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A comparison of 30-day complications following plate fixation versus intramedullary nailing of closed extra-articular tibia fractures

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ABSTRACT

Background and purpose: Tibial shaft fractures are often treated by intramedullary nailing (IMN) or plate fixation. Our purpose was to compare the 30-day complication rates between IMN and plate fixation of extra-articular tibial fractures.

Materials and methods: We conducted a retrospective analysis of prospectively collected patient demographics, comorbidities, and 30 day complications of isolated closed extra-articular tibial shaft fractures from 2006 to 2012 using the American College of Surgeon's National Surgical Quality Improvement Program (ACS-NSQIP) database. A 1:2 propensity-matched dataset was created to control for differences in preoperative demographics and comorbidities across the plate fixation and IMN groups. Univariate and multivariate analyses were used to assess differences in complications between the groups and the independent effects of plate fixation or IMN on complications.

Results: A total of 771 patients were identified with 234 (30.4%) in the plate fixation and 537 (69.6%) in the IMN group. We found no statistical difference in rates of wound complications, medical complications, reoperation, or mortality in our propensity matched analyses. Plate fixation was found to be independently associated with a lower risk of postoperative blood transfusion compared to IMN (odds ratio 0.326, $p = 0.032$). Plate fixation was not independently associated with any other examined complications.

Conclusions: We found no difference in 30-day postoperative complications between plate fixation and intramedullary nailing of isolated extra-articular tibia fractures with the exception of decreased postoperative transfusion requirements with plate fixation. We conclude that both procedures offer a similar short-term complication profile.

Introduction

Tibial shaft fractures are the most common long bone fracture, frequently requiring surgical intervention. Plate fixation and intramedullary nailing (IMN) are two surgical techniques employed to provide bony fixation of these fractures. Although plate fixation offers the ability to ensure accurate alignment under direct visualization, it often requires increased surgical exposure when a minimally invasive plate osteosynthesis (MIPO) approach is not used. This may result in tissue devitalization, which creates an environment that may increase the risk of wound complications and implant prominence [1,2]. IMN has become more popular due to its less invasive nature and potential for earlier weight bearing, but has been associated with malalignment rates as high as 29%, and anterior knee pain incidence of 37.5% when used for distal tibial shaft fractures [2–6].

Despite the frequency of these fractures, there have been limited studies comprehensively comparing the short-term post-operative course between these two techniques. Recent literature on extra-articular distal tibial shaft fractures has demonstrated no significant differences in surgical-site complication rates between plate fixation and IMN [3,4,7]. However, these studies did not assess whether IMN or plating were independent risk factors for surgical-site infections and wound complications when controlling for confounding patient demographics. Furthermore, we currently are unaware of any studies that have also compared specific post-operative medical and bleeding morbidity between plate fixation and IMN with a large patient sample size.

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In this study, we hope to answer these questions by using the National Surgical Quality Improvement Program (NSQIP) database of the American College of Surgeons (ACS). The aims of this study are (1) to establish baseline demographic data of patients receiving plate fixation and IMN for closed extra-articular tibia fractures, and (2) to examine whether any significant differences in post-operative complications exist between the two procedures when matching for pre-operative comorbidities.

Materials and methods

A retrospective analysis was conducted using the NSQIP participation database from 2006 to 2012. Trained surgical nurses collect prospective NSQIP data for 30 days following the primary procedure, which is collected in 8-day cycles, and monitored weekly. Furthermore, this data is de-identified to comply with the NSQIP participant user agreement. Demographics, comorbidities, and complications within 30 days following surgery are included in this data [8]. The methodology of data collection has been previously described [9].

Primary Current Procedural Terminology (CPT) codes of 27758 and 27759 were selected to identify patients undergoing open treatment of an extra-articular tibial shaft fracture (plate fixation and IMN, respectively). Cases with ICD-9 codes representing open fractures of the tibia were excluded (823.30, 823.32, 823.90, and 823.92). Cases containing "concurrent" and "other" CPT codes consisting of additional procedures unrelated to the primary procedure were excluded to isolate complications only related to the surgical treatment of interest. Additionally, all cases with "prior operations in the last 30 days" were deleted to evaluate complications only associated with the primary procedure, and to eliminate fractures that may have been treated in a staged fashion with external fixation. Furthermore, any case with missing or "Null" pre-operative variables used in our analysis was excluded.

Cases that met those parameters were then divided into two groups based on surgical intervention: plate fixation or IMN. Pre-operative demographics, comorbidities, and 30-day complications were compared between the two stratified sets. Demographics included age and gender. Comorbidities included smoking, diabetes, dyspnoea, ventilator requirement, history of severe chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), dialysis, disseminated cancer, chronic steroid use, >10% weight loss 6 months prior to surgery, bleeding disorders, hypertension requiring anti-hypertensive medications, pre-operative sepsis, and *American Society of Anesthesiologists physical status* (ASA) classification.

Post-operative complications included surgical site, medical, and postoperative transfusion requirement, as well as death and return to the OR within 30 days following the primary procedure. Surgical site complications included superficial, deep, and organ space infections as well as wound dehiscence. Medical complications consisted of myocardial infarction (MI), systemic sepsis, pneumonia, unplanned reintubation, pulmonary embolus, ventilator requirement, deep venous thromboembolism, and urinary tract infection. Postoperative transfusion involved bleeding that required at least 1 unit of transfusion. All variables were used as defined in the ACS-NSQIP user guide [10].

IBM SPSS Statistics version 22 was used to perform all statistics in this study. In all cases, a p value of 0.05 or less was deemed statistically significant. Univariate analysis with Fisher's exact test was employed to compare pre-operative variables of IMN and plate fixation. Independent samples t-test assuming equal variances was also employed to compare operative details between the two procedures. Propensity score matching was then utilized to reduce any bias by confounding pre-operative patient variables [11,12]. Because of a rough 1:2 ratio between plate fixation and IMN cases, a 1:2 nearest neighbour propensity-match was conducted after deriving propensity scores from a logistic regression model. The optimal calliper width was deemed to be 0.2 of the standard deviation of the logit of the propensity score [13]. Units outside of common support were discarded to decrease bias. After obtaining a well-matched cohort, Fisher's exact test was performed on the well-matched dataset.

Finally, in order to demonstrate if plate fixation or IMN were independently associated with higher risk of complications, multivariate regression analyses were performed with the propensity-matched dataset. Candidate pre-operative variables for each regression were screened from those with $p < 0.2$ and at least 5 incidences in each of the cohorts from our previous univariate analysis [14]. Surgical technique was included, and IMN served as the reference procedure. Hosmer–Lemeshow and c-statistics were calculated to assess the calibration and goodness-of-fit of the model, respectively [15].

Results

Unmatched cohort

771 patients undergoing IMN and plate fixation for closed tibial shaft fractures that met the inclusion criteria were identified (Fig. 1). Of these, 234 (30.4%) underwent plate fixation with 537 (69.6%) treated by an IMN. Univariate analysis demonstrated that patients undergoing IMN were more likely to be male (IMN 59.96%, plate fixation 49.57%, p = 0.009). All other pre-operative variables between the two cohorts were equivalent (Table 1). Univariate analysis demonstrated no significant difference in baseline medical complications (IMN 5.03%, plate fixation 3.42%, p = 0.451), surgical site complications (IMN 1.68%, plate fixation 1.71%, p = 1.000), death (IMN 0.37%, plate fixation 0.00%, p = 1.000), and return to the OR (IMN 1.68%, plate fixation 3.42%, p = 0.179).

IMN was associated with a significantly higher rate of 30-day transfusion requirement following surgery (IMN 5.96%, plate fixation 2.56%, p = 0.047). All other post-operative complications were equivalent between the IMN and plate fixation groups (Table 2).

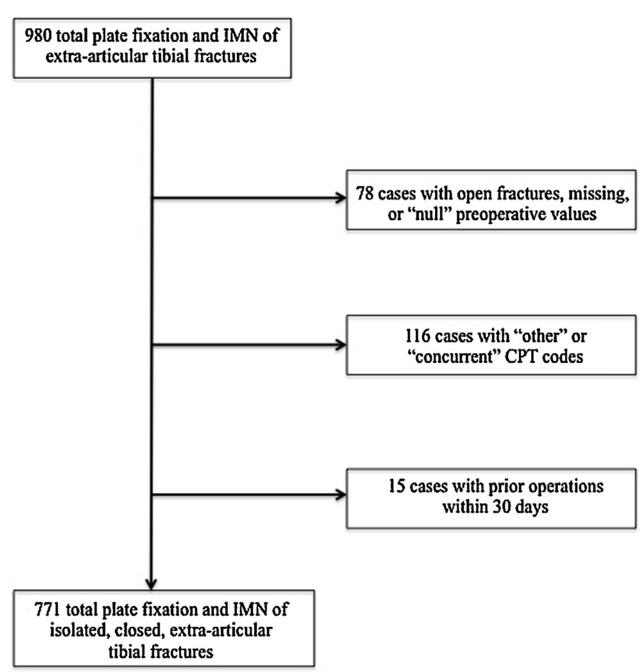

Fig. 1. Patient attrition diagram.

Table 1
Baseline patient characteristics.

Variable	IMN (*n*)	IMN (%)	Plate fixation (*n*)	Plate fixation (%)	*p*
Age ≥50	238	44.32	121	51.71	0.060
Male	322	59.96	116	49.57	0.009*
Diabetes	66	12.29	33	14.10	0.485
Dyspnoea	12	2.23	8	3.42	0.334
Ventilator dependent	2	0.37	0	0.00	1.000
COPD	19	3.54	8	3.42	1.000
CHF	3	0.56	3	1.28	0.375
Dialysis	10	1.86	3	1.28	0.764
Disseminated cancer	4	0.74	0	0.00	0.320
Steroid use	8	1.49	7	2.99	0.168
>10% weight loss	2	0.37	1	0.43	1.000
Bleeding disorder	12	2.23	23	9.83	0.578
Preoperative sepsis	37	6.89	14	5.98	0.576
Smoker	168	31.28	59	25.21	0.102
HTN	156	29.05	69	29.49	0.931
ASA ≥3	170	31.66	79	33.76	0.615

COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; HTN, hypertension; ASA, American Society of Anesthesiologists.
* Significant value ($p < 0.05$).

Propensity-matched cohort

A 1:2 propensity match of plate fixation and IMN cases was performed using an optimal calliper width of 0.07. Well-matched cohorts of 222 plate fixation and 402 IMN cases with no differences in pre-operative demographics and comorbidities were obtained (Table 3). In this propensity-matched group, univariate analysis once again demonstrated that patients undergoing IMN had higher rates of bleeding complications requiring transfusion ($p = 0.046$). All other post-operative outcomes including surgical site complications ($p = 1.00$), medical complications ($p = 0.664$), and return to the OR ($p = 0.240$) did not significantly differ between the two cohorts (Table 4).

Multivariate logistic regression analysis

Multivariate logistic regression models were created using our propensity-matched cohort to examine the independent impact of surgical procedure on 30-day complications of closed tibial shaft fractures (Table 5). After controlling for potential confounders, plate fixation of closed tibial shaft fractures was independently associated with a lower risk of postoperative transfusion requirement (odds ratio (OR) 0.326, 95% confidence interval (CI) 0.117–0.907, $p = 0.032$). Plate fixation was not associated with increased risk of surgical site complications (OR 1.024, CI 0.291–3.608, $p = 0.970$) or medical complications (OR 0.697, CI 0.280–1.734, $p = 0.437$). The accuracy of our models is demonstrated with *c*-statistic indices of 0.711–0.798.

Discussion

Extra-articular tibial shaft fractures are common fractures requiring operative treatment. Although several treatment methods exist, none of the fixation techniques are ideally suited for all combinations of bony and soft tissue injuries. The decision to proceed with either plate fixation or IMN is further complicated by evolving implant designs and surgical approaches.

There is limited published literature comparing methods of fixation for extra-articular tibia fractures with conflicting evidence regarding postoperative complications [3,4,7]. While plate fixation may offer an improved ability to achieve and maintain anatomic fixation, increased soft tissue and vascular disruption with resultant concern for post-operative infection and exposed hardware have weighed against the use of plate fixation. More recent retrospective review of distal tibial shaft fractures demonstrated that intramedullary nailing is associated with more frequent delayed fracture healing, malunion, and secondary operations, whereas prospective analysis demonstrated similar

Table 2
Baseline 30-day complication rates.

Complication	IMN (*n*)	IMN (%)	Plate fixation (*n*)	Plate fixation (%)	*p*
Any surgical site complication	9	1.68	4	1.71	1.000
Superficial wound infection	6	1.12	1	0.43	0.682
Deep wound infection	2	0.37	2	0.85	0.589
Organ space infection	1	0.19	1	0.43	0.515
Wound dehiscence	0	0.00	0	0.00	N/A
Any major medical complication	27	5.03	8	3.42	0.451
MI	1	0.19	1	0.43	0.515
Pneumonia	10	1.86	3	1.28	0.764
Unplanned reintubation	3	0.56	0	0.00	0.557
Pulmonary embolus	2	0.37	1	0.43	1.000
Ventilator requirement	3	0.56	0	0.00	0.557
UTI	8	1.49	2	0.85	0.732
DVT	3	0.56	0	0.00	0.557
Sepsis	4	0.74	1	0.43	1.000
Bleeding requiring transfusion	32	5.96	6	2.56	0.047*
Death	2	0.37	0	0.00	1.000
Return to OR	9	1.68	8	3.42	0.179

MI, myocardial infarction; UTI, urinary tract infection; DVT, deep vein thromboembolism; OR, operating room; N/A, not applicable.
* Significant value ($p < 0.05$).

Table 3
Propensity matched patient characteristics.

Variable	IMN (*n*)	IMN (%)	Plate fixation (*n*)	Plate fixation (%)	*p*
Age ≥50	188	46.77	113	50.90	0.357
Male	219	54.48	114	51.35	0.503
Diabetes	49	12.19	28	12.61	0.899
Dyspnoea	8	1.99	5	2.25	0.779
Ventilator dependent	0	0.00	0	0.00	N/A
COPD	11	2.74	6	2.70	1.000
CHF	0	0.00	1	0.45	0.356
Dialysis	3	0.75	2	0.90	1.000
Disseminated cancer	0	0.00	0	0.00	N/A
Steroid use	6	1.49	2	0.90	0.718
>10% weight loss	0	0.00	1	0.45	0.356
Bleeding disorder	17	4.23	11	4.95	0.689
Preoperative sepsis	24	5.97	13	5.86	1.000
Smoker	126	31.34	59	26.58	0.234
HTN	118	29.35	63	28.38	0.854
ASA ≥3	118	29.35	71	31.98	0.524

Hx, history; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; ASA, American Society of Anesthesiologists.

rates of infection, nonunion, and secondary procedures, with increased rate of malunion [3,4]. In our study, we show that plate fixation offers no increased risk of infection or wound complications at 30 days postoperative.

Using a large, multi-institutional database we are able to report the largest study to date comparing plate fixation to IMN treatment of isolated closed extra-articular tibia fractures. This database includes over 240 preoperative, intraoperative, and postoperative variables from over 250 nationwide hospitals and has been frequently used to characterize trends in orthopaedic surgery [16–20]. This system is the only national, risk-adjusted quality improvement system that is developed and validated by surgeons [10]. Our large cohort size and propensity matching sought to eliminate uncontrolled and confounding factors that limit the analysis of smaller single institution studies. With this analysis, we found no difference in overall medical or surgical complications between treatment with plate fixation or IMN. Surgical site complication rates for plate fixation and IMN were 1.71% and 1.68% respectively. Thirty-day reoperation rates were 3.42% and 1.68%, respectively. This data is consistent with previously published studies, with the SPRINT trial reporting a similar 1.93% reoperation rate for in patients treated with IMN [21]. Limited series on plate fixation in tibial shaft and distal tibial shaft showed infection rates ranging from 0 to 4.7% [22,3]. The infection rates in our study are at the lower end of this spectrum, potentially secondary to open tibia fractures being excluded from our analysis.

Importantly, we found that plate fixation was independently associated with decreased bleeding complications requiring at least 1 unit of packed red blood cells when compared to IMN, with an OR of 0.342. The aetiology of increased bleeding in IMN is unclear. One possibility is endosteal bleeding stemming from the reaming and placement of the nail. Reaming has been shown in sheep to immediately increase the surrounding periosteal blood supply by 6-fold, leading to potentially increased bleeding across the damaged periosteum at the fracture site in the acute postoperative period [23]. However this is based off an assumption of reaming with IMN fixation, which is the preferred technique in 76% of surgeons globally when treating closed low-energy tibial shaft fractures [24]. In contrast, plate fixation allows meticulous hemostasis during the procedure without disruption of endosteal bloody supply, leading to decrease post-operative bleeding. Lee et al. found similar results in a prospective randomized study of treatment of comminuted subtrochanteric fractures with a plating versus IMN in young adults, with 25% of plate fixation patients requiring transfusion compared to 59% of IMN patients ($p = 0.005$) [25]. Another explanation for this discrepancy in transfusion requirement may be secondary to tourniquet use during plating of extra-articular tibia fractures, which is

Table 4
Propensity matched 30-day complication rates.

Complication	IMN (*n*)	IMN (%)	Plate fixation (*n*)	Plate fixation (%)	*p*
Any surgical site complication	7	1.74	4	1.80	1.000
Superficial wound infection	4	1.00	1	0.45	0.660
Deep wound infection	2	0.50	2	0.90	0.619
Organ space infection	1	0.25	1	0.45	1.000
Wound dehiscence	0	0.00	0	0.00	N/A
Any major medical complication	17	4.23	7	3.15	0.664
MI	0	0.00	1	0.45	0.356
Pneumonia	7	1.74	3	1.35	1.000
Unplanned reintubation	2	0.50	0	0.00	0.541
Pulmonary embolus	1	0.25	0	0.00	1.000
Ventilator requirement	1	0.25	0	0.00	1.000
UTI	4	1.00	2	0.90	1.000
DVT	2	0.50	0	0.00	0.541
Sepsis	2	0.50	1	0.45	1.000
Bleeding requiring transfusion	23	5.72	5	2.25	0.046*
Death	0	0.00	0	0.00	N/A
Return to OR	6	1.49	7	3.15	0.240

MI, myocardial infarction; UTI, urinary tract infection; DVT, deep vein thromboembolism; OR, operating room; N/A, not applicable.
* Significant value ($p < 0.05$).

Table 5
Independent effects of plate fixation on complications.

Complication	Odds ratio	95% confidence interval	p	c statistic	Hosmer–Lemeshow
Surgical site complication	1.024	0.291–3.608	0.97	0.711	0.317
Medical complication	0.697	0.280–1.734	0.437	0.735	0.558
Bleeding complication requiring transfusion	0.326	0.117–0.907	0.032*	0.798	0.083

* Significant value ($p < 0.05$).

associated with significantly lower rates of blood loss following surgical plate fixation [26,27].

The limitations of our study include the 30-day postoperative window of ACS-NSQIP data collection. This limited window fails to capture long-term complications and secondary procedures such as hardware prominence, a common complication of plating. Additionally we cannot comment on the union rate, a commonly reported important outcome in tibia fractures. Furthermore, while the objective of our study was to evaluate safety and complication rates following these two procedures, functional outcomes, patient satisfaction, and radiological assessment cannot be made with the data available to us. Another major limitation is our reliance on CPT codes as a surrogate for surgical procedure performed. The CPT code for extra-articular tibia fractures does not specify whether the fracture pattern involves the proximal, middle, or distal third of the tibial shaft or whether plate fixation of the fibula was also completed. Our study reported a ratio to IMN to plate fixation treatment of approximately 2 to 1, which is a much higher rate of plate fixation preference than previously reported literature for tibial shaft fractures. An international survey by Bhandari et al. showed that 96% of surgeons would treat closed midshaft tibia fractures with IMN while 96% would treat closed high-energy fractures with IMN, while plate fixation was preferred in 3.2% and 2.1% of surgeons respectively [24]. A national survey of 450 Canadian orthopaedic surgeons showed similar results, with 87% of surgeons preferring IMN, compared to only 8% for plate fixation [28]. Given this pre-existing literature, we hypothesize that the majority of the plate fixation cohort in our study had specifically proximal or distal third tibial shaft fractures, but cannot make any definitive conclusions due to the limitation of our dataset. Additionally, the NSQIP database lacks information regarding mechanism of injury or potential soft tissue swelling, which may have contributed to this discrepancy in procedure preference.

Conclusions

In conclusion, we found no difference in 30-day postoperative complications between plate fixation and intramedullary nailing of isolated closed extra-articular tibia fractures, with decreased postoperative transfusion requirements with plate fixation. Our study establishes the baseline 30-day rates of medical and surgical site complications following the two procedures, which can be used as a benchmark for physicians when comparing risks of short term morbidity and mortality between the two techniques. We conclude that both IMN and plate fixation offer a similar short-term complication profile and can be used safely to treat these injuries. Further studies directly comparing the preoperative indications and functional, long-term outcomes should be conducted to further compare the efficacy of plate fixation and intramedullary nailing for extra-articular tibia fractures.

Conflict of interest statement

Author Anish R. Kadakia, M.D. has received funding from activities outside of this work, which have not influenced the subject of this study. These include: consulting for Acumed and BME, providing expert testimony for Legal Entities and INSPE, receiving grants from Synthes and Acumed, and receiving payment for lectures from Acumed. For the remaining authors, no conflict of interest or sources of funding were declared.

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