Eur J Trauma Emerg Surg (2016) 42:101–106
DOI 10.1007/s00068-015-0519-7

ORIGINAL ARTICLE

Open distal tibial shaft fractures: a retrospective comparison of medial plate versus nail fixation

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Received: 27 August 2014 / Accepted: 11 March 2015 / Published online: 25 March 2015

Abstract
Purpose Studies comparing open reduction internal fixation (ORIF) vs. intramedullary nailing (IMN) for distal tibia shaft fractures focus upon closed injuries containing small patient series with open fractures. As such, complication rates for open fractures are unknown. To characterize complications associated with ORIF vs. IMN, we compared complications based on surgical approach in a large patient series of open distal tibia shaft fractures.
Methods Through retrospective analysis at an urban level I trauma center, 180 IMN and 36 ORIF patients with open distal tibia fractures from 2002 to 2012 were evaluated. Patient charts were reviewed to identify patient demographics, fracture grade (G), patient comorbidities, and postoperative complications including nonunion, malunion, infection, hardware-related pain, and wound dehiscence. Fisher's exact tests compared complications between ORIF and IMN groups. Multivariate regression identified risk factors with statistical significance for the development of a postoperative complication.
Results One hundred and eighty IMN (G1 22, G2 79, and G3 79) and 36 ORIF (G1 10, G2 16, and G3 10) patients were included for analysis. ORIF patients had a higher rate of nonunion (25.0 %, $n = 9$) compared with IMN patients (10.6 %, $n = 20$, $p = 0.03$). No additional complication had a significant statistical difference between groups. Multivariable analysis shows only surgical method influenced the development of complications: ORIF patients had 2.52 greater odds of developing complications compared with IMN patients (95 % CI 1.05–6.02; $p = 0.04$).
Conclusions ORIF leads to higher rates of nonunion and significantly increases the odds of developing a complication compared with IMN for open distal tibia fractures. This is the first study investigating complication rates based on surgical approach in a large cohort of patients with exclusively open distal tibia fractures.

Keywords IMN · Plate · Tibia · Open fracture

Introduction

Several studies report the complication rates for patients with distal tibia fractures treated with open reduction internal fixation (ORIF) vs. intramedullary nailing (IMN) [1–5]. The vast majority of patients in these studies had closed injuries. The likely complications of distal tibia injuries treated with these aforementioned methodologies therefore primarily documents outcomes regarding closed fractures: ORIF enables improved alignment but is associated with an increased rate of infection, whereas IMN has a lower rate of infection but is associated with postoperative knee pain [1–5]. In contrast to closed injuries, open fractures of the distal tibia are more challenging to treat due to limited soft tissue coverage with historically higher rates of nonunion [6]. Treatment options similarly consist of IMN and ORIF, with the majority of ORIF patients treated with medial plates [7]. However, because previous studies used large percentages of closed fractures, it remains unknown whether open fractures of the distal tibia follow similar complication patterns as seen with closed injuries based on surgical approach.

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In a prospective trial, Im and colleagues found significantly higher rates of infection in the ORIF group (23 %) compared with IMN patients (3 %), but only 20 % of patients in this study had open fractures [1]. In a retrospective study, Janssen et al. [2] found greater rates of knee pain and malalignment in patients treated with IMN, but all patients in the study either had closed fractures or Gustilo–Anderson grade I open fractures. The results of these two studies were not replicated in a prospective study by Vallier's group, which found statistically similar rates of infection between the two groups but higher rates of nonunion and malunion with IMN patients [3]. Only 39 % of patients in this study had open fractures. Due to the mixed nature of these studies combining patients with open and closed fractures, it is difficult to discern whether ORIF or IMN results in fewer complications for the treatment of open distal tibia fractures.

In this paper, we present the results of the first retrospective study to date consisting of a large cohort of patients with exclusively open distal tibia fractures to determine whether IMN or ORIF affords better outcomes. To our knowledge, no study has yet investigated this issue of IMN vs. ORIF in a cohort solely consisting of open fractures of the distal tibia. By looking at complication rates, we determine whether any significant differences exist between these two surgical approaches to providing recommendations in the treatment of open injuries of the distal tibia.

Methods

After institutional IRB approval, all open tibia fractures treated with IMN at a single, level I trauma center were identified through Current Procedural Terminology (CPT) code search 27759 (treatment of tibial shaft fracture by intramedullary implant) and 11010–11012 (irrigation and debridement of open fractures) from January 1, 2002, to January 1, 2012. A total of 555 patients were identified. Patient medical records and radiographs were reviewed to exclude patients with closed fractures, injuries less than 4 cm or greater than 11 cm from the tibial plafond, or those with incomplete medical records. To identify patients with open tibia fractures treated with ORIF, we searched the institution's orthopedic database selecting patients treated from January 1, 2002, to January 1, 2012 using CPT code 27758 (open treatment of tibial shaft fracture with plate/screws). A total of 2246 patients were identified. As the treatment of distal tibia fractures has evolved to include minimally invasive plate osteosynthesis (MIPO), which is now a common method, medical records and radiographs were reviewed to include patients only treated with a medial plate. Patients with closed fractures or incomplete medical records were excluded.

Each patient meeting inclusion criterion underwent medical chart review for demographic information including age, gender, ASA score, hospital length of stay, and Gustilo–Anderson classification grade of open fracture and degree of open fracture contamination. Fractures were graded "clean contamination" if no debris was localized at the fracture site. Open wounds with debris were graded as "gross contamination." Thirty-one individual patient comorbidities including current smoking status, alcohol use, and history of cardiopulmonary disorders were also collected. All complications leading to further surgical intervention were recorded. Complications were categorized into infection, nonunion, malunion, hardware problems (i.e., removal of hardware due to pain), and surgical site dehiscence. Rates of overall and group (ORIF vs. IMN)-specific complications were compared using Fisher's exact tests. All patients were assessed as a whole to perform a multivariate regression controlling for age, gender, ASA score, hospital length of stay, race, fracture grade, and surgical procedure (IMN vs. ORIF) and 31 individual comorbidities (i.e., alcohol abuse, obesity, and diabetes) to determine whether any patient factors significantly influenced the development of complications.

Results

A total of 180 patients treated with IMN and 36 patients treated with ORIF were included in the final analysis. Demographic data for patients in each group are provided in Table 1. Patients treated with ORIF were older with an average age of 43 years compared with 38 years in the IMN group. Seventy-five percentage of all patients were male in each cohort, with a similar distribution of races between the two groups. Patients treated with ORIF had a higher percentage of patients with grade I fractures (27.8 vs. 12.2 %), whereas the IMN group had a higher percentage of patients with grade III fractures (43.9 vs. 27.8 %). Both groups had

Table 1 Patient characteristics for ORIF vs. IMN

Characteristic	ORIF ($n = 36$)	IMN ($n = 180$)
Average age in years (SD)	43.1 (17.6)	38.1 (14.1)
Gender		
Male (%)	27 (75.0 %)	135 (75.0 %)
Female (%)	9 (25.0 %)	45 (25.0 %)
Average ASA score (SD)	2.2 (0.7)	2.3 (0.8)
Race		
Caucasian	31 (86.1 %)	134 (74.4 %)
African–American	3 (8.3 %)	26 (14.4 %)
Other	2 (5.6 %)	18 (10.0 %)

similar proportions of grade II fractures (44.4 % for ORIF vs. 43.9 % for IMN).

Table 2 describes fracture characteristics representing each group. Each IMN was placed in a reamed fashion, and MIPO technique was employed for medial plate placement. The vast majority of patients in the ORIF cohort either sustained a fall from height or were involved in an MVC resulting in a distal extra-articular tibia fracture. Similarly, most of the patients in the IMN group were involved in an MVC and sustained a similar fracture pattern. Both groups had a similar open fracture grade distribution. Table 3 records the fracture grade and degree of contamination: There is no difference in the proportion of grossly contaminated injuries over any of the fracture types. Further analysis of these data shows no correlation between infection, nonunion, and degree of contamination.

Table 4 lists the complications for the two groups. When combining all complications within a group, there is no significant difference in overall complication rates between IMN (43.9 %, $n = 79$) and ORIF (44.4 %, $n = 16$). The ORIF group had a significantly higher rate of nonunion (25.0 %, $n = 9$) compared with IMN patients (10.6 %, $n = 20$, $p = 0.03$). There were no significant differences between the groups with respect to the other categories of complications.

After combining ORIF and IMN patients together in a multivariate regression to determine whether any risk factors were significantly associated with complications, only type of surgery (i.e., ORIF or IMN) was significant. ORIF patients were 2.52 times as likely to develop a complication compared with IMN patients (95 % confidence interval: 1.05–6.02; $p = 0.04$). Demographics such as age, gender, race, fracture grade, and patient comorbidities such as drug abuse, mental health issues, and cardiopulmonary problems were not significantly predictive of complication.

Table 5 provides a literature review and compares results from our study to extractable data from the five studies in the literature that have directly compared ORIF with IMN for the treatment of open distal tibia fractures [2–6]. Four out of the five studies included both open and closed fractures with little data on open fractures. Yang et al.'s 2006 study consisted only of all closed fractures.

Table 2 Fracture characteristics

Characteristic	ORIF ($n = 36$)	IMN ($n = 180$)
Mechanism of injury		
Fall	10 (38.5 %)	14 (7.8 %)
MVC	11 (42.3 %)	70 (38.9 %)
MCC	7 (26.9 %)	35 (19.4 %)
GSW	2 (7.7 %)	13 (7.2 %)
Pedestrian	2 (7.7 %)	22 (12.2 %)
Crush	1 (3.8 %)	10 (5.6 %)
Other	3 (11.5 %)	16 (8.9 %)
Classification (OTA)		
42-A2	0	3 (1.7 %)
42-B1	0	1 (0.6 %)
43-A1	9 (25 %)	68 (37.8 %)
43-A2	13 (36.1 %)	53 (29.4 %)
43-A3	13 (36.1 %)	54 (30.0 %)
43-B1	19 (2.8 %)	1 (0.6 %)
43-B3	0	3 (1.7 %)
Open fracture grade		
Grade I	10 (27.8 %)	22 (12.2 %)
Grade II	16 (44.4 %)	79 (43.9 %)
Grade IIIA	5 (13.9 %)	44 (24.4 %)
Grade IIIB	5 (13.9 %)	32 (17.8 %)
Grade IIIC	0	3 (1.7 %)

Table 3 Fracture grade and degree of wound contamination

	IMN (*N*, %)	ORIF (*N*, %)
Grossly contaminated	58 (33.1)	8 (22.2)
Clean	116 (66.2)	28 (77.8)

Table 4 Complication rates for ORIF vs. IMN

Complication	ORIF ($n = 36$)	IMN ($n = 180$)	p value
Infection	2 (5.6 %)	26 (14.4 %)	0.18
Nonunion	9 (25.0 %)	20 (10.6 %)	0.03
Malunion	1 (2.8 %)	3 (1.7 %)	0.52
Other bone*	1 (2.8 %)	5 (2.8 %)	0.99
Hardware-related pain	2 (5.6 %)	7 (3.9 %)	0.65
Wound dehiscence	1 (2.8 %)	18 (10.0 %)	0.21
Total complications	16 (44.4 %)	79 (43.9 %)	0.99

* Other bone includes delayed union and segmental defects

Discussion

Compared with other studies that incorporate both open and closed fractures, our study uniquely focused on a large cohort of open distal tibia fractures and demonstrated that patients are more likely to develop nonunions when treated with ORIF compared with IMN. We found no significant differences in the rates of other complications (i.e., infection and hardware problems) between the two groups. Interestingly, while there was no significant difference in the overall complication rates between ORIF and IMN, when controlling for patient demographics and clinical comorbidities, ORIF was 2.52 times more likely to result in the development of a complication compared with IMN.

Table 5 Selected results from studies directly comparing IMN to ORIF for distal tibia fractures

Study	Study population	Selected metrics	Outcome (IMN vs. ORIF)	*p* value
Im [1]	IMN: $n = 34$	Operation time	72 vs. 89 min	0.02
	ORIF: $n = 30$	Radiologic union	18 vs. 20 weeks	0.89
	Open and closed fractures*	Infection	2.9 vs. 20.0 %	0.03
		Average angulation	2.8° vs. 0.9°	0.01
		Functional ankle score	88.5 vs. 88.2 %	0.71
Yang [5]	IMN: $n = 13$	Mean union time	22.6 vs. 27.8 weeks	<0.05
	ORIF: $n = 14$	Postoperative valgus	3.7° vs. 0.5°	<0.05
	All closed fractures*	Malunion	23.0 vs. 7.0 %	0.24
		Ankle score	86/100 vs. 84/100	0.48
		Length of stay	6.4 vs. 6.5 days	0.96
Janssen [2]	IMN: $n = 12$	Operative time	123 vs. 107 min	0.07
	ORIF: $n = 12$	Radiographic union	21 vs. 19 weeks	0.44
	Open and closed fractures*	Time to weight bear	3.3 vs. 3.8 months	0.14
		Anterior knee pain	43/100 vs. 7/100	<0.05
Vallier [4]	IMN: $n = 76$	Infection	5.3 vs. 2.7 %	0.46
	ORIF: $n = 37$	Delayed union	5.3 vs. 0.0 %	0.29
	Open and closed fractures*	Nonunion	6.6 vs. 2.7 %	0.66
		Malunion	29 vs. 5.4 %	<0.01
Vallier [3]	IMN: $n = 56$	Deep infection	5.3 vs. 4.7 %	0.42
	ORIF: $n = 48$	Nonunion	9.8 vs. 3.5	0.04
	Open and closed fractures*	Malunion	27.3 vs. 12.9 %	<0.01
Avilucea (this study)	IMN: $n = 180$	Infection	14.4 vs. 5.6 %	0.18
	ORIF: $n = 36$	Nonunion	10.6 vs. 25.0 %	0.03
	All open fractures*	Malunion	1.7 vs. 2.8 %	0.52
		Hardware pain	3.9 vs. 5.6 %	0.65

No other patient factor was identified to significantly correlate with a complication requiring reoperation.

To our knowledge, only five studies have directly compared ORIF with IMN for the treatment of distal tibia fractures [1–5]. In Vallier et al.'s [3] 2011 prospective study comparing ORIF to IMN, the IMN group had a significantly higher rate of nonunion at 9.8 % compared with 3.5 % in the ORIF group. Similar results were seen in Vallier's 2008 retrospective study, which reported a 6.6 % nonunion rate in the IMN group compared with 2.7 % in patients treated with ORIF. Although we had a similar nonunion rate of 11 % in the IMN group, our ORIF group had a much higher nonunion rate, nearly 25 % [4]. The combination of open and closed fractures in Vallier et al.'s studies may have confounded the results and may not have truly characterized the incidence of nonunion or any other complication based on surgical approach. Studies have shown that open fractures are independently predictive of nonunion regardless of other risk factors [7, 8]. Given that our study consisted of only open fractures, patients in the ORIF group are more likely predisposed to nonunion compared with a mixed open and closed cohort as used by Vallier.

Reducing reoperations secondary to tibial nonunions is important considering that a study by Fong and colleagues found patients with tibial nonunions are 97 times more likely to have a reoperation compared with patients who did not develop nonunion [7]. Diaphyseal tibial fractures historically have high reoperation rates with reported incidences upwards of 12 % according to some series [8, 9]. As such, interventions aiming to reduce a reoperation would help curtail the development of additional complications as patients with tibial shaft nonunions have further been shown to have increased comorbidities, greater risks of additional fractures in the 2 years following nonunion, increased utilization of inpatient resources and outpatient physical therapy, and incur greater costs [8]. According to Antonova's 2013 study investigating the costs of tibial shaft nonunions, patients with tibial shaft fractures significantly cost more health care dollars to treat (~$25,500) compared with tibial shaft fractures that healed without complications (~$11,700) [8]. Knowing that the financial impact to address such a nonunion further emphasizes the need to employ a surgical approach that potentially may reduce the risk of nonunions.

Both Janssen et al.'s and Vallier's [1–3] group found increased rates of malunion in patients treated with IMN, with Im and Tae reporting significantly increased angulations in their intramedullary group. However, in our study,

we found that rates of malunion were approximately 2–3 % in each group. In the setting of a distal tibia fracture, IMN is a more technically challenging procedure, with the potential for technical factors including surgical skill significantly affecting outcomes [10, 11]. Surgeon variation may have accounted for some of the differences in our data compared with literature results, especially when considering Yang et al.'s [5] comparative study also found no significant difference in malunion rates between ORIF and shortened IMN. Perhaps more importantly, variations specific to IMN technique such as the number of static locking screws, the locations of the screws, and the type of nail used (reamed vs. non-reamed) also significantly affect outcomes [10–13]. Reamed nailing may significantly disrupt medullary blood supply, potentially resulting in delayed union and possible nonunion [3, 4]. Our data report on tibial nails inserted following intramedullary nailing. Although the medullary supply was disrupted in a distal tibia fracture, the nonunion rate was surprisingly higher in the ORIF group, a finding that further supports the use of an IMN in the setting of open fracture.

In comparison with Im et al. [1], our study did not demonstrate increased rates of infection with ORIF. A systematic review by Iqbal and Pidikti [14] found a higher infection rate with plating compared with nailing, although their review incorporated studies that again combined open and closed fractures. A cohort of all open fractures in our study may help explain similar infection rates between the ORIF and IMN groups. According to Patzakis, the most important factor in reducing infection rates for open fractures is early administration of antibiotics followed by debridement [15]. This recommendation is supported by Lack et al.'s [20] recent study recognizing in a univariate analysis of 137 patients that the rate of infection is decreased when antibiotics are administered within 66 min. Antibiotic prophylaxis for closed fractures is not as clear in cases not including prosthetics or implants. Studies with mixed open and closed fractures therefore may not have consistent practice with antibiotic administration, and therefore, increased rates of infection with ORIF may be confounded with the type of fracture at presentation (i.e., open vs. closed) and timing of antibiotic administration.

As an interesting comparison, Yang et al.'s study used a cohort of all closed fractures [5]. The only direct comparison between our studies is malunion rates. Yang found a higher rate (23 %) in the IMN group compared with 7 % in the ORIF group, although this difference was not significant. We similarly found no significant differences in malunions in our two groups, although the incidence of this complication was overall much lower in our study. It therefore remains to be seen whether closed fractures on a whole result in higher malunions compared with open fractures in this patient population.

Unique to our comparative study are results from our multivariate analysis. We incorporated eight demographic parameters and 31 clinically relevant patient comorbidities in our model. Only surgical approach had a significant impact on complication development and mirrors results from Bhandari's 2001 international survey querying surgeons' preferences on nails vs. plates for the management of open tibial fractures due to potentially lower rates of complications with nailing [16]. In this study, the overwhelming majority of surgeons preferred intramedullary nailing in lieu of plating (98.9–99.2 % of all surgeons) for all open fracture grades. These preferences shifted as fracture severity and grade increased with fewer surgeons electing to use IMN (48.4 %) in favor of external fixation (50.5 %). However, plating preferences still remained low. In our study, the overall complication rates between IMN and ORIF were within statistical similarity in our study. However, this univariate analysis failed to take into account multiple other factors that may influence the development of complications. Studies have shown that various patient comorbidities significantly affect the development of complications secondary to tibial shaft fractures, and it is therefore imperative that these factors are taken into account to determine true complication odds [8]. For example, our univariate analysis is in contrast to Vallier's randomized controlled study, where the IMN group had a 42 % complication rate (deep infections, nonunions, and malunions) compared with 21 % for the ORIF group [3]. Vallier's study did not incorporate multivariate analysis that may have shown a trend similar to our results in that ORIF procedures seem inherently riskier.

Our study had some limitations. For one, we only included ORIF patients treated with medial plating given that it is the most common treatment of ORIF of extra-articular distal tibia fractures. However, other ORIF approaches include using lateral plates or a combination of lateral and medial plates. It would be important to therefore note complication rates for these other variations of ORIF to assess for any differences in complication rates. Furthermore, other studies report that associated fibular fractures may impact complication rates and that metrics such as time to union, operation times, and costs associated with definitive fixation may considerably drive decision making toward one surgical technique over the other [16–19]. Additionally, it is important to note that selection bias was a limitation for this study since on a whole the IMN group is allowed to start weight bearing earlier and does not have further periosteal stripping as with ORIF. A future study should investigate these various aspects in a cohort of open fracture patients to note whether there are significant differences in ORIF and IMN groups. Finally, all data collected were at a single level I trauma center. Given that surgical skill and nail type may drive complication rates with IMN,

different rates of complications based on surgical skill and preference with types of nails, the generalizability of our results may be limited based on the experiences and preferences of the orthopedic surgeons at our institution.

Overall, considering the odds of developing any complication with ORIF compared with IMN and the higher chance of specifically developing nonunion, our study suggests that open distal tibia fractures are better treated with intramedullary nails. However, the practicing orthopedic surgeon must be comfortable with this technique, particularly in the setting of a distal tibia fracture where anatomic reduction may be difficult to achieve. Further studies elucidating factors associated with IMN technique in relation to open distal tibia fractures should be conducted to truly determine whether this surgical approach is superior.

Acknowledgments No financial support was received for this study.

Conflict of interest Author William Obremskey has previously consulted for biometrics, done expert testimony in legal matters, has a grant from the Department of Defense, and has been a Board Member of the OTA and SEFC. For the remaining authors, Frank R. Avilucea, Michael K. Ghiam, Vasanth Sathiyakumar, Sarah E. Greenberg, Rachel V. Thakore, Elvis Francois, Michael A. Benvenuti, Michael Siuta, Anne K. Smith, Jesse M. Ehrenfeld, Jason M. Evans, and Manish K. Sethi, no conflicts of interest were declared.

Copyrighted material/consent forms This study used no previously copyrighted materials or signed patient consent forms.

IRB approval This study has approval from the Vanderbilt IRB.

Ethical review committee statement This study was performed in accordance with the relevant regulations of the US Health Insurance Portability and Accountability Act (HIPAA) and the ethical standards of the 1964 Declaration of Helsinki.

Compliance with ethics guidelines All human and animal studies have been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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