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Can Patient-Reported Outcomes Measurement Information System estimate high-impact chronic pain after total shoulder arthroplasty?

Katherine S. Norman, PT, DPT, MS[a], M. Alan Brookhart, PhD[a], Oke Anakwenze, MD, MBA[b], Michael P. Bolognesi, MD[b], Maggie E. Horn, DPT, MPH, PhD[a,c], Adam P. Goode, PT, DPT, PhD[a,d], Steven Z. George, PT, PhD[a,d,*]

[a]*Department of Population Health Sciences, Duke University, Durham, NC, USA*
[b]*Division of Adult Reconstruction, Department of Orthopaedic Surgery, Duke University, Durham, NC, USA*
[c]*Division of Physical Therapy, Department of Orthopaedic Surgery, Duke University, Durham, NC, USA*
[d]*Department of Orthopaedic Surgery, Duke Clinical Research Institute, Duke University, Durham, NC, USA*

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Background: Identification of high-impact chronic pain (HICP) among patients receiving total shoulder arthroplasty (TSA) may allow for the design and implementation of tailored pain interventions to address the negative impact on postoperative outcomes and quality of life. This analysis sought to determine if Patient-Reported Outcome Measurement Information System (PROMIS) measures could be used to estimate HICP status following TSA.

Methods: This was a secondary analysis of a cohort of patients (n = 227) who received a TSA at a single, academic medical center, of whom 25 (11.5%) met HICP status postoperatively. Generalized linear models estimated HICP from each PROMIS measure of physical function, pain interference, sleep disturbance, anxiety, and dyspnea individually, then in a combined model. Area under the curve (AUC) was calculated using receiver operator characteristic curves to assess accuracy of each PROMIS measure to estimate HICP status for patients receiving TSA.

Results: Bivariate generalized linear models and mean difference analyses revealed individuals with HICP had worse PROMIS scores in every included domain (all *P* values < .01). Only pain interference (AUC = 0.964) and physical function (AUC = 0.907) PROMIS measures met criteria (AUC > 0.850) to accurately predict HICP. A pain interference score ≥58.3 and/or a physical function score ≤41.2 could be used to estimate HICP from PROMIS measures in this cohort.

Conclusion: Two PROMIS measures commonly administered in orthopedic surgery settings, physical function and pain interference, can be used to estimate HICP for patients receiving TSA. Further application and evaluation of these cutoff scores can be used to assist in refining assessment of outcomes for patients receiving TSA.

Identification of chronic pain, particularly high-impact chronic pain (HICP), through surveys and electronic health data have the potential to identify patients at risk of adverse surgical outcomes in order to implement targeted pain interventions.[27,32] Classification of chronic pain using HICP terminology is a more holistic view of pain, as HICP has been defined as pain that has persisted for at least 3 months combined with functional limitations in work, social, and/or daily activities.[7,27] Individuals with HICP exhibit reduced quality of life and overall health status with increased psychological distress, healthcare utilization, and risk of opioid misuse.[35] As reimbursement for the growing volume of joint arthroplasties is increasingly driven by patient-centered outcomes and quality of life metrics, extensive research has been done in hip and knee arthroplasty to better identify nuanced chronic pain conditions and tailor care plans; however, there has been less research on pain identification and optimization strategies in patients receiving total shoulder arthroplasty (TSA).[13,15,20,29] Given the burden of HICP on patient quality of life, healthcare utilization, and societal functioning, there is a need to better understand and identify HICP

The Duke University Health System Institutional Review Board approved this study (Pro00091740).

*Corresponding author: Steven Z. George, PT, PhD, Departments of Orthopaedic Surgery and Population Health Sciences, Duke Clinical Research Institute, 200 Morris St, Office 6510, Durham, NC 27701, USA.
E-mail address: Steven.George@duke.edu (S.Z. George).

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among patients receiving TSA in order to design and implement tailored pain interventions.[32]

Assessing for HICP is not part of routine practice in care for total joint arthroplasty (TJA), as it typically requires administration of additional patient-reported outcomes (PROs) such as the Graded Chronic Pain Scale Revised.[31] PROs are standardized instruments that can serve as metrics to indicate treatment success and quantify the impact of symptoms and/or extent of functional limitations from the patient perspective.[24,34] While PROs have been used broadly in TSA, majority of measures administered tend to be legacy measures. These legacy measures can be narrow in scope limiting comparison across other conditions or procedures, have high administrative burden leading to inconsistent administration, and there is a lack of consensus on a standardized measure creating clinical confusion from heterogeneity of outcomes being used.[2,23] To reduce the administrative burden and strive for standardized measurement, application of Patient-Reported Outcome Measurement Information System (PROMIS) has been advocated as a way to reduce the number of PROs collected while still capturing the patient's perspective of symptom and functional impairments.[23] Use of PROMIS is increasing in orthopedics, particularly as a means to compare outcomes across multiple orthopedic subspecialties.[18,19] Existing methods and evidence indicate PROMIS measures are comparable to other legacy measures for pain and disability and are suitable in patients with arthroplasty while offering decreased administrative burden.[11,26,28] Research has shown that PROMIS can estimate HICP status in total hip and knee arthroplasty, yet PROMIS measures have not been evaluated to estimate HICP status in TSA.[17]

The number of TSA surgeries performed annually is rising, and trends indicate that the incidence of TSA will continue to increase.[1,33] To facilitate effective management of postoperative pain among the growing volume of TSA, there is an unmet need to identify HICP in this population. Therefore, the aims for our study are: 1) to determine which PROMIS measures are associated with HICP in a cohort of patients following TSA; 2) to evaluate if a cutoff score can be calculated for estimating HICP from PROMIS measures; and 3) to ascertain if cutoff scores for estimating HICP status differ based on sociodemographic and/or surgical characteristics. Our findings will build on prior research to help inform identification of HICP and refine assessment of TSA outcomes. Additionally, this study will expand upon research to compare and evaluate the performance of PROMIS measures in the upper extremity as compared to lower extremity and in patients receiving TJA.

Materials and methods

Study population

This is a secondary analysis focusing on patients who received a TSA of a previously conducted retrospective, observational study of patients who underwent a TJA at a tertiary, academic medical center.[16,17] All patients received their TSA from an orthopedic surgeon from the Duke University Department of Orthopaedic Surgery. We identified patients who received a TSA from the electronic health record (EHR, Epic-Maestro Care; Epic Systems, Verona, WI, USA) between January 1, 2014, and January 31, 2020, using Current Procedural Terminology codes 23470, 23472, 23473, and 23474 to capture anatomic and reverse TSA, as well as primary or revision surgery data. The survey was distributed from July to November of 2020 using a random assignment strategy described previously.[16] The end date was purposefully selected to provide 6 months between postoperative period and initial survey distribution to accommodate for the minimum period for development of postoperative chronic pain.

Data collection

Eligible patients were contacted via email for the opportunity to participate in a postoperative survey that collected self-reported information on chronic pain, medication use for pain, and health-related quality of life. The primary study included patients who received total hip, knee, or shoulder arthroplasty, but this secondary analysis only analyzed patients who underwent a TSA and responded to the survey via email. A diagram of the cohort development is provided in Figure 1.

Survey distribution was conducted using survey groups designed to optimize response rates, accommodate multiple surgery interventions, and account for variability in time between postoperative period and survey administration. Eligible participants were contacted via email to provide informed consent and participate in the survey with a maximum of 2 follow-up emails. All survey data were collected and managed using Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, TN, USA), a secure, web-based software platform designed to capture and export data for research studies. Survey responses included PROMIS 6-item short forms for physical function, pain interference, sleep disturbance, and anxiety, plus a computer adaptive version for dyspnea. PROMIS measures have been extensively used in the general population and orthopedic surgery populations.[2] PROMIS measures use a t-score metric that is standardized and calibrated with standard population values for mean scores of 50 and standard deviation of 10. Higher scores indicate higher outcomes with the included domain, meaning higher scores in pain interference, sleep disturbance, anxiety, and dyspnea indicate worse outcomes, whereas higher scores in physical function indicate better outcomes.[4] The first two items of the Graded Chronic Pain Scale-Revised were used to categorize HICP status.[31] Patients met HICP status if they responded to "most or every day" to 2 questions: 1) in the past 3 months, how often did you have pain? and 2) in the past 3 months, how often did pain limit your life or work activities? This scale has been used to categorize HICP in a variety of patient populations, including TJA populations.[17,31]

In addition to the survey, we extracted demographics including age, sex, self-identified race, body mass index, tobacco history, and comorbidity count from the EHR.[17] Additionally, we collected information from the surgical encounter including preoperative pain rating (11-point numeric pain scale) within 30 days prior to surgery, surgical date, and number of TJA or any related procedures performed within the data extraction period. These variables were collected to adjust models based on clinically relevant factors such as preexisting pain or comorbidities, as well as indicators of healthcare utilization. We also collected information about the length of time from first surgery to time of survey completion to account for variability in the postoperative time to build comprehensive models.

Data analyses

Data analyses were completed in R (A Language and Environment for Statistical Computing Version 2023; R Foundation for Statistical Computing, Vienna, Austria). Demographic characteristics were analyzed using frequencies (%) for dichotomized, categorical variables or means and standard deviations for continuous variables. Comparison between participants with HICP vs. those without for demographic characteristics used chi-square testing, and comparison of PROMIS scores used Wilcoxon rank sum *t*-tests.

Our first analysis used separate generalized linear models to estimate HICP from each PROMIS measure of physical function, pain interference, sleep disturbance, anxiety, and dyspnea. We then fit a generalized linear model to predict HICP that incorporated all the PROMIS measures. We computed receiver operating

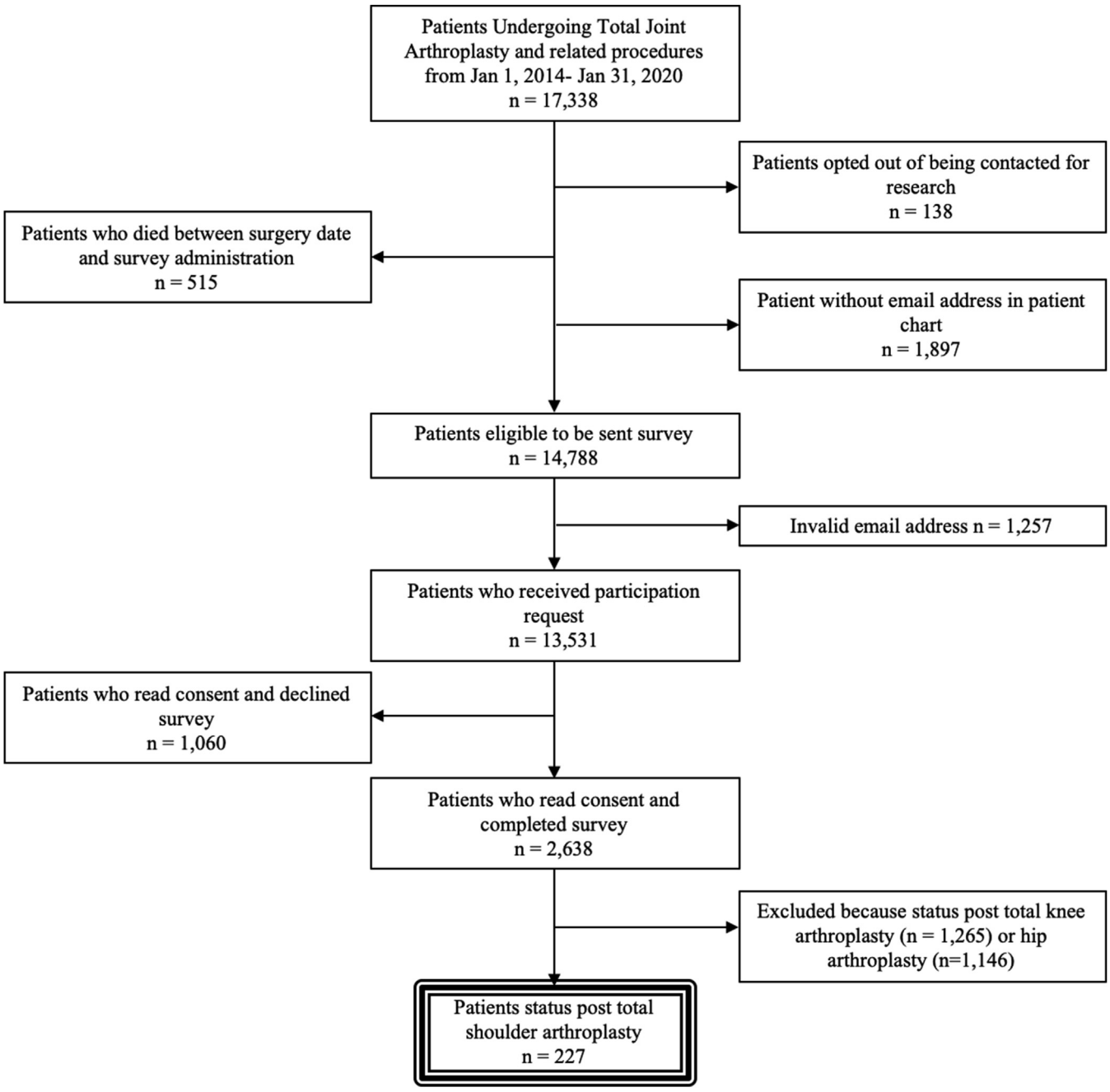

Figure 1 Participant flowchart.

characteristic curves for each model and assessed predicted accuracy using the area under the curve (AUC) for each PROMIS measure to determine if a cutoff score for each of the PROMIS measures could be used to estimate HICP status. If the AUC $\geq$ 0.85, then the PROMIS measure could be used to accurately estimate HICP.

Analytic considerations

Due to the relatively small sample size, we performed a cross-validation to reduce risk of overfitting the model. This includes running the model on a subset of the population, then re-running the model on a different subset to compare performance. We also performed sensitivity analyses by running adjusted models based on sex, age, primary or revision surgery, and tobacco use, which were selected based on clinical relevance to TSA, to determine if cutoff scores needed to be individualized based off *a priori* risk factors.

Results

There were 227 individuals who received a TSA and responded to the survey. There was complete PROMIS outcome data on 210/227 (92.5%) individuals, and 26/227 participants (11.5%) met the criteria for HICP. A summary of the full cohort is provided in Table I, including comparisons between participants with and without HICP. The majority of this sample identified as male (n = 125/227; 55.1%) and white (n = 217/227; 95.6%). Approximately 80% (n = 192/227) of the sample had a low (one or less) comorbid

Table I
Descriptive statistics of participants (n = 227).

	Overall cohort	No HICP	HICP
Sex (% female)	44.9% (102/227)	43.8% (88/201)	53.8% (14/26)
Age (mean ± std)	67 ± 9.68	67.9 ± 9.1	59.8 ± 11.1*
Age (% ≥65 years)	71.3% (162/227)	75.1% (151/201)	57.7% (15/26)*
BMI (% < 30)	58.2% (128/220)	59.2% (116/196)	50.0% (12/24)
Tobacco use (% no history)	47.8% (97/203)	47.8% (87/182)	47.6% (10/21)
Race (% White/Caucasian)	95.6% (217/227)	96.0% (193/201)	92.3% (24/26)
Number of surgeries (% 1 surgery)	84.6% (192/227)	84.6% (170/201)	84.6% (22/26)
Comorbidity (% 0-1)	79.7% (181/227)	79.6% (160/201)	80.8% (21/26)
Pain interference (mean ± std)	50.5 ± 9.0	48.5 ± 7.3	65.3 ± 6.1*
Physical function (mean ± std)	47.1 ± 8.2	48.6 ± 7.5	36.4 ± 5.2*
Sleep disturbance (mean ± std)	47.6 ± 9.2	46.5 ± 8.7	55.4 ± 9.1*
Anxiety (mean ± std)	46.9 ± 8.0	46.0 ± 7.3	53.3 ± 9.6*
Dyspnea (mean ± std)	31.4 ± 9.5	29.9 ± 7.9	42.7 ± 12.9*

HICP, high-impact chronic pain; *BMI*, body mass index; *std*, standard deviation; *AIDS*, acquired immunodeficiency syndrome; *HIV*, human immunodeficiency virus.
Notes: Comorbidity includes count of included diseases of diabetes, hemiplegia, renal disease, AIDS/HIV, rheumatic disease, peripheral vascular disease, myocardial infarction, liver disease, congestive heart failure, stroke, and cancer; number of surgeries indicates primary surgery compared to revision surgery.
*Indicates comparison of means is significant at the $P < .01$ level.

condition. Groups were comparable at baseline in demographics, with the exception of age, wherein the group with HICP had a lower mean age (59.8 ± 11.1 years) vs. those without (67.9 ± 9.1).

Regression analysis

In bivariate models, individuals with HICP demonstrated poorer outcomes across all PROMIS domains (Table II). For every one-point increase in a respective PROMIS measure, there was an increase in odds of HICP as follows: pain interference (44%), sleep disturbance (21%), anxiety (10%), and dyspnea (12%). For PROMIS physical function scoring higher score indicates better function; therefore, for every point increase, there was a 24% reduction in odds of HICP. In the multivariate model including all PROMIS measures, a one-point increase in pain interference score was associated with a 35% increase in odds of having HICP.

Receiver operating characteristic analysis

The AUC for association with HICP status and calculated cutoff score for each PROMIS measure are reported in Table III. Pain interference (AUC = 0.964, 95% confidence interval = 0.935-0.987) and physical function (AUC = 0.907, 95% confidence interval = 0.851-0.954) were able to accurately estimate HICP status based on our a priori threshold of AUC ≥ 0.850 and are depicted in Figures 2 and 3, respectively. Our analysis identified a cutoff PROMIS score of ≥58.3 for pain interference and ≤41.2 for physical function to identify HICP in patients who received a TSA. Other included PROMIS measures exhibited high AUCs yet did not meet the threshold for accurately estimating HICP. Additional models revealed little change in the AUC when including sex, age, primary or revision surgery, and tobacco use, obesity status, and race. Therefore, we did not calculate cut-off scores specific to any of these factors (eg, the same cut-off is score appropriate for men and women and for different age ranges).

Table II
Results from regression analysis of PROMIS and HICP.

PROMIS measure	Individual GLM Odds (95% CI)	Combined GLM Odds (95% CI)
Physical function	0.76 (0.70-0.81)	0.93 (0.81-1.07)
Pain interference	1.44 (1.18-1.76)	1.35 (1.09-1.66)
Sleep disturbance	1.12 (1.06-1.19)	1.03 (0.96-1.12)
Anxiety	1.10 (1.04-1.16)	1.04 (0.96-1.12)
Dyspnea	1.12 (1.06-1.17)	1.00 (0.93-1.08)

PROMIS, Patient-Reported Outcome Measurement Information System; *HICP*, high-impact chronic pain; *GLM*, generalized linear model; *CI*, confidence interval.

Table III
Receiver operator curve analysis and calculated cutoff scores for each PROMIS measure.

	Univariate ROC AUC (95% CI)	Cutoff score identified from ROC
Pain interference	0.964 (0.935-0.987)	58.3*
Physical function	0.907 (0.851-0.954)	41.2*
Sleep disturbance	0.763 (0.657-0.868)	53.5
Anxiety	0.724 (0.610-0.818)	52.6
Dyspnea	0.840 (0.756-0.907)	33.1

PROMIS, Patient-Reported Outcome Measurement Information System; *HICP*, high-impact chronic pain; *CI*, confidence interval; *ROC*, receiver operating characteristic; *AUC*, area under the curve.
*Indicates that the cutoff score identified meets criteria for accurate estimation of HICP from the PROMIS, measure (AUC ≥0.850).

Discussion

Our results indicate that the PROMIS pain interference and physical function measures can be used to estimate HICP status for patients following TSA. PROMIS measures of sleep disturbance, anxiety, and dyspnea did not demonstrate accurate estimation of HICP, yet were associated with poorer outcomes in individuals with HICP. This supports and expands upon prior research by our group that also found PROMIS pain interference and physical function demonstrated high accuracy for estimating HICP in total hip and knee arthroplasty.[17] These findings are important for improving identification of HICP among the growing volume of TJA, particularly in the most common arthroplasties of hip, knee, and shoulder. Further exploration of the benefits of identifying patients at risk of HICP is needed, given the extensive negative impact of HICP on postoperative outcomes and patient quality of life.[9,21] As physical function and pain interference PROMIS measures are already commonly utilized outcome measures in orthopedic surgery,[18] our analysis provides support that HICP can be estimated using PROMIS pain interference and/or physical function without drastically increasing administrative burden. These findings could aid in integration of PROs for use in clinical endpoints and postoperative outcomes in TJA research, registries, and clinical care practices.

A variety of upper extremity PROs are currently applied among patients receiving TSA, which often lack statistical rigor (ie, not validated in applied populations or have ceiling effects) and suffer

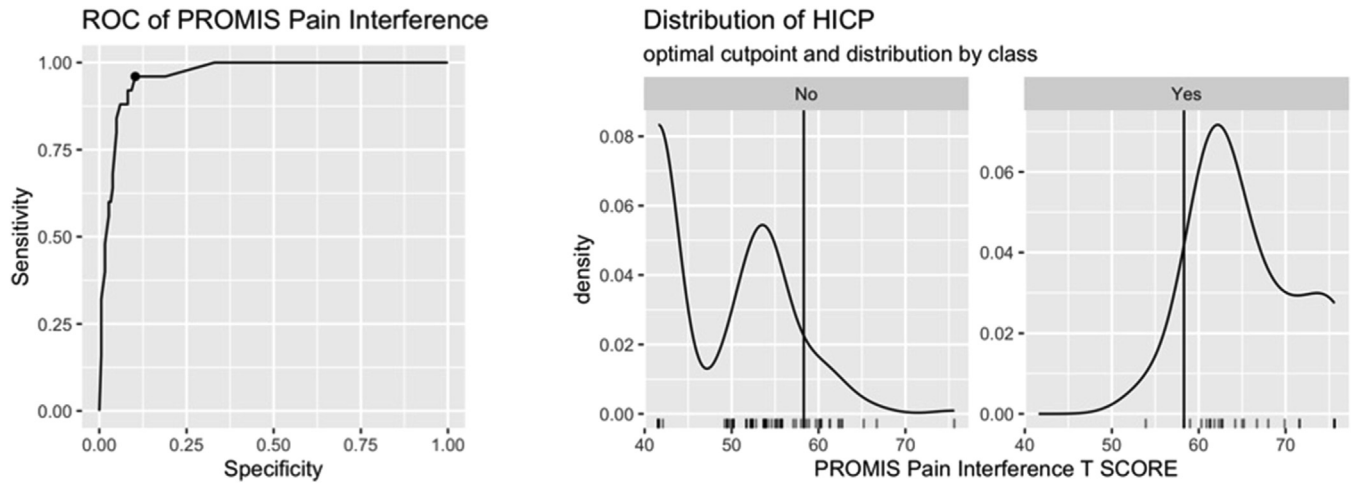

Figure 2 PROMIS pain interference ROC curve estimating HICP and distribution curves of PROMIS scores by HICP status. *ROC*, receiver operating characteristic; *PROMIS*, Patient-Reported Outcome Measurement Information System; *HICP*, high-impact chronic pain.

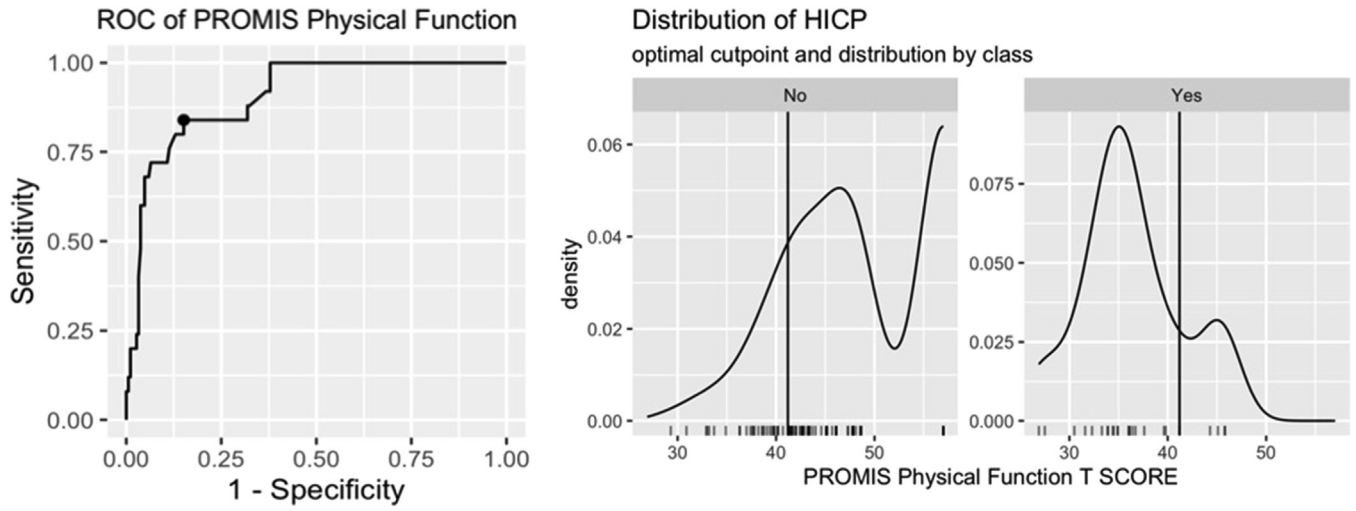

Figure 3 PROMIS physical function ROC curve estimating HICP and distribution curves of PROMIS scores by HICP status. *ROC*, receiver operating characteristic; *PROMIS*, Patient-Reported Outcome Measurement Information System; *HICP*, high-impact chronic pain.

from a lack of consensus on which measure(s) to use.[14,23] Our analysis adds to the evidence promoting use of PROMIS in patients receiving TSA, but is unique in that we assessed multiple PROMIS measures to determine which measure(s) can identify a specific clinical outcome of HICP in patients receiving TSA. Traditionally, PROMIS measures have been studied in comparison to legacy orthopedic measures and generic measures of health.[6,14] Research in patients receiving TSA have shown high correlation between the physical function measure and the Short-Form-36 (SF-36), American Shoulder and Elbow Surgeons assessment form, the Western Ontario Osteoarthritis Shoulder Index, and Quick Disability of Arm, Shoulder and Hand.[12,36] Preoperative measurements of PROMIS physical function, depression, and pain interference in patients undergoing TSA have shown the ability to predict postoperative outcomes and clinically meaningful improvement following TSA.[5] While these studies are informative for determining which PROs to use, they still require multiple PROs to be administered to reflect various defined patient outcomes. PROMIS is a concise yet comprehensive PRO that minimizes resource limitations for administration (eg, time, cost, personnel, etc.) due to widespread adoption. Research to identify and validate numerous interpretations of PROMIS scores (eg, identification of patients at risk of various adverse outcomes) may be a valid alternative with reduced survey administration to increase application in other orthopedic surgery populations, TJA registries, and machine learning algorithms.

Similar to trends in hip and knee arthritis, patients with shoulder arthritis are becoming more likely to be broadly enrolled in procedural-based or longitudinal diagnosis-based bundles, and evidence suggests a growing incidence of TSA within the already large volume of TJA.[1,3] Therefore, identification of patients at high risk of adverse outcomes, such as HICP, across all common arthroplasty types including shoulder may address unique challenges in utilization and cost outcomes to recognize atypical subgroups in value-based care analyses and policies. Standardizing PROMIS to identify patients with HICP across not only just TSA but also hip and knee arthroplasty could reduce time spent administering multiple outcome measures.[14] Additionally, standardizing PROMIS use could facilitate comparisons across clinical settings and patient conditions for research trials, registries, and health system metrics.[8] Often, TJA are performed to reduce pain, improve function, and restore quality of life, yet historic endpoints for these

surgeries (eg, revisions or mortality) may not reflect surgical "success" from the patient perspective.[34] Application of PROMIS reflects the multidimensional impacts of pain on individuals' physical, mental, social, and functional domains serving as a more comprehensive, patient-centered outcome in pain research and care.[7] This directly responds to urgent calls from regulatory agencies to incorporate PROs in clinical research and practice as a way to reflect the care experience from the patient perspective.[30,25] Using PROMIS to identify patients at risk of adverse outcomes across TJA would help better tailor care plans and expectations for TJA outcomes.

Previous research by our group also found that PROMIS pain interference and physical function measures could be used to accurately estimate HICP in patients receiving total hip and knee arthroplasty.[17] Interestingly, the previous study found that a pain interference score of 60 had an 89% probability of estimating HICP status in patients receiving hip or knee arthroplasty, and our study found that a similar score of 58.3 or higher was best for estimating HICP status in patients receiving TSA. The previous study also found physical function scores of 40 and 35 had a 78% and 90% probability, respectively, of estimating HICP status in patients receiving hip or knee arthroplasty. Our study found a physical function score of 41.3 or less to be the ideal cutoff for estimating HICP, indicating that patients receiving TSA with HICP might have more of a negative impact on physical functioning compared to hip and knee arthroplasty. Linking scores from both studies, identification of patients with HICP using pain interference cutoff scores appears comparable across hip, knee, and shoulder arthroplasty; however, using physical function cutoff scores may vary by surgery type.

Further exploration and validation of cutoffs generated by this analysis can help to estimate HICP through routine use of PROMIS measures. Benefits of using PROMIS to estimate HICP include informing clinical care, individualizing pain interventions, and ideal management of patients undergoing TJA, inclusive of hip, knee, and shoulder arthroplasties, which would likely have similar postoperative pain management strategies. Additional research examining how shoulder cutoff scores for HICP compare to cutoff scores in hip and knee helps to expand development of ideal postoperative pain management in patients with more complex clinical conditions. Furthermore, examining cutoff scores in larger and more diverse patient groups may help to recognize nuances in health-related quality of life impairments between upper and lower extremity TJA. These cutoffs can help physicians, rehabilitation professionals, and care coordinators to identify patients at higher risk of pain who may need additional pain interventions and education throughout the TJA care episode to optimize patient outcomes. This is especially relevant to identify patients who should have different metrics from the generic payment bundles to reduce inequitable consequences to providers and systems treating patients at risk of atypical, adverse outcomes. On a larger scale, establishing cutoff scores that are responsive to type of TJA could be used by artificial intelligence and machine learning to improve healthcare delivery by providing metrics for risk adjustments and predictive modeling.[22]

Future research could prospectively test accuracy of cutoff scores in a separate validation TJA cohort, as well as in other surgeries and rehabilitation populations, especially in a preoperative model to help refine scores for use in research and care. The statistical methods used in this analysis could be used to derive other clinically relevant proxy measures via PROMIS scores in other patient populations. Providing actionable indications (eg, cutoff scores) can enhance value-based care, support quality improvement initiatives, and promote shared decision-making for care surrounding not just TSA but TJA in general.[18,34] Building upon standardization and defined outcomes of PROMIS improves patient-centered outcomes for research endpoints and care delivery, as well as offering the opportunity to use big data to build population-based applications. Rather than restricting endpoints to clinically based metrics of revision or survivorship, incorporating PROMIS is much more reflective of patient-relevant factors such as return to activities of daily living and impacts on quality of life. Our findings could be used to inform use of PROMIS as a means to estimate preoperative to postoperative change to demonstrate the effectiveness or value of TJA in a patient-centered way beyond traditional endpoints of cost or procedural outcomes (ie, infection, revision, mortality, etc.).

Additional research is necessary as our analysis is not without limitations. Due to the relatively small sample size, it is possible that our models are overfitted and could overestimate HICP influence on PROMIS. Combined with the fact the sample is from a single institution, our sampling methods may limit generalizability to a larger patient population. Our sample was primarily of white individuals, which may not capture the impact of HICP on more racially and ethnically diverse populations; this is of particular importance given more diverse populations are more likely to have complex pain conditions such as HICP, so identified cutoff scores from this analysis may not be accurate in diverse populations with higher HICP prevalence.[10,35] We were limited to data in the EHR regarding demographic and socioeconomic factors and acknowledge that a more thorough analysis with these variables would help build more sensitive models. Additionally, we primarily used the short form of the PROMIS test, which has been less studied with regard to correlation of legacy measures compared to computer adaptive versions; however, we feel this makes our findings more approachable as it does not require an electronic medium for administration and reduces survey burden. Other PROMIS measures, particularly depression, would be ideal in future analyses, but this measure was not collected in the data for our secondary analysis. Finally, this analysis used only two questions from the Graded Chronic Pain Scale, and addition of other questions would help to differentiate among more nuanced categories of pain including no chronic pain, mild chronic pain, and bothersome chronic pain.

Conclusion

PROMIS pain interference and/or physical functioning accurately estimated HICP in patients receiving TSA, which will be useful to inform clinical care and future research in other orthopedic surgery populations or existing TJA registries. Specifically, this will assist in identification of complex pain conditions, as conditions like HICP are not traditionally assessed during orthopedic procedures; however, consideration of HICP assessment is warranted given the adverse effects on patient quality of life due to functional limitation and pain experience. Our analysis, combined with previous findings of HICP in TJA, will be useful for holistic management of patients following the most commonly received joint arthroplasty procedures. Future studies are needed to validate our cutoff scores in other clinical settings and among a more diverse sample to make findings more generalizable for widespread use in research studies and clinical practice.

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