Clin Orthop Relat Res (2015) 473:2099–2105
DOI 10.1007/s11999-014-4107-7

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

CLINICAL RESEARCH

What Are Risk Factors for 30-day Morbidity and Transfusion in Total Shoulder Arthroplasty? A Review of 1922 Cases

Chris A. Anthony MD, Robert W. Westermann MD, Yubo Gao PhD, Andrew J. Pugely MD, Brian R. Wolf MD, MS, Carolyn M. Hettrich MD, MPH

Received: 5 September 2014 / Accepted: 9 December 2014 / Published online: 19 December 2014

Abstract

Background Total shoulder arthroplasty (TSA) is an effective treatment for end-stage glenohumeral joint pathology with good long-term results. Previous descriptions of morbidity and blood transfusion in TSA are limited by preoperative risk factors and postoperative complications considered and single-center studies.

Questions/purposes The purpose of this study was to define in a group of patients undergoing TSA (1) the type and incidence of complications; (2) the frequency of and risk factors for both minor and major complications; and (3) the risk factors for bleeding resulting in transfusion.

Methods We retrospectively queried the National Surgical Quality Improvement Program database using Current Procedural Terminology billing codes and identified 1922 cases of TSA performed between 2006 and 2011. Postoperative outcomes were divided into one of four categories: any complication, major morbidity (systemic life-threatening event or a substantial threat to a vital organ) or mortality, minor morbidity (localized to the operative upper extremity or not posing a major systemic threat to the patient), or bleeding resulting in transfusion. Univariate and multivariate analyses were then used to identify risk factors for complications.

Results There were a total of 155 complications (8% of the 1922 patients identified). The most common complication was bleeding resulting in transfusion (82 patients [4.26%]) followed by urinary tract infections (27 patients [1.40%]), return to the operating room (14 patients [0.73%]), pneumonia (10 patients [0.52%]), and peripheral nerve injury (nine patients [0.47%]). The incidence of major morbidity was 2% (44 patients), which included five patients (0.26%) who died; the incidence of any minor morbidity was 7% (136 patients). After controlling for likely confounding variables, we found steroid use (odds ratio [OR], 3; 95% confidence interval [CI], 2–6), hematocrit < 38% (OR, 2; 95% CI, 1–3), American Society of Anesthesiologists (ASA) Class 4 (OR, 3; 95% CI, 1–7), and operating time > 2 hours (OR, 2; 95% CI, 1–3) as independent predictors of complication and congestive heart failure (OR, 12; 95% CI, 1–106) as an independent risk factor for major morbidity or mortality. Hematocrit < 38% (OR, 3; 95% CI, 2–6), resident involvement (OR, 3; 95% CI, 2–5), steroid use (OR, 3; 95% CI, 1–6), and ASA Class 3 versus 1 or 2 (OR, 2; 95% CI, 1–5) were independent risk factors for bleeding resulting in transfusion.

Conclusions Short-term morbidity after TSA is higher than previously reported. The prevalence of complications within 30 days of surgery and our outlined risk factors

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Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

C. A. Anthony (✉), R. W. Westermann, Y. Gao, A. J. Pugely, B. R. Wolf, C. M. Hettrich
The Department of Orthopaedic Surgery and Rehabilitation, University of Iowa Hospitals and Clinics, 200 Hawkins Drive, 01008 JPP, Iowa City, IA 52242, USA
e-mail: Chris-Anthony@uiowa.edu

should guide surgeon-driven preoperative patient evaluation, management, and counseling. Surgeons who perform TSA should be aware operative time > 2 hours is associated with increased complications. Patients with preoperative hematocrit < 38%, history of steroid use, ASA Class > 2, and patients with congestive heart failure should receive medical optimization before TSA.
Level of Evidence Level III, therapeutic study.

Introduction

Total shoulder arthroplasty (TSA) is an effective treatment for end-stage glenohumeral joint pathology with good long-term outcomes [32]. Dramatic increases in surgical volume for TSA have been demonstrated during the past two decades [7, 19, 23, 31]. Reported short-term complication rates after TSA vary. Previous reports have found postoperative complication rates of 2.8% to 3.6% at 30 days with exclusion of transfusion as a complication [10, 43]. Bleeding resulting in transfusion has been previously studied as an individual complication in the setting of TSA with transfusion rates ranging from 7% to 43% [15, 17, 30, 37, 41]. Low preoperative hemoglobin in the setting of TSA was found to be an independent risk factor for transfusion in a number of studies [15, 17, 30, 41]. Transfusion poses a small but present risk to patients, increased cost to hospitals and healthcare systems, and has been shown to be a modifiable complication in TKA and THA [13, 18, 30].

Previous work has been limited in the number of preoperative risk factors and postoperative complications considered as well as single-center studies and studies considering limited patient populations [8–10, 42, 43]. Given the nature and scope of previous work, we feel complications in TSA may be underestimated and not fully represented. Knowledge of risk factors for short-term morbidity is beneficial to surgeons and patients for many reasons. Patients with identifiable risk factors could be optimized before surgery; nonmodifiable risk factors could be incorporated into informed consent consultations and discussed with patients before deciding whether to proceed with TSA. Knowledge of risk factors might also be used to guide further study and clinical trials. Although previous authors have considered transfusion in the setting of TSA, their work has largely been single surgeon or single institution in nature [15, 17, 30, 41]. We seek to evaluate more robust patient, surgeon, and hospital populations when considering risk factors for transfusion in TSA.

The aims for our study were to define in a group of patients undergoing TSA: (1) the type and incidence of complications; (2) the frequency of and risk factors for both minor and major complications; and (3) to separately determine risk factors for bleeding resulting in transfusion.

Materials and Methods

Our retrospective study was deemed institutional review board-exempt and HIPPA-compliant. The National Surgical Quality Improvement Program (NSQIP) methodology has been previously well described and involves both academic and private medical institutions prospectively collecting patient data, including preoperative, operative, and 30-day outcomes from more than 480 hospitals throughout the United States [6, 11, 22]. The NSQIP database provides aggregate data from all participating surgical centers and does not allow for interpretation of data by individual hospitals or surgeons. Surgical clinical reviewers are responsible for NSQIP data collection. The surgical clinical reviewer collects prospective complication data over a 30-day postoperative period through chart review of patient postoperative progress notes and clinic visits in the outpatient setting. If a patient has not had a clinic visit within 30 days of a procedure, they are contacted by the surgical clinical reviewer to verify the presence or absence of complications or admissions at outside institutions. Furthermore, the surgical clinician reviewer directly contacts the treating surgeon if anything in the medical record is unclear. NSQIP data are consistently audited with interobserver disagreement rates of 1.56% [39].

We retrospectively surveyed the NSQIP database using Current Procedural Terminology (CPT) billing codes for TSA performed between 2006 and 2011. In our data collection, we used a singular CPT code for primary TSA (23472), which identified 1922 cases after exclusion of patients with a compromised surgical wound, preoperative sepsis, and emergent surgical cases. Given current CPT coding schemes, it was not possible to differentiate between TSA and reverse TSA. Osteoarthritis of the shoulder was the primary postoperative diagnosis in approximately 75% of patients followed by soft tissue injury to the shoulder (6%) and upper extremity fracture (3%). For our current study, postoperative outcomes were divided into one of four categories: "any complication," "major morbidity or mortality," "minor morbidity," and "bleeding requiring transfusion." In general, "major" complications were defined as a systemic life-threatening event or a substantial threat to a vital organ. We considered a complication "minor" if localized to the operative upper extremity and not posing a major systemic threat to the patient, as previously reported [38, 47]. Previously, our group has used similar methods to report incidence and risk factors of complications after elective knee arthroscopy

and elective shoulder arthroscopy [27, 28]. We included bleeding requiring transfusion as a minor complication and also considered it as a dependent variable in a separate analysis given its previously reported rate of occurrence in TSA [15, 17, 30, 37, 41]. The reason for transfusion is not made available through NSQIP. In both our univariate and multivariate analyses, mortality was included with major morbidity as the outcome, which was rare, and the patient numbers were not sufficient for an independent statistical analysis. For the outcome of "any complication," we included all morbidities listed under both major and minor morbidity and also included mortality. Hospital readmission was only recorded in the NSQIP database for the year 2011; subsequently, it was excluded from analysis. NSQIP applies strict definitions to patient comorbidities and complications. These definitions can be found in the NSQIP user file [6]. The numerous collected data points included patient demographic data, medical comorbidities, laboratory values, and surgical characteristics.

Our initial univariate analysis considered age, gender, race, body mass index, current alcohol abuse, current smoking status, recent weight loss, dyspnea, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), hypertension, diabetes, peripheral vascular disease, esophageal varices, disseminated cancer, steroid use, bleeding disorder, dialysis, chemotherapy in the previous 30 days, radiation therapy in previous 90 days, operation in the previous 30 days, American Society of Anesthesiologists (ASA) class, operative time, resident involvement, and patient functional status. We also included mean preoperative sodium, blood urea nitrogen, albumin, white blood cell count, hematocrit, platelet count, and international normalized ratio. Our analysis identified unadjusted differences between patients with and without complications using a t-test for continuous variables and a chi square test for categorical variables. Univariate analysis identified preoperative hematocrit $< 38\%$, ASA class, operative time > 2 hours, COPD, steroid use, low preoperative albumin, prior operation within 30 days, female sex, and low preoperative sodium as risk factors for any complication. For the outcome of minor morbidity, univariate analysis identified preoperative hematocrit $< 38\%$, ASA class, steroid use, operative time > 2 hours, low preoperative albumin, COPD, female sex, diabetes, low preoperative sodium, and dialysis as risk factors for complication. For the outcome of bleeding resulting in transfusion, univariate analysis identified hematocrit $< 38\%$, resident involvement, dialysis, esophageal varices, ASA class, steroid use, previous surgery in the past 30 days, female sex, diabetes, disseminated cancer, and COPD as risk factors for complication. Next, we attempted to control for confounders by conducting a multivariate logistic regression analysis. The outcome variable was any complication, major morbidity or mortality, minor morbidity, and bleeding resulting in transfusion. We included any variable in our multivariate model if the p value was < 0.1 in the univariate analysis and the variable had 85% complete data. Statistical significance across all models was considered as $p < 0.05$. We used SAS (Version 9.3; SAS Institute, Cary, NC, USA) to perform our statistical analysis. Model quality was evaluated by calibration using the Hosmer-Lemeshow test and discrimination with C statistics. The calibration test yielded a modified chi square statistic, and a p value > 0.05 indicated that the model was appropriate and fit the data well. Good discrimination is commonly reported to be between 0.65 and 0.85 and reflects how the C value relates to the accuracy of the model.

Results

Among 1922 patients who underwent TSA, 8% (155 patients) experienced at least one complication (Table 1). The incidence of patients who experienced at least one major morbidity was 2% (44 patients), which included five patient mortalities (0.26%); the incidence of patients who experienced at least one minor morbidity was 7% (136 patients) (Table 1). The most common complication was bleeding resulting in transfusion (82 patients [4.26%]) followed by urinary tract infections (27 patients [1.40%]), return to the operating room (14 patients [0.73%]), pneumonia (10 patients [0.52%]), peripheral nerve injury (nine patients [0.47%]), and surgical site complication or infection (six patients [0.31%]; three wound dehiscence, two superficial infections, one deep infection) (Table 1). Data for readmission from 2011 were available for 698 patients, and 26 (4%) of those patients were readmitted within 30 days (Table 1). After controlling for likely confounding variables, the multivariate analysis showed steroid use (odds ratio [OR], 3; 95% confidence interval [CI], 2–6), ASA Class 4 compared with 1 or 2 (OR, 3; 95% CI, 1–7), preoperative hematocrit $< 38\%$ (OR, 2; 95% CI, 1–3), and operating time > 2 hours (OR, 2; 95% CI, 1–3) as independent predictors of any complication (Table 2). After controlling for likely confounders, a multivariate analysis showed a history of CHF (OR, 12; 95% CI, 1–106) as an independent risk factor for major morbidity or mortality (Table 2). After controlling for likely confounders, multivariate analysis for minor morbidity showed ASA Class 4 compared with 1 or 2 (OR, 5; 95% CI, 2–12), steroid use (OR, 3; 95% CI, 1–5), hematocrit $< 38\%$ (OR, 2; 95% CI, 1–3), and operating time > 2 hours (OR, 2; 95% CI, 1–3) as independent predictors for minor morbidity (Table 2). After controlling for likely confounding variables, the multivariate analysis showed preoperative

Table 1. Frequency of complications in 1922 patients who underwent primary total shoulder arthroplasty

	Frequency	Percentage
Major complication		
Organ space infection	1	0.05
Sepsis	6	0.31
Septic shock	1	0.05
Deep SSI	1	0.05
Wound dehiscence	3	0.16
Pulmonary embolism	5	0.26
Ventilator > 48 hours	1	0.05
Unplanned intubation	2	0.1
Acute renal failure	0	0
Cardiac arrest requiring CPR	2	0.1
Myocardial infarction	4	0.21
Stroke/CVA with neurological deficit	3	0.16
Coma > 24 hours	0	0
Graft/prosthesis/flap failure	1	0.05
Return to OR	14	0.73
Total incidence of major complication	44	2
Minor complication		
Superficial SSI	2	0.1
Pneumonia	10	0.52
Urinary tract infection	27	1.4
DVT/thrombophlebitis	6	0.31
Bleeding transfusions	82	4.26
Peripheral nerve injury	9	0.47
Progressive renal insufficiency	0	0
Total incidence of minor complications	136	7
Mortality	5	0.26
Any complication	155	8
Readmission*	26 of 698	4

* Readmission data were collected only for 2011 and only 698 patients had this data point available; SSI = surgical site infection; CPR = cardiopulmonary resuscitation; CVA = cerebrovascular accident; OR = operating room; DVT = deep vein thrombosis.

hematocrit < 38% (OR, 3; 95% CI, 2–6), resident involvement (OR, 3; 95% CI, 2–5), steroid use (OR, 3; 95% CI, 1–6), and ASA Class 3 versus 1 or 2 (OR, 2; 95% CI, 1–5) to be independent risk factors for bleeding resulting in transfusion (Table 2).

Discussion

Few previous studies have described the short-term complications in the setting of TSA. Thus, we set out to define the incidence of and risk factors for these complications. As healthcare priorities have recently shifted toward outcomes measurement and quality assessment, the field of orthopaedic surgery has been relatively devoid of these data. Within our study, we sought to provide the baseline data after TSA from a large, multicenter national cohort. According to our findings, the frequency of short-term complications after TSA may be higher than previously appreciated at 8% [9, 10, 14, 43]. We reported the incidence of many relevant adverse events with bleeding resulting in transfusion being most common. We found many modifiable and nonmodifiable risk factors for major and minor complications including CHF, steroid use, preoperative hematocrit < 38%, and operative time > 2 hours. Finally, we identified risk factors for bleeding resulting in transfusion including preoperative hematocrit < 38%, resident involvement, steroid use, and ASA class.

Table 2. Predictors of morbidity in total shoulder arthroplasty identified through multivariate regression analysis

Risk factors	Adjusted odds ratio (95% confidence interval)
Risk of any complication	
Steroid use	3 (2–6)
ASA Class of 4 versus 1 or 2	3 (1–7)
Hematocrit < 38% versus > 38%	2 (1–3)
Operating time > 2 hours versus < 2 hours	2 (1–3)
Risk of major morbidity	
CHF	12 (1–106)
Risk of minor morbidity	
ASA Class of 4 versus 1 or 2	5 (2–12)
Steroid use	3 (1–5)
Hematocrit < 38% versus > 38%	2 (1–3)
Operating time > 2 hours versus < 2 hours	2 (1–3)
Risk of bleeding and transfusion	
Hematocrit < 38% versus > 38%	3 (2–6)
Resident involvement	3 (2–5)
Steroid use	3 (1–6)
ASA Class of 3 versus 1 or 2	2 (1–5)

ASA = American Society of Anesthesiologists; CHF = congestive heart failure.

To preface and place our findings within context, it is important to understand several limitations of our study. Given the nature of the NSQIP database, the followup in this study was limited to 30 days and longer-term followup studies would likely have higher complication rates and potentially additional risk factors. Because the rates in our study are already higher than those published in the literature, knowledge of these complication rates and risk factors is even more important. Additionally, given the nature of only one CPT code for TSA in the NSQIP database, we were unable to differentiate between TSA and reverse TSA, and previous reports suggest complication

rates differ between the procedures [8, 14]. Given the multicenter nature of our study and the data available, we were unable to determine the reason for transfusion in each surgical case or if there were protocols in place for transfusion in the setting of TSA at NSQIP institutions. We acknowledge that addition of these data would enhance the results of our study. We also were unable to identify the number of TSAs performed at each surgical center and we acknowledge the possibility that outcomes differ between high- and low-volume centers.

We found the overall incidence of having any complication within 30 days after TSA was 8%. The most prevalent complications were bleeding resulting in transfusion, urinary tract infection, and return to the operating room within 30 days. Although we found overall complication rates in the same range as previous reports, the overall complication rates at 30 days in our study were higher than previous findings in the population at large [9, 14, 43] and compared with the US veteran population [10]. The differences may be the result of how other authors defined complications. We evaluated a more comprehensive list of possible complications (Table 1) and included bleeding resulting in transfusion as a complication. Previous work has found postoperative complication rates of 2.8% to 3.6% at 30 days [10, 43] using NSQIP methodology, notably with bleeding resulting in transfusion excluded from their analysis along with other variables used in our study. We found that 4.26% of patients required transfusion and we note that if bleeding resulting in transfusion were excluded from our analysis, the overall complication rate in our study would decrease from 8% to 4%.We found 30-day mortality to be 0.26% at 30 days, which is slightly lower than reported in previous studies [9, 10, 40, 45]. We suspect that the variation in mortality may be the result of differences among the patient cohort demographics and a shorter collection time in our study. Surgeons should advise patients that bleeding resulting in transfusion is the most common complication in TSA and that other complications including urinary tract infection, return to the operating room, pneumonia, and death are relatively rare. Our stated prevalence of various complications acquired from a large, multicenter database presents the opportunity for hospitals and healthcare systems to conduct further work on quality improvement and cost analysis in the setting of TSA.

We found several important modifiable and nonmodifiable risk factors for TSA complications including CHF, steroid use, hematocrit $< 38\%$, and operative time > 2 hours. Our multivariate analysis showed a history of CHF as an independent risk factor for major morbidity or mortality with an increased OR of 12. When undergoing hip and knee arthroplasty, CHF has previously been found to be a risk factor for hip and knee periprosthetic joint infections, mortality, cardiac complications, and revision within 12 months of primary THA [2, 4, 5, 24, 33]. The risk of a major adverse event after TSA is generally rare; however, the odds of sustaining a major complication are high for patients with a history of CHF. Previous work has demonstrated that increased complexity of a surgical procedure is correlated with increased risk of complication [44] and that surgical complexity may or may not be reflected by length of the surgical procedure [27]. Operative time may also reflect the comfort level of the surgeon with the procedure and surgeon experience [36]. We found that operative time > 2 hours put patients at increased risk for a complication. In addition to our findings, an increase in overall complication rates has been found with increased surgical time (> 1.5 hours) in both knee (OR, 1.84) and shoulder arthroscopy (OR, 2.10) [27, 28]. Although we were unable to quantify the complexity of TSA cases in our study, we suggest that surgical complexity may be closely reflected by increased operative time and report that operative time > 2 hours is an independent risk factor for any complication. Known deleterious side effects of corticosteroid use include delayed wound healing, infection, and osteonecrosis [21, 25, 26, 35]. We found that steroid use was an independent risk factor with a threefold increase for experiencing any complication after undergoing TSA (OR, 3). Obesity and elevated body mass index have previously been associated with complications in TKA and THA [1, 12, 29]. We find no association between body mass index and complications in the setting of TSA. Patients with a history of CHF should receive special consideration, preoperative medical optimization, and be counseled about their potential risk for a major adverse event when considering TSA. Our data suggest that surgeons who perform TSA should be aware that operative time > 2 hours is associated with increased complications. We also suggest that the benefits of pre- and perioperative steroid therapy should be strongly weighed against the risk of increased complications when undergoing TSA. Furthermore, a multidisciplinary approach to perioperative care, including addressing necessity and dosing of steroids, should be considered.

Given the relatively high rate of transfusion in TSA (7%–43%) reported in the literature [15, 17, 30, 37, 41], we conducted an individual analysis of risk factors for bleeding resulting in transfusion. Previous work has demonstrated consensus regarding low patient preoperative hemoglobin percent as an independent risk factor for transfusion in the setting of TSA [15, 17, 30, 41]. Previous authors have recommended preoperative autologous blood donation in TSA for patients with preoperative hemoglobin levels between 110 and 130 g/L [30]. In the setting of TKA and THA, various preoperative hemoglobin optimization

strategies have been studied including autologous and allogeneic blood transfusion protocols, erythropoietin alpha, and tranexamic acid with varying degrees of success and cost-effectiveness [3, 13, 16, 18, 20, 34, 48]. Having used a large multicenter database, our study supports and extends previous results with our finding that a preoperative hematocrit $< 38\%$ is an independent predictor of transfusion. We found that neither male or female sex was an independent predictor of transfusion in TSA, which is notable considering other studies have identified female sex as an independent risk factor [15, 41]. We also report a relationship between resident involvement and need for transfusion in the setting of TSA. Previous studies found resident involvement in orthopaedic cases to increase patient operative time [36, 46] and, in select cases, patient morbidity [36]. Steroid use and ASA class were also found to be independent predictors of transfusion in the setting of TSA and to our knowledge have not been previously reported in the literature. Surgeons should consider preoperative optimization of patient hemoglobin and hematocrit levels, including autologous blood transfusion and protocols previously described in knee and hip arthroplasty. We found that resident involvement was a predictor of transfusion in the setting of TSA and suggest that appropriate measures be taken in the operating room to guide residents in efficiency and surgical techniques to minimize intraoperative blood loss. Finally, we report that female sex is not a risk factor for transfusion and physicians should not feel the need to counsel male and female patients differently regarding risk of transfusion in the preoperative period.

We determined the 30-day patient morbidity and mortality rate after TSA to be 8%. We identified steroid use, hematocrit $< 38\%$, ASA Class 4 compared with 1 or 2, operating time > 2 hours, and a diagnosis of CHF as independent risk factors for a complication. Independent risk factors for transfusion in the setting of TSA include hematocrit $< 38\%$, resident involvement, steroid use, and ASA Class 3 versus 1 or 2. Hospitals and healthcare systems should be aware of the frequency of complications associated with primary TSA when assessing quality and cost. We recommend surgeons should appropriately evaluate and medically optimize patients with CHF, elevated ASA Class > 2, and determine necessity and approach to pre- and perioperative steroid use with a multidisciplinary team. We also recommend appropriate preoperative workup and optimization of patients with low hematocrit to avoid elevated risk for transfusion. Finally, we advise surgeons to be aware of increased complications with operative time > 2 hours and to appropriately guide residents in efficiency and surgical practices that minimize blood loss.

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