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Individual risk factors for deep infection and compromised fracture healing after intramedullary nailing of tibial shaft fractures: A single centre experience of 480 patients

W.-J. Metsemakers [b,*], K. Handojo [b], P. Reynders [c], A. Sermon [a,b], P. Vanderschot [a,b], S. Nijs [a,b]

[a] KU Leuven – University of Leuven, Department Development and Regeneration, B-3000 Leuven, Belgium
[b] University Hospitals Leuven, Department of Trauma Surgery, B-3000 Leuven, Belgium
[c] Brugmann University Hospital, Department of Orthopaedic and Trauma Surgery, B-1000 Brussels, Belgium

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ABSTRACT

Introduction: Despite modern advances in the treatment of tibial shaft fractures, complications including nonunion, malunion, and infection remain relatively frequent. A better understanding of these injuries and its complications could lead to prevention rather than treatment strategies. A retrospective study was performed to identify risk factors for deep infection and compromised fracture healing after intramedullary nailing (IMN) of tibial shaft fractures.
Materials and methods: Between January 2000 and January 2012, 480 consecutive patients with 486 tibial shaft fractures were enrolled in the study. Statistical analysis was performed to determine predictors of deep infection and compromised fracture healing. Compromised fracture healing was subdivided in delayed union and nonunion. The following independent variables were selected for analysis: age, sex, smoking, obesity, diabetes, American Society of Anaesthesiologists (ASA) classification, polytrauma, fracture type, open fractures, Gustilo type, primary external fixation (EF), time to nailing (TTN) and reaming. As primary statistical evaluation we performed a univariate analysis, followed by a multiple logistic regression model.
Results: Univariate regression analysis revealed similar risk factors for delayed union and nonunion, including fracture type, open fractures and Gustilo type. Factors affecting the occurrence of deep infection in this model were primary EF, a prolonged TTN, open fractures and Gustilo type. Multiple logistic regression analysis revealed polytrauma as the single risk factor for nonunion. With respect to delayed union, no risk factors could be identified. In the same statistical model, deep infection was correlated with primary EF.
Conclusions: The purpose of this study was to evaluate risk factors of poor outcome after IMN of tibial shaft fractures. The univariate regression analysis showed that the nature of complications after tibial shaft nailing could be multifactorial. This was not confirmed in a multiple logistic regression model, which only revealed polytrauma and primary EF as risk factors for nonunion and deep infection, respectively. Future strategies should focus on prevention in high-risk populations such as polytrauma patients treated with EF.

Introduction

Tibial fractures are the most frequently encountered long bone fractures of the lower limbs [1]. Because of the specific anatomical features of the tibia, over 15% of these fractures are classified as open, representing the most common open long-bone injuries [2,3]. This is one of the reasons why infection and compromised fracture healing after treatment remain important complications. The overall infection rate after operative treatment of these injuries is about 1–4% [4]. Rates of deep infection range from 1% after operative fixation of closed low-energy fractures up to 30% in complex open tibia fractures [5,6]. Nonunion rates can be up to 17% according to data from large teaching centres [7] and these numbers are higher when open fractures are involved [4].

Tibial shaft fractures constitute a significant clinical challenge, as their outcome is unpredictable. Although several studies have investigated the subject in the past [4,7,8], these sometimes

* Corresponding author at: Department of Trauma Surgery, University Hospitals Leuven, Herestraat 49, 3000 Leuven, Belgium. Tel.: +32 16344666.
E-mail address: wilhelmus.metsemakers@uzleuven.be (W.-J. Metsemakers).

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complex injuries remain prone to complications and impaired limb function even in the hands of experienced trauma surgeons. Our study is a retrospective evaluation of a large-scale, single-centre experience. Standardised patient-care regimens were used, which is important, as already stated by previous authors [8,9]. We critically evaluated our treatment protocol, and tried to identify risk factors for deep infection and compromised fracture healing after intramedullary nailing (IMN) that can be addressed by future prevention strategies.

Patients and methods

Study design

The study protocol has been ethically approved by the advisory board of the University Hospitals Leuven and has been conducted following the good clinical practice guidelines.

The University Hospitals Leuven are a designated trauma referral centre in Belgium. Patients have been identified based upon their International Classification of Disease (ICD)-9 coding as having suffered from a tibial fracture. The injury data of the identified patients were retrieved from the hospital electronic patient file system and included in the study's database.

Between January 2000 and January 2012, the Department of Trauma Surgery treated 1407 patients with tibia fractures, of whom 623 underwent IMN. Patients were identified from the operating theatre logbooks, and all case notes were retrieved.

Inclusion criteria included skeletal maturity and tibial shaft fractures treated with IMN. The definition and classification of shaft fractures was based on the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification [10]. Open fractures were subdivided by the Gustilo–Anderson classification [11], which was determined at the time of initial debridement in the operating room.

Exclusion criteria were skeletal immaturity, amputation within 5 days of the accident, primary treatment with plate osteosynthesis, primary treatment outside the University Hospitals Leuven, presence of metaphyseal fractures, and presence of pathological fractures.

Patient demographics including age, sex, smoking, obesity (body mass index (BMI): $\geq$30), diabetes, American Society of Anaesthesiologists (ASA) classification, polytrauma (injury severity score (ISS): $>$16) [12,13], fracture type, open fractures, Gustilo type, time to nailing (TTN), primary external fixation (EF), reaming and length of hospital stay, were recorded.

The minimum follow-up period was 18 months, and follow-up was continued until there was evidence of union. The results were reviewed retrospectively using the patients' hospital and operation charts. The clinical records and radiographs were reviewed by three of the authors (WJM, KH, and SN) independently.

Treatment protocol

Surgery was undertaken on closed fractures at a mean of 1.5 days (range 1–6) after the injury. Open fractures were treated within 6 h with sterile wound irrigation, debridement and stabilisation of the fracture in the operating room. If appropriate, involvement of a plastic and reconstructive surgeon was done early in the treatment process. In severe cases, if necessary, definitive skeletal stabilisation and wound coverage were achieved within 72 h, and did not exceed 7 days [14]. Systemic prophylactic antibiotics were administered once before surgery for closed fractures and continued in case of open fractures until wound closure with a maximum of 5 days. Surgical fixation was performed by three types of tibial nails (DepuySynthes; Johnson & Johnson Co. Inc., New Jersey, USA): unreamed tibial nail (UTN), reamed tibial nail (RTN) and expert tibial nail (ETN). Another surgical treatment option was the external fixator (DepuySynthes; Johnson & Johnson Co. Inc., New Jersey, USA). The fixation type was chosen at the surgeon's discretion. Postoperative mobilisation started on day 1 under supervision of a physiotherapist. Full weight bearing within pain limits was allowed in cases of IMN. The first follow-up visits were planned at weeks 6 and 13 for clinical and radiological evaluation. Thereafter, scheduled appointments were made at intervals of 3 months until clinical and radiological healing had occurred. Nail removal was not planned as a standard procedure.

Outcomes

Outcome measures such as infection and compromised fracture healing were retrospectively assessed. Infection was classified into two groups, namely, superficial or deep infections, which were defined according to Dellinger et al. and CDC-guidelines [15,16]. A superficial wound infection was one located above the fascia, with erythema and tenderness. A deep infection was defined as an infection involving deeper tissues as muscular fascia and bone, which could necessitate removal of the osteosynthetic material.

Fracture healing was defined as follows: clinically, no pain or tenderness, and the patient able to walk without any means of support; and radiographically, three solid bridging callus ridges connecting the fracture fragment on both the anteroposterior and the lateral views. Compromised fracture healing was subdivided into two groups: delayed union and nonunion which were defined as a lack of clinical or radiographic evidence of healing at 6 and 12 months after the injury, respectively, and which required a secondary procedure. Secondary procedures included bone grafting of any kind; implant exchange with or without debridement of bone and soft tissue; and fracture dynamisation (by locking screw removal).

Statistical analysis

In our primary analysis, we performed a univariate analysis followed by a multiple logistic regression model, using the primary outcomes as dependent variables.

Major outcomes were the occurrence of deep infection, delayed union and nonunion. The following set of predictive variables was selected, based on our speculation that they contribute to deep infection: age, sex (male or female), smoking, obesity (BMI $\geq$ 30), ASA classification, diabetes, polytrauma (ISS $>$ 16), fracture type, open fractures, Gustilo type, TTN, primary EF and reaming. The same set of predictive variables was used to analyse delayed union and nonunion.

Data were described using frequency for the categorical variable or mean for continuous variables. After separating continuous variables into ordinal levels, the association between primary outcomes and predictive variables was tested using the Mantel-Haenszel Chi-Square test and the Spearman correlation coefficient. Multiple logistic regression was performed to minimise the effects of confounding. Sex was excluded from the multiple logistic regression analysis of deep infection because of 'structural zero' problems during the modelling.

All analyses were performed with SAS software (version 9.3; SAS Institute, Cary, North Carolina, USA) by the Statistics Research Centre of the Catholic University Leuven. The level of significance was set at 0.05 ($p < 0.05$).

Results

Demographics

During the 12-year study period, 507 patients with 513 fractures met the inclusion criteria. Of these, 16 patients were lost to