development. No difference was seen in the proportion of tears that enlarged in shoulders that underwent surgery (52%) compared to those managed nonoperatively (50%, p=0.67, Table 2). Likewise, no difference was seen in the timing of tear enlargement in relation to pain development between groups (p=0.51). No difference was seen in the severity of fatty muscle degeneration of the supraspinatus and infraspinatus muscles, collectively, in the ultrasound performed within 15 months after pain onset (if non-surgical) or between pain onset and surgery between groups (p=0.85).

Discussion

The natural history of asymptomatic rotator cuff tears has shown that tear enlargement is common and seen in 30–50% of shoulders within 5 years [13]. Although the link between tear progression and pain development is not absolute, tear enlargement has been identified as a significant risk factor for pain development in these shoulders. Given the prevalence of painful cuff disease in the ageing population, there exists a need to define risk factors that may be associated for the perceived need for surgical intervention. Our findings suggest that, in a cohort of newly painful degenerative rotator cuff tears, the variables associated with eventual surgery are primarily related to patient-specific rather than tear-specific factors. Patients choosing surgical intervention are younger and developed pain at a shorter interval of follow-up than those that maintained a nonoperative course. Subjects with larger increases in pain and greater declines in ASES score were more likely to undergo surgery as well. We found no association between tear type, tear size and rotator cuff muscle atrophy between groups. Additionally, hand dominance, upper extremity physical status and working status were not associated with the need for eventual surgery. Finally, we noted a higher likelihood of patients undergoing surgery for a newly painful cuff tear if they had previously undergone surgery in the contralateral shoulder.

The decision to perform surgery in shoulders with painful degenerative rotator cuff tears is influenced by many variables. Studies have shown that there are significant differences in surgical indications between surgeons [9] as well as geographic variances in the incidence of rotator cuff surgery [4, 25]. We sought to better define patient and tear-related factors that may play a role in surgical decision making. In our cohort, the surgical team offered a balanced discussion regarding options for treatment of the newly painful cuff tear and patients were counseled towards conservative treatment and continued surveillance. Ultimately, the decision for surgery was made by the patient due to either patient expectations and/or failure of nonoperative treatment. Previous studies have shown that patient expectations of the success of nonoperative treatment for painful rotator cuff tears strongly predicted the decision for early surgery [7]. For those that do respond to conservative treatment, the clinical improvement is often durable [1, 14, 15]. The current study found younger subjects and those that developed pain earlier in surveillance were more likely to undergo surgery. We are not aware of previous data showing a greater likelihood of surgery in younger patients, although findings of one study did not show a relationship of age to shoulder function in patients with painful rotator cuff tears [10]. In younger patients, tear severity tends to be lower with a predilection towards partial rather than full-thickness tears. Our findings are in contrast to

those of Jain et al. where they noted a shorter duration of symptoms and partial-thickness tears to be predictive of success with nonoperative treatment [12].

The severity of symptoms and disability due to a painful rotator cuff tear is highly variable and influenced by several factors, many of which are ill-defined. Our findings suggest that a greater increase in pain and greater decline in function as assessed by the ASES score was predictive of surgery. This is the first study that we are aware of to prospectively demonstrate these findings in a cohort of asymptomatic rotator cuff tears. Although pain can often be managed conservatively, at least short-term, the persistence of symptoms appears to be predicted by the initial severity of pain and decline in function in this cohort. Many studies have highlighted the role of emotional health on the perceived pain and disability due to a painful rotator cuff tear [5, 6, 20, 26]. One study demonstrated shoulder disability to be much closer related to mental health than tear size [26]. Although the decline in the RAND-12 mental component score was not associated with eventual surgery in our cohort, we only had a single measure of mental health (depression and/or anxiety) at baseline. Further analysis of anxiety and depression specific mental health scales, as performed in the above referenced studies, may have highlighted potential differences between groups.

Despite the association of younger age and future surgery, we did not find a relationship between upper extremity physical work demand, working status or hand dominance and eventual surgery. It appears that physical activity alone was not prognostic in this cohort. This finding contrasts that of Dunn et al. [7] who found that higher physical activity level was correlated to a higher likelihood of failure of conservative treatment for a rotator cuff tear. Brophy et al. have demonstrated that physical activity was not correlated with the size of a rotator cuff tear in patients managed nonoperatively [3]. Previous studies have also shown that tear size is not predictive of pain level and shoulder function in patients with degenerative cuff tears [6, 8, 10]. Furthermore, Dunn et al. did not find a relationship of rotator cuff tear characteristics and success with nonoperative treatment [7]. Our study findings are in agreement. Collectively, we did not find tear type to be related to eventual surgery, although a subgroup analysis did show a higher percentage of partial-thickness tears in the surgical group. Within the full-thickness tears, the tear size was not predictive of surgery.

Of great interest, there was no difference in the percentage of tears that enlarged between those that maintained a nonoperative course and those that underwent surgery. This study is the first to examine tear enlargement as a potential predictor of future surgery in a cohort of asymptomatic tears followed prospectively until the point of pain development. Although tear enlargement has been linked with the onset of pain in previously asymptomatic tears [13, 16] in this cohort, tear enlargement did not predict the need for surgery in the current period of follow-up. In this cohort, the majority of tears would be classified as small or medium sized tears, often not large enough to profoundly affect shoulder function or strength. Likewise, the majority of shoulders had minimal muscle atrophy which has been shown to be predictive of shoulder function [10]. Further follow-up is needed to determine the influence of further enlargement and progression of muscle degeneration over time in the shoulders that have been managed nonoperatively.

A notable finding of this study is the relationship of prior surgery in the contralateral shoulder to the likelihood of surgery in the newly painful study shoulder. Eighty-eight percent of subjects in the operative group underwent a cuff based surgery in the contralateral shoulder compared to 54% of subjects in the nonoperative group. This is a unique cohort in that we have captured subjects with bilateral rotator cuff disease. Certainly past experience with surgery and clinical outcomes could have a significant effect on expectations of surgery and potential outcomes of surgery in a shoulder with a newly painful cuff tear. Although patient expectations have previously been shown to be strongly related to outcomes of cuff repair surgery [11], we are not aware of any study that has examined the influence of prior cuff repair in the contralateral shoulder as a predictor of surgery. Because we did not examine the clinical results of surgery in the contralateral shoulder, we cannot conclude if a positive or negative clinical outcome of previous surgery would directly influence the decision to have surgery on the contralateral side. It does seem; however, that patients having undergone previous surgery may be more predisposed towards surgical management of a painful rotator cuff tear in the contralateral shoulder. It may be interpreted that patients perceived sufficient value in prior cuff surgery to elect for surgery in the shoulder followed in this study.

This study has several limitations that warrant discussion. After new pain development, the treatment algorithm was not standardized potentially creating surgical indication bias. All patients were evaluated by a clinician and the treatment paths were ultimately left to the discretion of the patient. The common practice for the treating surgeons was to recommend a nonoperative treatment course and the majority of patients were initially managed conservatively; however, some subjects elected for early surgery without completing a standardized minimum conservative treatment period. Therefore, the decision for surgery was not soley based upon response to treatment but patient expectations and perception of their need for treatment. Accordingly, this study reflects some patient bias related to perceptions of needed treatment. We feel this study design, however, reflects the purpose of the study, which was to examine patient and tear-related factors that are predictive of surgery and we also feel this treatment algorithm reflects common clinical practice. We did not have depression and anxiety specific measures of baseline mental health, factors that have been shown to affect perceived pain and disability in patients with rotator cuff tears. Additionally, we did not analyze shoulder range of motion, strength or specific outcomes of treatment in either the nonsurgical and surgical groups as this was outside the scope of this study. The ASES is strongly affected by the level of pain experienced by the patient. Although it may be inferred that the nonsurgical group had persistent functional limitations necessitating surgery, we did not examine shoulder function in a detailed manner. Finally, we did not examine the clinical results of surgery in the contralateral shoulder. It is possible that the outcomes of previous surgery may have influenced the ultimate choice of surgery in the newly painful shoulders in this cohort. Despite these limitations, we feel this study presents novel findings of a unique cohort of patients. This study has detailed longitudinal data regarding pain, function, activity level and rotator cuff tear characteristics analyzed with validated metrics.

Conclusions

In a cohort of patients with an asymptomatic rotator cuff tear who develop new pain, the predictors of eventual surgery are primarily related to patient rather than tear-related factors. Eventual surgery is more common in younger patients, those that develop pain earlier in surveillance, those with more pain and a greater decline in ASES scores and those with prior cuff related surgery in the contralateral shoulder. Occupational status, physical activity level, tear size and tear enlargement are not predictive of operative treatment at mid-term follow-up.

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Table 1.

Baseline Demographics and Tear Characteristics.

Covariate	Entire Cohort No.=169	No Surgery No.=121	Surgery No.=48	P – value*
At Study Enrollment				
Female gender, No. (%)	70 (41%)	50 (41%)	20 (42%)	0.94
Study side is dominant extremity, No. (%)	76 (45%)	50 (41%)	26 (54%)	0.14
Retired at enrollment, No. (%)	59 (35%) *missing 2*	46 (38%)	13 (28%) *missing 2*	0.34
Work shoulder demands at enrollment, No. (%):				
Sedentary	35 (21%)	25 (21%)	10 (21%)	0.29†
Labor	32 (19%)	27 (22%)	5 (10%)	
In Between	102 (60%)	69 (57%)	33 (69%)	
Tear type at enrollment, No. (%):				0.19†
Full-thickness	93 (55%)	70 (58%)	23 (48%)	
Partial-thickness	53 (31%)	32 (26%)	21 (44%)	
Control	23 (14%)	19 (16%)	4 (8%)	
Shoulder Activity Score, median [IQR]	9.0 [6.0] *missing 14*	9.0 [6.0] *missing 8*	10.0 [6.0] *missing 6*	0.25
Underwent contralateral cuff based shoulder surgery during surveillance, No. (%)	113 (67%)	70 (58%)	43 (90%)	**0.0006**
Underwent contralateral cuff-based surgery either (a) before surgery on the enrolled shoulder if the enrolled shoulder underwent surgery, or (b) at or before pain onset if the enrolled shoulder did not undergo surgery, No. (%)	107 (63%)	65 (54%)	42 (88%)	**0.0005**

No. = number of patients; IQR = interquartile range.

*P-value compares patients who did and did not undergo surgery by Cox proportional hazards regression.

†Covariate was modelled as an unordered categorical variable.

Table 2.

Characteristics at and in Relation to Pain Development.

Covariate	Entire Cohort No.=169	No Surgery No.=121	Surgery No.=48	P – value*
Age at pain onset (yr), mean (SD)	64.4 (8.9)	65.9 (8.7)	60.6 (8.3)	**0.0004**
Time between study enrollment and pain onset (yr), median [IQR]	2.6 [2.9]	3.0 [2.9]	1.9 [2.8]	**0.0002**
Tear type at visit prior to pain onset, No. (%):				
Full-thickness	105 (62%)	79 (65%)	26 (54%)	0.13†
Partial-thickness	46 (27%)	27 (22%)	19 (40%)	
Control	18 (11%)	15 (12%)	3 (6%)	
For full tears (No.=105) at visit prior to pain onset: tear width at visit prior to pain onset (mm), median [IQR]	13.0 [12.0] *missing: 3 massive*	13.0 [9.5] *missing: 3 massive*	11.0 [13.0]	0.52
For full tears (No.=105) at visit prior to pain onset: tear length at visit prior to pain onset (mm), median [IQR]	12.5 [10.0] *missing: 6 massive, 1 not measured*	13.0 [10.0] *missing: 4 massive, 1 not measured*	12.0 [11.0] *missing: 2 massive*	0.51
Tear enlargement prior to pain development or within 2.25yr of pain development (or until surgery), No. (%)	85 (50%)	60 (50%)	25 (52%)	0.67
Tear enlargement related to pain onset, No. (%):				
No enlargement before or within 2.25yr of pain development	84 (50%)	61 (50%)	23 (48%)	0.51†
First enlargement before pain development	41 (24%)	31 (26%)	10 (21%)	
First enlargement precisely at pain development	20 (12%)	13 (11%)	7 (15%)	
First enlargement after and within 2.25yr of pain development (or until surgery)	24 (14%)	16 (13%)	8 (17%)	
Cable disruption at or within 1.25yr after pain development (or until surgery), No. (%)	31 (23%) *missing 36*	20 (21%) *missing 27*	11 (28%) *missing 9*	0.22
Muscle degeneration, sum of architecture and echogenicity (most severe of supraspinatus and infraspinatus) at or within 1.25yr after pain development (or until surgery), No. (%):				
0 (normal)	126 (75%)	90 (75%)	36 (77%)	0.85
1	5 (3%)	5 (4%)	0 (0%)	
2	26 (16%)	16 (13%)	10 (21%)	
3	1 (1%)	1 (1%)	0 (0%)	
4 (severe)	9 (5%) *missing 2*	8 (7%) *missing 1*	1 (2%) *missing 1*	
Change‡ in ASES between enrollment and worst ASES at or within 1.25yr after pain development (or until surgery), mean (SD)	−37.5 (19.0)	−32.7 (17.2)	−49.7 (18.1)	**<0.0001**
Change‡ in pain numeric pain scale between enrollment and worst VAS at or within 1.25yr after pain development (or until surgery), mean (SD)	+4.7 (2.3)	+4.3 (2.2)	+5.9 (2.0)	**0.0001**

Covariate	Entire Cohort No.=169	No Surgery No.=121	Surgery No.=48	P – value*
Change‡ in RAND-12 mental component score between enrollment and worst VAS at or within 1.25yr after pain development (or until surgery), mean (SD)	−3.8 (10.0) *missing 21*	−4.2 (9.8) *missing 9*	−2.6 (10.6) *missing 12*	0.06
Change‡ in RAND-12 physical component score between enrollment and worst VAS at or within 1.25yr after pain development (or until surgery), mean (SD)	−3.8 (9.6) *missing 21*	−3.3 (9.5) *missing 9*	−5.3 (9.6) *missing 12*	0.15

No. = number of patients; yr = year; SD = standard deviation; IQR = interquartile range; ASES = American Shoulder Elbow Surgeons; VAS = visual analog scale.

*P-value compares patients who did and did not undergo surgery by Cox proportional hazards regression.

†Covariate was modelled as an unordered categorical variable.

‡Change is calculated by subtracting the value at enrollment from the value at follow-up.