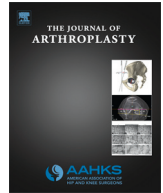




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Patient-Reported Allergies Are Associated With Poorer Patient Satisfaction and Outcomes After Lower Extremity Arthroplasty: A Retrospective Cohort Study

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ABSTRACT

Anecdotal evidence suggests that patient-reported allergies (PRAs) may exhibit prognostic value for patient-reported outcomes after lower extremity arthroplasty. This study's purpose was to investigate associations between PRAs, patient satisfaction and outcomes after total hip arthroplasty (THA) and total knee arthroplasty (TKA). PRAs in 274 patients undergoing primary THA and 257 patients receiving primary TKA were reviewed retrospectively. Satisfaction scores, baseline Western Ontario and McMaster Universities Arthritis Index (WOMAC), 2-year postoperative WOMAC and length-of-stay (LOS) were analyzed with PRAs. Increasing number of PRAs was significantly associated with worse satisfaction scores and worse WOMAC scores for TKA and THA, and it was significantly associated with increased LOS for TKA. These results may have implications for patient counseling and risk-adjusted outcome models.

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Despite generally excellent outcomes, dissatisfaction after primary total hip arthroplasty (THA) and primary total knee arthroplasty (TKA) is not uncommon [1–4]. While surgeon experience, surgical technique, and implant choice are important factors, patient-specific characteristics may adversely affect patient satisfaction and patient-reported outcomes (PROs) after lower extremity arthroplasty [5–24]. Anecdotal observation suggests that patients with multiple patient-reported allergies (PRAs) may represent a clinically challenging group of patients, who report worse satisfaction and outcomes after orthopedic surgery. Furthermore, there is evidence of a robust association between dissatisfaction with medical care and allergic-type symptoms without clear organic etiology [25]. Although the development of true metal hypersensitivity can lead to THA and TKA failure [26], to our knowledge, there are no published studies investigating the association between non-specific PRAs and patient-reported satisfaction and PROs after lower extremity arthroplasty.

The purpose of this study was to investigate the associations between baseline PRAs and (1) patient satisfaction two years after THA and TKA, (2) PROs two years after THA and TKA, and (3) hospital length-of-stay (LOS). We hypothesized that increasing number of

PRAs is associated with worse patient satisfaction, worse PRO scores, and increased LOS.

Materials and Methods

Institutional review board approval was obtained before the initiation of this retrospective cohort study. An electronic search of the medical record from a single, high-volume, tertiary care, private teaching hospital in an urban setting, using ICD-9 codes 81.51 (THA) and 81.54 (TKA), was conducted over an arbitrary 10-week period (October 2010 to December 2010) to identify all THA and TKA procedures performed during that time. Patients were excluded if they received bilateral surgery, hemiarthroplasty, hip resurfacing arthroplasty (HRA), had preoperative fracture, or underwent any concomitant procedure(s). Patients were also excluded if they received subsequent surgery in the 2 years following THA or TKA, if they did not complete baseline or 2-year outcome surveys for the institutional arthroplasty registry.

Basic demographic information, LOS, and PRAs were recorded from the electronic medical record. Charlson–Deyo Comorbidity Index (CDI), satisfaction ratings, and clinical outcome scores were obtained from the arthroplasty registry. A patient satisfaction questionnaire, using Likert-type scales, was administered two years after surgery. The questionnaire assessed patient satisfaction in regard to postoperative pain relief, ability to perform housework and yard work, ability to perform recreational activities, overall satisfaction, and subjective improvement in quality of life. Clinical outcomes scores were measured

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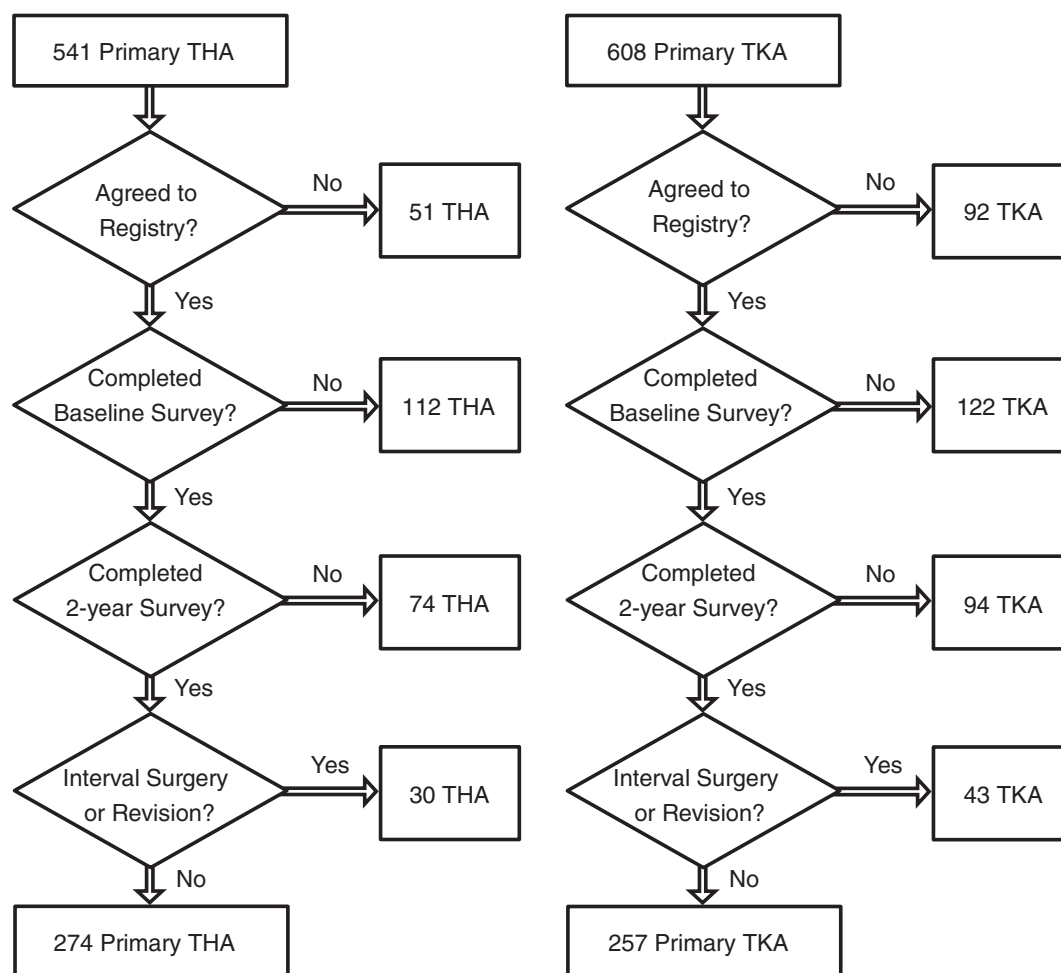


Fig. 1. Flowchart showing the formation of study cohorts for total hip arthroplasty (THA) and total knee arthroplasty (TKA).

using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). These were recorded within six months before surgery and at two years postoperatively.

Statistical Methods

THA and TKA were analyzed separately. Descriptive statistics were used to summarize baseline patient demographics, clinical characteristics, and PRAs. Means and standard deviations for continuous variables were calculated. Frequency and percentage were calculated for categorical variables.

For analysis, Likert-type scale responses from the satisfaction questionnaire regarding pain, housework, recreational activities and overall satisfaction were dichotomized into (1) somewhat to very satisfied, and (2) somewhat to very dissatisfied, or neither satisfied or dissatisfied. Similarly, responses to the survey regarding improved quality of life were dichotomized into (1) moderate to great improvement, or more improvement than ever dreamed possible, and (2) a little improvement, no improvement or worse. CDICs were dichotomized into (1) an index score of 0, and (2) a score ≥ 1 , for the regression analyses. Logistic regression was performed on satisfaction questions, treating PRA as a continuous variable. Multiple linear regression analyses were performed to examine the association between PRAs and WOMAC scores at baseline, two years post-surgery, and overall improvement in WOMAC at two years, with PRA analyzed as a continuous variable. All regression analyses were performed adjusting for age, gender, CDIC, and body mass index (BMI). Analyses of the WOMAC scores at two years

postoperatively and the change in WOMAC scores from baseline to two years postoperatively were adjusted for baseline scores.

All tests were two-sided, with a significance level of 0.05. All analyses were conducted using SAS for Windows 9.3 (SAS Institute Inc., Cary, NC).

Results

One thousand three hundred forty-one patients were initially identified from the electronic medical record, of which 192 patients were excluded for bilateral surgery, hemiarthroplasty, HRA, fracture care, or concomitant surgical procedure. After additional exclusion criteria were applied, 274 TKA and 257 THA were available for final analysis (Fig. 1). Baseline patient characteristics, including PRAs and WOMAC scores are summarized in Table 1. Approximately 53% of THA and TKA patients had no PRA, and 21.6% of THA and 25.7% of TKA had more than one PRA. 69.8% of allergens were medications, 16.2% were environmental exposures, and 14.0% were foods. The maximum number of PRA was 11 and 14 for THA and TKA, respectively.

Mean LOS for THA was 3.3 ± 0.9 days (median, 3.0 days) and 3.9 ± 1.1 days (median, 4.0 days) for TKA. In general, the majority of patient-reported satisfaction scores were positive (Table 2), and the mean changes observed in WOMAC scores at two years after arthroplasty met the criteria for clinical significance for TKA and THA patients (Table 3).

Despite generally high levels of patient-reported satisfaction at two years, logistic regression analysis demonstrated that increasing number of PRAs in THA patients was significantly associated with increased odds

Table 1
Baseline Patient Characteristics.

	THA (N = 274)	TKA (N = 257)
Demographics		
Age, mean $\pm$ SD	65.6 $\pm$ 10.6	67.5 $\pm$ 9.3
BMI, mean $\pm$ SD	27.3 $\pm$ 5.1	30.1 $\pm$ 5.6
Female, N (%)	143 (52.2%)	138 (53.7%)
Charlson–Deyo Comorbidity Index, N (%)		
0	213 (77.7%)	169 (65.8%)
1–2	53 (19.3%)	78 (30.4%)
3	8 (2.9%)	10 (3.9%)
Patient-reported allergies, mean $\pm$ SD	0.9 $\pm$ 1.5	0.9 $\pm$ 1.3
Baseline WOMAC scores, mean $\pm$ SD		
Pain	55.8 $\pm$ 18.3	55.6 $\pm$ 17.4
Stiffness	45.6 $\pm$ 19.0	46.4 $\pm$ 20.6
Function	51.2 $\pm$ 17.7	54.5 $\pm$ 17.5

THA = total hip arthroplasty; TKA = total knee arthroplasty; SD = standard deviation; BMI = body mass index; WOMAC = Western Ontario and McMaster Universities Arthritis Index.

for worse satisfaction scores across all queried domains (Table 4). Increasing number of PRAs in TKA patients was significantly associated with increased odds for decreased satisfaction in ability to do housework and recreational activities (Table 4). For both THA and TKA patients, each additional PRA was associated with approximately a 50% increased odds for poorer ratings on the improvement in quality of life after arthroplasty survey question.

Multiple linear regression analyses demonstrated that increasing number of PRAs was significantly associated with worse WOMAC pain, stiffness, and function subscale scores at baseline in TKA patients but not THA patients, after controlling for age, gender, CDCI, and BMI (Table 5). An increasing number of PRAs was significantly associated with worse WOMAC pain and function at 2 years after THA, and worse

Table 2
Summary of 2-Year Postoperative Patient-Reported Outcomes and Satisfaction Scores.

	THA (mean $\pm$ SD)	TKA (mean $\pm$ SD)
WOMAC scores at 2 years post-arthroplasty		
Pain	91.3 $\pm$ 13.1	85.6 $\pm$ 15.9
Stiffness	86.9 $\pm$ 9.6	79.0 $\pm$ 10.7
Function	91.1 $\pm$ 11.4	85.8 $\pm$ 11.2
Change in WOMAC scores at 2 years post-arthroplasty		
Pain	38.2 $\pm$ 17.9	33.5 $\pm$ 19.0
Stiffness	40.9 $\pm$ 21.5	31.9 $\pm$ 24.0
Function	40.1 $\pm$ 17.7	31.1 $\pm$ 19.2
Patient-reported satisfaction scores at 2 years post-arthroplasty	%	%
Relieving pain		
Somewhat to very satisfied	95.9%	94.5%
Somewhat to very dissatisfied, or neither satisfied or dissatisfied	4.1%	5.5%
Improve ability to do housework		
Somewhat to very satisfied	94.4%	90.4%
Somewhat to very dissatisfied, or neither satisfied or dissatisfied	5.6%	9.6%
Improve ability to do recreational activities		
Somewhat to very satisfied	90.3%	86.2%
Somewhat to very dissatisfied, or neither satisfied or dissatisfied	9.7%	13.8%
Overall		
Somewhat to very satisfied	94.4%	93.7%
Somewhat to very dissatisfied, or neither satisfied or dissatisfied	5.6%	6.3%
Improve the quality of your life?		
Moderate to great improvement, or more improvement than ever dream possible	97.0%	93.3%
A little improvement, no improvement or worse	3.0%	6.7%

THA = total hip arthroplasty; TKA = total knee arthroplasty; SD = standard deviation; WOMAC = Western Ontario and McMaster Universities Arthritis Index.

Table 3
Registry-Specific Minimal Clinically Important Differences and Changes At 2 Years Post-arthroplasty.

	THA		TKA	
	MCID ^a	MCIC ^b	MCID ^a	MCIC ^b
WOMAC Pain score	16.25	16.25	11.25	22.5
WOMAC Stiffness score	12.5	25	12.5	25
WOMAC Function score	13.2	30.88	16.18	26.96

THA = total hip arthroplasty; TKA = total knee arthroplasty; WOMAC = Western Ontario and McMaster Universities Arthritis Index.

^a MCID = minimal clinically important difference. Refers to differences observed between patients.

^b MCIC = minimal clinically important change. Refers to the change in health status from baseline to 2-year follow-up within patients.

WOMAC pain, stiffness, and function at 2 years after TKA, controlling for age, gender, CDCI, BMI and baseline WOMAC scores. Increasing number of PRAs was significantly associated with less improvement in WOMAC pain scores from baseline in THA patients, and with less improvement from baseline WOMAC pain, stiffness, and function scores in TKA patients, after controlling for other variables.

An increasing number of PRAs was significantly associated with increased LOS for TKA and not THA, although the observed effect size was small (Table 5).

Discussion

Our results support the primary study hypothesis that increasing number of PRAs is associated with worse patient satisfaction after TKA and THA. Likewise, PROs at two years after lower extremity arthroplasty were also generally worse with increasing number of PRAs. There was a small, but statistically significant, association between increasing number of PRAs and LOS for TKA but not THA.

Patient-reported outcomes evaluate treatments from the patient perspective, focusing primarily on subjective assessments of satisfaction, function with daily living tasks, pain, joint stiffness, general physical and mental health, and they are increasingly used as measures of success [27]. As such, PROs may have a role in future reimbursement rates for common orthopedic procedures [28,29]. It is therefore important to recognize factors that may portend poor results. Furthermore, a thorough understanding and identification of the preoperative factors that may influence the outcome of an arthroplasty is essential for alignment of surgeon and patient goals and expectations [30].

While implant alignment and function are important variables dictating THA and TKA results, patient-specific factors frequently influence subjective outcome measures in arthroplasty patients. In particular, advanced age [31], female gender [6,10], elevated BMI [6], race and ethnicity [10], lower education level and socioeconomic status [7,8], multiple

Table 4
Odds Ratios Relating Patient-Reported Allergies and Worsening Patient-Reported Satisfaction Scores.^a

	THA				TKA			
	OR	95% CI	P-value		OR	95% CI	P-value	
Relieving pain	1.55	1.15	2.09	0.0043	1.35	0.87	2.09	0.1824
Improve ability to do housework	1.37	1.05	1.79	0.0206	1.62	1.19	2.20	0.0021
Improve ability to do recreational activities	1.38	1.08	1.76	0.0097	1.44	1.07	1.93	0.0154
Overall satisfaction	1.45	1.10	1.90	0.0083	1.36	0.88	2.10	0.169
Improve the quality of your life?	1.51	1.07	2.13	0.0183	1.52	1.05	2.19	0.026

THA = total hip arthroplasty; TKA = total knee arthroplasty; OR = odds ratio; CI = confidence interval.

^a Results from logistic regression analysis, controlling for age, gender, Charlson–Deyo Comorbidity Index, and body mass index.

Table 5

Summary of Associations Between Number of Patient-Reported Allergies and Length-of-Stay and Outcome Scores.^a

	THA			TKA		
	Estimate	Standard Error	P-value	Estimate	Standard Error	P-value
Length of stay	0.02	0.03	0.4849	0.06	0.03	0.0395
Baseline WOMAC scores						
Pain	−1.08	0.68	0.1107	−1.91	0.57	0.0007
Stiffness	0.43	0.74	0.5621	−1.30	0.64	0.0427
Function	−0.57	0.67	0.3916	−2.01	0.58	0.0005
WOMAC scores at 2 years post-arthroplasty						
Pain	−1.24	0.46	0.0069	−1.21	0.56	0.0313
Stiffness	−1.25	0.73	0.0870	−1.64	0.75	0.0284
Function	−1.20	0.52	0.0217	−1.30	0.57	0.0221
Change in WOMAC scores at 2 years post-arthroplasty						
Pain	−0.95	0.45	0.0364	−1.21	0.56	0.0313
Stiffness	−0.59	0.71	0.4092	−1.58	0.74	0.0333
Function	−0.83	0.51	0.1063	−1.30	0.57	0.0221

THA = total hip arthroplasty; TKA = total knee arthroplasty; WOMAC = Western Ontario and McMaster Universities Arthritis Index.

^a Multiple linear regression analyses were performed, examining the association between number of patient-reported allergies and the listed dependent variables, controlling for age, gender, Charlson–Deyo Comorbidity Index, and body mass index.

medical comorbidities [11], preoperative pain level [12], and psychological variables [13–17,12,18–24] have been associated with worse patient-reported outcomes following lower extremity arthroplasty.

Surgeons and hospital staff have anecdotally reported that patients reporting more allergies have a lower overall post-surgical satisfaction. Therefore, we sought to identify and quantify the associations between PRAs, patient satisfaction ratings, WOMAC scores, and LOS after primary THA and TKA.

There are limitations to this study's results. First, formal allergy testing and psychological testing were not performed for the current study. The results may therefore suffer from omitted-variable bias. However, it may be advantageous to identify common, surrogate predictors of patient satisfaction and outcomes, such as PRAs, which are universally assessed during pre-surgical testing. Second, the Likert-type scale used for patient satisfaction is not a validated outcome tool, but Likert-type scales are the most commonly applied instruments utilized for satisfaction ratings [32]. Third, although the present study investigated a large series of consecutive lower extremity arthroplasty patients, only 52.6% of primary, unilateral THA and TKA completed baseline and two-year surveys. Of those submitting baseline surveys, 78.2% completed two-year surveys. These retention rates are comparable to other registry studies reporting 36% to 87% follow-up [33,34]. Although this may represent a source systematic bias, it is a nearly universal limitation of self-reported outcome-based research [35]. Finally, analyses were able to control for age, gender, comorbidities and BMI, but they were not controlled for race, ethnicity, preoperative severity of disease, education level and socioeconomic status, which have are known to influence outcomes after arthroplasty [7–11,31] and which may or may not be related to PRAs. Surgical approach, implant system, and bearing materials were not controlled for either. Most THA were performed through a posterolateral approach with a posterior soft tissue repair, and uncemented or hybrid fixation was used. Nearly all TKA used cement fixation and posterior stabilized implant designs. However, the data included THA and TKA performed by forty-two different surgeons, who implement different surgical techniques and postoperative rehabilitation protocols, which potentially extends the generalizability of the results.

Despite the limitations of the study design, in our cohort of consecutive THA and TKA, patient-reported allergies were strongly associated with increased odds of reporting worse patient satisfaction scores. Similarly, Hausteiner et al [25] found that there was a particularly strong association between self-reported dissatisfaction with medical care and

negative work-up for unexplained symptoms for assumed allergies. Our results quantify the association between PRA and patient satisfaction after lower extremity arthroplasty, with each additional patient-reported allergy associated with a 37% to 62% increase in the odds of reporting worse satisfaction ratings, depending on the type of joint arthroplasty and the satisfaction domain queried.

There were also statistically significant associations between increasing PRA and worse WOMAC subscale scores at 2 years postoperatively, after controlling for age, gender, CDCI and BMI. Furthermore, we observed a small, but statistically significant association, between hospital LOS and PRA in TKA patients. Observed estimates for WOMAC differences in the regression analyses were small (approximately 0.95–2.01 on a 100-point scale). Therefore, the magnitude of estimated effect sizes for an incremental PRA did not reach clinical significance for any WOMAC subscale score (Table 3), although many were statistically significant. Similarly, the magnitude of the effect for each PRA on TKA LOS was much less than one hospital day. Therefore, the regression models would only predict clinically significant effects in WOMAC scores and LOS in patients with a great number of PRAs (approximately 6 to 17).

Our results support the clinical wariness with which orthopedic surgeons sometimes approach treatment of patients with multiple PRAs. There is usually an assumed psychopathological substrate for this clinical concern, as there is an especially strong association between PRAs, unexplained symptomatology and psychiatric diagnoses [25,36–39]. Stemming from this observation, PRAs have been incorporated into diagnostic criteria for various somatoform disorders (SFD) [25,40] and other Axis I diagnoses [41]. Such diagnoses, including somatization [13], depression [13–17,12,18], anxiety [13,15,16,18,22] and panic disorders [13], have been associated with poor outcome after lower extremity arthroplasty, as have lower Short Form-36 mental component summary scores [14,15,19–21] and pain catastrophizing [23,24]. Furthermore, Giesinger et al [27] demonstrated that common PRO instruments used for orthopedic surgery are significantly influenced by patient factors other than the dimensions they purport to measure (e.g., function and stiffness). It should be noted that mental health history and/or scoring was not available for the present study.

Although PRAs are associated with poorer patient satisfaction and PROs after lower extremity arthroplasty, the data should be applied prudently. These data should not bias patient selection for THA and TKA surgery, but rather be used to guide surgeon and patient expectations for post-surgical outcomes. Also, it is important not to discount reported hypersensitivities. Reported allergies to nickel, cobalt or chromium are especially relevant to arthroplasty patients, as sensitivities to these metals may risk implant failure [26,42]. Yet, it's conceivable that other PRAs may play a role as independent variables in predictive models for lower extremity arthroplasty success. Such models may be used to create risk-adjusted outcome determinations that improve the measurement of post-surgical results [29], and these may lead to improved decision making and value for surgeons and patients [29,30].

Conclusions

In conclusion, the principal study hypothesis that increasing number of patient-reported allergies is associated with worse patient-reported satisfaction scores after total hip and knee arthroplasty was affirmed. Additionally, significant relationships were observed between PRAs and worse preoperative WOMAC scores for TKA patients, worse WOMAC scores after THA and TKA, and statistically significant increased LOS after TKA. Although the effect sizes for these latter observations did not meet the criteria for clinical significance, we believe that the satisfaction results support the prognostic value PRAs exhibit for the orthopedic surgeon counseling patients undergoing elective lower extremity arthroplasty surgery. Future studies may elucidate whether number of PRAs can be validated as a screening assessment to identify patients at

risk for suboptimal satisfaction and patient-reported outcomes after THA and TKA.

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