The Journal of Arthroplasty 29 (2014) 856–860

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Predictors of Early Complications of Total Shoulder Arthroplasty

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ARTICLE INFO

Article history:
Received 1 June 2013
Accepted 2 July 2013

Keywords:
total shoulder arthroplasty
joint replacement
complications
body mass index
comorbidity
transfusion

ABSTRACT

The authors hypothesized that age, body mass index (BMI), and medical comorbidities (graded with the Charleson Comorbidiy index [CCI]) could be used to predict early complications after TSA. The authors performed a retrospective review of primary TSAs with a minimum of 90-day follow-up. One hundred twenty-seven patients met the inclusion criteria. Complications occurred in 12 (9.4%) of patients. Major complications occurred in 1 patient (0.8%), medical in 8 (6.3%), and surgical in 4 (3.1%). CCI significantly correlated with complication rates and multivariate regression analysis demonstrated CCI to be the only significant determinant of overall complication rates ($P = 0.005$) and medical complication rates ($P = 0.015$). While BMI subgroup did not affect complication rates, transfusion rates, intra-operative blood loss, or operative time, our study may have been underpowered for this variable.

Total shoulder arthroplasty (TSA) offers significant pain relief and functional improvement in patients with degenerative joint disease of the glenohumeral joint with a functional rotator cuff [1–3]. Complications, however, occur in roughly 10% [4,5]. These complications range widely in severity and can include seroma formation, acute blood-loss anemia requiring transfusion [5–7], neurologic injury [8], dislocation [9], infection [10], cardiopulmonary complications [11], and even death [12]. Given that these procedures are performed on an elective basis, orthopaedic surgeons must develop a full understanding of the risk factors for the development of a complication so that patients can be accurately counseled pre-operatively.

Within the hip and knee arthroplasty literature, the risk factors that can contribute to post-operative complications include medical comorbidities and body mass index (BMI) [13,14]. Similar studies have been performed examining total shoulder arthroplasty complications in the intra-operative, peri-operative, and post-operative period [4–7,10–12,15–21]. However, the results of these studies have conflicted with one another and thus it remains unclear which factors are the most important determinants of post-operative complication rates. While some have identified medical comorbidities as significant determinants of cardiopulmonary complications [11] and mortality [12], others have found no correlation between medical comorbidities in rates of infection, revision surgery, or overall complication rates [10,16,19,20,22]. Similarly, BMI has been identified as a predictor of complications and need for revision in some studies [11,18,20,23], while others have either shown higher BMI to be protective or to have no effect [5,6,10,19,22]. Still other studies have examined complication rates without analyzing the effect of medical comorbidities or BMI [4,5,7,15]. Unfortunately, these studies have also combined primary TSA, revision TSA, reverse TSA, and/or humeral hemiarthroplasty [11,12]. These procedures have widely divergent complication rates. Complication rates after reverse TSA are 25-50% [24,25] while those after TSA are 10% [4,5]. In addition, some studies have included patients with proximal humeral fractures in their cohort, which significantly alters the patient population and circumstances of the risk/benefit discussion [16]. Given these difficulties with the previous literature little evidence exists to guide the surgeon as the complication rates and predictors after primary anatomic TSA.

DISCLOSURE(S): Gregory P. Nicholson, MD is a paid consultant for Tornier, and receives research support from Tornier, Ossur, Smith & Nephew. Royalties are received from Innomed, Inc. This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article. Anthony A. Romeo, MD receives royalties from Arthrex Inc.; is on the speakers bureau for Arthrex Inc.; is a paid consultant for Arthrex Inc.; receives research support from Arthrex Inc., DJO Surgical, Smith & Nephew, and Ossur; received other financial support from Arthrex Inc. and DJO Surgical; receives publishing royalties from Saunders/Mosby-Elsevier; serves on the editorial board for the Journal of Shoulder and Elbow Surgery and SLACK Incorporated, and serves as a board member for the American Orthopaedic Society for Sports Medicine, the American Shoulder and Elbow Surgeons, the Arthroscopy Association of North America, and Techniques in Shoulder and Elbow Surgery. These authors, their immediate families, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article. All authors declare no relevant financial conflicts of interest.

This study did not receive any financial support.

Ethical Board Approval: This study was approved by the Rush University Medical Center Institutional Review Board under protocol # 11102407.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2013.07.002.

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0883-5403/2904-0045$36.00/0 – see front matter
http://dx.doi.org/10.1016/j.arth.2013.07.002

Our primary questions with this study were: 1) What is the incidence and type of early complications after primary TSA by a single-surgeon in a consecutive series of patients? 2) Do medical cormorbidities predict these complications? 3) Does BMI predict these complications? 4) If both of these variables predict complications, which is a more important predictor? We hypothesized that 1) the incidence of complications would be similar to that published in the literature and that these would be primarily minor medical complications, 2) medical comorbidities would serve as primary determinant of rates of acute post-operative complications after TSA, 3) BMI would serve as a primary determinant of rates of acute post-operative complications after TSA, and 4) BMI would be more predictive of complication rates than medical comorbidities.

Materials and Methods

Our institutional review board approved this study. All patients who underwent TSA by the senior author with a minimum of 90-days of post-operative follow-up were included in this study. Exclusion criteria included a history of prior ipsilateral shoulder arthroplasty, or incomplete peri- or post-operative records. Indications for TSA included glenohumeral osteoarthritis, glenohumeral post-traumatic arthritis, and glenohumeral instability arthropathy.

The operative reports, peri-operative inpatient records, and post-operative outpatient records for each patient were reviewed and the following data was recorded: age, gender, BMI, laterality of the dominant extremity, laterality of the TSA, indication for TSA, medical comorbidities, length of the procedure in minutes (min), estimated intraoperative blood loss in milliliters (mL), specific implants, concomitant procedures, and the need for intra-operative or post-operative transfusion. All noted complications were recorded.

Medical comorbidities were quantified with the Charlson Comorbidity Index (CCI), an instrument validated for use in surgical patients [26–28]. This tool has been shown to be predictive of long-term mortality in patients based upon a score assigned to their medical conditions, such as renal dysfunction, oncologic history, and diabetes, assigning scores from 1–6 to each condition based upon their contribution to the risk of death [26–28]. CCI was calculated for each patient included in our study.

Complication Classification

Any event that deviated from the normal post-operative course was considered as a complication. Complications were then subdivided into "minor" and "major" as well as "medical" and "surgical" (Table 1). Complications that occurred locally at the operative site or that stemmed from the surgical site, such as instability, fracture, incisional breakdown, or transfusion due to operative blood loss were considered "surgical" while systemic complications such as renal insufficiency, myocardial infarction, and thromboembolic complications were considered "medical".

Statistical Analysis

All analyses were performed in SPSS 18 (IBM Inc., Armonk, NY). Descriptive statistics were calculated. An *a priori* decision was made to divide patients into three groups: Group 1 – normal BMI (BMI less than 25), Group 2 – BMI classified as overweight or "mildly obese" or class I obesity (BMI 25–35), and Group 3 – BMI classified as moderately/severely obese or class II or greater obesity (BMI >35) [30]. These group divisions were made based upon our anecdotal clinical experience, the mean and standard deviation of BMI of the average patient undergoing TSA and reverse TSA (RTSA) in the senior authors' practice (~30 ± 5), as well as evidence from the hip and knee arthroplasty literature suggesting that complication rates may not be increased until obesity is severe [14]. CCI was divided *a priori* into those patients with medical complications (CCI > 0) and those without (CCI = 0).

Table 1
Classification of Complications – Major and Minor, Medical and Surgical (Based Off of the Classification Scheme Described by Dindo et al [29].

Complication type	Definition	Example
Minor	Any deviation from the normal post-operative course that requires pharmacologic treatment	Medical: ileus, acute renal failure responding to fluids, urinary retention, blood sugar derangement, altered mental status, acute blood loss anemia requiring transfusion Surgical: cellulitis responding to oral antibiotics alone, lymphedema, shoulder stiffness, fracture not requiring additional fixation or change in postoperative protocol
Major	Potentially life-threatening complication requiring prolonged pharmacologic treatment or requiring surgical intervention	Medical: Death, Stroke, Myocardial infarction, Deep Vein Thrombosis, Pulmonary Emboli, Pneumonia Surgical: Dislocation, Deep infection, Any return to operating room, Fracture requiring change to post-operative protocol or requiring additional fixation

Komolgorov–Smirnov analysis was performed on continuous variables and all variables significantly differed from the normal distribution ($P < 0.05$). Thus Kruskal–Wallis test was performed to compare continuous variables between BMI groups and CCI groups. Statistical comparison of categorical variables involved the chi-square test.

Given concern that multiple variables may predict complication rates, multivariate logistic regression was planned to determine which variables served as the primary determinants of complication rates.

Results

One hundred and thirty-two consecutive patients underwent anatomic TSA. Five patients were excluded as they were revision cases, leaving 127 patients that met the inclusion criteria. These patients were 58% female with an average age of 66.3. The vast majority of patients underwent TSA for a diagnosis of osteoarthritis (120/127 patients) with a minority undergoing TSA for post-traumatic arthritis (4/127 patients) or instability-related arthropathy (3/127). Complications were infrequent, occurring in 9.4% of patients. The majority were classified as minor, with only a single major complication occurring (post-operative dislocation requiring revision surgery). An additional dislocation occurred, which was successfully treated with closed reduction and thus classified as minor. Medical complications occurred in eight patients and included urinary retention requiring catheterization (four patients), hypotension and tachycardia requiring transfer to our critical care unit for more intensive monitoring (two patients), severe nausea and vomiting limiting rehabilitation (one patient), and hyponatremia requiring free-water restriction (one patient). Surgical complications occurred in four patients and included two dislocations and three transfusions for acute blood loss anemia. No thromboembolic complications, infections, or mortalities occurred.

The mean CCI for the cohort was 0.3 (Table 3). BMI correlated with CCI ($P < 0.001$, Table 3). Mean age, operative indications, operative time, estimated blood loss, and percentage of patients requiring a transfusion did not differ between patients in CCI subgroups ($P > 0.244$ in all cases). Overall complication rates were significantly more frequent in the group with a CCI > 0 ($P = 0.024$). Significantly higher CCI scores were seen in those with a complication (0.75) as compared to those without (0.24, $P = 0.01$, Table 4). In addition,

Table 2
Complications Segregated by BMI Groups.

Complication	Total	BMI < 25	BMI 25-35	BMI > 35	*P* Value	CCI = 0	CCI > 0	*P* Value
Percent (and number) sustaining a complication	9.4 (12)	6.7 (1)	7.6 (7)	19 (4)	0.256	6.2(6)	20(6)	0.024
Percent (and number) sustaining a major complication	0.8 (1)	0 (0)	1.1 (1)	0 (0)	0.819	1(1)	0(0)	0.577
Percent (and number) sustaining a medical complication	6.3 (8)	6.7 (1)	4.4 (4)	14.3 (3)	0.243	4.1(4)	13.3(4)	0.070
Percent (and number) sustaining a surgical complication	3.1 (4)	0 (0)	3.3 (3)	4.8 (1)	0.714	2.1(2)	2(6.7)	0.207
Percent (and number) sustaining an infection	0 (0)	0 (0)	0 (0)	0 (0)	1.000	0(0)	0(0)	>0.999
Percent (and number) sustaining a dislocation	1.6 (2)	0 (0)	2.2 (2)	0 (0)	0.669	2.1(2)	0(0)	0.428
Percent (and number of) mortalities before final follow-up	0 (0)	0 (0)	0 (0)	0 (0)	1.000	0(0)	0(0)	>0.999

significantly higher CCI scores were seen in those with surgical complications (1.00) than those without (0.27, $P = 0.002$, Table 4).

Mean BMI for our cohort was 30.5 ± 5.9 (Fig.). Mean age, operative indications, operative time, estimated blood loss, and percentage of patients requiring a transfusion did not differ between patients in each BMI subgroup. Overall complication rates, major complication rates, medical complication rates, surgical complication rates, infection rates, dislocation rates, and mortality rates did not significantly differ between BMI subgroups ($P > 0.256$ in all cases, Table 2, Fig.).

Multivariate regression analysis with age, BMI subgroup, and CCI showed no significant correlations between age, BMI subgroup and overall complication rates, major complication rates, surgical complication rates, and medical complication rates ($P > 0.243$ in all cases, Table 5). However, significant correlations were observed between overall complication rates and CCI ($P = 0.005$, Table 5) and surgical complication rates and CCI ($P = 0.015$, Table 5). A post-hoc analysis performed to determine study power with respect to BMI found that a sample size of 253 patients would be required to find a difference between overall complications rates in those patients with a BMI of <30 and those patients with a BMI of >30, should one exist.

Discussion

Prior studies examining total shoulder arthroplasty complications in the intra-operative, peri-operative, and post-operative period have conflicted with one another and thus it remains unclear which factors are the most important determinants of post-operative complication rates [4–7,10–12,15–21]. This study sought to determine the incidence and determinants of peri-operative complications in a consecutive series of elective primary total shoulder arthroplasties performed by a single-surgeon. We hypothesized that medical comorbidities and BMI would serve as primary determinants of rates of acute post-operative complications after TSA and found that CCI predicted complications while BMI did not, although type II error is possible. In our study, the overall complication rate was 9.4% with most acute post-operative complications being minor medical complications (6.3%). Urinary retention and hypotension/tachycardia accounted for 75% of the observed minor medical complications. No deep venous thromboses or pulmonary emboli occurred and no chemical prophylaxis was routinely used in our cohort.

In our study CCI was the most significant predictor of post-operative complications. Similarly, Singh and colleagues have shown CCI to be a significant predictor for cardiac events, thromboembolic events, and mortality after TSA [11,12]. However, these authors and others have failed to find any correlation between CCI and periprosthetic sepsis [10], risk for revision surgery [19,20], functional outcomes [22], and mid-term implant failure [16]. The differences in surgical complication rates between patients with high and low CCI may be driven by differences in pre-operative hemoglobin rates, a correlation noted in some but not all previous comparative studies [6,7,23]. Alternatively, physicians may have a lower threshold to transfuse patients with more comorbidities. Previous series' have not found any correlation between pre-operative anti-coagulant use and transfusion rates [6,7,23].

BMI did not predict complications in our study. Due to the small sample size and overall low complication rates, type II error, failure to detect a difference that does exist, may have contributed to the lack of a difference between complication rates between BMI subgroups. Indeed, one past study did conclude that obesity leads to higher peri-operative complication rates [18]. This study, however, did not include a control group of non-obese patients, and thus no comparative conclusions can be drawn [18]. One previous series found complication rates to correlate with a BMI of 25–30 but not >30, a finding difficult to explain pathophysiologically due to the lack of a dose–response relationship [11]. Several past series have shown no correlation between obesity and post-TSA complications, suggesting that type II error may be less likely [5,6,10,11,19,22]. Singh and colleagues documented higher BMI as protective against 90 day mortality [12]. These same collaborators found no effect of BMI upon cardiac complications [11], periprosthetic sepsis [10], or revision surgery following TSA [19]. Authors at other institutions have found no effect of BMI upon functional outcomes [22] or transfusion rates [5,6].

Our study determined CCI to be a more important predictor of post-operative complications than BMI. Unpublished research at our own institution evaluating the impact of BMI on complications in reverse total shoulder arthroplasty (RTSA) has shown BMI to be a more important determinant of complications after RTSA than CCI. A

Table 3
Demographic and Intraoperative Characteristics Segregated by Body Mass Index (BMI).

Variable	Total	BMI < 25	BMI 25-35	BMI > 35	P Value	CCI = 0	CCI > 0	P Value
N	127	15	91	21	NA	97	30	NA
Mean age	66.3	65.8	65.2	65.2	0.940	65.8	65.7	0.549
Percent (and number) of female patients	46 (58)	67 (10)	40 (36)	62 (13)	0.045	44(43)	53(16)	0.388
Mean Charleson Comorbidity Index	0.30	0.07	0.17	1.00	<0.001	NA	NA	NA
Mean BMI	30.5	NA	NA	NA	NA	28.9	35.9	<0.001
Indications (number of subjects)								
Osteoarthritis	120	15	85	20	0.641	92	28	0.920
Post-traumatic arthritis	4	0	4	0		3	1	
Instability-related arthropathy	3	0	2	1		2	1	
Mean operative time (minutes)	117	112	111	120	0.067	118	116	0.922
Mean estimated blood loss	361	368	277	377	0.497	379	295	0.244
Percent (and number) requiring transfusion	2.4 (3)	0 (0)	2.2 (2)	4.7 (1)	0.638	1(1)	6.7(2)	0.076

NA = not applicable.

Table 4
Mean CCI (Charleson Comorbidity Index) of Those Cohorts of Patients Who Sustained Any Complication, a Major Complication, a Surgical Complication, and a Medical Complication as Well as Mean CCI for Those Patients Who did not Sustain a Complication, Major Complication, Surgical Complication, or Medical Complication.

	Mean CCI in Those Patients With a Complication	Mean CCI in Those Patients Without a Complication	P Value
All complications	0.75 ± 0.97	0.24 ± 0.52	0.010
Major complications	0.00 ± 0.00	0.29 ± 0.59	0.958
Surgical complications	1.00 ± 1.41	0.27 ± 0.54	0.002
Medical complications	0.63 ± 0.74	0.27 ± 0.58	0.111

Table 5
Significance (*P* Values) of Multivariate Logistic Regression Analyses Performed to Determine Whether Age, Body Mass Index (BMI) Subgroup (<25, 25–35, >35), or Charleson Comorbidity Index (CCI) Served as Significant Covariates With All Complications, Major Complications, Medical Complications, and Surgical Complications After Total Shoulder Arthroplasty.

	Age	BMI Subgroup	CCI
All complications	0.770	0.904	**0.005**
Major complications	0.406	0.819	0.620
Surgical complications	0.548	0.714	**0.015**
Medical complications	0.909	0.243	0.098

recent comparative series has corroborated these results [21]. Although BMI may serve as a determinant of complication rates after TSA and type II error is possible, BMI is a less important determinant of complications than CCI. While the reason for this difference between the effect of BMI and CCI on complications in RTSA compared to TSA will require further research, it could be due to higher overall complication rates with RTSA, difference in implant design, or differences in the dependence of implant stability upon soft tissue tension. Again, type II error may also play a role as complications are less frequent with TSA than with reverse TSA and thus a larger number of patients is necessary to find a difference, should one exist. Obesity has been correlated with an increased complication rate in the hip and knee arthroplasty literature [13,14,31]. This difference between TSA and THA/TKA risks may be due to differences in the soft tissue envelope, differences between operating on the upper extremity and the lower extremity, differences in intraoperative blood loss, or differences between the surgical techniques commonly employed in TSA and those in THA/TKA. Of note, the transfusion rate in our series was 2.4%, which is markedly lower from that in previous series: 43% [5], 25% [6], and 8.9% [23]. Based upon this low transfusion rate we agree with Millett and colleagues recommendation against autologous pre-donation in the setting of primary TSA [6]. It remains unclear what factors contributed to this difference. The authors suspect this low transfusion rate to be driven by the culture within our institution: the arthroplasty surgeons at our institution have worked closely with our internal medical teams to discuss the potential increased risk of infection in patients status-post total joint arthroplasty who receive transfusions [32,33].

There are several limitations to our study. The retrospective nature of the study could potentially have missed complications not recorded in the medical record. Data from patients who sought treatment for a complication at an outside institution who failed to report such events at routine follow-up may have been missed. Unmeasured confounding variables such as fasting blood glucose levels, pre-operative hemoglobin levels, present of cardiac wall motion abnormalities on stress test results, etc. could account for the differences observed. Measurement of these variables could help to better delineate the medical factors most responsible for driving higher complication rates. Future research will be necessary to examine the physiological processes that confer increased risk of peri-operative complications in those patients with medical comorbidities. Additionally, given the findings of our post-hoc power analysis, type II error may play a role in our findings with respect to BMI. It should be acknowledged that this study represents only early complications after primary total shoulder arthroplasty, and data presented within should not be used to quote overall complication rates.

Conclusions

Complication rates after primary anatomic TSA correlate with preoperative medical comorbidities. Surgeons may wish to incorporate

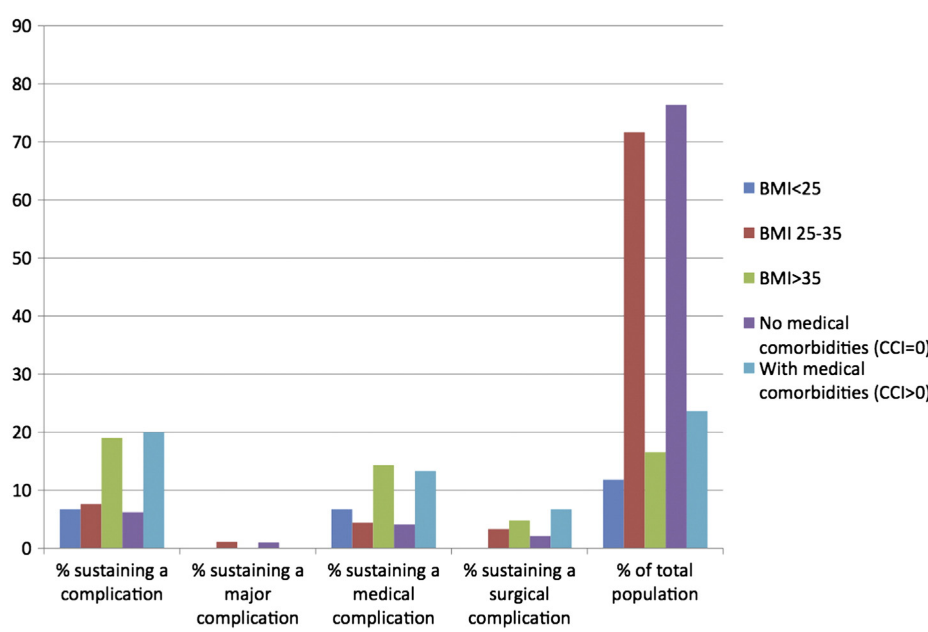

Fig. After division of those patients with BMI <25 (blue), those patients with BMI 25–35 (red), those patients with BMI >35 (green), those patients without medical comorbidities (CCI = 0, purple) and those patients with medical comorbidities (CCI > 0, teal) bars denote the percentage of patients sustaining a complication, the perfect of patients sustaining a major complication, the percentage of patients sustaining a medical complication, the percentage of patients sustaining a surgical complication, and the percentage of the total population in that subgroup.

this information into their pre-operative risk/benefit discussion. Future studies could focus on pre-operative testing for these comorbidities including hemoglobin and hemoglobin A1C levels.

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