

Shoulder Arthroplasty Outcomes in Patients With Multiple Reported Drug Allergies

Does Number of Drug Allergies Have an Effect on Outcome?

Brett D. Rosenthal,^{*†} MD, Michael J. Knesek,[†] MD, Cynthia A. Kahlenberg,[‡] MD, Harry Mai,[§] BS, and Matthew D. Saltzman,[†] MD

Investigation performed at Department of Orthopaedic Surgery, Northwestern University, Chicago, Illinois, USA

Background: The presence of multiple allergies has been correlated with worse outcomes for patients undergoing hip and knee arthroplasty, but the effect of allergies has not yet been elucidated with respect to shoulder arthroplasty.

Purpose/Hypothesis: The purpose of this study is to identify any discrepancies in shoulder arthroplasty outcomes with respect to reported drug allergies. We hypothesized that patients with multiple drug allergies would have inferior outcomes.

Study Design: Cohort study; Level of evidence, 3.

Methods: Included in the analysis were a single surgeon's cases between 2009 and 2014 of primary total shoulder arthroplasty with a minimum of 180 days of follow-up. Cases with fracture as the indication were excluded. Preoperative and postoperative metrics included visual analog scale (VAS) for pain, forward flexion range of motion, and Simple Shoulder Test (SST) results, and postoperative patient satisfaction scores were also collected. Chi-square and 1-way analysis of variance with Tukey post hoc analyses were performed when appropriate.

Results: A total of 98 patients were included (no allergies, $n = 51$; single allergy, $n = 21$; multiple allergies, $n = 26$). The proportion of females was greater with increasing number of allergies (no allergies, 31%; single allergies, 47%; multiple allergies, 88%; Pearson $\chi^2 = 22.5$; $P < .0001$). Both preoperatively and postoperatively, no difference was found between cohorts with respect to SST score, VAS score, or forward flexion. There was also no difference in postoperative satisfaction between cohorts. No difference between cohorts was identified when comparing the pre- to postoperative change in SST scores, VAS scores, or forward flexion.

Conclusion: The presence of single or multiple allergies is not correlated with worse outcomes after primary anatomic total shoulder arthroplasty.

Keywords: shoulder; arthroplasty; allergies; outcomes

Shoulder arthroplasty procedures are becoming increasingly common. Procedure volumes increased at annual rates of 6% to 13% from 1993 to 2007. Compared with

2007 levels, projected procedures were predicted to further increase by between 192% and 322% by the end of 2015.³ Shoulder arthroplasty remains the third most commonly performed joint replacement behind hip and knee arthroplasty.^{8,18,22,25,26} Satisfaction after shoulder arthroplasty has been variable, and the risk factors for dissatisfaction have not yet been completely elucidated. Correlations have been established between dissatisfaction and lower improvements in pain, function, and range of motion.⁶ Brenner et al² reported 75% satisfaction after shoulder arthroplasty at 11-year follow-up. Similarly, in a long-term follow-up study of shoulder arthroplasty in a younger patient population (<50 years), the authors found that nearly 50% of patients who underwent either total shoulder arthroplasty or hemiarthroplasty graded their result as unsatisfactory.²³

Graves et al⁵ recently reported that patients with 4 or more reported allergies had less improvement in outcome

*Address correspondence to Brett D. Rosenthal, MD, Department of Orthopaedic Surgery, Northwestern University, 676 North Saint Clair Street, Suite 1350, Chicago, IL 60611, USA (email: brett.rosenthal@northwestern.edu).

[†]Department of Orthopaedic Surgery, Northwestern University, Chicago, Illinois, USA.

[‡]Department of Orthopaedic Surgery, Hospital for Special Surgery, New York, New York, USA.

[§]Department of Orthopaedic Surgery, University of California—Los Angeles, Los Angeles, California, USA.

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measures after hip and knee replacement surgery. The authors argued that multiple reported allergies may function as a surrogate for a mental health survey and assist in identifying patients at high risk of having poor postoperative outcomes. Similarly, patient-reported metal allergies are associated with poorer functional outcomes after total knee arthroplasty and worse mental health scores after total hip arthroplasty.¹⁶ To our knowledge, no similar study has been performed within the shoulder arthroplasty literature. We hypothesized that patients with multiple reported allergies would have worse outcome measures, range of motion, and satisfaction scores after shoulder arthroplasty procedures.

METHODS

Institutional review board approval was obtained for this study. The institutional review board waived the requirement for informed consent due to retrospective design, minimal risks, and general consent for inclusion in research studies at time of treatment. Preoperative evaluation of patients who were candidates for shoulder arthroplasty procedures included baseline visual analog scale (VAS) pain scores, Simple Shoulder Test (SST) scores, and range of motion measures including forward flexion. Range of motion was measured by the primary surgeon using goniometry at each encounter. At the first patient visit and then again on the day of surgery, patients were asked to list any "allergies." Their answers were then recorded into the electronic medical record. At 3 months, 6 months, and all subsequent postoperative office visits, patients were once again asked to provide VAS pain scores, repeat the SST, and undergo an evaluation of the shoulder, including measurement of active forward flexion. Additionally, they were asked to provide a satisfaction score (0-10), with 0 being completely unsatisfied and 10 being completely satisfied.

The cohort for our study included patients who had elective primary anatomic total shoulder arthroplasty by a single surgeon over the course of a 6-year period from 2009 to 2014. We included all patients aged 18 years and older and excluded individuals who were undergoing revision surgery or surgery for a traumatic proximal humerus fracture. We identified 98 patients at our academic institution who met the aforementioned criteria and had at least 180 days of follow-up after their index procedure.

Patient drug allergies were obtained from a review of the electronic medical record systems utilized at our institution (EPIC and Powerchart). Within our hospital system, allergy data can be submitted to the electronic medical record by any provider a patient comes in contact with, and thus, these fields were often populated by their primary care physician and confirmed on their visit to our clinic. Food allergies were excluded. Drug reactions that patients classified as "sensitivities" were not considered as allergies for the purposes of this study.

Statistical analyses were performed using JMP software (version 11.2.1; SAS Institute Inc). Three cohorts were studied: patients with no allergies, patients with a single allergy, and patients with multiple allergies. Baseline

demographics were compared between cohorts with chi-square (eg, sex, indication) and analysis of variance (ANOVA) with post hoc Tukey (eg, age, body mass index [BMI]) testing. Mean VAS pain, SST, active forward flexion range of motion, and satisfaction scores were compared between cohorts with ANOVA and post hoc Tukey testing. The preoperative, postoperative, and difference (postoperative minus preoperative) means of these metrics were compared in this fashion. An alpha level of 0.05 was used as the threshold of statistical significance.

RESULTS

A total of 98 patients who met the aforementioned criteria were identified; 88.8% (n = 87) of cases had degenerative joint disease as the primary indication. The mean (\pm SD) follow-up duration was 1.50 ± 0.79 years. Half of patients (50%) were female, and the mean age was 67.7 years at the time of surgery. The majority (52.0%, n = 51) of cases were performed on patients with no reported allergies, 21.4% (n = 21) with a single reported allergy, and 26.5% (n = 26) with multiple reported allergies.

Baseline demographic ANOVA testing did not identify any statistically significant differences in age or BMI between cohorts. The proportion of females was greater with increasing number of allergies (no allergies, 31%; single allergies, 47%; multiple allergies, 88%; Pearson $\chi^2 = 22.5$; $P < .0001$). Chi square analysis did not reveal any differences in indication, side, or procedure type between cohorts.

Preoperatively and postoperatively, no statistically significant difference was found between cohorts with respect to SST score, VAS pain score, or active forward flexion. As such, no differences were found between cohorts with respect to change in SST scores, VAS scores, or forward flexion. Additionally, there were no differences in postoperative satisfaction between cohorts. These outcome metrics are summarized in Table 1.

DISCUSSION

Shoulder arthroplasty remains a very effective treatment for glenohumeral arthritis, and similar to joint replacement for hip and knee arthritis, excellent outcomes can be achieved.¹² Many individuals attain improved outcomes with regard to pain relief and quality-of-life measures. There still remain some individuals, however, who do not achieve the expected improvements. Identifying patients who may be at risk for a poor outcome is becoming increasingly important with the advent of accountable care organizations and as government and insurance companies are moving toward payments based on patient reported satisfaction, among other measures. Dissatisfaction after total shoulder arthroplasty has been previously correlated with diminished improvements in pain, function, and range of motion.⁶ Additionally, patient-reported metal allergies have been associated with poorer functional and mental health after total knee and hip

TABLE 1
Pre- and Postoperative Outcome Metrics^a

Outcome Measure	Preoperative				Postoperative				Change			
	No Allergies	Single Allergy	Multiple Allergies	P	No Allergies	Single Allergy	Multiple Allergies	P	No Allergies	Single Allergy	Multiple Allergies	P
SST score	3.6 ± 2.5 (n = 44)	3.2 ± 2.3 (n = 18)	3.5 ± 2.2 (n = 21)	.81	9.2 ± 2.8 (n = 45)	10.2 ± 2.2 (n = 18)	8.8 ± 3.2 (n = 18)	.31	5.5 ± 2.8 (n = 39)	6.6 ± 3.5 (n = 15)	4.8 ± 3.3 (n = 16)	.28
VAS score	6.1 ± 2.6 (n = 45)	5.8 ± 1.7 (n = 19)	6.7 ± 1.7 (n = 21)	.41	1.6 ± 2.3 (n = 45)	0.6 ± 1.1 (n = 18)	1.4 ± 2.1 (n = 18)	.20	-4.6 ± 3.2 (n = 42)	-5.2 ± 2.3 (n = 17)	-5.8 ± 2.7 (n = 16)	.36
Forward flexion	109 ± 21 (n = 51)	111 ± 25 (n = 21)	115 ± 24 (n = 25)	.57	158 ± 23 (n = 50)	170 ± 5 (n = 21)	163 ± 23 (n = 25)	.07	50 ± 27 (n = 50)	60 ± 25 (n = 21)	49 ± 29 (n = 25)	.34
Satisfaction	—	—	—		8.7 ± 2.1 (n = 44)	9.6 ± 1.3 (n = 17)	8.9 ± 1.5 (n = 18)	.21	—	—	—	

^aFF, forward flexion; SST, Simple Shoulder Test; VAS, visual analog scale.

arthroplasties, respectively.¹⁶ It was our hypothesis that individuals in our practice with multiple allergies may be a part of the subset of patients with worse outcome measures. It is important to recognize that many allergies listed in the patient medical records are actually adverse drug reactions and not allergies. An adverse drug reaction is defined as a noxious, unintended, and undesired side effect of a drug that occurs when the drugs are given for prevention, diagnosis, and treatment.¹⁴ These were excluded for the purposes of our study in an attempt to study outcomes in patients who truly had drug allergies compared with those without.

The hypothesis that patients with multiple drug allergies may be a risk factor for worse function, pain, range of motion, and satisfaction after shoulder arthroplasty procedures was not demonstrated by this study. Our data suggest that for elective primary anatomic total shoulder arthroplasty, self-reported allergies have no bearing on typical outcome metrics. We did find that females were more likely to demonstrate multiple allergies, which is similar to what has been previously reported in the literature for patients undergoing hip and knee arthroplasty.¹⁷ Regardless, their outcomes were no different than that of males in our analysis.

Self-reported allergies and multiple drug intolerance syndrome (a condition defined by having >3 drug hypersensitivities) have been shown to have a high level of correlation with the presence of depression and anxiety.^{4,19} Prior analysis within the hip and knee arthroplasty literature have demonstrated that mental well-being significantly predicted self-rated health postoperatively.²⁰ Similarly, patients with psychological distress had worse self-perceived preoperative and postoperative subjective disability but had no difference in objective improvements.⁹ With these considerations in mind, we had hypothesized that similar to the hip and knee arthroplasty literature, multiple self-reported allergies would correlate with worse outcomes. This, however, was not demonstrated.

So why do allergies have a negative correlation to hip and knee arthroplasty outcomes, but not total shoulder outcomes? We can only speculate based on the data available. Prior observational studies regarding multiple drug intolerance syndrome identified patients with this diagnosis as

older, heavier (higher BMI), and more likely female.¹⁵ While BMI was not significantly different between cohorts in our analysis, the study by Graves et al⁵ did not compare BMI as an independent variable, which could allow for potential confounding. If the multiple allergy cohort resembles what is typical based on prior observations, the presence of obesity may explain the worse outcomes identified. While a negative association between obesity and outcomes has been well-established after total hip and knee arthroplasty,^{1,10,13,21} the correlation is far less obvious after total shoulder arthroplasty.^{7,11,24}

This analysis was limited by its retrospective design, which limited the ability to discern between true drug allergies and mere sensitivities. Nonetheless, the metric of self-reported “allergies” is a variable of interest as well as it may function as a surrogate for mental health surveys. Additionally, the retrospective nature limited the ability to reliably identify the presence of anxiety and/or depression, which although highly associated with self-reported drug allergies, may function as a confounder or effect modifier to the outcomes of interest.

CONCLUSION

The presence of single or multiple self-reported allergies does not correlate with worse function, satisfaction, pain, or range of motion after elective primary anatomic total shoulder arthroplasty.

REFERENCES

- Alvi HM, Mednick RE, Krishnan V, Kwasny MJ, Beal MD, Manning DW. The effect of BMI on 30 day outcomes following total joint arthroplasty. *J Arthroplasty*. 2015;30:1113-1117.
- Brenner BC, Ferlic DC, Clayton ML, Dennis DA. Survivorship of unconstrained total shoulder arthroplasty. *J Bone Joint Surg Am*. 1989;71:1289-1296.
- Day JS, Lau E, Ong KL, Williams GR, Ramsey ML, Kurtz SM. Prevalence and projections of total shoulder and elbow arthroplasty in the United States to 2015. *J Shoulder Elbow Surg*. 2010;19:1115-1120.
- De Pasquale T, Nucera E, Boccascino R, et al. Allergy and psychological evaluations of patients with multiple drug intolerance syndrome. *Intern Emerg Med*. 2012;7:41-47.

5. Graves CM, Otero JE, Gao Y, Goetz DD, Willenborg MD, Callaghan JJ. Patient reported allergies are a risk factor for poor outcomes in total hip and knee arthroplasty. *J Arthroplasty*. 2014;29(suppl): 147-149.
6. Jacobs CA, Morris BJ, Sciascia AD, Edwards TB. Comparison of satisfied and dissatisfied patients 2 to 5 years after anatomic total shoulder arthroplasty. *J Shoulder Elbow Surg*. 2016;25:1128-1132.
7. Jiang JJ, Somogyi JR, Patel PB, Koh JL, Dirschl DR, Shi LL. Obesity is not associated with increased short-term complications after primary total shoulder arthroplasty. *Clin Orthop Relat Res*. 2016;474:787-795.
8. Kim SH, Wise BL, Zhang Y, Szabo RM. Increasing incidence of shoulder arthroplasty in the United States. *J Bone Joint Surg Am*. 2011;93: 2249-2254.
9. Lavernia CJ, Alcerro JC, Brooks LG, Rossi MD. Mental health and outcomes in primary total joint arthroplasty. *J Arthroplasty*. 2012;27: 1276-1282.
10. Ledford CK, Millikan PD, Nickel BT, et al. Percent body fat is more predictive of function after total joint arthroplasty than body mass index. *J Bone Joint Surg Am*. 2016;98:849-857.
11. Li X, Williams PN, Nguyen JT, Craig EV, Warren RF, Gulotta LV. Functional outcomes after total shoulder arthroplasty in obese patients. *J Bone Joint Surg Am*. 2013;95:e160.
12. Lo IK, Litchfield RB, Griffin S, Faber K, Patterson SD, Kirkley A. Quality-of-life outcome following hemiarthroplasty or total shoulder arthroplasty in patients with osteoarthritis. A prospective, randomized trial. *J Bone Joint Surg Am*. 2005;87:2178-2185.
13. Lübbecke A, Zingg M, Vu D, et al. Body mass and weight thresholds for increased prosthetic joint infection rates after primary total joint arthroplasty. *Acta Orthop*. 2016;87:132-138.
14. MacPherson RD, Willcox C, Chow C, Wang A. Anaesthetist's responses to patients' self-reported drug allergies. *Br J Anaesth*. 2006;97:634-639.
15. Macy E, Ho NJ. Multiple drug intolerance syndrome: prevalence, clinical characteristics, and management. *Ann Allergy Asthma Immunol*. 2012;108:88-93.
16. Nam D, Li K, Riegler V, Barrack RL. Patient-reported metal allergy: a risk factor for poor outcomes after total joint arthroplasty? *J Arthroplasty*. 2016;31:1910-1915.
17. Omer HM, Hodson J, Thomas SK, Coleman JJ. Multiple drug intolerance syndrome: a large-scale retrospective study. *Drug Saf*. 2014;37: 1037-1045.
18. Padejimas EM, Maitenfort M, Lazarus MD, Ramsey ML, Williams GR, Namdari S. Future patient demand for shoulder arthroplasty by younger patients: national projections. *Clin Orthop Relat Res*. 2015;473: 1860-1867.
19. Patten SB, Williams JVA. Self-reported allergies and their relationship to several Axis I disorders in a community sample. *Int J Psychiatry Med*. 2007;37:11-22.
20. Perruccio AV, Davis AM, Hogg-Johnson S, Badley EM. Importance of self-rated health and mental well-being in predicting health outcomes following total joint replacement surgery for osteoarthritis. *Arthritis Care Res*. 2011;63:973-981.
21. Polat G, Ceylan HH, Sayar S, Kucukdurmaz F, Erdil M, Tuncay I. Effect of body mass index on functional outcomes following arthroplasty procedures. *World J Orthop*. 2015;6:991-995.
22. Schwartz BE, Savin DD, Youderian AR, Mossad D, Goldberg BA. National trends and perioperative outcomes in primary and revision total shoulder arthroplasty: trends in total shoulder arthroplasty. *Int Orthop*. 2015;39:271-276.
23. Sperling JW, Cofield RH, Rowland CM. Neer hemiarthroplasty and Neer total shoulder arthroplasty in patients fifty years old or less. Long-term results. *J Bone Joint Surg Am*. 1998;80:464-473.
24. Statz JM, Wagner ER, Houdek MT, et al. Outcomes of primary reverse shoulder arthroplasty in patients with morbid obesity. *J Shoulder Elbow Surg*. 2016;25:e191-e198.
25. Trofa D, Rajaei SS, Smith EL. Nationwide trends in total shoulder arthroplasty and hemiarthroplasty for osteoarthritis. *Am J Orthop (Belle Mead NJ)*. 2014;43:166-172.
26. Wirth MA, Rockwood CA. Complications of total shoulder-replacement arthroplasty. *J Bone Joint Surg Am*. 1996;78:603-616.