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Symptoms of pain do not correlate with rotator cuff tear severity

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Symptoms of Pain Do Not Correlate with Rotator Cuff Tear Severity

A Cross-Sectional Study of 393 Patients with a Symptomatic Atraumatic Full-Thickness Rotator Cuff Tear

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Background: For many orthopaedic disorders, symptoms correlate with disease severity. The objective of this study was to determine if pain level is related to the severity of rotator cuff disorders.

Methods: A cohort of 393 subjects with an atraumatic symptomatic full-thickness rotator-cuff tear treated with physical therapy was studied. Baseline pretreatment data were used to examine the relationship between the severity of rotator cuff disease and pain. Disease severity was determined by evaluating tear size, retraction, superior humeral head migration, and rotator cuff muscle atrophy. Pain was measured on the 10-point visual analog scale (VAS) in the patient-reported American Shoulder and Elbow Surgeons (ASES) score. A linear multiple regression model was constructed with use of the continuous VAS score as the dependent variable and measures of rotator cuff tear severity and other non-anatomic patient factors as the independent variables. Forty-eight percent of the patients were female, and the median age was sixty-one years. The dominant shoulder was involved in 69% of the patients. The duration of symptoms was less than one month for 8% of the patients, one to three months for 22%, four to six months for 20%, seven to twelve months for 15%, and more than a year for 36%. The tear involved only the supraspinatus in 72% of the patients; the supraspinatus and infraspinatus, with or without the teres minor, in 21%; and only the subscapularis in 7%. Humeral head migration was noted in 16%. Tendon retraction was minimal in 48%, midhumeral in 34%, glenohumeral in 13%, and to the glenoid in 5%. The median baseline VAS pain score was 4.4.

Results: Multivariable modeling, controlling for other baseline factors, identified increased comorbidities ($p = 0.002$), lower education level ($p = 0.004$), and race ($p = 0.041$) as the only significant factors associated with pain on presentation. No measure of rotator cuff tear severity correlated with pain ($p > 0.25$).

Conclusions: Anatomic features defining the severity of atraumatic rotator cuff tears are not associated with the pain level. Factors associated with pain are comorbidities, lower education level, and race.

Level of Evidence: Prognostic Level III. See Instructions for Authors for a complete description of levels of evidence.

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A commentary by Frederick A. Matsen III, MD, is linked to the online version of this article at jbjs.org.

For many orthopaedic disorders, such as osteoarthritis, symptoms correlate with disease severity[1-3]. However, symptoms related to rotator cuff tears are not as predictable. It is well known that many people in the general population have an asymptomatic rotator cuff tear[4-6]. Patients may become asymptomatic following rotator cuff repair despite evidence that the repair failed on magnetic resonance imaging (MRI) or ultrasound imaging[7]. Nonoperative treatment for full-thickness rotator cuff tears is often successful despite a lack of tendon healing[8-11]. As a result, the link between rotator cuff tears and symptoms is not clearly established. Pain is a frequently cited symptom associated with rotator cuff tears and is often used as an indication for surgery[12-15]. The objective of this investigation was to determine if the pain level is related to the severity of the rotator cuff disease. We used a cross-sectional design to test the hypothesis that increased pain correlates with greater rotator cuff tear severity.

Materials and Methods

The MOON (Multicenter Orthopaedic Outcomes Network) Shoulder Group is a team of sixteen fellowship-trained orthopaedic surgeons and research personnel from nine geographically dispersed sites, representing both academic and private practice settings, within the United States. This group was formed to conduct large multicenter studies on conditions of the shoulder.

From May 2004 through October 2006, the MOON Shoulder Group met regularly to formulate research questions of interest; develop and standardize radiographic and MRI protocols; assemble validated behavioral and patient-oriented outcome assessment forms for data collection; and conduct validation studies on MRI classification of rotator cuff tears[16], classification of rotator cuff tears based on arthroscopic videos[17], and radiographic findings associated with rotator cuff disease[18]. In addition, the group performed systematic reviews of the literature to evaluate rehabilitation following rotator cuff repairs[19], summarize the literature regarding indications for surgical treatment of rotator cuff tears[20], and determine the effectiveness of physical therapy in treating rotator cuff disease while developing an evidence-based protocol[21].

TABLE I Demographic Features of Cohort

	No. of Patents	Female (N = 190)	Male (N = 203)
Age* *(yr)*	393	63.2 ± 10.2	62.1 ± 9.9
BMI* *(kg/m²)*	388	28.3 + 7.2	29.0 ± 5.1
Involved side	390		
Nondominant		27% (51/188)	35% (70/202)
Dominant		73% (137/188)	65% (132/202)
Race	389		
Other		7% (13/187)	4% (9/202)
Black		12% (23/187)	4% (8/202)
White		81% (151/187)	92% (185/202)
Education	392		
High school or less		27% (51/189)	35% (72/203)
Some college		31% (59/189)	21% (43/203)
Bachelor's degree		20% (38/189)	19% (39/203)
Graduate degree		22% (41/189)	24% (49/203)
Marital status	391		
Other		5% (10/189)	3% (7/202)
Divorced		20% (37/189)	9% (18/202)
Married		48% (90/189)	82% (165/202)
Single		10% (18/189)	3% (6/202)
Widowed		18% (34/189)	3% (6/202)
Employment	392		
Full-time		38% (72/189)	55% (112/203)
Part-time		12% (23/189)	7% (14/203)
Retired		34% (64/189)	32% (65/203)
Homemaker		9% (17/189)	0% (0/203)
Not working		7% (13/189)	6% (12/203)
Smoking	390		
No		90% (170/188)	90% (182/202)
Yes		10% (18/188)	10% (20/202)

*The values are given as the mean and standard deviation.

TABLE II Features of Rotator Cuff Disease in the Cohort

	No. of Patients	Female (N = 190)	Male (N = 203)
Duration of symptoms	390		
<1 mo		6% (12/189)	9% (18/201)
1-3 mo		22% (41/189)	22% (44/201)
4-6 mo		22% (41/189)	18% (37/201)
7-12 mo		18% (34/189)	11% (23/201)
>12 mo		32% (61/189)	39% (79/201)
Involved tendons	383		
Supraspinatus		75% (139/186)	70% (137/197)
Supraspinatus + infraspinatus ± teres minor		20% (37/186)	22% (44/197)
Subscapularis		5% (10/186)	8% (16/197)
Retraction	390		
Minimal		49% (92/188)	48% (96/202)
Midhumeral		34% (63/188)	35% (70/202)
Glenohumeral		13% (25/188)	12% (25/202)
Glenoid		4% (8/188)	5% (11/202)
Superior migration	380		
No		87% (163/187)	82% (158/193)
Yes		13% (24/187)	18% (35/193)
Torn tendons	384		
1		75% (139/186)	70% (139/198)
≥2		25% (47/186)	30% (59/198)
MRI quantity of supraspinatus	387		
Normal		40% (74/186)	53% (107/201)
<25% atrophy		31% (58/186)	22% (45/201)
25-50% atrophy		22% (40/186)	13% (27/201)
50-75% atrophy		6% (12/186)	7% (15/201)
Complete atrophy		1% (2/186)	3% (7/201)
Acromion shape	377		
Type I		13% (23/182)	10% (20/195)
Type II		70% (127/182)	73% (142/195)
Type III		18% (32/182)	17% (33/195)
Acromiohumeral interval* *(mm)*	339	8.0, 10.0, 11.0 (9.8 ± 6.8)	8.0, 10.0, 11.0 (10.2 ± 7.2)

*The values are given as the lower quartile, median, upper quartile (mean and standard deviation).

The indications for surgery for atraumatic rotator cuff tears are not clear[12,20,22], and our research group could not develop standard indications for surgery by consensus. Therefore, the group conducted a prospective cohort study to assess the nonoperative treatment of atraumatic full-thickness rotator cuff tears with use of the physical therapy protocol derived from the systematic review. We expected that nonoperative treatment would succeed for some patients, who would then decline surgical intervention, while it would fail for others, who would then undergo rotator cuff repair. By identifying features that distinguish these groups, we sought insight into the risk factors for failure of nonoperative management to better define the appropriate indications for surgery. To test the hypothesis that pain correlates with measures of rotator cuff tear severity, we performed a cross-sectional study of data derived from this population when patients initially presented to the treating physician. Sample-size requirements for that study were formulated with the events-per-variable approach, with ten events as the minimum number to avoid overfitting of the model. Baseline data on the first 393 subjects enrolled into the ongoing prospective cohort study were used in the present study.

Institutional Review Board Approval

Institutional review board approval was obtained at all participating sites before enrollment of the first patient.

Inclusion and Exclusion Criteria

All patients eighteen to 100 years old with an MRI-documented full-thickness atraumatic symptomatic rotator cuff tear were invited to participate. Exclusion criteria included an injury that precipitated the pain, pain determined to be related to the cervical spine, scapular pain, previous shoulder surgery, glenohumeral arthritis, inflammatory arthritis, adhesive capsulitis, a previous proximal humeral fracture, a symptomatic contralateral rotator cuff tear, and dementia.

Protocol

Patients were recruited over a four-year period (January 2007 to January 2011). At the initial visit, patients completed a questionnaire that detailed demographic data and included the following validated patient-reported outcome measures: the Short Form-12 (SF-12)[23], American Shoulder and Elbow Surgeons (ASES) score[24], Western Ontario Rotator Cuff (WORC) Index[25], Single Assessment Numeric Evaluation (SANE) score[26], Self-Administered Comorbidity Questionnaire (SCQ)[27], and the Shoulder Activity Scale[28]. Patient demographic information including age, sex, race, employment status, Workers' Compensation or automobile insurance claims, and tobacco use history were also collected at the time of enrollment.

Physicians at each site examined patients and images and recorded information regarding shoulder motion, strength, tenderness, provocative signs, and descriptors of radiographs and MRI scans. The following MRI features used to assess the severity of a rotator cuff tear had reasonably high interobserver agreement when studied by our research group[16] and were used in this analysis: (1) the rotator cuff tendons that were seen to be involved by the tear on MRI (72% agreement, kappa = 0.55), (2) retraction in the sagittal plane seen on MRI as described by Patte[29] (63% agreement, kappa = 0.44), (3) presence of superior humeral head migration on standing anteroposterior radiographs (52% agreement, kappa = 0.26), and (4) amount of supraspinatus atrophy[30] seen on MRI (59% agreement, kappa = 0.25).

Statistical Methods

To evaluate the association between shoulder pain and other baseline factors, a multivariable linear multiple regression model was fit with use of a continuous visual analog scale (VAS) pain score (item 3 from the ASES patient form[24]) as the dependent variable. Independent variables included in the model were age, sex, body mass index (BMI), duration of symptoms, activity level, handedness, education, occupation, race, smoking status, patient expectations, tendons torn, retraction, humeral head migration, and amount of atrophy in the supraspinatus.

We did not assume linearity of covariate effects but only assumed smoothed relationships, using restricted cubic regression splines. Missing values of predictor variables were imputed with use of multiple imputation incorporating predictive mean matching and flexible additive imputation models as implemented in the *aregImpute* function available in the Hmisc package in R[31]. This procedure involves predicting missing values on the basis of nonmissing observed data—essentially finding matches for the missing values. A regression model is fit to the observed data, then the missing values for a particular covariate are matched to the closest set of observed values on the basis of the regression fit, and then missing values are imputed on the basis of the closest set of observed values. This process was repeated ten times; hence, the imputed values were averaged over ten imputations. Pooling of low-prevalence categories was performed for data reduction to preserve degrees of freedom in the model, and to avoid convergence problems with the model. Specifically, American Indian, Asian, and Hawaiian were collapsed into an "other" category for race; disabled and unemployed were combined into a "not working" category for employment status; and no high school and some high school were collapsed into a "high school or less" category for education. Statistical analysis was performed with free open-source R statistical software (www.r-project.org).

Population and Rotator Cuff Demographics

The group evaluated 2233 patients who presented with a rotator cuff tear during the enrollment period; 1280 of these patients were excluded because of a traumatic tear (38%), previous surgery (11%), bilateral disease (8%), neck disorder (6%), frozen shoulder (2%), glenohumeral dislocation (3%), rheumatoid disease (1%), or fracture (1%). Of the remaining 953 patients eligible to enroll in the study, 452 (47%) elected to do so. The first 393 patients in this cohort were included in the present cross-sectional study, in which we used data from the first visit at the time of the initial enrollment in the study.

The average age of the patients who enrolled was sixty-two years, whereas the average age of those who did not was fifty-eight years ($p < 0.001$).

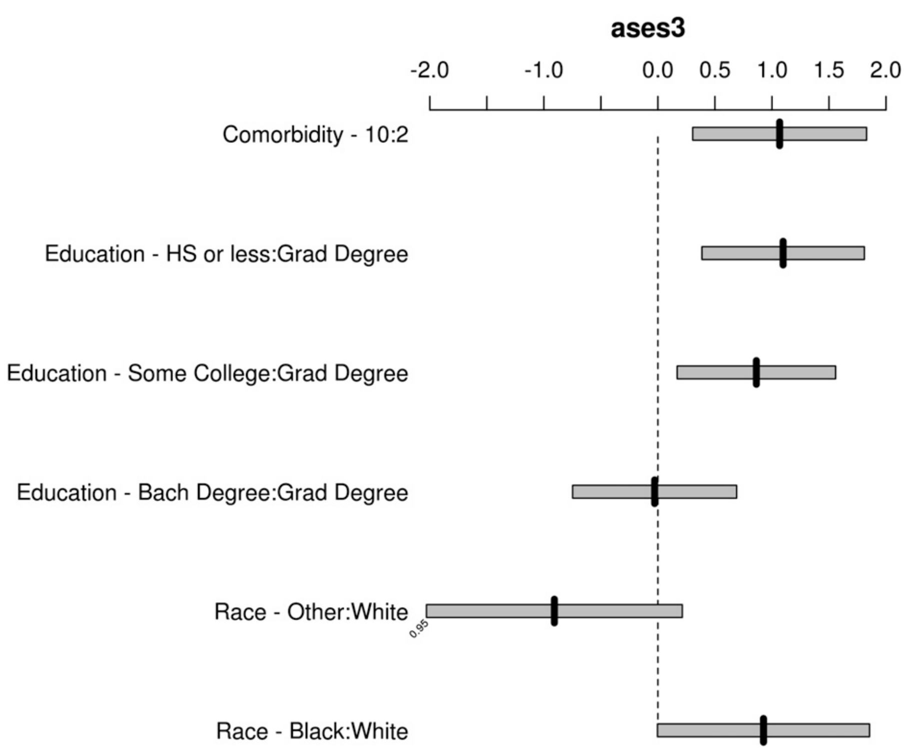

Fig. 1

Plot of the effects of the significant predictors in the model. The gray bars represent the 95% CI for the mean effect. The mean effect of comorbidity on pain was determined by comparing those with an SCQ score of 2 with those with a score of 10; the VAS pain score (ases3) was increased by 1.07 (95% CI: 0.31, 1.83) in the latter group. HS = high school, Grad = graduate, and Bach = Bachelor's.

Equal numbers of men and women enrolled, whereas 63% of those who did not enroll were male; this was a significant difference ($p < 0.001$).

Demographic Data for the Study Population

The median age of the study population was sixty-one years (range, thirty-one to ninety years), and 52% were male. The dominant arm was affected in 69% of the subjects; 90% were nonsmokers. Other demographic features, including race, education level, and employment status, are listed in Table I stratified by sex. Twenty-three percent of the patients had already tried some physical therapy, 40% had received injections, and 80% had tried nonsteroidal anti-inflammatory drugs. The median baseline VAS pain score was 4.4.

MRI Features of the Rotator Cuff Tears

The tears involved only the supraspinatus in 72% of the patients. Retraction was minimal in 48% of the patients and was to the midpart of the humeral head in 34%. Superior humeral head migration was present in 16% of the patients. Tear characteristics stratified by sex are listed in Table II.

Source of Funding

Sources of funding included an unrestricted gift from the Arthrex Corporation, and a research funding grant specific to the investigation from the National Football League (NFL) Foundation, which were used to support research personnel and pay for supplies and computer hardware and software. Career development grants from the National Institutes of Health (NIH) and the American Orthopaedic Society for Sports Medicine (AOSSM) supported Dr. Dunn.

Results

Factors Associated with Pain

Greater pain was associated with an increased number of comorbidities ($p = 0.002$), a lower education level ($p = 0.004$), and race ($p = 0.041$). Measures of tear severity, including the tendons involved ($p = 0.5$), amount of retraction ($p = 0.9$), presence of humeral head migration ($p = 0.3$), and amount of fatty degeneration of the supraspinatus ($p = 0.4$), were not associated with pain. These findings were adjusted for the other covariates included in the model—specifically, duration of symptoms, occupation, smoking status, activity level, BMI, dominant arm, and patient expectations. A summary-of-effects plot is shown in Figure 1 with the 95% confidence intervals (CIs) for the mean effects.

While the SCQ score, a lower level of education, and race were significant factors, the respective point estimates shown in Figure 1 do not represent a clinically meaningful difference in the VAS pain score, which is 1.4 cm for subjects with rotator cuff disease[32]. However, using the nomogram in Figure 2, one can estimate the cumulative effects of the predictors on pain. For instance, the nomogram can be used to estimate the effect of race, education level, and comorbidity (allowing the other factors depicted on the nomogram to default to the left-most category, which contributes no points to the calculation) as follows. A sum

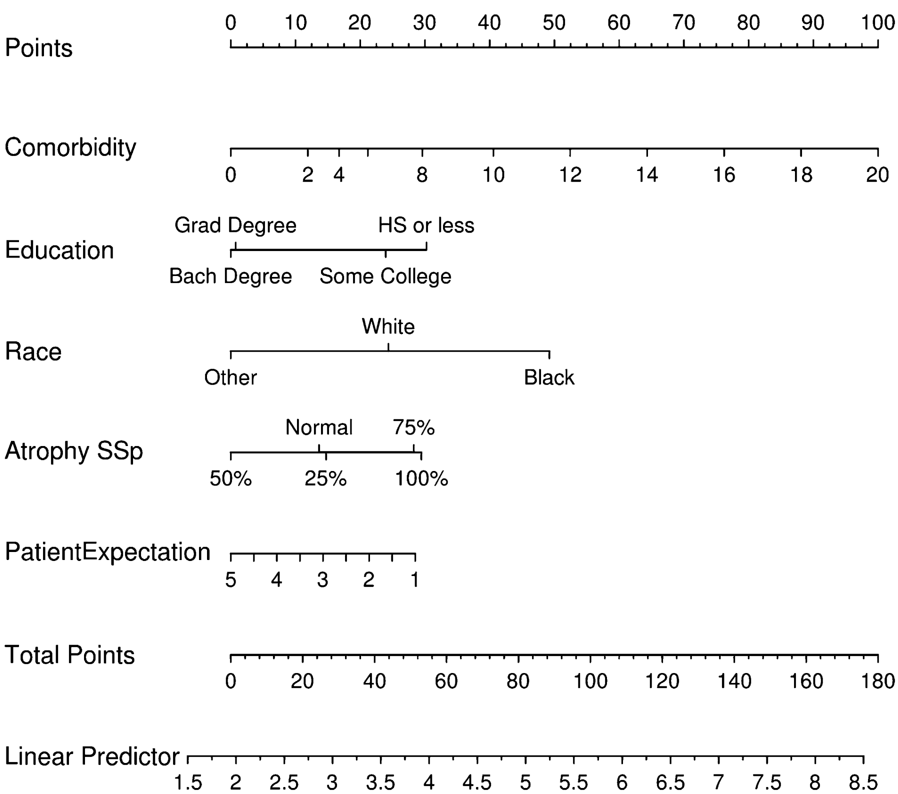

Fig. 2

Nomogram for the model predicting an individual patient's VAS pain score. First, each variable is marked on the appropriate scale, and the number of points for each is derived from the "Points" scale at the top of the nomogram. Then the points are totaled, and the total value is marked on the "Total Points" scale. Viewing down, one then derives the predicted pain score on the scale labeled "Linear Predictor." For ease of interpretation not all predictors included in the model are shown in the nomogram. HS = high school, Grad = graduate, Bach = Bachelor's, and SSp = supraspinatus.

of the points for a subject of black race, an SCQ of 10, and a high-school education (~45 points for black race, ~40 points for an SCQ of 10, and 29 points for a high-school education) equals 114 total points, with a predicted VAS pain score of 5.6. When this is compared with a subject of white race who has an SCQ of 2 and a graduate degree (~25 points for white, ~12 points for an SCQ of 2, and ~2 points for a graduate degree equals a total of 39 points, with a predicted VAS pain score of ~3.3, the difference in the predicted VAS pain scores is 2.3, which would be considered a clinically meaningful difference.

Discussion

This cross-sectional study demonstrated no correlation between the level of pain reported by patients and any anatomic measure of rotator cuff tear severity. The level of pain did correlate with nonanatomic features, including increased number of comorbidities, race, and lower education level.

There are several study limitations, the foremost of which is the cross-sectional design using only baseline data from a prospective cohort, which made causal inferences difficult. Other limitations include the potential for selection bias, as patients who were less willing to have surgery may have been more inclined to participate and patients may have self-selected on the basis of their level of symptoms, and performance bias, as some patients may have received medications, acupuncture, or other pain-relieving treatments that we did not examine. Also, generalizability may be limited as many patients presented with a history of trauma and were excluded from the study. Despite these potential limitations, our study included nearly 400 subjects from multiple practices across the United States. Thus, the results of this study may be generalizable to the symptomatic patients with a rotator cuff tear in the United States population within the limitations described above.

Patients with atraumatic orthopaedic conditions typically present with pain, and that pain often correlates with the severity of the disorder[1-3]. This does not appear to be the case with rotator cuff tears as our data suggest that there is no relationship between pain severity and rotator cuff tear severity. There are abundant data to suggest that the relationship between pain and rotator cuff tears is not robust. Nonoperative treatment of symptomatic, atraumatic, full-thickness rotator cuff tears is successful in approximately 75% of patients[8-11]. Patients who have a failed repair of a rotator cuff tear are often pain-free, and their outcomes may be indistinguishable from those in patients with an intact repair[7]. Finally, the prevalence of asymptomatic rotator cuff tears is high. If one uses a conservative estimate that 10% of the population over the age of sixty-five years in the United States has a full-thickness rotator cuff tear[6], then on the basis of 2010 census data[33] more than four million citizens in the United States have a full-thickness rotator cuff tear. With this very large number as a denominator and the approximately 250,000 rotator cuff surgical procedures performed each year in the United States[34] as a numerator, only 6% of patients with a full-thickness rotator cuff tear have surgery each year. These different lines of evidence suggest that many rotator cuff tears are not associated with pain.

Natural history studies have demonstrated that, in some patients, pain may be associated with enlargement of an asymptomatic rotator cuff tear. Yamaguchi et al. studied progression of asymptomatic rotator cuff tears in twenty-three patients with a contralateral symptomatic rotator cuff tear. The asymptomatic shoulder became symptomatic over a period averaging 2.8 years after the initial ultrasound study[35]. Nine of the twenty-three remained asymptomatic, and fourteen became symptomatic. Of the nine who remained asymptomatic, two had progression of the asymptomatic rotator cuff tear. Of the fourteen who became symptomatic, seven had rotator cuff tear progression. While this study demonstrated that those with tear progression are more likely to develop pain, it also showed that tear progression can develop without pain and that pain can develop without tear progression. The average 10-cm VAS pain score in the symptomatic group was 2.9 cm higher than that in the asymptomatic group.

In the study by Moosmayer et al., fifty patients with an asymptomatic rotator cuff tear and a contralateral symptomatic rotator cuff tear were followed over three years[36]. Eighteen patients (36%) developed symptoms, with an increase of 3.3 cm in the 10-cm VAS pain score, and the increase in tear size over time was greater in the newly symptomatic group than in the asymptomatic group. Confounding this was the finding that the long head of the biceps tendon developed more pathologic changes in the newly symptomatic group than in the asymptomatic group. What is not known is whether the increase in pain with rotator cuff tear progression diminishes with exercise or with time. One might expect that patients with larger rotator cuff tears would report a longer duration of symptoms, but this is not the case[37].

It appears that the majority of rotator cuff tears are asymptomatic. Rotator cuff tears can progress in some patients; this progression may occur without symptoms in some but will be associated with symptoms in many. The amount of pain associated with tear progression (approximately 3 cm on a 10-cm pain VAS) is less than the median value seen in our study (4.4 cm), suggesting that the pain with cuff tear progression may not be great enough to drive patients to seek medical attention. The data also suggest that patients with a rotator cuff tear may develop pain without tear progression, suggesting that other sources of pain, such as the long head of the biceps, may be present[38,39].

Indications for surgical repair of chronic, atraumatic rotator cuff tears are not clearly defined and have little uniformity[12,20,22], which may explain the widespread geographic variation in rotator cuff surgery rates[40]. Patients in whom a rotator cuff repair has failed report outcome scores that are not significantly different from those for patients whose repair has healed, unless the outcome score includes a large component for strength, in which case those with a healed repair have better scores[7,11]. Weakness or loss of function may be a better indication for rotator cuff repair than pain in patients with an atraumatic symptomatic rotator cuff tear.

In conclusion, patients who present with shoulder pain without a history of an injury and with MRI evidence of a rotator cuff tear present a dilemma to physicians as the literature lacks high-level evidence to help us make decisions regarding appropriate treatment. In this large cross-sectional study of patients with an atraumatic, symptomatic full-thickness rotator cuff tear, the patient's pain had no correlation with anatomic measures of the severity of the rotator cuff tear. Because the relationship between pain and the presence of a rotator cuff tear is not robust, when a patient presents with pain as the primary symptom, it may not be accurate to assume that the accompanying rotator cuff tear is responsible for the pain. ■

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