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PROMIS CAT forms demonstrate responsiveness in patients following arthroscopic rotator cuff repair across numerous health domains

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Background: Recent studies of patients with rotator cuff tears have demonstrated improved efficiency with Patient-Reported Outcomes Measurement Information System (PROMIS) when compared with traditional patient-reported outcome measures (PROM). However, these studies have been cross-sectional in nature and the responsiveness of PROMIS computer adaptive test (CAT) forms has not been evaluated. The purpose of this study was to determine the responsiveness of PROMIS CAT assessments in patients undergoing arthroscopic rotator cuff repair.

Methods: All patients undergoing arthroscopic rotator cuff repair by one of 3 fellowship-trained surgeons were included in the study. PROMIS CAT upper extremity physical function (''PROMIS-UE''), pain interference (''PROMIS-PI''), and depression (''PROMIS-D'') scores from preoperative and 6-month postoperative visits were collected and analyzed. Patient-centric demographic factors, tear size, and biceps involvement were also correlated to preoperative and postoperative PROMIS scores.

Results: A total of 101 patients were enrolled in the study. The average age was 59.8 ± 8.9 years with 51 males (50.5%). Preoperative PROMIS-UE, PROMIS-PI, and PROMIS-D CAT scores improved significantly from 29.8 ± 6.0, 62.6 ± 5.1, and 48.4 ± 8.7, respectively, to 40.9 ± 9.8, 51.2 ± 9.3, and 42.9 ± 9.0, respectively, at 6-month follow-up ($P < .001$). Preoperative correlations were found between PROMIS-UE and PROMIS-PI scores ($P < .001$) and between PROMIS-PI and PROMIS-D scores ($P = .001$). No significant correlation was found between PROMIS-UE and PROMIS-D scores ($P = .08$), preoperatively. Preoperative PROMIS-UE, PROMIS-PI, or PROMIS-D scores were not correlated with rotator cuff tear size ($P = .4$).

Conclusion: PROMIS CAT forms demonstrate responsiveness in patients undergoing arthroscopic rotator cuff repair across numerous domains.

Level of evidence: Basic Science Study; Validation of Outcome Instruments

Keywords: Arthroscopy; rotator cuff; injury; surgery; shoulder; function; pain; depression

This study was approved by the Henry Ford Health System Institutional Review Board Committee (No. 11361).

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Approximately 250,000 arthroscopic rotator cuff repairs are performed in the United States each year, representing a significant estimated societal savings of $3.44 billion.[14] Several patient-reported outcome measures (PROM) have been created and validated for patients undergoing rotator cuff repair; however, there is widespread inconsistency with how these PROM are used and reported in the literature.[13] Moreover, collection of long-term, follow-up PROM electronically has proven challenging.[12] Improvement of PROM administration and collection would optimize the understanding of patient responses to treatment.

In order to address these concerns, the National Institutes of Health created Patient-Reported Outcomes Measurement Information System (PROMIS), which is a series of PROM forms that are dynamic, efficient to administer, and have a standardized scoring system. Recently, several studies have demonstrated favorable psychometric properties of PROMIS computer adaptive test (CAT) forms, especially when compared with legacy and other traditional PROM.[16] In patients with rotator cuff tears, PROMIS CAT measures have been shown to be more efficient, require fewer answers from the patient, and thus reduce administration times compared with legacy PROM forms.[10] PROMIS CAT forms are scored in a standardized format, where a score of 50 represents that of a reference population, and a deviation of 10 points represents 1 standard deviation. Therefore, for example, a PROMIS UE score of 60 would denote physical function that was 1 standard deviation greater than that of the reference population.[13]

Multiple studies have validated PROMIS CAT in patients with rotator cuff tears; however, no study to date has documented responsiveness, or the ability of the score to change over time with recovery, of these forms in patients undergoing rotator cuff repair.[1,16] In patients undergoing partial meniscectomy, Bernholt et al[3] demonstrated the responsiveness of multiple PROMIS CAT domains in the early postoperative period, but similar responsiveness of PROMIS has not been studied after arthroscopic rotator cuff repair.

The purpose of this study was to investigate the responsiveness of multiple PROMIS CAT domains in patients undergoing arthroscopic rotator cuff repair. We hypothesize that measures of upper extremity physical function, pain interference, and mental health will all significantly improve after rotator cuff repair.

Methods

Institutional board review approval was obtained before study initiation. A total of 101 patients who underwent arthroscopic rotator cuff repair by one of 3 fellowship-trained surgeons, between July 2017 and March 2018, were included in this study. Three PROMIS CAT forms were administered to patients: Upper Extremity Physical Function-CAT v2.0 (''PROMIS-UE''), Pain Interference CAT v1.1 (''PROMIS-PI''), and Depression CAT v1.0 (''PROMIS-D''). Pain interference is a measure of the detriment toward a patient's life due to pain. A greater score in each instrument reflects more of the item being measured. For example, a higher PROMIS-UE score would indicate greater physical function, whereas a higher PROMIS-PI score would indicate more pain detriment to the patient's life.

Inclusion criteria were as follows: patients undergoing a rotator cuff repair who were at least 18 years of age and could communicate in English. Exclusion criteria included the presence of an active infection, refusal to complete PROMIS CAT forms, or inability to communicate in English. All procedures were performed by one of 3 fellowship-trained orthopedic surgeons at a multisite integrated health care system. All PROMIS CAT questionnaires were completed on a tablet computer (iPad tablet; Apple, Cupertino, CA, USA) using a web-based application

Table I Patient characteristics

Variable		
Age*	59.8 ± 8.9	(37-79)
Sex		
Male†	51	50.5%
Female†	50	49.5%
BMI*	30.6 ± 5.7	(20.58-50.75)
MHI*	$61,723 ± $23,752	($25,951-$130,699)
Race		
White†	61	60.4%
Black/African American†	26	26.3%
Asian†	4	4.0%
Other†	9	8.9%
Smoking status		
Never smoker†	56	55.4%
Former smoker†	35	34.7%
Current smoker†	10	9.9%
Tear size (cm)*	2.0 ± 1.1	(0.4-5.5)
Small†	21	20.8%
Medium†	66	65.3%
Large†	14	13.9%
Tendonosis and tears†		
Supraspinatus	16	15.8%
Infra+supra	13	12.9%
Infra+supra+subscap	54	53.5%
Supra+subscap	18	17.8%
Biceps procedure†		
Tenodesis	29	28.7%
Tenotomy	17	16.8%
None	55	54.5%
Clinic visit (postoperative days)*	36 ± 7	(19-55)
Preoperative visit	84 ± 9	(63-106)
Postoperative visit	180 ± 37	(121-267)

SD, standard deviation; *BMI*, body mass index; *MHI*, median household income.

* Values are expressed as mean ± SD (minimum-maximum)

† Values are expressed as number (percentage).

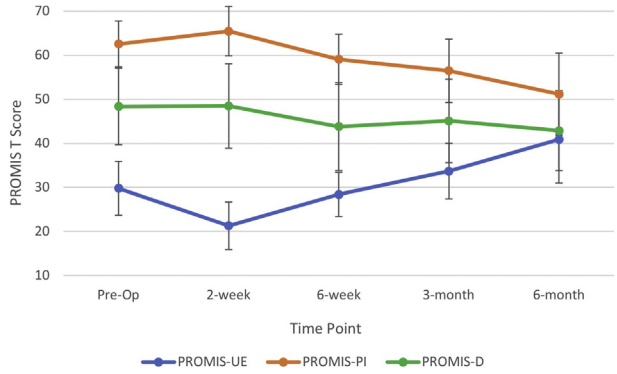

Figure 1 Patient-Reported Outcomes Measurement Information System (PROMIS) scores change over time (mean ± standard error of the mean). Patients show improvement in all 3 health domains after rotator cuff repair. *UE*, upper extremity; *PI*, pain interference; *D*, depression.

service for secure survey collection (REDCap, Nashville, TN, USA).[8]

In addition, preoperative magnetic resonance imaging and ultrasounds were retrospectively reviewed for each patient for tear size and tendons involved. All tears were characterized by their greatest width in the anterior-posterior direction, with those less than 1.0 cm designated as small, between 1.0 cm and 3.0 cm designated as medium, and tears greater than 3 cm designated as large. Operative notes were also reviewed to determine management of the long head of the biceps tendon. These interventions included biceps tenodesis, biceps tenotomy, or no significant intervention. Patient-centric factors including age, gender, race, employment status, body mass index, tobacco use, and estimated median household income (MHI) were retrospectively collected from electronic medical records. Using a previously published methodology, each patient was assigned an estimated MHI value. A patients' zip code of residence and a United States Census Bureau website for MHI estimations (https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk) were used to collect this value.[6]

Statistical analysis

The primary outcome of interest in this study was the responsiveness of PROMIS scores at the 6-month follow-up time point. Analysis of variance with Post Hoc Least Significant Difference was used to determine significant levels of difference of PROMIS-UE, PROMIS-PI, or PROMIS-D between preoperative score and postoperative scores. General Linear Model Univariate analysis was used to determine significant levels of difference of PROMIS-UE, PROMIS-PI, or PROMIS-D between time points, tear sizes, tendon management, and patient-reported demographics. Pearson and Spearman's tests were used to identify correlation between PROMIS scores and tear size. Principal component analysis (Rotation Method: Varimax rotation with Kaiser Normalization) was performed to determine which factor could predict the improvement of upper arm function, pain interference, and depression PROMIS domain scores. All analyses were performed using SPSS software (Version 25; IBM, Armonk, NY, USA), and a P value smaller than .05 was considered statistically significant.

Results

In total, 101 patients were included in this study. A total of 14 additional patients were excluded as they were lost to follow-up. The average age was 59.8 years, which included 51% males. Complete demographic and rotator cuff tear characteristics can be found in Table I.

Baseline PROMIS CAT scores were 29.8 ± 6.1, 62.6 ± 5.2, and 48.4 ± 8.7 for PROMIS-UE, PROMIS-PI, and PROMIS-D, respectively. At follow-up, all these scores significantly improved to 40.9 ± 9.9, 51.2 ± 9.3, and 42.9 ± 9.1, respectively ($P < .001$ for all) (Fig. 1; Table II). Compared with female patients, male patients presented with higher PROMIS-UE scores ($P < .001$). Male patients also exhibited lower PROMIS-PI scores than the female group ($P < .001$). PROMIS-D scores were not statistically different between genders ($P = .918$). Comparison of PROMIS subdomains between races revealed that white patients had significantly higher PROMIS-UE and lower PROMIS-PI scores than black/African American patients ($P < .001$). PROMIS-D scores were not statistically different between these 2 races ($P = .479$).

Factor analysis demonstrated that postoperative improvement of upper limb function was correlated with improvement of PROMS-PI and PROMIS-D scores ($P < .001$ for both). Improvement of PROMIS-PI was significantly correlated with the race of the patient ($P = .041$). Improvement of PROMIS-D was significantly correlated with improvement in the PROMIS-PI domain, as well as

Table II Multiple comparisons of PROMIS scores between preoperative and postoperative time points

Time points	PROMIS-UE	*P* value	PROMIS-PI	*P* value	PROMIS-D	*P* value
Preoperative	29.8 ± 6.1		62.6 ± 5.2		48.4 ± 8.7	
2 weeks	21.3 ± 5.4	**.000**	65.5 ±5.6	**.028**	48.5 ± 9.6	.933
6 weeks	28.4 ± 5.0	.263	59.1 ± 5.7	**.003**	43.8 ± 10.0	**.003**
3 mo	33.7 ± 6.3	**.001**	56.5 ± 7.2	**.000**	45.1 ± 9.5	**.027**
6 mo	40.9 ± 9.9	**.000**	51.2 ± 9.3	**.000**	42.9 ± 9.1	**.000**

PROMIS, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity; *PI*, pain interference; *D*, depression.
Bold values are statistically significant.

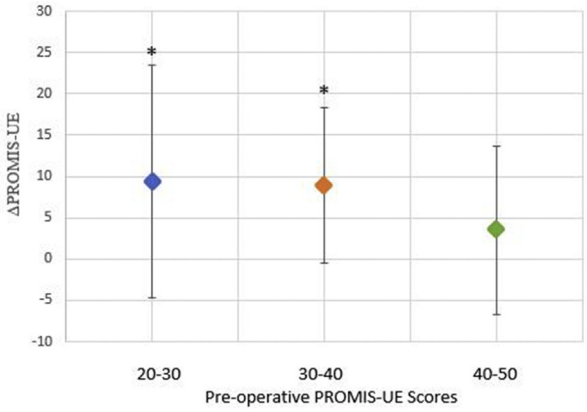

Figure 2 Change in Patient-Reported Outcomes Measurement Information System-upper extremity (PROMIS-UE) scores when compared with preoperative PROMIS-UE score. Bars marked with an * denote statistical significance ($P < .05$).

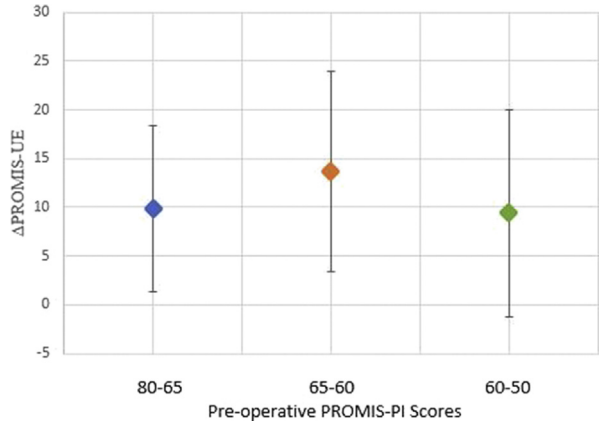

Figure 3 Change in Patient-Reported Outcomes Measurement Information System-upper extremity (PROMIS-UE) scores when compared with preoperative pain interference (PROMIS-PI) score.

with increased age and tear size ($P < .001$, $P = .032$, and $P = .073$, respectively). Figs. 2 and 3 depict the changes seen in postoperative PROMIS-UE scores based on preoperative PROMIS-UE and PROMIS-PI scores, respectively. When assessing the correlation of preoperative PROMIS domains against one another, we found that PROMIS-UE and PROMIS-PI exhibited moderate correlation with each other ($R^2 = -0.511$, $P < .001$). Significant correlation, although weak, was also found between PROMIS-PI and PROMIS-D ($R^2 = 0.377$, $P = .001$). No significant correlation was found between PROMIS-UE and PROMIS-D ($R^2 = -0.196$, $P = .08$) (Table III). We found that postoperative PROMIS domains PROMIS-UE and PROMIS-PI exhibited strong correlation with one another ($R^2 = -0.701$, $P < .000$). We also found moderate correlations between PROMIS-UE and PROMIS-D ($R^2 = -0.431$, $P < .001$), as well as PROMIS-PI and PROMIS-D ($R^2 = 0.549$, $P < .001$) (Table III).

Discussion

The results of this study indicate that PROMIS CAT domains are responsive in patients undergoing rotator cuff repair. Statistically significant improvements in PROMIS-UE, PROMIS-PI, and PROMIS-D were observed 6 months postoperatively.

Cross-sectional studies of PROMIS CAT assessments have demonstrated validity and efficiency in patients with upper extremity pathology.[7,9,11,15] In addition, the recently validated upper extremity physical function assessment has demonstrated improved sensitivity in patients with upper extremity disorder. However, in order to justify widespread use of PROMIS-UE in patients with rotator cuff tears, responsiveness—or change in outcome scores over time—must be demonstrated in a surgical cohort. The results of this study confirm our hypothesis that all 3 PROMIS CAT domains of PROMIS-UE, PROMIS-PI, and PROMIS-D demonstrate responsiveness after surgery. The major strength of this study is that, unlike other recent studies, we follow a single-patient cohort with preoperative and postoperative assessments. Prior studies, which were cross-sectional in nature only, observe these patient cohorts at a single time point and are unable to assess PROMIS CAT score changes over time. In our study, PROMIS CAT scores improve from 29.8 to 40.9 for PROMIS-UE, 62.6 to 51.2 for PROMIS-PI, and 48.4 to 42.9 for PROMIS-D between preoperative and postoperative time points.

Our study shows extensive correlations between PROMIS CAT forms both preoperatively and postoperatively. Postoperative domain correlations were much stronger, hinting at a relationship between functional recovery, mitigation of pain, and mental health status. Studies performed by Wylie et al[17] previously demonstrated that depression and anxiety are correlated with pain and physical dysfunction in patients with rotator cuff pathology. Ayers et al[2] demonstrated the profound impact that

Table III Correlation of PROMIS domains

Domain	R^2	*P* value	Correlation strength
Preoperative			
PROMIS-UE and PI	−0.511	**.000**	Moderate
PROMIS-UE and D	−0.196	.08	None
PROMIS-PI and D	0.377	**.001**	Weak
Postoperative			
PROMIS-UE and PI	−0.701	**.000**	Strong
PROMIS-UE and D	−0.431	**.000**	Moderate
PROMIS-PI and D	0.549	**.000**	Moderate

PROMIS, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity; *PI*, pain interference; *D*, depression.
Bold values are statistically significant.

emotional health has on functional outcomes in patients undergoing orthopedic surgery. Our study found that as patients progress through their postoperative course, PROMIS-UE and PROMIS-D scores exhibit a negative correlation. This result echoes the results of the cohort study performed by Chen et al[4] investigating PROMIS scores and postoperative outcomes after primary anterior cruciate ligament reconstruction. Cho et al[5] discussed the negative effect that anxiety and depression have on a patient's ability to self-assess pain, physical disability, and quality of life when scheduled to undergo elective rotator cuff repair. The decreased PROMIS-D scores after surgery in our study suggest that rotator cuff repair leads to a reduction in the depressive symptoms addressed on the PROMIS platform in patients with rotator cuff pathology to a degree that can be reflected in their PROMIS scores. Furthermore, improvements in both the PROMIS-PI and PROMIS-D domains were correlated with improvements in PROMIS-UE, suggesting a multifaceted mechanism in functional recovery after rotator cuff repair.

This study is not without limitations. All patients in this study are from a metropolitan area and were able to communicate in English. Therefore, results may not be generalizable to other geographies or patient populations. However, a wide range of MHIs were included, thereby demonstrating diverse socioeconomic status in our patient population. An additional limitation of this study is the lack of assessment of cognitive ability and/or computer abilities in our patient cohort. Finally, PROMIS CAT scores were not correlated to other legacy PROM, such as American Shoulder and Elbow Surgeons, Disabilities of the Arm, Shoulder and Hand, and Simple Shoulder Test scores. However, numerous studies have already validated PROMIS-UE as a PROM in this patient cohort.[16]

Conclusion

PROMIS CAT domains of PROMIS-UE, PROMIS-PI, and PROMIS-D demonstrated responsiveness and significant improvements in patients undergoing rotator cuff repair. Neither rotator cuff tear size nor biceps involvement was found to impact PROMIS CAT scores. Because of the ease and efficiency of administering these assessments, clinicians should consider adapting patient-reported outcome practices to include PROMIS CAT.

Disclaimer

Stephanie Muh is a paid consultant for DePuy, a Johnson & Johnson company, and Exactech, Inc. Eric C. Makhni is a paid consultant for Smith & Nephew and receives publishing royalties, financial or material support from Springer. All the other authors, their immediate family, and any research foundation, with which they are affiliated, did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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