

Preoperative Performance of the Patient-Reported Outcomes Measurement Information System in Patients With Rotator Cuff Pathology

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Purpose: To evaluate the Patient-Reported Outcomes Measurement Information System upper extremity item bank (PROMIS UE) and physical function computerized adaptive test (PROMIS PF CAT) in patients with rotator cuff (RC) pathology at their preoperative clinic visit. **Methods:** Patient data were collected from January 2015 to September 2015. Patients with a preoperative diagnosis of RC pathology were prospectively enrolled at the time of their surgical indication for RC repair. Each patient was asked to fill out the Western Ontario Rotator Cuff Index (WORC), American Shoulder and Elbow Surgeons Shoulder Assessment Form, Marx Shoulder Activity Scale, Short Form 36 Health Survey Physical Function and General Health (SF-36 PF and GH), EuroQol-5 Dimension (EQ-5D), PROMIS PF CAT, and PROMIS UE. Correlation was defined as excellent (>0.7), excellent-good (0.61 - 0.7), good (0.4 - 0.6), and poor (0.2 - 0.3). **Results:** Patient data were collected from January 2015 to September 2015. No patients were excluded from participation in the study. In 82 patients with preoperative RC pathology, the PROMIS UE showed excellent correlation with American Shoulder and Elbow Surgeons Shoulder Assessment Form ($r = 0.77$, $P < .01$), WORC ($r = 0.73$, $P < .01$), and the EQ-5D ($r = 0.73$, $P < .01$); there was excellent-good correlation with the SF-36 PF ($r = .66$, $P < .01$) and PROMIS PF CAT ($r = .70$, $P < .01$). The PROMIS PF CAT showed excellent correlation with the SF-36 PF ($r = 0.77$, $P < .01$); there was excellent-good correlation with EQ-5D ($r = 0.65$, $P < .01$) and WORC ($r = 0.61$, $P < .01$). There were no significant floor or ceiling effects using the PROMIS UE item bank or PROMIS PF CAT. **Conclusions:** We report that in a patient population with preoperative RC pathology, the PROMIS UE and PROMIS CAT are valid patient-reported outcome alternatives that have high correlation with traditional shoulder and upper extremity patient-reported outcomes. We find a decreased question burden using the PROMIS PF CAT. We find no significant floor or ceiling effects present in the PROMIS UE or PROMIS PF CAT. **Level of Evidence:** Level II, prospective diagnostic study.

Rotator cuff (RC) tears are common with previous work reporting a high prevalence of both symptomatic and asymptomatic tears.¹ RC tears have been shown to be a function of age^{1,2} with full thickness tears increasing over time.^{2,3} Although indications vary by surgeon, operative treatment is usually reserved for

symptomatic younger patients with full thickness tears (>1 - 1.5 cm).²

Patient-reported outcome (PRO) instruments are beneficial and standard of care in evaluating orthopaedic treatment.^{4,5} Given that orthopaedic care intends to improve function and quality of life, proven PRO instruments that assess function and quality of life are essential.⁶ The medical outcomes study Short Form-12 (SF-12) is an abbreviated version of the Short Form-36 (SF-36)⁷; both are commonly used general health PRO instruments used to assess general health-related quality of life⁷⁻⁹ (Appendix Table 1, available at www.arthroscopysjournal.org). Commonly used PRO instruments when evaluating RC and upper extremity pathology include the Western Ontario Rotator Cuff Index (WORC), American Shoulder and Elbow Surgeons Shoulder Assessment Form (ASES), and the Marx Shoulder Activity Scale (Marx) (Appendix Table 1). Previous authors have reported validity and moderate to very good reliability of the WORC in patients with RC disease.¹⁰⁻¹²

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The National Institutes of Health developed the Patient-Reported Outcomes Measurement Information System (PROMIS) in an effort to advance PRO measurement. This involved the creation of question banks for major health domains using item response theory and computerized adaptive test (CAT) tools for administering these newly developed PROs.¹³ With computerized adaptive testing, responses to individual questions as well as the relations between questions in a specific health domain are examined,^{5,14} and only the most appropriate questions for the respondent's level are administered from the item bank. This allows for fewer questions to be administered while maintaining measurement precision compared with traditional PRO instruments, which require varying levels of completion to be used.^{5,15-17} The PROMIS upper extremity item bank (PROMIS UE) comprises 16 questions that assess musculoskeletal upper extremity pathology (Appendix Table 1, available at www.arthroscopyjournal.org). The PROMIS physical function CAT version 1.2 (PROMIS PF CAT) consists of 121 potential questions and is a broad assessment of overall physical function and musculoskeletal health (Appendix Table 1). Previous authors have considered the PROMIS methodology in foot and ankle, trauma, and hand and upper extremity orthopaedic patients finding that the PROMIS PF CAT showed superior efficiency and was valid when compared with traditional PRO instruments.^{5,15,18,19} Prior work has validated the PROMIS PF CAT against the ASES in patients with RC disease.⁶ In addition, others have found the PROMIS UE to be valid in patients with hand/elbow pathology²⁰ and shoulder instability.¹⁹ Despite the potential benefits of the PROMIS methodology, some have suggested that the PROMIS may have less discriminatory power in healthy populations¹⁷ and be prone to ceiling effects. Previously, in a population of younger patients (18-21 years old) with operative shoulder instability, significant ceiling effects were found when using PROMIS instruments.¹⁹

We identify RC pathology as a common shoulder condition, and in an effort to appropriately track and follow patients with operative RC pathology, we identify the need for PROs that are both valid and efficient. We feel this study seeks to confirm the findings of Beckmann et al.⁶ regarding the use of PROMIS PF CAT. Furthermore, this study considers the PROMIS UE, which notably previous work⁶ did not consider. We feel our addition of the PROMIS UE item bank is a significant contribution to the literature and worthy of publication to surgeons caring for upper extremity musculoskeletal disease. The purpose of this investigation was to evaluate the PROMIS UE and PROMIS PF CAT in patients with RC pathology at their preoperative clinic visit. We hypothesized that (1) there would be moderate to high correlation between the PROMIS UE and PROMIS PF CAT with

traditional orthopaedic PROs covering similar health domains (SF-36 PF, WORC, ASES) and low correlation with instruments measuring other health domains (SF-36 GH, Marx); (2) PROMIS instruments would not show ceiling effects; and (3) the PROMIS PF CAT would show a decreased question burden compared with traditional PROs in patients with preoperative RC pathology.

Methods

Patient data were collected from January 2015 to September 2015. Ninety-one consecutive patients with a preoperative diagnosis of RC pathology were prospectively enrolled by a research assistant at the time of their surgical indication for RC repair. Participants prospectively completed the ASES (10 questions), Marx (7 questions), SF-36 PF (10 questions), EuroQol-5 Dimension (EQ-5D, 5 questions), WORC (21 questions), PROMIS PF CAT (4-12 questions), and PROMIS UE (16 questions) instruments on an in-office computer kiosk before a routine, preoperative office visit. Patient age, body mass index, gender, and operative side were obtained from a chart review and subsequent descriptive analyses were completed. Descriptive analyses were completed using frequency distributions and estimation of summary measures. We assessed construct validity of PROMIS PROs by investigating their correlation with other instruments that measured physical function (convergent validity, ASES, WORC, SF-36 PF) and with instruments measuring other health domains (divergent validity, Marx activity score, SF-36 GH). The Shapiro-Wilk test, histograms, and Q-Q plots were used to assess the normality of variables. Relations between PROs were subsequently described using Pearson or Spearman correlation coefficients with correlation defined as excellent (>0.7), excellent-good ($0.61-0.7$), good ($0.4-0.6$), or poor ($0.2-0.3$) based on prior work.²¹ Floor and ceiling effects are considered present when an instrument is not able to measure individuals whose abilities lie outside the measurement range (i.e., above or below the lowest or highest possible score on an instrument). In our study, ceiling and floor effects were measured by determining the percentage of subjects with the highest and lowest possible score, respectively. As previous working groups have proposed, if more than 15% of individuals scored the lowest or highest possible total score on a PRO,²² floor or ceiling effects were considered to be present. An a priori power analysis was calculated. To detect a correlation of 0.4 (moderate) between PROs with 80% power and an alpha of 0.05, a sample size of 46 was required. A P value $< .05$ was considered statistically significant; statistical software (SAS version 9.4, SAS Institute, Cary, NC) was used for analyses. This study was deemed Health Insurance Portability and Accountability Act compliant and approved by our institutional review board.

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