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Incidence and predictors of early complications following primary and revision total ankle arthroplasty

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ABSTRACT

Background: Total ankle arthroplasty (TAA) offers an effective option for end-stage osteoarthritis. The incidence and preoperative risk factors for early adverse events (AEs) following primary and revision TAA may be useful information for providers.
Methods: A large database was queried from 2010 to 2016 to identify 905 patients of whom 818 underwent primary TAA (90.4%) and 87 underwent revision TAA (9.6%). Data on patient demographics, comorbidities, and hospital length of stay were analyzed as risk factors for reported 30-day AEs.
Results: The overall AE rate was 5.5% (50/905) for the entire cohort. AEs occurred more frequently for revision TAA (9/87) than primary TAA (41/818) cases (OR 2.43, p = 0.022). Age (OR 1.03, p = 0.045), BMI (OR 1.04, p = 0.046), and revision TAA (OR 2.56, p = 0.002) were independent risk factors for 30-day AEs in multivariate analysis.
Conclusions: Older age, higher BMI, and revision cases are associated with a higher risk of AEs.

1. Introduction

Arthritis of the ankle is a significant source of pain and disability affecting approximately 1–2% of the population [1–3]. Traditionally, ankle arthrodesis has been the treatment of choice for end-stage osteoarthritis. However in the last twenty years, total ankle arthroplasty (TAA) has offered an attractive alternative in select patients to preserve functional range of motion [4]. TAA was previously associated with high complication rates and implant failure, but with advances in implant design and increased familiarity of operative techniques, complications have decreased. As such, the relative utilization of TAA to ankle arthrodesis in hospitals across the United States has increased more than four-fold from 3.1% in 1991 to 12.6% in 2010 [4–6]. However, the reported rate of complications following primary TAA still remains high, with 20% requiring revision within five years [7]. Although the rate of postoperative complications in revision TAA is currently not well known, the reported rate of infection after primary TAA ranges from 2% to 8.5%, greater than the rate of infection following total knee and hip arthroplasty [8–13].

Known risk factors for the development of postoperative complications after primary TAA include age, gender, obesity, tobacco use, history of pneumonia, prior ankle surgery, prolonged hospitalizations, poor wound healing, preoperative medical comorbidities, and American Society of Anesthesiologists (ASA) classification [8,10,12,14–16]. Werner et al. found that obese patients undergoing primary TAA had a notable increase in risk of 90-day perioperative complications, including infections, revisions, and DVTs compared with non-obese patients [15]. Spirt et al. also discovered that patients younger than 54 years had a 2–3 fold increased incidence of revision in comparison to older patients [14]. Despite published studies on potential preoperative risks for complications in primary TAA, limited data exists regarding the incidence and predictors for complications in revision TAA. Furthermore, few studies have reported on the short-term postoperative complications following primary and revision TAA, with the majority of the literature focusing on implant survivorship and failure.

The purpose of this study was to identify the incidence and predictors of early perioperative complications following primary and revision TAA using a large patient sample size. We used the American College of Surgeons' (ACS) National Surgical Quality Improvement Program (NSQIP) database to identify characteristics

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and outcomes for patients who underwent primary and revision TAA in participating hospitals. We hypothesized that early complications of TAA are relatively uncommon and that revision TAA would be associated with increased incidence of adverse events, hospital length of stay, discharge to inpatient facility, hospital readmissions, and mortality compared to primary TAA.

2. Materials and methods

We performed a retrospective review of the ACS NSQIP database. The ACS NSQIP is a prospective, multi-institutional program that collects perioperative data on over 150 patient variables from over 500 NSQIP-participating hospitals in the United States. Reported data are acquired from medical records, operative reports, and patient interviews by trained clinical reviewer, and are compliant with the Health Insurance Portability and Accountability Act. Data are collected through postoperative day (POD) 30, including after discharge.

All patients who underwent primary and revision TAA from 2010 to 2016 were identified using CPT codes 27702 and 27703, respectively. In total, 905 primary and revision TAAs from 905 patients were identified from 2010 to 2016 in the NSQIP series. Bilateral TAA cases were not included. Patient characteristics collected from the registry included patient age, sex, race, height, weight, smoking history, functional health status, American Society of Anesthesiologists (ASA) class, and medical comorbidities including diabetes, chronic obstructive pulmonary disorder (COPD), liver disease with ascites, congestive heart failure (CHF), hypertension, and dialysis-dependent kidney disease. Body mass index (BMI) was calculated for each patient's height and weight. Functional status was defined as the patient's ability to perform activities of daily living either independently or in a partially dependent manner within the 30 days prior to admission.

Data on postoperative medical complications within 30 days was collected including: deep vein thrombosis (DVT), pulmonary embolism (PE), pneumonia, acute renal failure, urinary tract infection (UTI), cardiac arrest, myocardial infarction (MI), cerebrovascular accidents (CVA), sepsis, and death. Surgical complications data on postoperative superficial and deep surgical site infection (SSI), reoperation, and blood transfusion were also collected for both cohorts. Data was also collected on discharge destination (e.g. home versus facility), hospital readmissions, and total hospital length of stay (LOS). An AE was defined as a patient having any listed medical complication, surgical complication, or post-discharge readmission. This study was sensitive to both minor and major complications and are independent of readmission. For example, a patient with a UTI and a readmission are considered separate. LOS data was sorted according to both a two-tiered (e.g. outpatient with discharge within <24 h versus traditional inpatient stay) and three-tiered classification (e.g. LOS 0 days, 1 day, and 2+ days).

Descriptive statistics and comparison of baseline characteristics was performed using chi-square (χ^2) testing for categorical variables, independent samples t-test for continuous variables, and independent samples median test with Yates' continuity correction for age. Bivariate logistic regression was used to compute the association between revision TAA and individual postoperative AEs including medical complications, surgical complications, and hospital readmission. Linear regression was similarly used to assess the risk-adjusted relationship between TAA and hospital LOS. Multivariate logistic regression was also used to determine independent predictors of any 30-day AEs using age, gender, BMI, ASA classification, and revision (versus primary) TAA as covariates. These five predetermined variables were chosen to optimize the total number of covariates with a target of approximately 10 events per covariate to minimize model instability. For all comparative analysis, patients who underwent revision TAA or outpatient surgery were treated as the exposed groups and patients who underwent primary TAA and inpatient surgery, respectively, were treated as the control groups. Standardized OR, 95% confidence intervals, and p-values were computed using the methods described by Bland and Altman [17]. Statistical significance was defined as $p < 0.05$ and all statistical analyses were performed using SPSS 21 software (IBM Corporation, Armonk, NY).

3. Results

Of the total 905 patients identified, 818 underwent primary TAA (90.4%) while 87 underwent revision TAA (9.6%) (Table 1). The

Table 1
Comparison of baseline demographics and characteristics of patients undergoing primary and revision total ankle arthroplasty (TAA).

Baseline patient characteristic	All TAA patients (n = 905)	Primary TAA (n = 818)	Revision TAA (n = 87)	p-Value
Age (years, median)[a]	65	65	64	0.995
Female (%)	49.7%	50.0%	46.5%	0.538
White (%)	96.0%	96.1%	96.0%	0.160
Body mass index (BMI)[b]	30.6 ± 5.9	30.7 ± 6.0	30.1 ± 5.1	0.436
Functional health status				0.616
Independent	98.3%	98.4%	97.7%	
Partially dependent	1.7%	1.6%	2.3%	
ASA classification (continuous)[b]	2.3 ± 0.6	2.3 ± 0.6	2.4 ± 0.7	0.339
ASA classification (ordinal)				0.287
1	4.6%	4.5%	5.7%	
2	57.7%	58.3%	51.7%	
3	36.2%	35.9%	39.1%	
4	1.4%	1.2%	3.4%	
Diabetes (%)	12.9%	13.0%	12.6%	0.934
Smoker, current (%)	7.3%	6.9%	7.3%	0.881
COPD (%)	2.2%	2.3%	1.1%	0.479
Ascites (%)	0.0%	0.0%	0.0%	N/A
CHF (%)	0.2%	0.2%	0.0%	0.644
Hypertension (%)	54.1%	54.3%	52.9%	0.803
Dialysis (%)	0.2%	0.1%	1.1%	0.052

COPD = chronic obstructive pulmonary disease, CHF = chronic heart failure.
All other comparisons performed using chi-square analysis.
[a] Statistical comparison performed using independent samples median test.
[b] Statistical comparison performed using independent sample t-test.

median age in the primary and revision TAA cohort was 65 and 64 years, respectively. In univariate analysis, baseline characteristics were not significantly different between the two cohorts ($p > 0.05$) (Table 1).

The overall rate of AEs in patients undergoing primary and revision TAA was 5.5% (50/905). The most frequent individual AEs were hospital readmission (2.1%), UTI (0.9%), reoperation (0.8%), superficial SSI (0.8%), deep SSI (0.6%), and transfusion (0.6%). All other queried complications including death and postoperative medical complications occurred in <0.5% of the total cohort. AEs occurred more frequently for revision TAA (9/87) than primary TAA (41/818) cases (OR 2.43 [1.14–5.19], $p = 0.022$). Bivariate logistic regression revealed that patients undergoing revision TAA had a significantly higher risk of developing deep SSIs (2.3% versus 0.4%, OR 6.39 [1.05–38.79], $p < 0.05$); all other postoperative surgical and medical complications occurred at statistically comparable rates (Table 2). Hospital readmission and 30-day mortality rates were also not statistically significantly different between the two cohorts (Table 2). Furthermore, total hospital LOS (2.4 ± 2.5 days versus 1.9 ± 1.3 days, $p = 0.084$) and rates of discharge to inpatient facility (9.4% versus 6.3%, $p = 0.349$) was not statistically significantly different between patients undergoing primary and revision TAA.

Multivariate logistic regression analysis revealed that age (OR 1.03 [1.01–1.05, $p = 0.045$), BMI (OR 1.04 [1.01–1.08], $p = 0.046$), and revision TAA (OR 2.56 [1.40–4.66], $p = 0.002$) were independent risk factors for 30-day AEs (Table 3). Sex and ASA classification were not found to be independent risk factors for 30-day AEs in this model.

Of the 905 patients identified in the query, 109 (12.0%) were outpatient TAA (defined as discharge within <24 h), while 796 (88.0%) were performed on an inpatient basis. In the outpatient group, the incidence of AEs was 5/109 (4.6%) and in the inpatient group, the incidence was 45/796 (5.6%). Outpatient TAA was not associated with a statistically different incidence of 30-day AEs compared to inpatient TAA (OR 0.80 [0.31–2.07], $p = 0.648$). When analyzed with respect to LOS, patients with LOS of 0, 1, or 2+ days had AE rates of 4.5% (2/44), 6.0% (10/168), and 5.5% (38/693), respectively. Three-tier analysis performed with respect to LOS data found that patients who underwent same-day discharge (LOS 0 days, OR 0.80 [0.19–3.52], $p = 0.790$) and discharge on POD1 (LOS 1 day, 1.09 [0.53–2.24], $p = 0.812$) following TAA also had no statistically significant difference in 30-day AEs compared to patients who had LOS $\geq$2 days.

Table 3
Assessment of risk factors for 30-day adverse events following total ankle arthroplasty (TAA) using multivariate logistic regression.

Covariate	Odds ratio (OR) (95% CI)	p-Value
Age	**1.03 (1.01–1.05)**	**0.045**
Sex (female)	1.23 (0.79–1.92)	0.370
Body mass index (BMI)	**1.04 (1.01–1.08)**	**0.046**
ASA classification	1.26 (0.85–1.89)	0.251
Revision (vs. primary) TAA	**2.56 (1.40–4.66)**	**0.002**

Multivariate logistic regression used to determine independent predictors of any 30-day adverse events. Bold values are statistically significant findings since $p < 0.05$.

4. Discussion

Ankle arthritis continues to be a debilitating disease affecting a significant portion of the United States population. Recent advances in design and improved survivorship have made TAA an attractive alternative to fusion that is performed in increasing frequency for the treatment of end-stage ankle arthritis [4]. Despite improvements in TAA design, studies have shown that rates of complications and revision following TAA are still higher than rates following total hip and knee arthroplasty [8,15]. Thus, it is important to identify risk factors that predispose patients for complications following TAA to improve surgeon decision-making and patient counseling. The purpose of this study was to identify the incidence and predictors of short-term perioperative complications in primary and revision TAA using a large patient sample across multiple institutions using the ACS NSQIP database. Our study showed that early AEs are relatively uncommon and that increased age, BMI, and revision TAA were independent predictors of 30-day AEs.

The overall rate of short-term complications following TAA was 5.5% in our study, generally consistent with prior reports [18,19]. A 2016 study by Mercer et al. concluded that the reporting of

Table 2
Relative incidence of postoperative complications associated with primary and revision total ankle arthroplasty (TAA) using bivariate logistic regression.

Complications (within 30 days)	All TAA patients (n = 905)	Primary TAA (n = 818)	Revision TAA (n = 87)	Odds ratio (OR) (95% CI)	p-Value
Medical complications					
Death	0.3% (3)	0.4% (3)	–	–	–
Deep vein thrombosis (DVT)	–	–	–	–	–
Pulmonary embolism	0.1% (1)	0.1% (1)	–	–	–
Pneumonia	0.2% (2)	0.2% (2)	–	–	–
Acute renal failure	–	–	–	–	–
Urinary tract infection	0.9% (8)	0.7% (6)	2.3% (2)	3.18 (0.63–16.02)	0.160
Cerebrovascular accident	–	–	–	–	–
Cardiac arrest	–	–	–	–	–
Myocardial infarction	0.1% (1)	0.1% (1)	–	–	–
Postoperative sepsis	0.1% (1)	0.1% (1)	–	–	–
Surgical complications					
Superficial SSI	0.8% (7)	0.7% (6)	1.1% (1)	1.57 (0.19–13.22)	0.676
Deep SSI	**0.6% (5)**	**0.4% (3)**	2.3% (2)	**6.39 (1.05–38.79)**	**0.044**
Reoperation	0.8% (7)	0.6% (5)	2.3% (2)	4.79 (0.86–26.53)	0.073
Transfusion	0.6% (5)	0.5% (4)	1.1% (1)	2.36 (0.26–21.41)	0.443
Other					
Hospital readmission (any reason)	2.1% (18)	1.8% (14)	4.6% (4)	2.88 (0.93–8.97)	0.068
Overall adverse events (any reason)*	**5.5% (50)**	**5.0% (41)**	**10.3% (9)**	**2.43 (1.14–5.19)**	**0.022**

Bold values are statistically significant findings since $p < 0.05$.

* Overall adverse events include patients who had at least one complication and/or hospital readmission, e.g. patient with a reoperation requiring a hospital readmission counts as one adverse event.

complications and adverse outcomes following TAA was highly variable in a review of 117 studies and that no consistent standard of timing or terminology was observed [20]. Some authors have reported complications rates as low as 1.4% and as high as 15.4% [16,21]. Possible explanations for this variability may be attributed to the subjective definition of complications and use of different ICD-9 codes [18]. Other possibilities include differences in duration and frequency of follow-up after TAA, small numbers of complications in case series, or the grouping of complications [10,15].

Our study is consistent with several reports that higher BMI is a preoperative risk factor for complications following TAA [15,19,22]. Werner et al. found in a large database analysis that obese patients were two to three times more likely to incur 90-day morbidity including PE, DVT, infection, MI, CVA, UTI, and pneumonia [15]. Schipper et al. also noted that obese individuals were nearly three times more likely to have implant failure than non-obese patients at five-year follow-up [19]. In contrast, Gross et al. found no difference in complication rates, such as infections or revisions, in obese primary TAA patients compared to non-obese patients [23]. Conversely, another study reported that BMI $<19\ kg/m^2$ was an independent risk factor for infection at three and six months following TAA [8]. These differences may be explained by variability in the timing for evaluation of complications. BMI may be a more significant risk factor for the development of postoperative complications in the short-term, as studies have shown varying complication rates beyond six months postoperatively [10,12]. This is especially important because BMI remains a modifiable risk factor that may help improve patient outcomes.

Besides obesity, we found that older age was a short-term risk factor for postoperative complications in TAA. This is in contrast to other studies that have focused mainly on intermediate to long-term results. Althoff et al. and Spirt et al. both reported that younger patients were more likely to have joint infections and reoperations after a TAA [8,14,24]. Similar findings have been reported in total knee arthroplasty. Specifically, younger age at implantation implies that the implant will need to function longer as these patients tend to be more active resulting in increased prevalence of secondary posttraumatic arthritis and polyethylene wear [25]. While younger age may be a predictor for long-term complications following TAA, data on short-term complication risks is less well-studied. Our results suggest that greater age may be a potential risk factor for early readmission and medical complications.

In contrast to other studies, sex and ASA classification were not found to be risk factors for postoperative complications following TAA in this investigation [16,26]. Pakzad et al. found that female sex and higher ASA classification were associated with increased LOS [26]. Zhou et al. found that male sex and increased medical comorbidities were predictors for developing at least one complication (DVT, infection, or reoperation) within 30 days following TAA in 2340 patients [16]. They noted that the overall complication rate was low at 1.4%. These observed differences may be related to the overall low incidence of complications in general following TAA; thus, variability in findings may be expected.

This study is among the first to report that revision TAA results in increased risk for short-term adverse events. Although revision arthroplasty is a known risk factor for medical complications and has been well studied in the hip and knee, few studies have specifically reported on revision TAA as a risk for complications [27–29]. For instance, Kessler et al. reported that patients with prior ankle surgery were 4.5 times more likely to develop an infection following TAA [10]. Revision arthroplasty is associated with longer operative time and previously violated surrounding soft tissue, which may make patients more susceptible to exogenous infections. Here, revision TAA was 6.4 times more likely to develop deep SSI compared to primary TAA within 30 days. Although the absolute incidence of deep SSI was low in this study, the incidence of infection may actually be greater in the long-term, as Keesler et al. reported that more than 75% of all reported infections may occur after 90 days of TAA [10]. In addition, such short-term complication profiles have important financial implications as the average cost of in-hospital care is double for SSI versus non-SSI patients [30].

We also found no difference in 30-day AEs between outpatient and inpatient TAA. So far, only two single-institution studies have evaluated the safety of outpatient TAA and have reported similar results [21,31]. Mulligan and Parek reported in their series of 13 outpatient TAA patients that there were no increased complications, adverse medical events, readmissions, or reoperations within 90 days compared to those who underwent overnight stay or inpatient TAA [31]. Borenstein et al. also found in their single institution review of 65 outpatient TAA patients that there was no increase in complications or readmissions at a mean follow-up of 16.6 months [21]. Satisfaction rates have also been favorable as 15/21 (71.4%) patients stated they would elect for outpatient TAA again [32]. These results suggest that same day or overnight stay surgery can be performed safely.

Our retrospective study design has several limitations. Firstly, patient outcomes and complication data in the ACS NSQIP series are limited to 30 days postoperatively. Thus rates of infection and medical complications beyond this time frame could not obtained. This may be an important consideration as studies have shown that less than half of all TAA infections are diagnosed within the first three months following surgery [12]. In addition, although the sample size in our study may be sufficiently large, the overall rate of complications following TAA is low which may cause and partially explain the variability in reported findings among studies. We also acknowledge that no pre-hoc power analysis was performed and that this may limit conclusions that may be derived from this study design. Despite these limitations, our study includes a large sample of patient data that is derived from multiple institutions, anonymized, less susceptible to publication bias, and reliable in quality.

In summary, primary and revision TAA are both relatively safe procedures with a low overall incidence of short-term complications, although revision TAA was found to have relatively higher risk. Our results also demonstrate TAA can be performed safely in the outpatient setting with no significant increase in the risk of adverse events. Risk factors for postoperative complications following TAA include older age, increased BMI, and revision TAA. Provider knowledge of the incidence and risk factors identified in the present study may help with risk stratification and patient counseling to further reduce complications following elective TAA.

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Conflict of interest

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