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Characterizing MCID and assessing the role of preoperative PROMIS scores in predicting outcomes for reverse total shoulder arthroplasty at 2-year follow-up

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ABSTRACT

Background: The Patient-Reported Outcomes Measurement Information System (PROMIS) has gained more ground as a reliable and efficient means of collecting patient outcomes in different shoulder surgeries. The purpose of this study is to determine if preoperative PROMIS scores are able to predict improvement in postoperative PROMIS scores and anchor this data to determine if a patient will achieve MCID after reverse total shoulder arthroplasty (RTSA). We hypothesize that preoperative PROMIS will significantly correlate, with anchor questions allowing clinicians to predict which patients are most likely to achieve MCID after RTSA.

Methods: Three PROMIS CAT forms (PROMIS Upper Extremity Physical Function CAT v2.0 ("PROMIS-UE"), PROMIS Pain Interference v1.1 ("PROMIS-PI"), and PROMIS Depression v1.0 ("PROMIS-D")) were provided to all patients scheduled to undergo RTSA by board-certified shoulder and elbow surgeons at 1 institution. Demographic data was collected, including age, median household income, zip code, body mass index, sex, smoking status, and race. All patients enrolled in the study were contacted and asked the same 3 anchor questions pertaining to the 3 PROMIS CAT forms above.

Results: A total of 71 patients (52.1% male) were included in our cohort with an average age of 67.8 years (standard deviation, 8.4). Mean follow-up time point was 21.4 months (standard deviation, 9.9) after surgery. Neither preoperative PROMIS-UE, nor preoperative PROMIS-PI showed any significant predictive ability to achieve their respective domain MCIDs (AUC: 0.564 and 0.631, respectively). PROMIS-UE and PROMIS-PI improved to a significant degree at an average 21.4 months postoperatively from 29.2 ± 5.8 and 63.8 ± 4.8 to 39.8.9 ± 8.9 and 50.0 ± 9.7, respectively. Improvements in PRMOIS-D scores were insignificant at average 21.4 months (Baseline: 49.8 ± 8.0 vs. 44.5 ± 9.4 at final follow-up). Using anchor-based analysis to determine MCID, we found the following MCID values for PROMIS-UE, PROMIS-PI, and PROMIS-D: 7.0, -6.6, and -3.9, respectively. ROC analysis revealed MCID values for PROMIS-UE, PI, and D as 7.0, -6.6, and -3.9 respectively (AUC:

Approval for this study was received from Henry Ford Health System Institutional Review Board Committee (no. 11361).

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0.743, 0.805, 0.601). SCB values for PROMIS-UE, PI, and D were identified as 8.4, -12.1, and -4.0, respectively (AUC: 0.883, 0.932, 0.652).

Conclusions: PROMIS-UE and PROMIS-PI questionnaires can adequately assess the symptoms and outcomes of RTSA patients out to two years postoperatively. Preoperative baseline PROMIS-UE, PROMIS-PI, and PROMIS-D scores cannot adequately predict achievement of MCID in patients indicated for primary RTSA when using anchor-based methods at final follow-up, and should not be used to counsel patients on surgery or guide postoperative treatment.

Level of Evidence: Level II

Since its 2004 approval by the Food and Drug Administration, the incidence of reverse total shoulder arthroplasty (RTSA) has grown rapidly, increasing from 7.3 cases per 100,000 persons in 2012 to 19.3 cases per 100,000 persons in 2017.[1,3] Evidence suggests that use of RTSA has excellent clinical efficacy for a number of glenohumeral conditions, including rotator cuff arthropathy, massive irreparable rotator cuff tears, and proximal humerus fractures.[2-4,16] Surgical outcomes are typically reported and tracked using legacy patient-reported outcome (PRO) questionnaires such as Constant and American Shoulder and Elbow Surgeons score. Recently, the Patient-Reported Outcomes Measurement Information System (PROMIS) CAT (Computer Adaptive Test) has established itself as a more reliable, precise, and efficient means of collecting patient outcomes when compared to legacy PROs.[8,9] Past studies have demonstrated significant correlations between legacy PROs and PROMIS while using PROMIS Upper Extremity (PROMIS-UE) in patients with glenohumeral arthritis and rotator cuff disease.[9,14,15,18] Further evidence shows that preoperative PROMIS scores can be used to predict postoperative PROMIS outcomes in a variety of orthopedic surgeries by estimating and correlating with the minimal clinically important difference (MCID).[5,6,11,17]

MCID is the smallest difference between 2 variables of the same outcome measure that a patient recognizes as favorable.[26] Statistically significant improvement does not always yield clinical improvement from the perspective of the patient,[13] so, MCID can help unblur the line between a statistically significant outcome and one that is actually clinically significant.[26] There are 2 methods to determine MCID. First, the distribution-based method, uses statistical analysis to determine the score variance among patients enrolled in a study to elucidate statistically significant change; this method focuses only on distribution within a given sample. Second, the anchor method, attempts to estimate MCID by taking the perspectives of patients into account when assessing changes in outcome measures. Typically, subjective patient perspectives are determined by asking anchor questions at some point after treatment.[22,26] Anchoring determines what variations in data are not due to chance or randomness by allowing us to compare any change in a patient's outcome score with their anchor data.[26] Both methods have their own benefits and shortfalls, however, many authors are in agreement that basing MCID in patient perspective is a better method, given the definition of MCID.[11,25,26]

To date, there is little, if any, literature that uses PROMIS to estimate MCID in patients undergoing RTSA with anchor-based methods. Given this, our purpose is twofold. We wish to estimate MCID among RTSA patients using PROMIS and we wish to determine the predictive validity of preoperative PROMIS scores for postoperative PROMIS scores using an anchor-based MCID approach to better predict how likely a patient is to reach MCID after RTSA. Our hypothesis is that using preoperative PROMIS and correlating this with anchor questions will allow clinicians to accurately predict which patients are most likely to achieve MCID after RTSA.

Materials and methods

A full institutional review board submission was completed for this project and approved before any data was collected. Patients scheduled for RTSA by a board-certified shoulder and elbow surgeon were given three PROMIS CAT forms: PROMIS Upper Extremity Physical Function CAT v2.0 ("PROMIS-UE"), PROMIS Pain Interference v1.1 ("PROMIS-PI"), and PROMIS Depression v1.0 ("PROMIS-D"). PROMIS CAT forms were administered via iPad (Apple, Inc., Cupertino, CA, USA) using a secure, web-based platform for recording and storing research data (REDCap, Vanderbilt University, Nashville, TN, USA). Patients were included if they were scheduled for RTSA, above 18 years of age, and were capable of speaking English. Patients were excluded if they refused to fill out a preoperative PROMIS CAT form or if they did not fill out a postoperative PROMIS CAT. Patients were also excluded if they underwent a revision operation before their first postoperative visit, they suffered a proximal humerus fracture, or if they developed an intraarticular infection. The CAT format of the PROMIS forms assesses patient responses and varies the order, type, and number of questions each patient received based on their responses. Adaptive measures like this reduce the time it takes to complete each form and patient overload.[20] All domains underwent normalization to a mean score of 50 and a standard deviation of 10. Additionally, high scores in any particular domain constitute more of that measure. Therefore, having a high score in PROMIS-UE suggests better physical function of the upper extremity whereas a high score in PROMIS-PI suggests that the patient is having more pain in their everyday life.

Along with PROMIS CAT, we collected demographic information, such as age, median household income, zip code, body mass index, sex, smoking status, and race (Table I). Zip code was cross referenced with a United States Census

Table I – Patient demographics.

Characteristic	Mean	Standard deviation	Mean change (Postoperative - Preoperative)
Age	67.8	8.4	
Sex, n (%)			
Male	37 (52.1%)		
Female	34 (47.9%)		
MHI	$68,052	$23,583	
Smoking Status			
Never	25 (35.2%)		
Former	42 (59.2%)		
Current	4 (5.6%)		
Race			
White/Caucasian	52 (73.2%)		
African American	18 (25.4%)		
Native American/Alaskan Native	1 (1.4%)		
Follow-up (mo)	21.4	9.9	
Preoperative PROMIS-UE	29.2	5.8	
Preoperative PROMIS-PI	63.8	4.8	
Preoperative PROMIS-D	49.8	8.0	
Postoperative PROMIS-UE	39.8*	8.9	+8.3
Postoperative PROMIS-PI	50.0*	9.7	-9.4
Postoperative PROMIS-D	44.5*	9.4	-9.3

MHI, Median Household Income; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, Upper Extremity Physical Function; *PI*, Pain Interference; *D*, Depression.

* Indicates statistically significant differences between pre- and post-operative measures ($P < .001$).

Bureau website (https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk) to determine median household income.

All patients enrolled in the study were called out to 2-year follow-up and asked the same three anchor questions, one for each PROMIS CAT form used in the study. One assessed functional improvement after surgery (PROMIS-UE), one assessed how pain impacts the patient's daily life (PROMIS-PI), and the last assesses how each patient's mental health has changed since surgery (PROMIS-D). All questions have been validated and used in previous studies.[24]

Statistical analysis

The primary outcome of interest in the present study was to establish anchor-based values for MCID achievement in each PROMIS domain. Power analysis revealed the study would require 50 pair-wise comparisons to achieve 80% power. Aggregate data was compiled and presented in Table I. Paired Samples t-tests were conducted on pair-wise PROMIS domain scores for preoperative and postoperative scores. Chi-square and analysis of variance (ANOVA) measures were conducted to identify any differences among change in PROMIS domain t scores and patient-centric factors. Bivariate correlations were assessed using Pearson correlation coefficients (r) to show associations between PROMIS domains and patient-centric data. Correlation coefficients were interpreted as follows: high (> 0.70), high-moderate (0.61-0.69), moderate (0.40-0.60), moderate-weak (0.31-0.39), or weak (< 0.31).[21]

Minimal clinically important difference (MCID) was calculated using the anchor-based methodology. Anchor questions were posed alongside postoperative PROMIS forms to assess change in domain, the following options were provided for physical function, pain, and depression changes: "Gotten Worse", "About the Same", "A Bit Better", "Significantly Better", and "Complete Improvement". Patients were then dichotomized into "no change" and MCID groups, as well as "no change" and substantial clinical benefit (SCB) groups. Receiver operating characteristic (ROC) analysis was used with MCID and SCB groupings to assess which delta-PROMIS domain scores were optimized for determination of MCID and SCB. Optimization was determined through both area-under-the-curve (AUC) analysis and Youden's index assessment. AUC values greater than 0.700 were considered acceptable for determination of MCID and SCB values. Youden's J Statistic was calculated with the following formula: J = sensitivity + sensitivity − 1. Thus, coordinated plots were exported and assessed for maximal value of J. Any domains with AUC values greater than 0.700 were used for further ROC analysis in determining predictive ability of respective preoperative

PROMIS domains. All analyses used a significance level of 5%. SPSS software was used for all statistical analyses (Released 2017; IBM SPSS Statistics for Windows, Version 25.0; IBM Corp., Armonk, NY, USA).

Results

The present study was retrospective in nature. Using Current Procedural Terminology (CPT) code 23472, we identified 108 patients who had shoulder arthroplasty and reached our other inclusion criteria. Of these, 20 were removed due to overlap of CPT code between RTSA and total shoulder arthroplasty. From the remaining 88 patients, we were unable to follow-up with 17. Of these 17, 1 patient was deceased and 16 did not have adequate contact information to be contacted. This left 71 patients in our final cohort, a response rate of 80.68%.

A total of 71 patients (52.1% Male) undergoing RTSA were included, with a mean age of 67.8 ± 8.4 years. The mean follow-up period was 21.4 ± 9.9 months. All 71 implants showed intactness on radiological exams, at latest follow-up, and no revision surgeries or further complications were noted to date. Complete patient demographics can be seen in Table I.

Paired Samples t-tests showed significant improvement of each PROMIS domain at 2-year follow-up. Preoperative PROMIS-UE, PI, and D were 29.2 ± 5.8, 63.8 ± 4.8, 49.8 ± 8.0 and improved to 39.8 ± 8.9, 50.0 ± 9.7, and 44.5 ± 9.4, respectively ($P < .001$), Table I. Bivariate correlations were assessed and found significantly strong interactions between preoperative PROMIS-UE and preoperative PROMIS-PI, as well as postoperative PROMIS-UE and postoperative PROMIS-PI (R^2= -0.769 and -0.645, $P < .001$). The R^2 values between preoperative PROMIS-UE and Delta UE, preoperative PROMIS-PI and Delta PI, and preoperative PROMIS-D and Delta D revealed weak correlational strength ($R^2 = 0.246$; $R^2 = -0.183$; $R^2 = -0.416$, respectively). Further bivariate correlations and their respective R^2 values can be seen in Table II.

ROC analysis revealed MCID values for PROMIS-UE, PI, and D as 7.0, -6.6, and -3.9 respectively (AUC: 0.743, 0.805, 0.601). SCB values for PROMIS-UE, PI, and D were identified as 8.4, -12.1, and -4.0, respectively (AUC: 0.883, 0.932, 0.652). Due to both clinically significant outcomes (CSOs) being below the 0.700 threshold for PROMIS-D, these values cannot be indicative of true patient change. This data is displayed in Table III. PROMIS-UE and PROMIS-PI subsequently underwent ROC analysis to assess any predictive ability for achievement of MCID with their respective preoperative scores. Preoperative PROMIS-UE scores were not predictive of achievement of PROMIS-UE MCID (AUC: 0.564, CI: 0.421-0.707, $P = .376$). Similarly, PROMIS-PI scores were not predictive of achievement of PROMIS-PI MCID (AUC= 0.631, CI: 0.583-0.778, $P = .106$).

Chi-square and ANOVA tests revealed some significant findings for both MCID and SCB cohorts. Patients who achieved PROMIS-PI MCID were significantly older than those who did not achieve MCID (69.0 ± 8.2, 63.7 ± 8.0; $P = 0.026$). Similarly, these patients who achieved PROMIS-PI MCID had higher MHI than those who did not ($71,132 ± 22,685, $58,269 ± 24,387; $P = .049$). Also, patients who achieved SCB for PROMIS-UE were significantly older than those who did not (71.3 ± 8.5, 66. 5 ± 8.0; $P = .033$). Results of the entire analysis can be viewed on Table IV.

Table II – Correlation of PROMIS domains and patient-centric factors.

Domain	R^2	P value	Correlation strength
Preoperative			
PROMIS-UE and PI	-0.769	**<.001**	Strong
PROMIS-UE and D	-0.147	.223	Very Weak
PROMIS-UE and Delta UE	0.246	**.039**	Weak
PROMIS-PI and Delta PI	-0.183	**.185**	Very Weak
PROMIS D and Delta D	-0.416	**<.001**	Moderate
PROMIS-PI and D	0.239	**.045**	Weak
Delta UE and Delta PI	0.557	**<.001**	Moderate
Delta UE and Age	0.251	**.035**	Weak
Postoperative			
PROMIS-UE and PI	-0.645	**<.001**	Strong
PROMIS-UE and D	-0.490	**<.001**	Moderate
PROMIS-PI and D	0.577	**<.001**	Moderate
PROMIS-PI and Age	-0.333	**.005**	Weak
PROMIS-PI and D	0.502	**<.01**	Moderate
PROMIS-PI and MHI	-0.255	**.032**	Weak
PROMIS-D and BMI	-0.241	**.044**	Weak
Delta			
PROMIS-UE and PI	-0.557	**<.001**	Moderate
PROMIS-UE and D	-0.262	**.027**	Weak
PROMIS-PI and D	0.400	**.001**	Moderate
PROMIS-UE and Age	0.251	**.035**	Weak
PROMIS-PI and Age	-0.257	**.031**	Weak
PROMIS-D and Preoperative D	-0.416	**<.001**	Moderate
PROMIS-UE and Preoperative UE	-0.246	**.039**	Weak

PROMIS, Patient-Reported Outcomes Measurement Information System; *UE*, Upper Extremity Physical Function; *PI*, Pain Interference; *D*, Depression.

Discussion

Our results suggest that patients who undergo primary RTSA will experience significant improvements in PROMIS-UE and PROMIS-PI at approximately two years postoperatively. However, patients are unlikely to significantly improve in the PROMIS-D domain at 2 years. A patient's clinical improvements can be assessed with MCID values of 7.0 and -6.6 and SCB values of 8.4 and -12.1 for PROMIS-UE and PROMIS-PI, respectively. Lastly, although ROC univariate analysis for MCID revealed an AUC of 0.743 for PROMIS-UE and 0.805 for PROMIS-PI, and ROC univariate analysis for SCB revealed an AUC of 0.883 for PROMIS-UE and 0.932 for PROMIS-PI, these data are based on weak correlational strength (Preoperative PROMIS-UE and Delta UE $R^2 = 0.246$; Preoperative PROMIS-PI and Delta PI $R^2 = -0.183$; Preoperative PROMIS-D and Delta D $R^2 = -0.416$). Therefore, an RTSA patient's achievement of MCID at 2-year follow-up for PROMIS-UE, PROMIS-PI, and PROMIS-D cannot be reliably predicted using any of these three patient reported outcome measures preoperatively and they should not be used to counsel patients or guide postoperative treatment. When controlling for patient

Table III – Anchor-based PROMIS CSO values.

	MCID			SCB		
Domain	Value	AUC	CI	Value	AUC	CI
PROMIS-UE	7.0	0.743	0.588-0.898	8.4	0.883	0.750-1.000
PROMIS-PI	-6.6	0.805	0.654-0.955	-12.1	0.932	0.861-1.000
PROMIS-D	-3.9	0.601	0.451-0.750	-4.0	0.652	0.472-0.831

AUC, Area Under the Curve; *CI*, Confidence Interval; *MCID*, Minimal Clinically Important Difference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, Upper Extremity Physical Function; *PI*, Pain Interference; *D*, Depression; *SCB*, Substantial Clinical Benefit.

Table IV – Correlation of demographic and other factors on patient outcomes.

	MCID			SCB		
	Not Achieved	Achieved	*P* value	Not Achieved	Achieved	*P* value
PROMIS-UE						
Age, yr	65.7 ± 8.4	68.3 ± 8.0	0.558	66.5 ± 8.0	71.3 ± 8.5	**0.033**
MHI, $	60,851 ± 28,761	69,821 ± 19,476	0.091	66,240 ± 22,292	73,013 ± 26,820	0.287
BMI	31.0 ± 5.8	30.8 ± 6.4	0.614	30.4 ± 6.2	31.9 ± 7.0	0.407
Sex			0.647			0.393
Male	8 (57.1)	29 (50.9)		29 (55.8)	8 (42.1)	
Female	6 (42.9)	28 (49.1)		23 (42.1)	11 (57.9)	
Smoking			0.211			0.609
Never	5 (35.7)	20 (35.1)		16 (30.8)	9 (47.4)	
Former	7 (50.0)	35 (61.4)		33 (63.5)	9 (47.4)	
Current	2 (14.3)	2 (3.5)		3 (5.8)	1 (5.3)	
Race			0.386			0.350
Caucasian	9 (64.3)	44 (77.2)		38 (73.1)	15 (78.9)	
African American	5 (35.7)	13 (22.8)		14 (26.9)	4 (21.1)	
PROMIS-PI						
Age, years	63.7 ± 8.0	69.0 ± 8.2	**0.026**	66.7 ± 8.4	69.7 ± 8.2	0.150
MHI, $	58,269 ± 24,387	71,132 ± 22,685	**0.049**	64,172 ± 23,150	75,193 ± 23,136	0.059
BMI	30.3 ± 6.0	31.0 ± 6.6	0.702	31.1 ± 6.4	30.3 ± 6.7	0.623
Sex			0.322			0.845
Male	8 (47.1)	29 (53.7)		26 (56.5)	11 (44.0)	
Female	9 (52.9)	25 (46.3)		20 (43.5)	14 (56.0)	
Smoking			0.147			0.396
Never	4 (23.5)	21 (38.9)		14 (30.4)	11 (44.0)	
Former	11 (64.7)	31 (57.4)		30 (65.2)	12 (48.0)	
Current	2 (11.8)	2 (3.7)		2 (4.3)	2 (8.0)	
Race			0.074			0.237
Caucasian	10 (58.8)	43 (79.6)		34 (73.9)	19 (76.0)	
African American	7 (41.2)	11 (20.4)		12 (26.1)	6 (24.0)	

BMI, Body Mass Index; *MHI*, Median Household Income; *MCID*, Minimal Clinically Important Difference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *UE*, Upper Extremity Physical Function; *PI*, Pain Interference; *SCB*, Substantial Clinical Benefit.

demographics and various patient variables, we found that greater age and greater median household income were associated with achieving MCID and greater age was associated with achieving SCB. In total, patients who achieved clinically significant outcomes did not have statistically different patient-centric factors than those who did not.

There is good evidence in the orthopedic PROMIS literature suggesting that PROMIS CAT is a valid and efficient measure of patient outcomes in the upper extremity.[5,8,10,11] Evidence exists that preoperative PROMIS CAT is a strong predictor of postoperative PROMIS outcomes for primary reverse shoulder arthroplasty (ROC univariate analysis AUC: 0.74 for PROMIS PF, 0.76 for PROMIS PI, and 0.82 for PROMIS-D)[11] and a moderate predictor of postoperative PROMIS outcomes for total shoulder arthroplasty (ROC univariate analysis AUC: 0.67 for PROMIS-PF; 0.69 for PROMIS-PI; 0.67 for PROMIS-D).[5] When Chen et al performed multivariate analysis, they found strong predictability for PROMIS-PF and PROMIS-D (ROC multivariate analysis AUC: 0.70 and 0.71, respectively) and excellent predictability for PROMIS-PI (ROC multivariate analysis AUC 0.87).[5] These studies had final follow-up of 9.6 months[11] and 3 months,[5] respectively, suggesting that PROMIS may be adequate for predicting earlier postoperative outcomes[5,6,8,10,11,17] but is less able to predict more long-term outcomes as evidenced by our average follow-up time of 21.4 months.

Aside from the difference in length of follow-up, perhaps the most important difference between the present study and those published by Franovic et al and Chen et al is the methodology. Both of these studies used distribution-based methods when calculating MCID whereas we used anchor-based methods. Perhaps anchor-based methods don't work as well for surgeries of the shoulder such as RTSA, whereas distribution-based methods might have better predictive value for surgeries of this type as has been suggested for reverse shoulder arthroplasty[11] and total shoulder arthroplasty.[5] As far as we know, this is the only anchor-based study to calculate MCID using PROMIS questionnaires in a cohort made up entirely of RTSA patients. Therefore, there are no other papers with which to compare MCID values. However, using an anchor-based method allows for better insight into a patient's perceptions of their improvements, or lackthereof, compared to non-anchoring methods.[13,26] In using the anchor-based method to caluculate MCID, our results may better describe the relationship between preoperative PROMIS and achievement of postoperative MCID than ditribution-based reports.[11,25,26] However, some portend that 1 methodology may not be superior to the other.[7,19] Although our data suggest that PROMIS CAT forms don't have strong predictive ability for RTSA, that's not to say they shouldn't be used. PROMIS CAT questionnaires have high validity and reliablity,[8] reduced floor to ceiling effects compared to legacy PROs,[12] reduce patient and administration burden,[20] and are stronlgy correlated with legacy PROs,[14,23] making them an attractive choice for surgeons looking to adopt PRO measures for their practice.

This study has limitations. Firstly, because of the variability in follow-up for those who underwent RTSA, selection bias may have existed. The follow-up period included patients who presented over the course of years which could have resulted in excluding of patients who returned for a visit in the appropriate follow-up time frame. This also could have altered the data because patients who had better outcomes may not have been as likely to return for follow-up appointments. These limitations exemplify barriers to the retrospective design of this study and need to be considered in future studies. Overall, the limitations here can be evaluated in subsequent studies that aim to evolve the use of MCID data in RTSA patients.

Conclusions

PROMIS-UE and PROMIS-PI questionnaires can adequately assess the symptoms and outcomes of RTSA patients out to 2 years postoperatively. However, preoperative baseline scores cannot adequately predict if a patient will achieve MCID in patients indicated for primary RTSA when using anchor-based methods at final, long-term follow-up. Therefore, preoperative PROMIS scores should not be used to counsel patients on surgery or guide postoperative treatment out to 2 years.

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