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Original article

Patient-Reported Metal Allergy: A Risk Factor for Poor Outcomes After Total Joint Arthroplasty?

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ABSTRACT

Background: Metal sensitivity after total joint arthroplasty has been of increased concern, but the impact of a patient-reported metal allergy on clinical outcomes has not been investigated. The purpose of this study was to report the incidence and impact of patient-reported metal allergy after total knee arthroplasty (TKA) and total hip arthroplasty (THA).

Methods: This was a retrospective, institutional review board–approved investigation of patients undergoing a primary, elective total joint arthroplasty between 2009 and 2011. All patients completed a preoperative questionnaire asking about drug and environmental allergies. In January 2010, a specific question was added regarding the presence of a metal allergy. University of California at Los Angeles Activity, Short Form 12 (SF-12), Modified Harris Hip, and Knee Society scores were collected preoperatively and at most recent follow-up. Overall cohorts of metal allergy and nonmetal allergy patients were compared, and a 1:2 matching analysis was also performed.

Results: Nine hundred six primary THAs and 589 primary TKAs were included. The incidence of patient-reported metal allergy was 1.7% before January 2010 and 4.0% after (overall 2.3% of THAs and 4.1% of TKAs); 97.8% of metal allergy patients were female. After TKA, postoperative Knee Society Function, Symptoms, Satisfaction, and Expectation scores were all decreased in the metal allergy cohort ($P < .001$-.002). After THA, metal allergy patients had a decreased postoperative SF-12 Mental Component Score and less incremental improvement in their SF-12 Mental Component Score vs the nonmetal allergy cohort ($P < .0001$ and $P = .001$, respectively).

Conclusion: Patient-reported metal allergy is associated with decreased functional outcomes after TKA and decreased mental health scores after THA.

With the recognition of catastrophic aseptic reactions and periprosthetic osteolysis associated with large-diameter metal-on-metal (MOM) bearings, taper-trunnion corrosion, and modular neck prostheses in total hip arthroplasty (THA), the clinical impact of metal sensitivity and allergic reactions has received increased attention [1-5]. However, metal sensitivity as a cause of persistent pain after total joint arthroplasty (TJA) has been studied in orthopedic surgery for decades [6-12]. In 1977, Benson et al [6] noted 28% of patients receiving an MOM McKee prosthesis to have a positive skin patch test postoperatively, vs 2.6% receiving a Charnley prosthesis, noting a potential relationship between metal sensitivity and component loosening in patients who receive an MOM THA device.

In the absence of a clear source of metal debris, diagnosis of a true metal allergy as the cause of persistent pain and symptoms after TJA remains difficult. Based on positive skin patch testing, approximately 10%-20% of the population is metal sensitive, but the association between cutaneous reactions and response to an implanted orthopedic device remains unclear [13]. Therefore, attributing persistent symptoms after TJA to metal sensitivity remains a diagnosis of exclusion.

Recently, the potential impact of patient-reported allergies on outcomes after TJA has been studied, testing the hypothesis that multiple reported allergies may be a surrogate for mental health factors shown to be negative prognostic indicators [14-16]. However, the impact of a patient-reported metal allergy on clinical

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outcomes was not assessed. To our knowledge, neither the overall incidence of patients presenting for TJA who report a metal allergy nor its potential impact on clinical outcomes has been reported. This information could prove useful in addressing patient expectations and may impact risk adjustment for expected outcomes after TJA if clinical differences are significant. Therefore, the purposes of this study were to (1) identify the overall incidence of patients who report having a metal allergy who present for THA or total knee arthroplasty (TKA) and (2) assess the impact of reporting a metal allergy on clinical outcomes after TJA. Our hypothesis is that patient reporting of a metal allergy would be associated with worse outcomes after TJA.

Materials and Methods

This study was an institutional review board–approved retrospective review of a single institution's joint arthroplasty database between January 2009 and January 2011. Inclusion criteria were patients over the age of 18 years undergoing a primary, elective THA or TKA who agreed to participate in the joint arthroplasty registry. Exclusion criteria were patients who underwent a revision TJA procedure as their index procedure at our institution and at the time of inclusion in our institution's joint arthroplasty database, patients who required any reoperation on their affected joint or had signs of radiographic component loosening, or a prior history of infection in the affected joint. Of note, no patients who were enrolled for their primary TJA during this time period had undergone a revision TJA procedure for a diagnosis of metal allergy or aseptic lymphocyte predominant vasculitis-associated lesions. Exclusion criteria were selected to compare patients with presumably well-performing implants. Baseline patient demographics including gender, age, and body mass index (kg/m^2) were collected.

University of California at Los Angeles (UCLA) Activity Score [17], Short Form 12 Scores (SF-12; Physical Component Score [PCS] and Mental Component Score [MCS]) [18], Modified Harris Hip Score (MHHS; for THA patients) [19], and Knee Society Score (KSS; for TKA patients) [20] were collected for patients preoperatively and at each patient's most recent follow-up visit. KSSs were separated into the subdomains of Function, Symptoms, Satisfaction, and patient Expectation for analysis. This information was recorded into the institutional database using a Patient Analysis and Tracking System (Axis Clinical Software Inc, Portland, OR). In addition, all patients completed an intake patient questionnaire in which medical comorbidities and any environmental, food, or medication allergies are self-reported at their initial visit, with all responses recorded into the electronic medical record system (Allscripts, Chicago, IL). In January 2010, a question was added to the intake questionnaire specifically asking whether the patients believed they were allergic to any metals. Before this date, there was no specific query of metal allergy in the questionnaire. Presence or absence of a self-reported metal allergy was reviewed for each patient along with 21 commonly reported environmental and drug allergies. Specific skin patch or lymphocyte transformation testing was not performed for those reporting a metal allergy. Our study cohort consisted of patients who underwent primary TKA or THA in the interval from 1 year before this date to 1 year after the introduction of the metal allergy question to the intake form. During the study period, 5 surgeons enrolled patients with the majority using implants avoiding cobalt alloys (due to the presence of nickel, cobalt, and chrome) in patients reporting the use of a metal allergy. For TKA, this included the use of an Oxinium (Oxidized Zirconium; Smith and Nephew Inc, Memphis, TN) femoral component with a titanium alloy tibial baseplate. For THA, this included the use of an Oxinium or ceramic femoral head with titanium alloy acetabular and femoral components.

Statistical Analysis

Patients were divided into 2 cohorts: those with a self-reported metal allergy (metal allergy cohort) and those without. The incidence of metal allergy reporting was calculated for the interval before and after introduction of the metal allergy question to the intake questionnaire. Statistical analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, WA). Independent student's *t* tests were used to compare the overall mean and incremental improvement in outcome scores between the metal allergy and nonmetal allergy cohorts with a P value of $<.05$ considered statistically significant. Patients were included in the nonmetal allergy cohort if they did not report a metal allergy, regardless of the presence or absence of other environmental or drug allergies. Chi-square and Fisher's exact tests were used to compare categorical variables among cohorts, including the percentage of patients in each cohort reporting $\geq$4 allergies, with a P value of $<.05$ considered statistically significant.

A 1:2 case-matched analysis was also performed using Custom Excel Visual Basic scripts to match each patient in the metal allergy cohort to 2 patients in the nonmetal allergy cohort based on gender (same), age (±7 years), body mass index (BMI; ±5 units), preoperative SF-12 PCS and MCS (±9 points), preoperative MHHS (for THA patients, ±10 points), and preoperative KSS (for TKA patients, ±10 points). Potential nonmetal allergy patients were filtered and prioritized based on similarities for each of the aforementioned criteria and selected to create a new matched patient list for comparison with preoperative clinical scores being considered of increased importance when matching. Statistical comparisons were then performed using the same method as with the overall metal allergy and nonmetal allergy cohorts.

Results

During the 2-year study period, 1495 primary TJA cases were identified and included in this investigation (906 primary THAs: 60.6% and 589 primary TKAs: 39.4%). The mean age of the overall cohort was 59.1 ± 13.6 years, the mean BMI was 30.5 ± 6.6 kg/m^2, and 58.3% of patients were female.

Before the introduction of the specific metal allergy question on the intake questionnaire in January 2010, the incidence of patient-reported metal allergy in patients undergoing primary TJA was 1.7% (11 of 646 patients: 1.2% of THA and 2.5% of TKA patients, Table 1). This increased to 4.0% (34 of 849 patients: 3.2% of THA and 5.2% of TKA patients) after addition of a question asking specifically about a metal allergy. This difference in incidence was significant ($P = .01$).

Table 1
The Incidence of Patient-Reported Metal Allergy.

	Time Interval	# Reporting Metal Allergy	# Reporting No Metal Allergy	Total	Incidence of Self-Reported Metal Allergy (%)
THA	Pre metal allergy question	5	400	405	1.2
	Post metal allergy question	16	485	501	3.2
TKA	Pre metal allergy question	6	235	241	2.5
	Post metal allergy question	18	330	348	5.2
THA + TKA	Pre metal allergy question	11	635	646	1.7
	Post metal allergy question	34	815	849	4.0

THA, total hip arthroplasty; TKA, total knee arthroplasty.