

Operative Distal Humerus Fractures in Older Patients: Predictors for Early Complications Based on a National Database

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Abstract *Background:* Open reduction internal fixation (ORIF) and total elbow arthroplasty (TEA) have both been utilized in the treatment of distal humerus fractures in patients over 65 years of age. Comparisons of early complications between these procedures have not been well described. *Questions/Purposes:* The purpose of this study is to evaluate complication rates in the treatment of distal humerus fractures in elderly patients and to utilize prediction models to identify risk factors associated with postoperative complications. Additionally, to compare ORIF and TEA treatment. *Methods:* A retrospective case series was performed by querying the National Surgical Quality Improvement Program for both ORIF and TEA performed for distal humerus fractures in patients over the age of 65 years between 2005 and 2014. We examined both preoperative risk factors and complications within 30 days in these three groups. *Results:* The sample included 216 ORIF and 65

TEA cases. No outcomes examined differed significantly between treatment groups. The most common outcome for both groups was bleeding requiring transfusion (8%). The observed effect size for the association between procedure and the composite morbidity outcome indicated little to no association ($\phi = 0.004$). Furthermore, no presurgery variables were found to be significantly associated with procedure type. The only predictor with a significant independent association with the composite outcome, regardless of procedure type, was ASA class 3/4. *Conclusion:* Clinical complications were low no matter the type of treatment. Low preoperative hematocrit was a risk factor in both ORIF and TEA.

Keywords distal humerus fracture · total elbow arthroplasty · elderly · older patient · NSQIP

Introduction

Distal humerus fractures can be challenging to treat due to complex articular anatomy, the propensity for elbow stiffness, and fixation failure. In older patients, osteoporotic bone and metaphyseal comminution can complicate operative repair. Nonoperative treatment results in loss of motion and disability due to prolonged immobilization [17, 29]. Open reduction and internal fixation (ORIF) has been shown in many studies to improve outcomes over nonoperative treatment [13, 15, 17, 18, 22, 29].

Total elbow arthroplasty (TEA) has become an accepted alternative for the treatment of severely comminuted distal humerus fractures, yet the evidence for patient selection, complications, and functional outcomes are conflicting [1, 2, 3, 4, 6, 8–11, 21, 26]. For example, while one meta-analysis revealed trends toward less major complications following TEA compared with ORIF, a prospective randomized study revealed similar complication rates between the two groups [11, 21]. These conflicting findings warrant

Level of Evidence: Level IV: Prognostic Study

Work performed at George Washington University.

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further investigation using a more diverse dataset. Furthermore, to our knowledge, very few studies have focused on identifying the preoperative risk factors for short-term complications.

Palvanen et al. [23] predicted a threefold increase in the incidence of osteoporotic distal humerus fractures in the Finnish female population by 2030. This increase, likely to be true for the US population as well, makes determination of the most effective treatments for specific patients even more important. Moreover, utilizing a national database such as the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), as opposed to single-institution databases, will allow for greater external validity and increase the applicability of our results to the general population. Our goal is to determine if these findings can inform clinical decision-making in order to reduce patient morbidity and mortality.

The purposes of this study are as follows: (1) examine the rates and types of early complications in operatively treated distal humerus fractures, (2) use prediction models to identify preoperative risk factors of a composite morbidity marker, and (3) determine whether the two types of procedure (ORIF vs. TEA) are equivalent in association with morbidity and mortality. We predicted overall low complication rates in the 30-day period with equivalent results in the two procedure types.

Patients and Methods

The NSQIP database provides retrospective data for 30 days from operative procedure. We queried the years 2005–2014 using ICD-9 (International Classification of Diseases, Ninth Revision) codes of 812.4x and 812.5x and with current procedural terminology (CPT) codes indicating TEA (24363 and 24587) or ORIF (24545, 24546, and 24586) elbow surgery. Cases with CPT codes indicating removal of implant (20680 and 20670) were excluded to remove any revision procedures. Cases where age was <65 were excluded from the case series.

There were 281 cases meeting inclusion criteria, 216 of which received ORIF, while 65 received TEA. Mean patient age was 78 ± 8 , mean BMI was 27 ± 7 , and 83% were female.

Outcomes of interest included 30-day mortality, postsurgery LOS >7 days, bleeding, wound events, clotting events, return to OR, and a composite outcome which was coded yes if any of these events occurred. Noted Predictors included demographics (age, race, sex, BMI, smoking, and nonindependent functional status), comorbidities (hypertension (HTN), diabetes mellitus (DM), bleeding disorder, chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF)), laboratory values (hematocrit, serum creatinine, and white blood cells), open (812.5x) vs. closed (812.4x) fracture, and treatment type (ORIF and TEA).

Continuous variables were checked for normality and transformed if necessary using natural log or coded into quartiles. ORIF versus TEA cases were compared on

pretreatment variables using chi square for categorical variables and two-tailed independent group *t* tests or the non-parametric Kruskal-Wallis test for continuous variables. Multivariate logistic regression was used with the composite morbidity variable as the outcome, to examine predictors with independent associations with morbidity. The predictor variables that were eligible to be included in this analysis were any that had $p < 0.20$ in univariate analysis, as well as procedure (ORIF vs TEA). We also tested a series of logistic regression models that included interaction terms with procedure (using a separate model for each predictor \times procedure interaction), for each of the other predictors, in order to determine whether these predictors had different associations with the outcome in each treatment group.

In order to test the probability of obtaining a finding of equivalence between treatments if, in fact, there was a meaningful association, we conducted an empirical post hoc power analysis using 1000 simulated data sets. We created each data set using 200 ORIF and 60 TEA cases, using random selection of the number of events in each group from a binomial distribution, assuming a 20 and 10% event probability in the ORIF and TEA groups, respectively. A binomial test was then used to determine the probability that the observed effect size (ϕ) would be less than 0.01 (a very small observed effect). SAS (version 9.3, Cary, NC) was used for all data analysis with $p < 0.05$ considered significant.

Results

None of the outcomes examined differed significantly between treatment groups (Table 1). Of the outcomes examined, the least common were 30-day mortality (<1%), wound events (<1%), and clotting events (1%). The most common morbidity was bleeding requiring transfusion (8%). Five percent of cases required postsurgery LOS >7 days. Overall, 16% of patients had one or more morbidity or mortality outcomes.

There were no presurgery variables significantly associated with procedure outcome (Table 1). However, four predictors had near significance associated with TEA (sex, CHF, HTN, and ASA class 3 or 4) and were used in a multivariate model. Open versus closed fracture was not significantly associated with the composite outcome (open, 20% positive; closed, 15% positive; $p = 0.71$).

The only predictor with a significant independent association with the composite outcome was ASA class 3/4 (versus class 1/2; OR 2.41 [1.04–5.61], $p = .04$, Table 2). Patients with ASA class 3 or 4 had adjusted odds of reaching the composite outcome 141% higher than patients with ASA class 1 or 2. The association of procedure type with the composite outcome remained nonsignificant after adjusting for covariates (OR for ORIF 1.20 [0.54–2.66], $p = 0.66$). None of the interactions were significant, indicating no difference in association with the outcome for any of the predictors between ORIF and TEA procedures.

The observed effect size for the association between procedure (ORIF vs TEA) and the composite outcome was

Table 1 Comparison of presurgery variables and outcomes between treatment groups

Presurgery variable	All cases (n = 281)	ORIF (n = 216)	TEA (n = 65)	p
Age (years), mean ± SD	78.1 ± 7.6	77.9 ± 7.5	78.8 ± 8.0	.42
Sex female	233 (82.9%)	175 (81.0%)	58 (89.2%)	.12
Race				.27
Black	8 (2.9%)	8 (3.7%)	0 (0%)	
White	222 (79.0%)	168 (77.8%)	54 (83.1%)	
Other/Unk	51 (18.2%)	40 (18.5%)	11 (16.9%)	
Nonindependent functional status	55 (19.6%)	43 (19.9%)	12 (18.5%)	.80
Smoking	18 (6.4%)	15 (6.9%)	3 (4.6%)	.77
BMI (kg/m ²), mean ± SD	27.4 ± 6.5	27.4 ± 6.7	27.3 ± 5.6	.92
DM	66 (23.5%)	53 (24.5%)	13 (20.0%)	.45
HTN	201 (71.5%)	149 (69.0%)	52 (80.0%)	.08
COPD	25 (8.9%)	20 (9.3%)	5 (7.7%)	.70
CHF	3 (1.1%)	1 (0.5%)	2 (3.1%)	.13
ASA 3 or 4	184 (65.5%)	136 (63.0%)	48 (73.9%)	.11
Bleeding disorder	31 (11.0%)	22 (10.2%)	9 (13.9%)	.41
Serum creatinine	0.97 ± 0.74	0.97 ± 0.79	0.98 ± 0.54	.96
Hematocrit	35.3 ± 4.4	35.4 ± 4.3	34.9 ± 4.6	.38
WBC	8.8 ± 3.0	8.9 ± 3.0	8.4 ± 3.0	.27
Open fracture	15 (5.3%)	12 (5.6%)	3 (4.6%)	.71
Outcome variable				
30-Day mortality	2 (0.7%)	1 (0.5%)	1 (1.5%)	.41
Transfusion	23 (8.2%)	16 (7.4%)	7 (10.8%)	.39
Wound event	2 (0.7%)	2 (0.9%)	0 (0%)	.99
Clotting event	3 (1.1%)	3 (1.4%)	0 (0%)	.99
Return to OR	7 (2.5%)	6 (2.8%)	1 (1.5%)	.99
Postsurgery LOS >7 days	13 (4.6%)	11 (5.1%)	2 (3.1%)	.74
Composite outcome	44 (15.7%)	34 (15.7%)	10 (15.4%)	.94

$\phi = 0.004$ indicating little or no association. In the post hoc empirical power analysis using 1000 simulated data sets, we found that based on a true difference of 20 vs. 10% event rate in ORIF vs. TEA, the probability of obtaining an observed $\phi < 0.01$ was 0.03 (exact confidence limits 0.02–0.043), indicating that the small observed effect size we found was unlikely to occur by chance if the true effect was a 20 vs 10% event rate difference.

Discussion

Distal humerus fractures in older patients can be challenging. High degrees of comminution, poor bone stock, and failure of fixation have spurred controversy in the appropriate treatment [24]. Recent studies have reported conflicting results in terms of complication rates between ORIF and TEA. This study aimed to identify the complication rates associated with different treatments. Additionally, we aimed to develop prediction models to identify the at-risk patients.

While the NSQIP is very versatile in its possibilities for retrospective studies, there are many inherent shortcomings

with the use of the database. For example, the cohort size of 281 cases of distal humerus reconstructions between 2005 and 2014 recorded in this database is relatively small compared to the actual number performed nationwide. Gay et al. [10] found a sample of 1155 total elbow arthroplasties using the New York Statewide Planning and Research Cooperative System with 43–69% of those being performed for trauma. Comparing this sample size with the number of patients in our study clearly reveals limitations in data. Additionally, this study only examines results in a 30-day period due to limitations of the database. To conclude equivalency of arthroplasty or ORIF, follow-up measured in years would be required. Additionally, radiographs are unavailable in the database limiting conclusions to determine why ORIF vs TEA was performed.

ORIF has been successfully used in older patients [14, 15, 17]. Although, most studies include patients in many age ranges and not just those over 65 years [24]. Younger patients have been shown to have good to excellent results [12, 25]. There is variability in the literature regarding complication rates in older patients treated with ORIF, 4–14% [14, 15, 17]. Compared with the aforementioned studies, our

Table 2 Multivariate logistic regression results

Predictor	OR (95% confidence interval)	p	Regression parameter (SE)
ORIF vs. TEA	1.20 (0.54–2.66)	.66	0.09 (0.20)
Female sex	0.99 (0.42–2.34)	.98	−0.005 (0.22)
HTN	1.51 (0.64–3.55)	.34	0.21 (0.22)
CHF	2.10 (0.18–24.59)	.56	0.37 (0.63)
ASA 3/4	2.41 (1.04–5.61)	.04	0.44 (0.22)

Bold represents a significant independent association with composite outcome

findings were similar with low overall complication rates, 15.7%, with bleeding requiring transfusion being the most common (7.4%).

Total elbow arthroplasty has been shown to be a viable alternative to ORIF in elderly patients [1, 2, 3, 8, 11, 19, 21, 26]. In a systematic review of results reported for TEA by Little et al. [20], 86 papers were reviewed, totaling 3618 arthroplasty cases, with the most recent papers being in 2003. They found complication rates to range widely from 14 to 80% with a median of 33%. Ishii et al. [16] reported one case of humeral shaft fracture and two cases of ulnar nerve palsy in 32 patients undergoing TEA for RA. Fritsche et al. [7] reported a higher complication rate in 33 patients undergoing TEA for distal humerus fractures. Ellwein et al. [5] compared the results of ORIF and TEA and it was found that the ORIF group had a 4.4 times higher risk for major complications. Our findings demonstrated a low complication rate, 15.4%. Bleeding requiring transfusion was the most common short-term complication in the TEA group (10.8%), similar to the ORIF group. Since transfusions are associated with risks of infection, allergic reactions, and lung injury, among other complications, future studies should focus on assessing the consequences of blood transfusion in the surgical treatment of distal humerus fracture patients using longer follow-up times.

In a meta-analysis by Githens et al. [11], totaling 563 patients who were treated with either ORIF or TEA, results trended toward less major complications following TEA. McKee et al. [21] published a prospective randomized study comparing ORIF to TEA that showed similar complication rates to ORIF. Our study revealed no significant differences in early complications in the ORIF group compared with the TEA group.

While complication variables examined in this study were all relatively low thus suggesting safe distal humerus fracture treatment options in elderly patients, both length of stay >7 days (4.6%) and return to OR (2.5%) are concerning and raise the question of how these rates can be lowered. Future studies should focus on identifying causes for increased length of stay and return to OR in postoperative distal humerus fracture patients in order to better anticipate and prevent complications.

This study did not identify any preoperative variables significantly associated with procedure type, possibly suggesting a homogenous study cohort that would allow feasible prediction models to be performed. In our prediction models, it was determined that the only predictor with a significant independent association with the composite outcome was ASA class 3/4 (OR 2.41 [1.04–5.61], $p = 0.04$). Recent studies [27, 28] reaffirm our findings of an association between high ASA and postoperative complications. As a result, this result has the ability to guide the decision-making process in the treatment of distal humerus fractures.

Our study indicates no difference in association with the composite outcome score for any of the predictors studied between ORIF and TEA procedures. While we did not originally power this study as an equivalency trial, the post hoc empirical power analysis results allow us to

conclude that if the actual event rates had been 20 and 10% in the ORIF and TEA group, respectively, there is a low probability that we would have obtained a difference between groups as low as we did. Therefore, we can conclude that if we define a clinically meaningful difference in rates of the composite outcome as a 10% difference, these two treatments appear to be equivalent for this outcome.

We have compared outcomes for ORIF and TEA for distal humerus fractures in patients >65 years old and found no significant differences. Overall rates of complications were low in both groups, similar to previous studies [7, 14–17, 20]. Unlike the abovementioned studies, we developed a prediction model for complications and found that patients with ASA class 3 or 4, regardless of procedure type, had a significant independent association with our composite outcome. The findings reported in this study can help guide the discussion of risks associated with both types of procedures, identify vulnerable patients, and be utilized as a starting point in discussing safe and equivocal methods of treating distal humerus fractures.

Compliance with Ethical Standards

Conflict of Interest: Gleb Medvedev, MD, Charles Wang, BS, and Richard Amdur, PhD, have declared that they have no conflicts of interest. Robert Neviasser, MD, reports personal fees from Saunders/Mosby-Elsevier, outside the work. Andrew Neviasser, MD reports personal fees from Depuy Mitek and Synthes, outside the work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: N/A

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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