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Many patients fail to achieve MCID for PROMIS upper extremity and pain interference following nonoperative management of rotator cuff tears

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Background: Efficacy of nonoperative treatment for rotator cuff tears has been debated, especially for full-thickness tears. The purpose of this study was to a) define the minimal clinically important difference (MCID) of nonoperative treatment with regard to Patient-Reported Outcomes Measurement Information System (PROMIS) pain interference (PI) and upper extremity (UE), and b) determine the proportion of patients with both partial and full-thickness tears (PTRCT, FTRCT) who achieve this improvement following initial nonoperative treatment. We hypothesized that >75% of PTRCT and FTRTC patients would achieve MCID for PROMIS PI and UE.

Methods: We performed a retrospective cohort study evaluating nonoperatively managed patients with image-confirmed PTRCT and FTRCT. Treatment modalities and follow-up PROMIS scores at least 6 months after their initial visit were recorded. Using a distribution technique, MCID was calculated.

Results: A total of 111 FTRCT and 68 PTRCT patients were included with at least 6 months of follow-up. At 6 months from initial presentation, the MCID for PROMIS UE was 3.75 and 3.95 for FTRCT and PTRCT patients, respectively. For PROMIS PI, the MCID was 3.35 and 3.90 for FTRCT and PTRCT, respectively. In total, 41% of FTRCT and 41% of PTRCT achieved MCID for PROMIS UE. Thirty-four percent of FTRCT and 35% of PTRCT achieved MCID for PROMIS PI.

Conclusion: The majority of patients undergoing nonoperative treatment for supraspinatus/infraspinatus rotator cuff tears did not achieve MCID at 6 months for PROMIS PI (34% for FTRCT and 35% for PTRCT) or UE (41% for FTRCT and 41% for PTRCT).

Rotator cuff tears (RCTs) are among the most common causes of shoulder pain in adults, affecting two to four million individuals in the United States per year.[16,31] These injuries may lead to significant pain and disability with impaired activities of daily living, sleep, work, and exercise.[19] A variety of variables contribute to the shared decision-making in deciding on whether to undergo surgery, such as pain, degree of dysfunction and disability, tear extent, age, activity level, and health comorbidities.[1,5,22,24,26,29] For those hoping to avoid surgery, patients are often prescribed a course of anti-inflammatories, physical therapy, home exercise programs, and even receive corticosteroid injections to achieve pain relief.

Variable success of nonoperative treatment for RCTs has been reported in prior literature.[2,17,18,34,35] In a systematic review of 57 randomized controlled trials investigating RCTs, Khatri et al reported rapid improvement over 12 months in Constant Scores regardless of treatment, operative, or nonoperative.[18] Song et al compared time to improvement in nonoperative and operative treatment of RCTs in a multicenter cohort study.[34] Their group observed that the probability to achieve minimal clinically important difference (MCID) for Shoulder Pain and Disability Index was 0.40 (95% confidence interval, 0.29-0.50) for nonoperative compared to 0.06 (95% confidence interval, 0.00-0.12) for surgical treatment at approximately 3 months postintervention. They found similar results using the American Shoulder and Elbow Surgeons (ASES) metric at 3 months, as well. However, when evaluating the same cohort at approximately 1 and 2 years, surgical management was favored in achieving MCID. Alternately, Moosmayer et al evaluated 51 patients undergoing nonoperative treatment and 52 patients undergoing operative treatment for RCTs and found that at 6 and 12 months, the surgical group performed better in terms of Constant and ASES scores.[23] In collection, these studies examine a variety of patient-reported outcome (PRO) tools and ultimately

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provide little consensus on which patients benefit from nonoperative treatment in terms of patient demographics, tear characteristics, and temporal relationship of symptomology.

Due to the heterogeneity in legacy PROs,[21] the National Institute of Health introduced the Patient-Reported Outcomes Measurement Information System (PROMIS) in an attempt to standardize the way that clinicians evaluate patient outcomes.[27,37] Many studies have established PROMIS as a reliable and effective assessment in measuring outcomes in patients with RCTs,[3] allowing physicians to evaluate upper extremity (UE) physical function, pain interference (PI), and mental health.[7] Currently, the literature is unclear about which patients would benefit from nonoperative management of RCTs and what is defined as a successful outcome. At this time, there are no studies that have established MCID for PROMIS nonoperative management of RCTs. Therefore, the purpose of this study was to a) define the MCID of nonoperative treatment with regard to PROMIS PI and UE and b) determine the proportion of patients with both partial and full-thickness supraspinatus/infraspinatus tears who achieve this improvement following initial nonoperative treatment. We hypothesized that >75% of PTRCT and FTRTC patients would achieve MCID for PROMIS PI and UE.

Methods

A retrospective cohort study was performed on patients from 1/2/2020 to 3/24/2021 with ultrasound (US) or magnetic resonance imaging (MRI) confirmed partial or full-thickness supraspinatus and infraspinatus RCTs who were treated nonoperatively at a high volume integrated healthcare system. Adult patients >18 years old were included if treatments included rest, activity modification, physical therapy, and/or corticosteroid injection for their condition. Patients were excluded if any point during the study period they underwent surgery for their RCT or had the presence of a subscapularis tear. Patients were identified by electronic medical record search for International Classification of Diseases (ICD)-10 diagnosis codes of M75.100, M75.101, M75.110, M75.111, M75.112, M75.120, M75.121, and M75.122. This search was for patients who had imaging documenting full-thickness or partial-thickness tear by US or MRI, which has shown similar accuracy between modalities.[12,25] Full-thickness tear size was also assessed via US or MRI and categorized using the following grading system: small (<1 cm), medium (1-2.9 cm), large (3-4.9 cm), and massive (>5 cm).[9,33] In the event that a patient had 2 torn tendons, one partial-thickness and one full-thickness, they were placed in the full-thickness tear group.

At our institution, all patients routinely complete PROMIS assessments at all clinical visits, regardless of having surgery. In patients with shoulder complaints, these consist of the PROMIS Upper Extremity Computer Adaptive Test (CAT) v2.0 (“PROMIS UE”) and the PROMIS Pain Interference CAT v1.1 (“PROMIS PI”). All PROMIS domains are designed to follow a normal distribution with a mean T score of 50 and a standard deviation (SD) of 10.[15] PROMIS scores were recorded if they were at least 6 weeks after the initial visit.

Statistical analysis

MCID was determined using a distribution-based method.[11] The MCID was determined to be the minimum change in PROMIS scores that corresponded to a SD of 0.5. This value is used as 0.5 SD represents the limit of human mental discriminative capacity and corresponds to MCID in a number of different studies.[28] Paired sample *t*-tests were used to assess significant differences between baseline and 6 months follow-up achievement of MCID for PROMIS scores in the FTRCT and PTRCT cohorts. Pearson chi-square and independent samples *t*-tests were utilized to analyze any significant differences in the achievement of MCID based on patient demographic, clinical, or treatment characteristics. Chi-square tests were used to compare MCID achievement between PTRCT and FTRCT patients for both PROMIS UE and PROMIS PI. All analyses used a significance level of 5%. SPSS software was used for all statistical analyses (IBM SPSS Statistics for Windows Version 27.0; IBM Corp., Armonk, NY, USA). A univariate logistic regression model was created to assess for predictors of achieving MCID including baseline PROMIS scores, age, body mass index, employment, smoking status, sex, race, and treatment type.

Table I
Patient demographics of combined cohort.

Characteristics	Mean or N (%)	SD
Age	61.14	12.23
Sex		
Male	69 (39.9)	
Female	104 (60.1)	
Smoking status		
Never	103 (59.9)	
Former	52 (30.2)	
Current	15 (8.7)	
Unknown	2 (1.2)	
Race		
White/Caucasian	90 (53.3)	
Black/African American	68 (40.2)	
Asian	8 (4.7)	
Arab American	1 (0.06)	
Other	2 (1.2)	
Employment		
Employed	84 (48.3)	
Retired	29 (16.7)	
Unemployed	16 (9.2)	
Unknown	45 (25.9)	
Follow-up (days)	152.12	125.03
Tear type		
Full-thickness	111 (62.0)	
Partial-thickness	68 (38.0)	
Tear size		
Small (<1.0 cm)	10 (9.3)	
Medium (1.0-2.9 cm)	75 (69.4)	
Large (3.0-4.9 cm)	3 (2.8)	
Massive (>5.0 cm)	20 (18.5)	
Supraspinatus involvement		
Complete tear	108 (60.3)	
Partial tear	65 (36.3)	
No supraspinatus involvement	6 (3.4)	
Infraspinatus involvement		
Complete tear	20 (11.2)	
Partial tear	26 (14.5)	
No infraspinatus involvement	133 (74.3)	
Treatment		
Physical therapy	99 (55.6)	
Physical therapy + steroid injection	3 (1.7)	
Steroid injection	67 (37.6)	
Steroid injection + opioids	1 (.01)	
Opioids	8 (4.5)	
Body mass index	31.19	6.53

SD, standard deviation.

Results

In total, 311 patients met the inclusion criteria, and 179 (58%) completed surveys up to 24 weeks and were included in the final analysis. The average age of the combined full-thickness and partial-thickness tear cohorts was 61.14 ± 12.23 years. There were 69 males (39.9%) and 104 females (60.1%). Of the 179 patients, 10 (9.3%) had small tears, 75 (69.4%) had medium tears, 3 (2.8%) had large tears, and 20 (18.5%) had massive tears. The mean follow-up days from pretreatment to post-treatment were 152.12 ± 125.03 (Table I).

Table II
Summary of baseline and follow-up score.

Statistic	Baseline score	Follow-up score	*P* value
Combined			
PROMIS UE v2.0 (n = 158)			
Mean (SD)	31.4 (7.7)	34.4 (9.6)	<.01
Median (IQR)	31.0 (26.5-36.0)	33.0 (28.0-40.0)	-
Range	15.0-61.0	15.0-64.0	-
PROMIS PI CAT v2.0 (n = 173)			
Mean (SD)	62.5 (7.1)	60.5 (7.7)	<.01
Median (IQR)	63.0 (59.0-67.0)	62.0 (56.0-66.0)	-
Range	26.0-79.0	34.0-80.0	-
Full-thickness tear			
PROMIS UE v2.0 (n = 95)			
Mean (SD)	30.8 (7.5)	33.6 (9.8)	<.01
Median (IQR)	30.0 (26.0-35.0)	32.0 (27.0-37.0)	-
Range	15.0-53.0	15.0-64.0	-
PROMIS PI CAT v2.0 (n = 107)			
Mean (SD)	62.9 (6.7)	60.9 (7.9)	<.01
Median (IQR)	63.0 (59.0-67.0)	62.0 (56.0-66.3)	-
Range	41.0-79.0	34.0-80.0	-
Partial-thickness tear			
PROMIS UE v2.0 (n = 63)			
Mean (SD)	32.5 (7.9)	35.6 (9.3)	<.01
Median (IQR)	32.0 (27.0-37.5)	35.5 (28.3-40.8)	-
Range	15.0-61.0	19.0-61.0	-
PROMIS PI CAT v2.0 (n = 66)			
Mean (SD)	62.2 (7.8)	60.7 (8.0)	<.01
Median (IQR)	62.0 (58.0-65.0)	61.0 (54.0-65.0)	-
Range	26.0-76.0	39.0-78.0	-

IQR, interquartile range; *PI*, pain interference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *SD*, standard deviation; *UE*, upper extremity.

Baseline to final follow-up scores at 24 weeks were compared (Table II). When looking at combined tear types, the overall group demonstrated significant improvements in PROMIS UE (31.4 [7.7]-34.4 [9.6]) from baseline to final scores, respectively, and PROMIS PI (62.5 [7.1]-60.5 [7.7]). When stratifying by tear type, the full-thickness tear group also demonstrated significant score improvements for PROMIS UE (30.8 [7.5]-33.6 [9.8]) and PI (62.9 [6.7]-60.9 [7.9]). Partial thickness tear also reported significant improvements for UE (32.5 [7.9]-35.6 [9.3]) and PI (62.2 [7.8]-60.7 [8.0]).

The greatest change from baseline to follow-up was seen in the PTRCT PROMIS UE group with a change of 3.1 ($P < .01$). The FTRCT group showed improvement for PROMIS UE from 30.8 to 33.6 ($P < .01$). For PROMIS PI, the FTRCT group improved from a baseline score of 62.9 to 60.9 ($P < .01$) and the PTRCT group showed the smallest change from baseline, improving from 62.2 to 60.7 ($P < .01$).

We then calculated the MCID by using a distribution method. The MCID for PROMIS UE was determined to be 3.99, 3.75, and 3.95 for combined, FTRCT, and PTRCT, respectively. For PROMIS PI, MCID was determined to be 3.54, 3.35, and 3.90 for combined, FTRCT, and PTRCT, respectively. In total, 41% of FTRCT and 41% of PTRCT achieved MCID for PROMIS UE, while 34% of FTRCT and 35% of PTRCT achieved MCID for PROMIS PI. When comparing PROMIS UE scores between FTRCT and PTRCT patients, there were no statistically significant differences in achievement of MCID for PROMIS UE ($P = .98$) or for PROMIS PI ($P = .31$) (Table III). Stratification of FTRCT by tear size showed that 28% of patients with small and medium tears achieved MCID for PROMIS UE compared to only 14% of patients with large and massive tears ($P = .21$). For PROMIS PI, 27% of patients with small and medium tear patients achieved MCID compared to only 9% of patients with large and massive tears ($P = .08$).

Univariate analysis found that higher baseline PROMIS UE score was associated with lower likelihood of achieving MCID for PROMIS UE in FTRCT and PTRCT (odds ratio [OR] = 0.93, 0.87-0.99, $P = .046$ and OR = 0.91, 0.83-0.99, $P = .04$, respectively) (Tables IV and V). Patients with PTRCT who had higher baseline PROMIS PI scores were more likely to achieve MCID for PROMIS PI (OR = 1.13, 1.02-1.24, $P = .015$) (Table VII). Additionally, it was found that patients with FTRCT who were Asian were more likely to achieve MCID for PROMIS-UE at 6 months (OR = 25.33, 2.41-266.80, $P = .01$) (Table IV). There were otherwise no statistically significant predictors in achieving MCID for PROMIS UE or PI for FTRCT or PTRCT (Tables IV-VII).

Table III
Distribution-based MCID achievement for PROMIS measures at 6 months.

Statistic	MCID value	# Achieved MCID	% Achieved MCID
Combined			
PROMIS UE (n = 158)	3.99	65	41
PROMIS PI (n = 173)	3.54	59	34
Full-thickness tear			
PROMIS UE (n = 95)	3.75	39	41
PROMIS PI (n = 107)	3.35	36	34
Partial-thickness tear			
PROMIS UE (n = 63)	3.95	26	41
PROMIS PI (n = 66)	3.90	23	35
Full-thickness tear stratification by size			
Small/Medium tear			
PROMIS UE (n = 72)	3.82	20	28
PROMIS PI (n = 82)	3.27	22	27
Large/Massive tear			
PROMIS UE (n = 21)	3.47	3	14
PROMIS PI (n = 22)	3.65	2	9

MCID, minimal clinically important difference; *PI*, pain interference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity.

Discussion

The present study established the MCID for PROMIS UE (3.99) and PI (3.54) for patients who had successfully avoided surgery and continued with nonoperative treatment of supraspinatus/

Table IV
Pretreatment predictors in achievement of MCID with PROMIS UE at 6 months after treatment for full-thickness rotator cuff tear patients.

Covariate	Level	Odds ratio (95% CI)	OR *P* value
Pretreatment PROMIS UE		0.93 (0.87-0.99)	.046
Pretreatment PROMIS PI		1.08 (0.99-1.16)	.06
Age		0.97 (0.92-1.02)	.18
Body mass index		0.98 (0.89-1.07)	.59
Employment	Retired	0.68 (0.21-2.26)	.53
	Unemployed	0.46 (0.05-4.21)	.49
	Employed	-	-
Smoking status	Current	0.00 (0.00)	.99
	Former	0.75 (0.26-2.19)	.60
	Never	-	-
Sex	Female	0.96 (0.35-2.62)	.94
	Male	-	-
Race	Black	2.40 (0.795-7.26)	.12
	Asian	25.33 (2.41-266.80)	.007
	Arab American	0.00 (0.00)	.99
	White	-	-
Tear size	Large or massive	0.43 (0.12-1.63)	.217
	Small or medium	-	-
Treatment	Opioids	0.00 (0.00)	.99
	Physical therapy + steroid injection	1.89 (0.11-32.01)	.67
	Physical therapy	-	-

CI, confidence interval; *MCID*, minimal clinically important difference; *PI*, pain interference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity.

Table V
Pretreatment predictors in achievement of MCID with PROMIS UE at 6 months after treatment for partial-thickness rotator cuff tears.

Covariate	Level	Odds ratio (95% CI)	OR *P* value
Preoperative PROMIS UE		0.91 (0.83-0.99)	.036
Preoperative PROMIS PI		1.08 (0.97-1.19)	.16
Age		0.98 (0.94-1.03)	.45
Body mass index		0.94 (0.83-1.06)	.29
Employment	Retired	0.00 (0.00)	.99
	Unemployed	0.00 (0.00)	.99
	Unknown	2.76 (0.82-9.33)	.10
	Employed	-	-
Smoking status	Current	1.34 (0.28-6.43)	.72
	Former	0.67 (0.15-2.94)	.60
	Never	-	-
Sex	Female	1.76 (0.52-5.94)	.36
	Male	-	-
Race	Black	0.53 (0.14-1.98)	.35
	Asian	1.2 (0.09-14.78)	.89
	White	-	-
Treatment	Steroid injections	1.03 (0.31-3.45)	.97
	Opioids	3.25 (0.18-58.06)	.42
	Physical therapy	-	-

CI, confidence interval; *MCID*, minimal clinically important difference; *PI*, pain interference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity.

infraspinatus RCTs. While the majority of patients were able to make improvements in PROMIS UE and PI measures, less than half of patients achieved MCID for PROMIS UE (41% for FTRCT, 41% for PTRCT) and pain (34% for FTRCT, 35% for PTRCT). There was no statistically significant difference in the achievement of MCID between FTRCT and PTRCT for pain or UE physical function. These results highlight that there remains a significant proportion of patients not achieving MCID for PROMIS UE and PI for those avoiding surgery with nonoperative management of RCTs.

Monitoring clinical progress with PROs provides another objective measure to assess if patients are making reasonable improvements from nonoperative management of RCTs. Goldberg et al performed a retrospective study and evaluated patients undergoing nonoperative treatment of RCTs using the Simple Shoulder Test (SST), a series of 12 questions that evaluates the function of the involved shoulder. Their group found that 59% of patients experienced significant improvement at 2.5 ± 1.6 years, defined as an increased score on SST.[13] They also found that 30% of patients experienced worsened symptoms (decreased SST score) and 11% of patients remained unchanged after nonoperative management. Bokor et al evaluated outcomes of nonoperative management using the shoulder chart by the ASES and the physical examination to calculate the University of California Los Angeles (UCLA) scores pretreatment and post-treatment.[4] They found that 34 out of 53 patients (74%) had slight or no discomfort after nonoperative treatment, suggesting that the majority of patients tolerated nonoperative treatment well without complications or requiring surgery. Although these studies did not examine MCID, our study found a lower proportion, 34%-41% reaching MCID for PROMIS UE and PI, of patients demonstrating success of nonoperative treatment compared to both Goldberg and Bokor et al. While these studies report on the success of nonoperative treatment of RCT based on PRO surveys, the clinical significance of these surveys is limited.

Of the current studies available that looked to establish percent achievement of MCID with nonoperative treatment, most groups focused on full-thickness RCTs and used a myriad of PROs such as the Oxford Shoulder Score, Subjective Shoulder Value, Constant, ASES and the Visual Analog Scale (VAS) scoring systems to evaluate outcomes.[8,10,14,38,39] Shepet et al synthesized the therapy protocols and outcomes of nonoperative management of massive, irreparable RCTs.[32] Their group found considerable variability in MCID achievement between 10 studies, ranging from 32% to 96% for Oxford Shoulder Score, Subjective Shoulder Value, Constant Score, ASES, and VAS scores. However, these results are limited to only massive, irreparable tears. Additionally, Tashjian et al examined 81 patients undergoing nonoperative management of RCTs and found that 56% reached MCID (1.4 cm) for VAS after 6 weeks of nonoperative treatment and that older patients and nondominant shoulders necessitated larger changes in VAS to reach MCID.[35] In contrast to Tashjian et al, our study found a much lower proportion of only 34%-41% of patients reaching MCID for nonoperative treatment of RCTs. Their study, however, was significantly limited by lacking stratification by tear characteristics, only collecting VAS scores, and monitoring only after 6 weeks of nonoperative treatment. To date, very few studies have specifically examined the role of patient and tear characteristics and no studies have investigated

Table VI
Pretreatment predictors in achievement of MCID with PROMIS PI at 6 months after treatment for full-thickness rotator cuff tear patients.

Covariate	Level	Odds ratio (95% CI)	OR *P* value
Pretreatment PROMIS UE		1.03 (0.97-2.00)	.38
Pretreatment PROMIS PI		1.07 (0.99-1.15)	.07
Age		1.01 (0.97-1.06)	.56
Body mass index		1.03 (0.95-1.12)	.48
Employment	Retired	0.64 (0.18-2.27)	.49
	Unemployed	0.80 (0.15-4.32)	.79
	Unknown	1.19 (0.38-3.80)	.77
	Employed	-	-
Smoking status	Current	0.00 (0.00)	.99
	Former	0.83 (0.30-2.26)	.71
	Never	-	-
Sex	Female	1.21 (0.46-3.19)	.70
	Male	-	-
Race	Black	1.017 (0.38-2.74)	.97
	Asian	3.73 (0.47-29.53)	.21
	White	-	-
Tear size	Large or massive	0.27 (0.06-1.26)	.097
	Small or medium	-	-
Treatment	Steroid injections	0.46 (0.16-1.28)	.14
	Opioids	0.00 (0.00)	.99
	Physical therapy + steroid injections	2.44 (0.15-41.23)	.54
	Physical therapy	-	-

CI, confidence interval; *MCID*, minimal clinically important difference; *PI*, pain interference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity.

Table VII
Pretreatment predictors in achievement of MCID with PROMIS PI at 6 months after treatment for partial-thickness rotator cuff tear patients.

Covariate	Level	Odds ratio (95% CI)	OR *P* value
Pretreatment PROMIS UE		0.98 (0.91-1.05)	.57
Pretreatment PROMIS PI		1.13 (1.02-1.24)	.015
Age		1.00 (0.96-1.04)	.96
Body mass index		0.97 (0.89-1.07)	.55
Employment	Retired	0.00 (0.00)	.99
	Unemployed	1.52 (0.22-10.38)	.67
	Employed	-	-
Smoking status	Current	1.03 (0.22-4.80)	.97
	Former	0.92 (0.26-3.28)	.90
	Unknown	2.40 (0.14-42.26)	.55
	Never	-	-
Sex	Female	0.81 (0.28-2.36)	.71
	Male	-	-
Race	Black	0.80 (0.25-2.59)	.71
	Asian	4.55 (0.37-55.54)	.24
	White	-	-
Treatment	Steroid injections	1.50 (0.51-4.42)	.46
	Opioids	0.00 (0.00)	.99
	Physical therapy	-	-

CI, confidence interval; *MCID*, minimal clinically important difference; *PI*, pain interference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, upper extremity.

PROMIS scores and achieving clinically meaningful results for nonoperatively treated RCTs after 6 months.

When directly comparing nonoperative treatment to surgical management of RCTs, the available literature remains inconclusive. Piper et al conducted a systematic review to evaluate nonoperative vs. operative treatments of FTRCT and found a statistically significant difference favoring surgery in both Constant and VAS scores at 12 months.[30] Brindisino et al similarly found in 6 trials that surgery had greater improvements in pain (VAS) and function (Constant Scores) at 6, 12, and 24 months, although did not reach MCID.[6] In Song et al's multicenter cohort study, their group found that nonoperative management had a statistically significant greater proportion of patients achieving MCID at 3.3 months compared to the operative management group.[34] Interestingly, they also found that when looking at the achievement of MCID at 15.5 months and 24.7 months that the surgical outperformed nonsurgical groups. These aforementioned studies suggest there may be some benefit to surgery compared to nonoperative management but fail to achieve MCID and demonstrate convincing evidence of the superiority of operative treatment.

Interestingly, previous work by Tramer et al highlighted that 2 years after arthroscopic rotator cuff repair, 81% and 65% of patients achieve MCID for PROMIS UE and PI, respectively.[36] In contrast, our study only found 34%-41% success in achieving MCID for nonoperative treatment for these same PROMIS UE and PI outcomes. Relative to the success of surgery, as defined by reaching MCID, a large proportion of patients in our study are failing to meet these metrics. These findings call to question whether we are properly indicating patients for nonsurgical management or if these PROs are adequately capturing and defining success in the setting of nonoperative management. The present study is unfortunately unable to make conclusions beyond 6 months of nonoperative management or directly compare to surgical treatment. However, this study uniquely leverages real-world evidence by examining patients in their natural state without research interventions, therefore eliminating any potential Hawthorne effect. To our knowledge, this is the first study to examine rates of achieving MCID from PROMIS surveys for nonoperatively managed RCTs.

There are a number of limitations in this study. The completion rates for PROMIS surveys were 73% for PI and 66% for UE physical function, which introduces a potential nonresponse bias.[20] This lack of compliance additionally limits follow-up beyond 6 months for this study. It is possible that patients involved in this study received surgery beyond the time of chart review of 6 months or may have undergone surgery at another institution. Patients were excluded if they failed nonoperative treatment and had surgery, which isolates the present cohort to patients who were more likely successful with nonoperative management and may skew the overall results. However, the goal of this study was to specifically assess the proportion of patients reaching MCID in a cohort of patients undergoing nonoperative management over a 6-month period. The goal of this study was not intended to compare the MCID between operative and nonoperative patients, which is an area of interest for future studies. Additionally, patients received a spectrum of nonoperative treatment modalities, leading to a lack

of standardization in treatments that may introduce heterogeneity in the results. Similarly, a variety of physical therapy locations and providers existed, leading to varying quality of care and outcomes. For the administration of PROMIS surveys, there was variation of the days between pretreatment and post-treatment surveys, which may influence the mean change in PROMIS scores. Similarly, while Asians were found to be more likely to achieve MCID for FTRCT PROMIS-UE, there were only 8 patients who identified as Asian, leading to significant variability, and ultimately limits conclusions based on race/ethnicity due to insufficient numbers. Finally, while we were able to stratify by tear thickness, we were unable to assess for the influence of fatty infiltration and tear size on outcomes due to the variability of patients receiving MRI vs. USs and the limited number of patients available to stratify the analysis, respectively.

Conclusion

The majority of patients undergoing nonoperative treatment for supraspinatus/infraspinatus RCTs did not achieve MCID at 6 months for PROMIS PI (34% for FTRCT and 35% for PTRCT) or UE physical function (41% for FTRCT and 41% for PTRCT).

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References

1. Baggett ND, Schulz K, Buffington A, Marka N, Hanlon BM, Zimmermann C, et al. Surgeon use of shared decision-making for older adults considering major surgery: a secondary analysis of a randomized clinical trial. JAMA Surg 2022;157:406-13. https://doi.org/10.1001/jamasurg.2022.0290.
2. Bartolozzi A, Andreychik D, Ahmad S. Determinants of outcome in the treatment of rotator cuff disease. Clin Orthop Relat Res 1994;308:90-7.
3. Beckmann JT, Hung M, Bounsanga J, Wylie JD, Granger EK, Tashjian RZ. Psychometric evaluation of the PROMIS physical function computerized adaptive test in comparison to the American shoulder and Elbow Surgeons score and simple shoulder test in patients with rotator cuff disease. J Shoulder Elbow Surg 2015;24:1961-7. https://doi.org/10.1016/j.jse.2015.06.025.
4. Bokor DJ, Hawkins RJ, Huckell GH, Angelo RL, Schickendantz MS. Results of nonoperative management of full-thickness tears of the rotator cuff. Clin Orthop Relat Res 1993;294:103-10.
5. Boss EF, Mehta N, Nagarajan N, Links A, Benke JR, Berger Z, et al. Shared decision making and choice for elective surgical care: a systematic review. Otolaryngol Head Neck Surg 2016;154:405-20. https://doi.org/10.1177/0194599815620558.
6. Brindisino F, Salomon M, Giagio S, Pastore C, Innocenti T. Rotator cuff repair vs. nonoperative treatment: a systematic review with meta-analysis. J Shoulder Elbow Surg 2021;30:2648-59. https://doi.org/10.1016/j.jse.2021.04.040.
7. Chen RE, Papuga MO, Nicandri GT, Miller RJ, Voloshin I. Preoperative patient-reported outcomes measurement information system (PROMIS) scores predict postoperative outcome in total shoulder arthroplasty patients. J Shoulder Elbow Surg 2019;28:547-54. https://doi.org/10.1016/j.jse.2018.08.040.
8. Christensen BH, Andersen KS, Rasmussen S, Andreasen EL, Nielsen LM, Jensen SL. Enhanced function and quality of life following 5 months of exercise therapy for patients with irreparable rotator cuff tears - an intervention study. BMC Musculoskelet Disord 2016;17:252. https://doi.org/10.1186/s12891-016-1116-6.
9. Cofield RH. Subscapular muscle transposition for repair of chronic rotator cuff tears. Surg Gynecol Obstet 1982;154:667-72.
10. Collin PG, Gain S, Nguyen Huu F, Lädermann A. Is rehabilitation effective in massive rotator cuff tears? Orthop Traumatol Surg Res 2015;101:S203-5. https://doi.org/10.1016/j.otsr.2015.03.001.
11. Copay AG, Subach BR, Glassman SD, Polly DW Jr, Schuler TC. Understanding the minimum clinically important difference: a review of concepts and methods. Spine J 2007;7:541-6. https://doi.org/10.1016/j.spinee.2007.01.008.
12. Farooqi AS, Lee A, Novikov D, Kelly AM, Li X, Kelly JD 4th, et al. Diagnostic accuracy of ultrasonography for rotator cuff tears: a systematic review and meta-analysis. Orthop J Sports Med 2021;9:23259671211035106. https://doi.org/10.1177/23259671211035106.
13. Goldberg BA, Nowinski RJ, Matsen FA 3rd. Outcome of nonoperative management of full-thickness rotator cuff tears. Clin Orthop Relat Res 2001;382:99-107.
14. Gutiérrez-Espinoza H, Arriagada-Núñez V, Araya-Quintanilla F, Zavala-González J, Rubio-Oyarzún D, Sfeir-Castro R, et al. Physical therapy in patients over 60 years of age with a massive and irreparable rotator cuff tear: a case series. J Phys Ther Sci 2018;30:1126-30. https://doi.org/10.1589/jpts.30.1126.
15. HeathMeasures. Promis. Available from: http://www.healthmeasures.net/score-and-interpret/interpret-scores/promis. Accessed February 1, 2023.
16. HSS. Rotator cuff tears, injuries and treatments. 2022. Accessed June 28, 2022.
17. Itoi E, Tabata S. Conservative treatment of rotator cuff tears. Clin Orthop Relat Res 1992;275:165-73.
18. Khatri C, Ahmed I, Parsons H, Smith NA, Lawrence TM, Modi CS, et al. The natural history of full-thickness rotator cuff tears in randomized controlled trials: a systematic review and meta-analysis. Am J Sports Med 2019;47:1734-43. https://doi.org/10.1177/0363546518780694.
19. Longo UG, Facchinetti G, Marchetti A, Candela V, Risi Ambrogioni L, Faldetta A, et al. Sleep disturbance and rotator cuff tears: a systematic review. Medicina (Kaunas) 2019;55:453. https://doi.org/10.3390/medicina55080453.
20. Makhni EC, Higgins JD, Hamamoto JT, Cole BJ, Romeo AA, Verma NN. Patient compliance with electronic patient reported outcomes following shoulder arthroscopy. Arthroscopy 2017;33:1940-6. https://doi.org/10.1016/j.arthro.2017.06.016.
21. Makhni EC, Steinhaus ME, Morrow ZS, Jobin CM, Verma NN, Cole BJ, et al. Outcomes assessment in rotator cuff pathology: what are we measuring? J Shoulder Elbow Surg 2015;24:2008-15. https://doi.org/10.1016/j.jse.2015.08.007.
22. de Mik SML, Stubenrouch FE, Balm R, Ubbink DT. Systematic review of shared decision-making in surgery. Br J Surg 2018;105:1721-30. https://doi.org/10.1002/bjs.11009.
23. Moosmayer S, Lund G, Seljom U, Svege I, Hennig T, Tariq R, et al. Comparison between surgery and physiotherapy in the treatment of small and medium-sized tears of the rotator cuff: a randomised controlled study of 103 patients with one-year follow-up. J Bone Joint Surg Br 2010;92:83-91. https://doi.org/10.1302/0301-620x.92b1.22609.
24. Morris RS, Ruck JM, Conca-Cheng AM, Smith TJ, Carver TW, Johnston FM. Shared decision-making in acute surgical illness: the surgeon's perspective. J Am Coll Surg 2018;226:784-95. https://doi.org/10.1016/j.jamcollsurg.2018.01.008.
25. Naqvi GA, Jadaan M, Harrington P. Accuracy of ultrasonography and magnetic resonance imaging for detection of full thickness rotator cuff tears. Int J Shoulder Surg 2009;3:94-7. https://doi.org/10.4103/0973-6042.63218.
26. Niburski K, Guadagno E, Mohtashami S, Poenaru D. Shared decision making in surgery: a scoping review of the literature. Health Expect 2020;23:1241-9. https://doi.org/10.1111/hex.13105.
27. NIH. PROMIS (patient-reported outcomes measurement information system). Available from: http://www.healthmeasures.net/promis. Accessed June 28, 2022.
28. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care 2003;41:582-92. https://doi.org/10.1097/01.Mlr.0000062554.74615.4c.
29. Oh LS, Wolf BR, Hall MP, Levy BA, Marx RG. Indications for rotator cuff repair: a systematic review. Clin Orthop Relat Res 2007;455:52-63. https://doi.org/10.1097/BLO.0b013e31802fc175.
30. Piper CC, Hughes AJ, Ma Y, Wang H, Neviaser AS. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. J Shoulder Elbow Surg 2018;27:572-6. https://doi.org/10.1016/j.jse.2017.09.032.
31. Rees JL. The pathogenesis and surgical treatment of tears of the rotator cuff. J Bone Joint Surg Br 2008;90:827-32. https://doi.org/10.1302/0301-620X.90B7.19874.
32. Shepet KH, Liechti DJ, Kuhn JE. Nonoperative treatment of chronic, massive irreparable rotator cuff tears: a systematic review with synthesis of a standardized rehabilitation protocol. J Shoulder Elbow Surg 2021;30:1431-44. https://doi.org/10.1016/j.jse.2020.11.002.
33. Singh JP. Shoulder ultrasound: what you need to know. Indian J Radiol Imaging 2012;22:284-92. https://doi.org/10.4103/0971-3026.111481.
34. Song A, DeClercq J, Ayers GD, Higgins LD, Kuhn JE, Baumgarten KM, et al. Comparative time to improvement in nonoperative and operative treatment of rotator cuff tears. J Bone Joint Surg Am 2020;102:1142-50. https://doi.org/10.2106/JBJS.19.01112.
35. Tashjian RZ, Deloach J, Porucznik CA, Powell AP. Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease. J Shoulder Elbow Surg 2009;18:927-32. https://doi.org/10.1016/j.jse.2009.03.021.

36. Tramer JS, Yedulla NR, Ziedas AC, Patel M, Franovic S, Muh SJ, et al. Risk factors for failure to achieve minimal clinically important difference and significant clinical benefit in PROMIS computer adaptive test domains in patients undergoing rotator cuff repair. J Shoulder Elbow Surg 2022;31:1416-25. https://doi.org/10.1016/j.jse.2022.01.125.
37. Wright RW, Baumgarten KM. Shoulder outcomes measures. J Am Acad Orthop Surg 2010;18:436-44. https://doi.org/10.5435/00124635-201007000-00006.
38. Yian EH, Sodl JF, Dionysian E, Schneeberger AG. Anterior deltoid reeducation for irreparable rotator cuff tears revisited. J Shoulder Elbow Surg 2017;26:1562-5. https://doi.org/10.1016/j.jse.2017.03.007.
39. Zingg PO, Jost B, Sukthankar A, Buhler M, Pfirrmann CW, Gerber C. Clinical and structural outcomes of nonoperative management of massive rotator cuff tears. J Bone Joint Surg Am 2007;89:1928-34. https://doi.org/10.2106/jbjs.F.01073.