



Preoperative PROMIS Cluster Profiles Predict Two-Year Outcomes in Shoulder Surgery Patients

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Disclosures

I (and/or my coauthors) have something to disclose

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INTRODUCTION

- Patient-reported outcome (PRO) metrics are important measures of clinical improvement following orthopaedic procedures, but meaningful clinical interpretation of these assessments remains difficult.
- The Patient-Reported Outcomes Measurement Information System (PROMIS) is a validated and standardized computer adaptive testing (CAT) system that allows for fast and reliable collection of various domains such as Physical Function, Pain Interference, Social Satisfaction, Fatigue, Anxiety, and Depression.
- The clinical utility of single preoperative PROMIS domains has been studied, but individual domains are inherently limited in their clinical value as they cannot provide a comprehensive assessment of the patient's preoperative status.
- George et al. performed a clustering analysis combining multiple baseline PROMIS domains to create 4 distinct patient cluster profiles based on level of physical impairment and mental health distress.
- Yet, the prognostic value of clustering patients based on multiple preoperative PROMIS domains remains unclear.

OBJECTIVES

- The purpose of the study was to determine the prognostic value of grouping shoulder surgery patients into clusters profiles based on preoperative PROMIS for two-year postoperative outcomes.

HYPOTHESIS

- We hypothesize that patients in better preoperative PROMIS cluster profiles will have better postoperative outcomes at two years, while patients in worse baseline clusters will have greater improvement from baseline despite overall worse postoperative scores.



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METHODS

- 761 patients underwent elective shoulder surgery at a single urban academic medical center and were prospectively enrolled in an orthopaedic registry.
 - Of those patients, 533 (70.0%) patients completed 2-year follow up.
- Patients were administered questionnaires to assess demographic information and patient-reported outcomes preoperatively and at two years postoperatively.
- PRO questionnaires were administered for:
 - PROMIS in six domains (Physical Function, Pain Interference, Social Satisfaction, Fatigue, Anxiety and Depression)
 - American Shoulder and Elbow Surgeons Shoulder Score (ASES)
 - Numeric Pain Scale (NPS) for operative shoulder and whole body
 - Marx Activity Rating Scale (MARS) Upper extremity and Tegner Activity Scale (TAS)
 - Musculoskeletal Outcomes Data Evaluation and Management Scale (MODEMS) preoperative and postoperative met expectations domains
 - Surgical satisfaction (SSQ-8) at two years postoperatively

METHODS

- A k-means cluster analysis was used to identify preoperative PROMIS clusters.
- Chi-square or Wilcoxon ranked sum tests were utilized for bivariate analyses
- Least-squares multivariate analysis was used to identify if the cluster groupings were independent predictors for 2 year and change outcomes.



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RESULTS

- A k-means cluster analysis based on four preoperative PROMIS domains (Physical Function, Pain Interference, Fatigue and Anxiety) classified patients in 4 distinct cluster profiles based on functional status and mental health (Table 1):
 - “Normal Function”
 - “Mild Impairment”
 - “Impaired without Distress”
 - “Impaired with Distress”
- Impaired with distress was the largest cluster, accounting for 166 patients (31.1% of the overall cohort; Table 1)
- More impaired cluster status was associated with higher rates of arthroplasty, female gender, preoperative opioid use, lower income, greater ASA score, among other sociodemographic and operative factors.

Table 1: Preoperative Patient-Reported Outcomes Measurement Information System (PROMIS) Domain Profiles of Empirically Derived Clusters

| PROMIS domain | Preoperative PROMIS Cluster | | | | P-value |
|---------------------|-----------------------------|--------------------------|-----------------------------------|--------------------------------|---------|
| | Normal Function (N=114) | Mild Impairments (N=134) | Impaired without Distress (N=119) | Impaired with Distress (N=166) | |
| Physical Function | 51.8 (6.3) | 46.9 (4.7) | 38.4 (6.0) | 35.1 (6.0) | <0.0001 |
| Pain Interference | 53.1 (5.6) | 59.2 (4.4) | 63.2 (4.4) | 68.2 (4.4) | <0.0001 |
| Fatigue | 40.8 (6.5) | 50.5 (5.3) | 54.2 (7.2) | 63.8 (6.1) | <0.0001 |
| Social Satisfaction | 52.2 (9.4) | 43.0 (6.0) | 40.0 (7.0) | 34.4 (6.4) | <0.0001 |
| Anxiety | 45.9 (6.5) | 57.9 (4.8) | 49.8 (5.0) | 63.4 (5.6) | <0.0001 |
| Depression | 40.9 (6.7) | 49.7 (7.8) | 45.8 (7.2) | 56.7 (8.3) | <0.0001 |

Abbreviations: PROMIS, Patient-Reported Outcome Measurement Information System.
Note: Reported as Mean (SD).



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RESULTS

- Better cluster status was associated with better postoperative PRO scores whereas worse cluster status was associated with worse PRO scores (Table 2).
 - However, worse cluster status also was associated greater improvement from baseline for most two-year PROs.

| Two-year Patient-Reported Outcome (PRO) Metrics | Preoperative PROMIS Cluster Profile | | | | P-value: Two-year (Change) values |
|---|--|---|---|--|-----------------------------------|
| | Normal Function Two-year (Change) values | Mild Impairments Two-year (Change) values | Impaired without Distress: Two-year (Change) values | Impaired with Distress: Two-year (Change) values | |
| PROMIS Physical Function | 58.1 (6.3) | 52.9 (6.0) | 48.1 (9.7) | 45.3 (10.2) | <0.001 (0.005) |
| PROMIS Pain Interference | 45.8 (-7.4) | 49.2 (-10.1) | 52.6 (-10.6) | 57.2 (-11.1) | <0.001 (0.11) |
| PROMIS Fatigue | 40.1 (-0.6) | 46.4 (-4.2) | 48.6 (-5.1) | 55.5 (-8.3) | <0.001 (<0.001) |
| PROMIS Social Satisfaction | 58.4 (6.3) | 53.0 (9.8) | 49.7 (9.7) | 45.4 (11.0) | <0.001 (0.11) |
| PROMIS Anxiety | 43.1 (-2.6) | 50.7 (-7.1) | 48.4 (-1.4) | 55.1 (-8.2) | <0.001 (<0.001) |
| PROMIS Depression | 41.1 (0.4) | 47.9 (-1.8) | 47.5 (1.6) | 51.5 (-4.7) | <0.001 (<0.001) |
| ASES | 90.0 (27.8) | 83.5 (38.4) | 75.6 (36.3) | 63.0 (35.8) | <0.001 (0.01) |
| MARS | 62.2 (1.3) | 57.1 (2.6) | 43.9 (-6.3) | 34.8 (-10.3) | <0.001 (0.06) |
| Tegner Postop | 5.7 (1.8) | 4.6 (1.9) | 3.5 (1.8) | 2.8 (1.8) | <0.001 (0.68) |
| Numeric Pain Scale - Whole Body | 1.2 (0.78) | 2.2 (1.02) | 2.9 (0.55) | 4.1 (0.68) | <0.001 (0.74) |
| Numeric Pain Scale - Operative Shoulder | 1.0 (-2.7) | 1.7 (-3.4) | 2.2 (-3.0) | 3.4 (-3.4) | <0.001 (0.27) |
| MODEMS Met Expectation* | 88.4 | 77.2 | 69.9 | 60.7 | <0.001 |
| SSQ8* | 89.7 | 82.5 | 79.0 | 72.6 | <0.001 |

Bold values indicate statistically significant difference (p < 0.05) among clusters in given PRO metric.

Note: Mean two-year value given with mean change value in parentheses.

*No preoperative to postoperative change PRO value exists for MODEMS Met Expectations and SSQ8.



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RESULTS

- More impaired clusters were also associated with greater probability of achieving MCID on PROMIS Physical Function, Fatigue, and Depression (Table 3).

Table 3: Percent (%) That Achieve MCID^a by Cluster Profile

| PROs | Preoperative PROMIS Cluster Profile | | | | P-value |
|-------------------------------------|-------------------------------------|-----------------|---------------------------|------------------------|------------------|
| | Normal Function | Mild Impairment | Impaired without Distress | Impaired with Distress | |
| PROMIS Physical Function | 31.6% | 31.8% | 38.1% | <u>46.1%</u> | 0.034 |
| PROMIS Pain Interference | 47.3.0% | 49.6% | 49.6% | 52.4% | 0.87 |
| PROMIS Fatigue | 11.9% | 21.7% | 33.9% | <u>38.9%</u> | <0.001 |
| PROMIS Social Satisfaction | 41.7% | <u>50.0%</u> | 46.1% | 46.5% | 0.66 |
| PROMIS Anxiety | 25.2% | <u>37.7%</u> | 21.1% | 35.9% | 0.01 |
| PROMIS Depression | 7.6% | 18.5% | 9.9% | <u>26.9%</u> | <0.001 |
| MARS | 75.7% | 65.9% | 78.2% | 75.0% | 0.29 |
| ASES | 82.5% | <u>92.2%</u> | 83.7% | 81.5% | 0.09 |
| % Achieved Completely Better Status | <u>85.9%</u> | 67.0% | 73.3% | 59.5% | <0.001 |

Percentages of given cluster that achieved MCID in two-year PRO metric given. **Bolded font indicates statistically significant difference (p < 0.05) among clusters in % that achieved MCID for given PRO metric.** Underlined values indicate highest % MCID achievement among statistically significant clusters in given PRO metric.

^aNote: MCID was defined as achieving a 10-point improvement on all PROMIS domains, a 12.5 improvement on MARS, and a 6.4 improvement on ASES. Scores that were worsened by these amounts were not considered as achieving MCID



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RESULTS

- Better preoperative PROMIS cluster profile was independently predictive of better two-year outcomes across nearly all PROs while the most impaired cluster was independently predictive of worse two-year outcomes for the same PROs (Table 4).
- Worse preoperative cluster status was also independently predictive of greater improvement in most outcomes except ASES (Table 5).

Table 4 Multivariable Regression for Relevant Two-Year Outcome Metrics

| Two-Year PRO Metric Model | Preoperative PROMIS Cluster Estimates | | | | R ² |
|---------------------------------------|---------------------------------------|------------------|---------------------------|------------------------|----------------|
| | Normal Function | Mild Impairments | Impaired without Distress | Impaired with Distress | |
| PROMIS Physical Function | 3.86 | -0.06 | -1.17 | -2.63 | 0.42 |
| PROMIS Pain Interference | -2.85 | -0.47 | 0.47 | 2.86 | 0.34 |
| PROMIS Fatigue | -4.86 | 0.34 | -0.40 | 4.93 | 0.40 |
| PROMIS Social Satisfaction | 4.12 | -0.54 | -0.51 | -3.06 | 0.34 |
| PROMIS Anxiety | -4.44 | 1.68 | -1.67 | 4.43 | 0.20 |
| PROMIS Depression | -4.63 | 1.30 | 0.10 | 3.24 | 0.22 |
| ASES | 6.10 | 2.90 | 0.16 | -9.11 | 0.35 |
| MARS | 4.84 | 4.22 | -1.47 | -7.60 | 0.35 |
| Tegner Postop | 0.75 | 0.18 | -0.26 | -0.67 | 0.42 |
| NPS Operative Shoulder | -0.73 | -0.04 | -0.10 | 0.87 | 0.25 |
| NPS Whole Body | -0.61 | -0.21 | -0.02 | 0.84 | 0.37 |
| SSQ8 | 5.95 | 0.38 | -2.10 | -4.23 | 0.19 |
| Completely Better Status ^a | 0.86 | -0.22 | -0.06 | - | 0.09 |

Table 5 Multivariable Regression for Relevant CHANGE Two-Year Outcome Metrics

| CHANGE Two-Year PRO Metric Model | Preoperative PROMIS Cluster | | | | R ² |
|----------------------------------|-----------------------------|------------------|---------------------------|------------------------|----------------|
| | Normal Function | Mild Impairments | Impaired without Distress | Impaired with Distress | |
| PROMIS Physical Function | -4.54 | -3.51 | 3.08 | 4.97 | 0.26 |
| PROMIS Pain Interference | 5.13 | 0.24 | -2.14 | -3.22 | 0.15 |
| PROMIS Fatigue | 5.75 | 1.48 | -1.94 | -5.29 | 0.17 |
| PROMIS Social Satisfaction | -5.37 | 0.13 | 1.87 | 3.37 | 0.13 |
| PROMIS Anxiety | 3.65 | -2.17 | 2.62 | -4.10 | 0.14 |
| PROMIS Depression | 2.24 | -0.22 | 2.07 | -4.08 | 0.12 |
| MARS | 3.73 | 6.17 | -2.85 | -7.05 | 0.05 |
| ASES | -8.40 | 4.33 | 2.44 | 1.63 | 0.08 |

For both Tables 4 & 5:

Bolded font indicates statistically significant (p < 0.05) estimates.

Scaled estimates (p-value) given and in reference to 0, except Completely Better Status^a estimates in reference to Impaired with Distress Cluster.

Variables incorporated were those significantly associated with PROMIS cluster group on bivariate analysis



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DISCUSSION

- Grouping patients based on only 4 preoperative PROMIS domains has prognostic value in predicting two-year postoperative outcomes for shoulder surgery patients even when possible confounding sociodemographic factors are controlled for.
- Cluster status was associated with various demographic, socioeconomic, and operative/medical factors.
- Better preoperative PROMIS cluster status predicts superior two-year outcomes.
- Worse preoperative cluster status was associated with worse two-year scores, but also substantial improvement and reached MCID on multiple PROs despite lower overall levels of postoperative satisfaction and “Completely Better” rates.

CONCLUSION

- **This study demonstrates that preoperative PROMIS clusters based on as little as 4 domains have prognostic value in predicting shoulder surgery outcomes.**
- **Clustering patients based on multiple PRO domains is a novel, more holistic, and potentially more clinically useful application of PRO metrics for the shoulder surgery patients.**



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