Phenotyping 1-year Dissatisfaction and Poor Outcomes in Primary Total Knee Arthroplasty Patients with PAM, PROMIS, and OSPRO-YF: Baseline Data Results from 267 Consecutive TKA Patients

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INTRODUCTION: The clinical success of total knee arthroplasty (TKA) has led to it being the single largest surgical expenditure for the Centers for Medicare and Medicaid Services. (1) However, 10-20% of TKA patients are dissatisfied after surgery. (2-3) Dissatisfaction is associated with body mass index (BMI), advanced age, individuals who are biologically female, anxiety, depression, kinesiophobia, unmet expectation and other variables. (4) Psychosocial problems may affect up to 20% of the population, with almost half of these patients untreated. (5) Patients who have signs of low self-efficacy or activation are consistently associated with worse surgical outcomes and postoperative quality of life. (6) These psychosocial factors may influence patient compliance with care, outcomes, and satisfaction. Thus, the ability to properly identify patients who are deemed high risk for dissatisfaction and poor outcomes is crucial to allow surgeons to target preoperative optimization to provide maximum value patients, payors, and health systems. To this end, the long-term objective of this study is to identify the proportion of patients undergoing TKA who are at high risk for dissatisfaction or poor outcomes by the utilization of the Patient Activation Measure (PAM), Patient Reported Outcomes Measurement Information System (PROMIS), and Optimal Screening for Prediction of Referral and Outcomes-Yellow Flag (OSPRO-YF). Utilization of the PAM and PROMIS scores is limited in the TKA patient population. Use of the OSPRO-YF has not been reported in the TKA patient population to date.

METHODS: This is a single site, prospective, observational study, where we enrolled 267 consecutive patients undergoing TKA within our institution. Subjects were asked to complete a PAM survey, PROMIS survey, and OSPRO-YF questionnaire. Patients also filled out questionnaires/surveys preoperatively, 6 weeks follow-up, 90-day follow-up, and at 1 year. The primary outcome is the mean pre-surgery PAM score among patients who are satisfied versus those that are dissatisfied. To calculate the study sample size assumptions were made based on previous studies in total joint arthroplasty populations. To show a mean difference of 15 points in the pre-surgery PAM scores in patients who are satisfied versus dissatisfied requires 23 subjects per group. Satisfaction is assessed at 1 year. Demographic variables were collected from individual patient information extracted from subject's chart. Included subjects are those older than 18 years of age undergoing primary TKA. Excluded subjects are patients with any previous knee surgery beyond a knee scope. A poor outcome is defined as a manipulation under anesthesia, emergency room visit within 90 days, readmission within 90 days, or reoperation within 1 year. For this preliminary analysis of the baseline data, we compared the hypothesized "high risk group" (PAM levels 1 or 2) versus "low risk group" (PAM levels 3 or 4) based on previous studies. (6)

RESULTS: Among the 267 enrolled subjects, 244 (91%) are classified as low risk PAM 3 or 4. There was no difference in age sex, race, or laterality between groups. The low vs. high-risk pre-op phenotype comparison is summarized in Table 1. Of note, high-risk subjects had higher PROMIS Pain score (63.16 ± 4.35 vs, 59.58 ± 6.03; p<0.01) and higher PROMIS depression score (50.8 ± 8.5 vs. 46.02 ± 8.2; p<0.01), but there was no difference in preoperative PROMIS physical function score (p=0.71) and KOOS Jr scores (p=0.34). High-risk subjects tended to have a significantly higher mean number of "flags" on OSPRO-YF subscale measures PHQ9 (48% vs. 18%; p<0.001), STAI (39% vs. 14%; p<0.01), STAXI (26% vs. 6%; p<0.001), PSEQ (70% vs. 46%; p=0.03), SER (61% vs 37%; p=0.03). Additionally, high-risk patients have a significantly higher number of "flags" on the OSPRO-YF negative mood domain (65% vs. 27%; p<0.0001) and have a higher median OSPRO-YF yellow flag count (7 vs 4; p<0.01).

Table 1. Baseline Data	PAM Level 1 and 2 (n=23)	PAM Level 3 and 4 (n=244)	
	Mean (St. Dev.)	Mean (St. Dev.)	p-value
PROMIS Physical Function	38.77 (5.47)	39.24 (5.82)	0.71
PROMIS Pain	63.16 (4.35)	59.58 (6.03)	<0.01
PROMIS Depression	50.81 (8.50)	46.02 (8.20)	<0.01
KOOS Jr.	47.11 (16.66)	50.58 (12.17)	0.34
PHQ9	Yes 11 (47.83) No 12 (52.17)	Yes 45 (18.44) No199 (81.56)	<0.001
STAI	Yes 9 (39.13) No 14 (60.87)	Yes 35 (14.34) No 209 (85.66)	<0.01
STAXI	Yes 6 (26.09) No 17 (73.91)	Yes 14 (5.74) No 230 (94.26)	<0.001
FABQ-PA	Yes 15 (65.22) No 8 (34.78)	Yes 111 (45.49) No 113 (54.51)	0.07
FABQ-W	Yes 11 (47.83) No 12 (52.17)	Yes 129 (52.87) No 115 (47.13)	0.64
PCS	Yes 12 (52.17) No 11 (47.83)	Yes 110 (45.08) No 134 (54.92)	0.51
TSK	Yes 17 (73.91) No 6 (26.09)	Yes 140 (42.62) No 104 (57.38)	0.12
PASS	Yes 13 (56.52) No 10 (43.48)	Yes 102 (41.80) No 142 (58.20)	0.17
PSEQ	Yes 16 (69.57) No 7 (30.43)	Yes 113 (46.31) No 131 (53.69)	0.03
SER	Yes 14 (60.87) No 9 (39.13)	Yes 91 (37.30) No 153 (62.70)	0.03
CPAQ	Yes 15 (65.22) No 8 (34.78)	Yes 129 (52.87) No 115 (47.13)	0.26
OSPRO Negative Mood Domain	Yes 15 (65.22) No 8 (34.78)	Yes 66 (27.05) No 178 (72.95)	0.0001
Fear Avoidance Domain	Yes 20 (86.96) No 3 (13.04)	Yes 182 (74.59) No 62 (25.41)	0.19
Positive Affect Coping Domain	Yes 18 (78.26) No 5 (21.74)	Yes 158 (64.75) No 86 (35.25)	0.19
OSPRO Yellow Flag Counts	Median (IQR) 7 (3-8)	Median (IQR) 4 (1-7)	<0.01

DISCUSSION: Preliminary analysis of this prospective dataset demonstrate a significant correlation among low patient activation (PAM 1 or 2) and nearly half of the yellow flags across the OSRPO-YF subscales as well as the PROMIS pain and PROMIS depression subscales. While the relationship between these preoperative measures and satisfaction at 1 year have yet to be determined we hypothesize that at least some of these measures will identify domains for preoperative optimization and therapeutic intervention to significantly improve value.

SIGNIFICANCE/CLINICAL RELEVANCE: ~20% of TKA patients are dissatisfied with their surgical outcome at 1-year. While optimizing known modifiable risk factors (e.g., BMI, blood glucose, acute infections) may improves TKA outcomes, low activation thresholds that warrant pre-op interventions have not been defined. Thus, establishing PAM, PROMIS and OSPRO-YF thresholds for high-risk patients whose activation level could be modified prior to elective TKA is of great value to patients and healthcare systems.

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