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Correlation of Patient Reported Outcome Measurement Information System (PROMIS) with American Shoulder and Elbow Surgeon (ASES), and Constant (CS) scores in idiopathic adhesive capsulitis

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Purpose: To correlate the Patient Reported Outcomes Measurement Information System Upper Extremity (PROMIS UE) score with pre-existing validated outcome scores, American Shoulder and Elbow Surgeons score (ASES), and Constant score (CS) in patients with idiopathic adhesive capsulitis (AC).

Methods: Patients with a clinical diagnosis of idiopathic AC (''freezing'' or ''frozen'' phases) who agreed to complete the ASES, CS, and PROMIS UE scores during their office visit were included in this study. Trained researchers performed the objective clinical assessments on the included patients. Responses to the 3 outcome scores were statistically analyzed and compared using Pearson correlation coefficients. Floor and ceiling effects were calculated.

Results: The final cohort included 100 patients with AC, of whom there were 72% female and 87% right hand dominant, with a mean age of 55 years. The PROMIS UE required fewer question responses (5.02 ± 1.84) compared with the fixed question burden with ASES (12) and CS (9). The mean outcome scores were 34.6 ± 2.5 (PROMIS UE), 55 ± 22 (ASES), and 51 ± 16 (CS). The PROMIS UE displayed an excellent correlation with both the ASES ($r = 0.80$, 95% confidence interval [0.72, 0.86], $P < .001$) and CS ($r = 0.76$, 95% confidence interval [0.67, 0.83], $P < .001$). Neither ceiling nor floor effects were present.

Conclusion: The PROMIS UE displayed comparable efficacy to commonly used legacy outcome scores (ASES and CS) in AC. A lower question burden with the PROMIS UE carries potential for wider acceptability with the researchers and patients with shoulder pathology.

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

Keywords: PROMIS; ASES; Constant score; adhesive capsulitis; frozen shoulder; outcome scores

Idiopathic adhesive capsulitis (AC) or frozen shoulder in one of the most painful and debilitating shoulder conditions characterized by shoulder pain and loss of both active and passive range of motion (ROM) without a defined underlying cause.[10] Idiopathic AC occurs in approximately 2% to

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5% of the population and is more predominantly seen in women between ages 40 and 60 years. The etiology of idiopathic AC continues to be incompletely understood, but the underlying pathology appears to be consistent and includes abnormal fibrotic process affecting the glenohumeral capsule and ligaments.[5,14-16,25,26,33] The natural history of idiopathic AC has been studied extensively and is often referred to be a continuum of 3 phases, namely, the ''freezing'' phase, the ''frozen'' phase, and the ''thawing'' phase. The ''freezing'' phase is characterized by intense shoulder pain and involuntary stiffness.[7] The next phase, ''frozen'' phase, involves reduction in pain but the presence of persistent shoulder stiffness.[7] The final, ''thawing'', phase is characterized by lack of shoulder pain with progressive improvement in ROM over a variable period of time.[7] AC is universally regarded as one of the most painful and debilitating conditions of the shoulder, which affects the quality of life and the ability to perform activities of daily life in a considerable manner.

Patient reported outcome (PRO) measurements and satisfaction scores are means of assessing the quality and efficacy of treatment in medicine. They are imperative to the clinical management as they allow medical providers to gain insight into the natural history of conditions, measure improvements in treatment, and compare different treatments. Currently, numerous validated PRO measures are available to evaluate upper extremity (UE) shoulder function, including the American Shoulder and Elbow Surgeons (ASES) score, Constant-Murley score (CS), Disabilities of Arm, Shoulder, and Hand (DASH, QuickDASH), and the University of California, Los Angeles (UCLA) Shoulder score. However, the majority of these outcome measurement tools require considerable time and effort on part of the patient and physician, and these outcome measures are not adaptive and sensitive to variables that lead to ceiling and floor effect.[27] In 2004, the National Institutes of Health developed the Patient Reported Outcomes Measurement Information System (PROMIS), an instrument based on item response theory that uses computer adaptive testing (CAT), to evaluate a variety of health domains including physical function.[8,22] The PROMIS UE tool is specifically designed for the UE conditions but has not yet been validated for use in AC of shoulder, which is associated with considerable pain and affects global functioning of the shoulder (ROM, strength, and function).[2,23,32] Furthermore, the PROMIS UE tool has not been compared with outcome scores, such as CS, that are commonly used outside North America.

The purpose of this study was to compare the efficacy of the PROMIS UE CAT with the traditional legacy instruments including the ASES and CS in patient with idiopathic AC. Our hypothesis is that the PROMIS UE CAT would highly correlate with the ASES and CS as a measure of patient reported disability. We chose AC for this study because it is associated with considerable shoulder pain, limited ROM, and global loss of shoulder function, which is sensitive to precise evaluation using standard outcome measures.

Materials and methods

Study design: prospective observational study

Patient recruitment

In this prospective study spanning from December 2018 to May 2019, patients diagnosed clinically with idiopathic AC (''freezing'' and ''frozen'' phases) were invited to participate in this study. In total, 100 consecutive patients were seen by 3 shoulder and elbow surgeons at a single academic institution and completed the ASES, CS, and PROMIS UE CAT scores. The authors included patients who were presenting for an initial visit and those coming for a follow-up visit. Eligible patients were required to be over 18 years of age and have a clinical diagnosis of idiopathic AC and no known cause of secondary shoulder stiffness (no antecedent shoulder trauma or fracture, or glenohumeral arthritis on radiographs). A priori power analysis was conducted by a biostatistician to determine sample size requirements for study. To achieve a 95% power using a 2-sided hypothesis test with a significance level of .05, a minimum sample size of 38 was required.[28]

Outcome measures and data collection

Each patient gave informed consent and completed questionnaires including the PROMIS UE CAT, ASES, and CS. All data were collected and stored securely using REDCap (Vanderbilt University, Nashville, TN, USA). The PROMIS UE CAT, ASES, and CS have all been previously evaluated individually with respect to precision, construct, and validity, and the results indicate that each is psychometrically sound.[3,17,20,31,34,35] Within the PROMIS UE CAT and ASES questionnaires, patient responses were scored on a scale ranging from a lower functioning (unable to do) to a higher functioning (no difficulty) level. Physician reported clinical measurements for the CS were completed using a goniometer and dynamometer by 2 research coordinators involved with the study and verified by the senior author.

The PROMIS initiative uses CAT, which takes each individual's previous answer into account when asking subsequent questions. This CAT reduces patient response burden because unlike legacy instruments (ASES, CS, UCLA, DASH) all questions need not be answered. PROMIS can be used to test various domains including the physical function (PF). Initially, upper and lower extremity disabilities were not separated, and investigations were undertaken to see if the PROMIS UE CAT could measure UE disability and compared with the QuickDASH.[6,12,13] The UE PROMIS tool was devised to differentiate the UE function from the lower extremity function. The item response theory suggests that comparable measurements can be obtained across patients even if they have answered a different set of questions, enabling the precise and efficient collection of patient data. The PROMIS UE CAT consists of a total of 46 items, all of which have been selected from other broadly accepted outcome instruments.[30] All questions except for 1 offer patients the same 5 answer choices: (1) without difficulty, (2) with a little difficulty, (3) with some

difficulty, (4) with much difficulty, and (5) unable to do. The average score is 50 with the standard deviation (SD) being 10 points. Previous studies have validated the PROMIS UE CAT for use in normal populations, displaying appropriate psychometric properties.[3,18,30] However, there are no studies to date investigating its reliability in patients with idiopathic AC, which represents a global dysfunction of shoulder with shoulder pain (night pain and rest pain), limitation of ROM (active and passive), and poor shoulder function

The ASES score is a validated and commonly used outcome assessment tool in the United States.[1] It is composed of a series of questions, each with 4 answer choices evaluating the patient's ability to perform common daily activities. All questions offer patients the same 4 answer choices: (1) without difficulty, (2) with some difficulty, (3) with much difficulty, and (4) unable to do. The test is scored on a 0 to 100 scale, with higher scores indicating less inhibited functional capabilities. Half of the total outcome score is patient reported, and other half is objectively assessed by the examiner.

The CS was first presented in 1987 as a way to evaluate overall shoulder function across a variety of diagnoses.[9] It is popular outside the United States.[1,21] The CS was included in this study to increase global application of this study, because it is deemed the gold standard for shoulder assessment in Europe.[29] The CS scale has a total of 100 points (higher totals indicate better function) assessing 4 aspects of shoulder pathology: pain, activities of daily living, ROM, and strength. The patient reported components (pain and activities of daily living) can garner a total of 35 points, whereas the ROM and strength assessment, as performed by an examiner, can have a maximum of 65 points. The ROM and strength are measured using a goniometer and dynamometer.

Data analysis and statistics

As the primary outcome of this study was the correlation of the PROMIS UE CAT with the ASES and CS, Pearson correlation coefficients (r) were calculated between the PROMIS UE CAT and each of the ASES and CS, respectively. Demographic data were analyzed using standard descriptive statistics. Previous correlation-based studies have suggested a Pearson correlation coefficient (r) of approximately 0.5-0.6.[3,11] Correlation coefficients were interpreted in the following manner based on prior literature: excellent ($r > 0.7$), excellent-good ($0.61 \leq r \leq 0.7$), good ($0.31 \leq r \leq 0.6$), and poor ($0.2 \leq r \leq 0.3$).[1,12] The secondary outcome measure was the comparison of question response burden associated with each outcome score. Average time required to complete each survey was not recorded. Means and SDs were calculated for each outcome score (PROMIS UE CAT, ASES, and CS) as well as for the question burden of the PROMIS. Ceiling and floor effects were considered present if greater than 15% of patients in the cohort scored the highest or lowest possible score, respectively.[2]

Results

Demographic characteristics

A total of 90 patients, all of whom met the aforementioned inclusion, were included in the study, and they completed the PRO scores at their initial visit. In addition, 10 patients completed the PRO scores at follow-up appointment and a set of study questionnaires, resulting in 100 data points. These patients did not have any treatment before this appointment. This cohort included 72% female, 87% right hand dominant, 54% white, and 23% African Americans (Table I). The mean age in the cohort was 55 years (SD, 8.8 years; range, 29-83 years).

Table I Patient demographics (total cohort, n = 100)

Parameter	Value, % (n)
Sex	
Male	28 (29)
Female	72 (71)
Age (yr)	
21-30	1 (1)
31-40	3 (3)
41-50	21 (21)
51-60	52 (52)
61-70	16 (16)
71-80	5 (5)
>80	1 (1)
Race	
White	54 (54)
Black/African American	24 (24)
Asian/Pacific Islander	15 (15)
Native American	0.0 (0)
More than 1 race	2 (2)
Unknown/Not reported	5 (5)
Ethnicity	
Hispanic or Latino	10.0 (10)
Not Hispanic or Latino	90.0 (90)
Marital status	
Single or never married	35 (35)
Married	56 (56)
Divorced/Separated	7.8 (7)
Widowed	2.2 (2)
Education level	
High school	18 (18)
Bachelor's degree	47 (47)
Graduate/Professional degree	35 (35)
Level of activity	
Not active	14 (14)
Somewhat active	61 (61)
Very active	25 (25)
Hand dominance	
Right	87 (87)
Left	11 (11)
Ambidextrous	2 (2)

Correlation with established outcome instruments

The mean PROMIS UE CAT score for the cohort was 34.7 (SD, 2.54; range, 18.5-54.5) (Fig. 1). The mean ASES score was 55.3 (SD, 22.1; range, 5-98), and the mean CS was 51.5 (SD, 16.3; range, 22-90). The PROMIS UE CAT

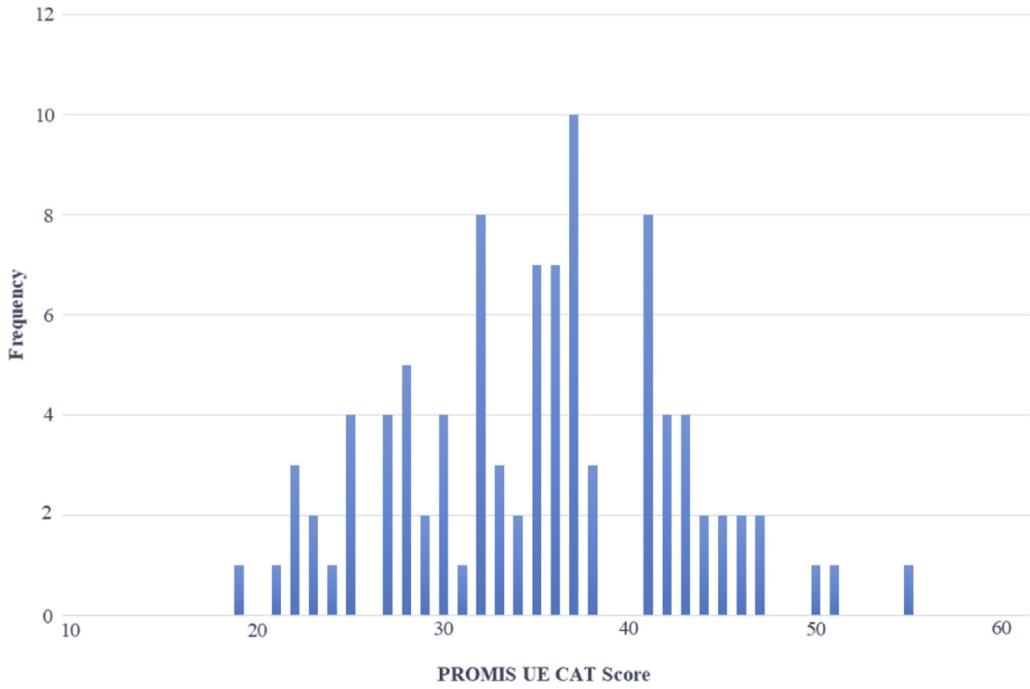

Figure 1 Histogram of Patient Reported Outcomes Measurement Information System Upper Extremity Computerized Adaptive Test (PROMIS UE CAT) scores.

demonstrated an excellent correlation with both the ASES ($r = 0.80$; 95% confidence interval, 0.72-0.86; $P < .001$) and the CS ($r = 0.76$; 95% confidence interval, 0.67-0.83; $P < .001$) (Table II). There was no ceiling or floor effect noted in the PROMIS UE CAT, as only 1 patient attained the minimum score of 18.5 and 1 patient attained the maximum score of 54.5.

Patient response burden

The PROMIS UE CAT required an average of 5 questions (SD, 1.84) for the full cohort, demonstrating a lower question burden as compared with the ASES (12 questions) or CS (9 questions) (Figs. 2, 3 and Table II).

Discussion

This study demonstrates an excellent correlation between the PROMIS UE CAT and the ASES and CS in newly diagnosed or previously treated patients with idiopathic AC. The average question burden for the patients was lower for the PROMIS UE CAT compared with the Constant and ASES questionnaires.

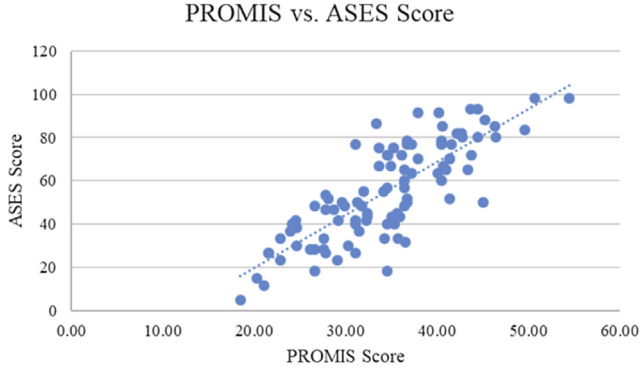

Figure 2 Correlation between Patient Reported Outcomes Measurement Information System Upper Extremity Computerized Adaptive Test (PROMIS UE CAT) and American Shoulder and Elbow Surgeons (ASES) scores: $r = 0.80$, $P < .001$.

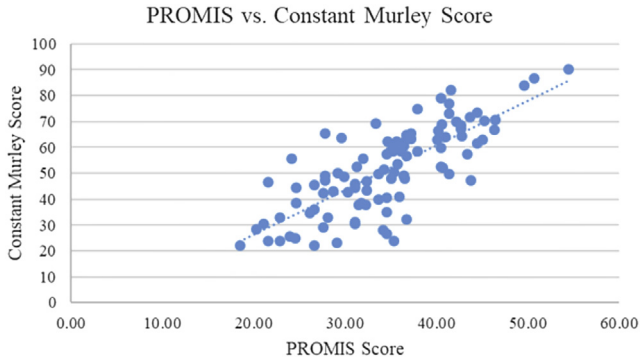

Figure 3 Correlation between Patient Reported Outcomes Measurement Information System Upper Extremity Computerized Adaptive Test (PROMIS UE CAT) and Constant-Murley score (CS): $r = 0.76$, $P < .001$.

Table II PROMIS, ASES, and CS cohort data

	Full cohort (n = 100)
PROMIS	
Number of questions	5.02 ± 1.84
t-score and SD	34.65 ± 2.54
ASES	
Number of questions	12
Score	545.35 ± 22.11
CS	
Number of questions	9
Score	51.59 ± 16.28
Pearson correlation (*r*)	
PROMIS vs. ASES	0.80 (0.72-0.86) ($P < .001$)
PROMIS vs. CS	0.76 (0.67-0.83) ($P < .001$)

PROMIS, Patient Reported Outcome Measurement Information System; *ASES*, American Shoulder and Elbow Surgeons; *CS*, Constant score; *SD*, standard deviation.

We chose AC for this study because it is associated with considerable shoulder pain, limited ROM, and global loss of shoulder function, which can be reliably assessed by common legacy instruments for UE conditions (ASES, CS). In this study, all 3 outcome assessment tools (PROMIS UE CAT, ASES, and CS) were sensitive to pick up functional outcome deficits in UE due to AC. The PROMIS UE CAT demonstrated a linear positive correlation with the ASES and CS. Prior studies have compared the PROMIS UE CAT with other shoulder conditions. The study by Minoughan et al[24] corroborated this study's findings and showed an excellent correlation of the PROMIS with the ASES (0.72) and SST ($r = 0.82$) in patients with shoulder pain. It also showed that it took significantly less time to complete the PROMIS PF UE compared with the established PRO.[24] The PROMIS UE CAT has shown to be an effective outcome-reported tool in patients with other shoulder pathologies. Dowdle et al[11] demonstrated that in patients who underwent primary total shoulder arthroplasty, the PROMIS UE had a good correlation with traditional PRO tools including SF-36 PF ($r = 0.53$), ASES ($r = 0.55$), and EQ-5D ($r = 0.48$). The authors also demonstrated that the PROMIS tool required less questions to complete compared with other outcome questionnaires.[11] This study's results are similar to findings in the aforementioned studies. However, none of the aforementioned studies compared the PROMIS UE CAT score with the CS, which is commonly used outside the United States. The PROMIS system is an initiative in North America and not popular outside the United States. CS is one of the most commonly reported outcome scores for shoulder pathology in Europe, and findings from our study provide objective evidence for investigators who want to incorporate the PROMIS UE CAT in their clinical practice to decrease patient response burden without compromising on reliable representation of outcomes.[4] No other study has compared the PROMIS UE CAT with CS.

The question burden for the patients with the PROMIS UE CAT questionnaire was considerably lower compared with the ASES and CS. This is because the computer adaptiveness helps eliminate redundant questions and further decreases time required to complete the questionnaire. Although we did not record the time required to complete each questionnaire, we used the number of questions required by the patient to fill out questionnaires as a surrogate for the time burden for each outcome instrument. In today's digital world, surveys and feedback are very common and not always well received by consumers. One of the biggest cited reasons is the time and effort required to complete surveys. Although the objective assessment of ROM and strength by the physician is important, PRO measures are now more popular because they are less time consuming and can be done online at the patient's discretion.[24] Furthermore, PRO tools are as sensitive as outcome scores that are surgeon reported. One of the proposed benefits of the adaptive PROMIS scoring system is decreased time burden and effort by the patient.[24] In the entire cohort, the average question burden for the PROMIS UE CAT was 5 ± 2 compared with the ASES (12 questions) and CS (9 questions) and confirms findings noted by others with the PROMIS scoring system.[2,19,24] In contrast to previous literature, it has been discussed that versions of the PROMIS questionnaire lacked the ability to appropriately differentiate higher functioning patients, leading to the ceiling effect.[12] In contrast, our study did not demonstrate any ceiling or floor effects in using the PROMIS UE CAT in patients with AC. In addition, there were neither ceiling nor floor effects seen with the ASES or CS. This indicates that each tool is fully capable of differentiating both high and low functioning patients.

The strengths of this study include a large cohort of patients, prospective standardized data collection including the objective assessment of ASES and CS scores and their correlation with the PROMIS and not just the PROs, and a priori categorization of primary outcomes. However, there are also several important limitations in the construct of this study. First, there is a possibility that patients experienced questionnaire fatigue because they were required to fill out 3 different PRO measurements in 1 sitting, which could have affected our findings.[2,24] Second, we did not have longitudinal follow-up of patients, and future longitudinal prospective studies are required to investigate the efficacy of PROMIS after treatment and also estimate minimal clinically important difference values for the PROMIS score. Third, our investigation did not include patients who underwent surgical intervention, who would likely have a higher level

of postoperative function, likely leading to a higher probability of a ceiling effect.

Conclusion

The PROMIS UE displayed comparable efficacy to commonly used legacy outcome scores (ASES and CS) in AC. A lower question burden with the PROMIS UE carries potential for wider acceptability with the researchers and patients with shoulder pathology. Future longitudinal studies are required to document the efficacy of the PROMIS UE score in assessing response to treatment, including surgery in UE shoulder conditions.

Disclaimer

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