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Original Article

Perioperative adverse events in distal femur fractures treated with intramedullary nail versus plate and screw fixation

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ARTICLE INFO

Article history:
Received 29 April 2015
Accepted 4 October 2015
Available online 1 November 2015

Keywords:
Distal femur
Fracture
NSQIP
Intramedullary nail
Internal fixation

ABSTRACT

Background: To compare 30-day outcomes in patients treated for a distal femur (DF) fracture with plate fixation (PF) or intramedullary nail (IMN).
Methods: Differences in rates of any adverse events (AAE), serious adverse events (SAE), infectious complications, and mortality were explored between groups in the ACS-NSQIP database.
Results: There were 511 PF and 44 IMN patients. The PF group and IMN groups had similar rates of AAEs ($p = 0.35$), SAEs ($p = 0.46$), infectious complications ($p = 1.00$), and mortality ($p = 0.39$).
Conclusions: DF fractures treated with IMN have equivalent short-term outcomes compared to those treated with PF.

1. Introduction

Distal femur (DF) fractures are severe lower extremity injuries that present several challenges to orthopedic surgeons with regard to implant choice and postoperative management. Several fixation methods are available for treatment of these fractures, including plate fixation (PF) that includes blade plates, dynamic condylar screws, and locking plates or intramedullary nails (IMN).[1,2] Fixed angle locking plates are currently the most commonly used method, though studies have given conflicting results on the utility of this construct for improving clinical and functional outcomes compared to IMN. IMN have comparable benefits to PF, including indirect fracture reduction and high healing rates. Some evidence suggests that IMN provide less stiffness than locking plates and may promote better callus formation compared to locking plates.[1] However, treatment of DF fractures with IMN may be difficult in comminuted metaphyseal fractures with coronal plane involvement and result in increased complication rates.[2,3] Given the increasing incidence of these injuries in both young and older populations, improved

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http://dx.doi.org/10.1016/j.jor.2015.10.009
0972-978X/

characterization of the prognosis of these two surgical treatments is critical.

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) is a multi-institutional outcomes database that presents a unique opportunity to better elucidate factors contributing to adverse events in the perioperative period with increasing use in the field of orthopedics. The ACS-NSQIP database has been described in several publications in detail. A defined set of patient demographics, medical history, as well as adverse events are collected prospectively in a standardized manner across numerous hospital sites. Over 150 variables are collected and over 350 hospitals participate with site visits and system auditing implemented to ensure integrity and validity of data.[4,5] Numerous studies have utilized NSQIP in the surgical literature, and it is accepted as a high quality, powerful data source.[6–8] To our knowledge, few studies have compared perioperative outcomes of these two fixation methods for DF fractures, and none have utilized a database, such as NSQIP, for these fractures. The purpose of this study was to compare rates of perioperative complications in patients with DF fractures treated with IMN versus PF and identify patient characteristics that increase the risk of adverse events in these fractures.

2. Materials and methods

The NSQIP database was queried initially for DF fractures using the postoperative diagnosis variable (International Classification of Diseases, 9th Revision [ICD-9] codes 821.20–821.39). Patients with DF fractures were then cross-referenced to concomitant primary Current Procedural Terminology (CPT) codes 27509, 27511, 27513, 27514 for the PF group, and with primary CPT code 27506 for the IMN group. A comorbidity score was calculated with a modified Charlson comorbidity index (CCI) calculated to fit available data as previously described by Bohl et al.[9] Treatment groups were compared in terms of age, sex, race, functional status prior to injury, modified CCI, body mass index (BMI), American Association of Anesthesiologists (ASA) status, and several other factors. Differences between groups were explored using Pearson's chi-square tests for categorical variables and independent *t*-tests for continuous variables.

A serious adverse event (SAE) included any of the following: death, a coma for more than twenty-four hours, ventilator for more than forty-eight hours, unplanned intubation, stroke/cerebrovascular accident, pulmonary embolism, cardiac arrest, myocardial infarction, acute renal failure, sepsis, septic shock, or return to the operating room. Infectious complications were defined as occurrence of superficial surgical site infection, deep surgical site infection, organ space infection, sepsis, or septic shock. Remaining NSQIP adverse events were combined with the SAE and infectious complications to comprise the any adverse event (AAE) category. This categorization of adverse events and infectious complications was consistent with methods used in similar previous studies utilizing the NSQIP database.[7,9,10]

Differences between treatment groups for complication categories were explored using Pearson's chi-square tests and Fisher's exact test. Multivariate logistic regression analyses comparing SAEs, AAEs, infectious complication rates, and mortality were performed controlling for patient characteristics. A post hoc separate analysis of pulmonary embolism rates between the PF and IMN groups was performed using multivariate logistic regression as well. Odds ratios (OR) with 95% confidence intervals (CI) are presented for multivariate analyses. All statistical tests were carried out using SPSS software version 20.0 (SPSS Inc, Chicago, IL). $p < 0.05$ was considered significant for all analyses.

3. Results

A total of 555 patients met inclusion criteria for this study. In this cohort, 511 (92%) were treated with PF and 44 (8%) were treated with IMN. There were no significant differences between PF and IMN cohorts with regards to age (71.22 ± 15.96 vs. 74.50 ± 15.06, $p = 0.19$), BMI (28.45 ± 12.15 vs. 27.70 ± 14.12, $p = 0.70$), sex ($p = 0.19$), or modified CCI (3.18 ± 1.7 vs. 3.6 ± 2.1, $p = 0.15$). Patients in the IMN group had a higher proportion of patients with ASA score ≥3 (88.64 vs. 73.78, $p = 0.03$). A detailed summary of patient characteristics is included in Table 1.

Table 1 – Patient demographics and characteristics.

	Plate fixation (N = 511)	Intramedullary nail (N = 44)	*p* value
Demographic			
Age, years	71.22 ± 15.96	74.50 ± 15.06	0.19
Female sex (%)	75.34	84.09	0.19
Race (%)			0.90
White	79.84	81.82	
Black	5.48	6.82	
Asian	2.27	1.96	
Other	9.09	12.72	
Preoperative comorbidities			
BMI, kg/m^2	28.45 ± 12.15	27.70 ± 14.12	0.70
Functional status (dependent) (%)	28.96	40.91	0.11
Outpatient (%)	2.35	4.55	0.31
Smoker within 1 year (%)	16.44	18.18	0.77
Alcohol use (%)	4.04	0	0.61
Steroid use (%)	5.87	4.55	1.00
Weight loss (%)	0.59	2.27	0.21
Diabetes (%)	26.03	20.45	0.42
Dyspnea (%)	11.74	6.82	0.46
Hypertension (%)	68.11	63.64	0.54
COPD (%)	10.96	6.82	0.61
Dialysis (%)	2.74	0	0.27
Open wound/ wound infection (%)	8.22	4.55	0.56
Modified CCI	3.18 ± 1.70	3.60 ± 2.10	0.15
Operative variables			
ASA 3 or 4 (%)	73.78	88.64	0.03
Wound class 1 or 2 (%)	97.26	100	0.62
Emergency (%)	28.18	22.73	0.44
Mean operative time, min	105.51 ± 50.25	87.09 ± 37.82	0.02
LOS, days	6.29 ± 11.84	6.80 ± 3.79	0.78

Table 2 – Thirty-day postoperative complications and outcomes in plate fixation versus intramedullary nail repair.

Factor	Plate fixation (N = 511)	Intramedullary nail (N = 44)	p value
Any complication	45.01	52.27	0.35
Serious adverse event	11.55	6.82	0.46
Infectious complications	4.11	2.27	1.00
Mortality	3.72	0	0.39
Blood transfusion	33.46	38.64	0.49
Superficial wound infection	0.59	2.27	0.28
Deep wound infection	0.39	0	1.00
Organ space infection	0.39	0	1.00
Wound dehiscence	0	0	–
Pneumonia	2.54	0	0.61
Unplanned intubation	2.15	0	1.00
Venous thromboembolism	2.74	9.09	0.046
Failure to wean from ventilator	0.20	0	1.00
Renal insufficiency	0.59	0	1.00
Acute renal failure	0.59	0	1.00
Urinary tract infection	5.48	4.55	1.00
Stroke	0.20	0	1.00
Coma	0	0	–
Peripheral nerve injury	0	0	–
Cardiac arrest	0.20	0	1.00
Myocardial infarction	1.57	0	1.00
Graft/implant failure	0	0	–
Sepsis	1.96	0	1.00
Septic shock	0.98	0	1.00
Reoperation	2.54	4.55	0.34

Values listed as percentages.

The PF group and IMN group had similar rates of SAEs (11.55% vs. 6.82%, $p = 0.46$), AAEs (45.01% vs. 52.27%, $p = 0.35$), infectious complications (4.11% vs. 2.27%, $p = 1.00$), and mortality (3.72% vs. 0%, $p = 0.39$) (Table 2). PF compared to IMN patients had a longer total operation time (105.51 ± 50.25 min vs. 87.09 ± 37.82 min, $p = 0.02$) and no difference in hospital length stay though (6.29 ± 11.84 vs. 6.80 ± 3.79 days, $p = 0.78$). Comparisons of individual adverse event types between treatment groups revealed the IMN group had significantly higher pulmonary embolism rates compared to the PF group (4.55% vs. 0.59%, $p = 0.05$). This finding did not remain significant in multivariate analysis.

Multivariate analyses revealed PF versus IMN did not impact SAE rates ($p = 0.36$), AAE rates ($p = 0.37$), infectious complications ($p = 0.45$), or mortality ($p = 1.00$). ASA status ≥3 was independently associated with occurrence of AAE (OR: 1.64, 95% CI: 1.07–2.53, $p = 0.02$), SAE (OR: 1.70, 95% CI: 1.10–2.64, $p = 0.02$), infectious complications (OR: 1.95, 95% CI: 1.29–2.95, $p = 0.001$), and mortality (OR: 1.70, 95% CI: 1.11–2.59, $p = 0.01$) (Table 3). Increased patient age was independently associated with SAE (OR: 1.95, 95% CI: 1.00–1.03, $p = 0.05$) and mortality (OR: 1.01, 95% CI: 1.00–1.25, $p = 0.03$).

Univariate analyses for the overall group indicated history of smoking had no impact on SAE ($p = 0.79$), AAE ($p = 0.50$), infectious complications ($p = 0.43$), or mortality ($p = 0.34$). Similarly, increased BMI was not associated with SAE ($p = 0.99$), AAE ($p = 0.14$), infectious complications ($p = 0.16$), or mortality ($p = 0.96$).

Table 3 – Multivariate analysis demonstrating independent predictors of any adverse event, serious adverse events, infectious complications, and mortality.

Factor	OR	95% CI	p value
Any adverse event			
ASA ≥ 3	1.64	1.07–2.53	0.02
Serious adverse event			
ASA ≥ 3	1.70	1.10–2.64	0.02
Age	1.95	1.00–1.03	0.05
Infectious complication			
ASA ≥ 3	1.95	1.29–2.95	0.001
Mortality			
ASA ≥ 3	1.70	1.11–2.59	0.01
Age	1.01	1.00–1.25	0.03

4. Discussion

The characterization of risk factors for complications in DF fractures is particularly important for orthopedic trauma surgeons. Our goal was to assess complication rates following DF PF versus IMN ORIF and determine which patient factors may predict postoperative complications. To the authors' knowledge, this is the largest study to date to assess complication rates in DF stratified by PF versus IMN fixation method. In this study, we have demonstrated that DF fractures treated with IMN and PF have very high rates of overall adverse events though the two treatments did not differ statistically from one another with regard to perioperative outcomes.

Few studies are available for direct comparison. Because complications recorded and assessed between studies of DF fractures vary, it is difficult to contrast these results to previous findings. The AAE rates of 44% in PF and 50% in IMN are higher than those cited by other investigators.[11,12] In a retrospective study by Hoffmann et al. of 243 surgically treated DF fractures treated with locked PF, 12.6% had surgical complications, the most common of which was deep infection.[13] Initial results from an ongoing trial conducted by Tornetta et al. in a randomized trial for 156 patients undergoing PF or IMN for distal femur fractures demonstrated slightly improved functional results for the IMN patients across groups though differences did not reach statistical significance. A total of 5 pulmonary embolisms/deep vein thromboses as well as one death were reported for their cohort though breakdown between groups was not reported. Revision surgery for failure or nonunion was needed in 5% of IMN and 8% of PF patients. The time period for these complications was not reported, and may not be comparable to this cohort given the nature of the NSQIP database.[14]

Demirtaş et al. in a series of 32 patients found no difference in complications, duration of union, and functional results between retrograde IMN and bridge plating for extra-articular DF fractures. However, their study did not report on incidence of early postoperative adverse events in the groups and the reported complications included implant failure and malunion, which are not included in the ACS-NSQIP database.[3] This current study's findings are supported by a much larger patient cohort and add the benefit of providing prospectively collected data. Though an increased VTE rate of 9.1% compared to 2.7% was noted in the IMN group, overall rates of AAE, SAE, and infectious complications were comparable between the treatment groups. We were unable to find any previous studies denoting an increased risk of VTE for DF fractures treated with IMN. DF fracture patients treated with IMN are usually allowed to bear weight earlier given the nature of the load sharing construct making the higher rates of VTE found in this study counterintuitive. Comparisons of patient pre-operative characteristics make it unlikely that differences in treatment group comorbidities contribute to this disparity. Reasons for this increased VTE rate in the IMN group warrant further investigation.

The VTE rate of 2.7% in the PF group is comparable to the 2.3% rate cited by Kammerlander et al. in a study of 43 geriatric patients with DF fracture.[15] A separate study of 24 elderly patients treated with locking plates found a 25% rate of deep vein thrombosis in the early postoperative period, which is substantially higher than the rate found in the PF group for this study.[16] In contrast to these studies, the current investigation was not limited to the geriatric population and may have had overall healthier patients. However, a prior study by Shulman et al. reviewing 57 geriatric patients with operatively managed DF fractures reported similar outcomes to younger patients.[17]

This study was limited by several characteristics inherent to the ACS NSQIP database. Outcomes are only measured within the 30-day period and the database does not report outcomes specific to orthopedics, such as functional status, patient satisfaction, pain, or more detailed fracture pattern information.[5,18] The indications for IMN versus PF in DF fracture treatment are dependent on many factors: the degree of comminution, coronal plane involvement, bone quality, and distal extent of the fracture. Only Type A and simple type C fractures are amenable to both IMN and PF, and thus only in these situations would a comparison between fixation methods be completely valid. Because these descriptors are not present in the NSQIP database, it is difficult to validate the direct comparison of patients undergoing these two procedures for DF fractures.[19]

The small number of IMN cases in this study makes it difficult to draw final conclusions about the observed differences between treatment groups. The classification of DF fractures in NSQIP based on ICD-9 codes cross-referenced with CPT codes impeded a larger selection of cases. Although DF fractures included were limited to ICD-9 codes 821.20–821.39, some DF cases undergoing treatment with IMN may be coded as femoral shaft fractures (812.01). Despite reducing study size, this strategy was implemented to ensure the integrity of case selection and allow more valid conclusions to be drawn from statistical comparison. Other studies utilizing NSQIP have relied on CPT codes to classify cases, which may not only capture more patients, but also may confound the validity of results.[20] Inclusion of long-term follow-up data would also be beneficial to answer lingering questions regarding the comparative functional utility of these two fixation methods.

Of interest, patient factors, such as smoking and obesity, did not impact rates of complications in this study. Smoking and obesity should however not be discounted as risk factors given previous studies finding an increased risk of infection for patients with these characteristics, including those sustaining DF fractures treated with locking plates.[10,11] In addition, it is has been reported that obesity may impact long-term functional outcomes and union rates in DF fractures.[12] Nevertheless, our findings may assuage physician concerns for increased postoperative complications in these patients to some extent.

5. Conclusion

This study's findings support the findings of other studies that no major differences in overall postoperative course have been seen in DF fractures treated with IMN versus PF. An increased ASA class and age were independently associated with higher AAE rate, SAE rate, infectious complications, mortality and SAE rates and mortality, respectively. Though not significant in the multivariate analysis, patients treated with IMN were seen to have higher rates of VTE and should be monitored closely for development of this complication postoperatively. IMN patients also had longer operative times but equivalent hospital length of stay compared to the PF group. Despite limitations, the multicentered nationwide nature of NSQIP data makes these results more generalizable to practice patterns of U.S. medical centers than those in other studies. We believe this study provides the most comprehensive information on comparative rates of postoperative complications and assessment of risk factors for DF fractures treated with IMN versus PF to date. Orthopedic surgeons can factor these findings into their clinical decision-making process and to inform patient-centered family discussions when preparing for surgical management of DF fractures.

Conflicts of interest

The authors have none to declare.

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