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Risk factors for nonunion after intramedullary nailing of femoral shaft fractures: Remaining controversies

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ABSTRACT

Introduction: Intramedullary nailing (IMN) is the preferred treatment for femoral shaft fractures in adults. Although previous studies published good outcomes, some controversies remain. The purpose of this retrospective study was to identify factors that influence outcome after IMN for femoral shaft fractures.

Materials and methods: Between July 1998 and July 2013, we treated 230 patients with 248 femoral shaft fractures. Statistical analyses were performed to determine predictors of nonunion. The following set of variables was selected based on the speculation that they would contribute to the outcome: sex (male or female), smoking, obesity, polytrauma, fracture type, open fractures, Gustilo type, primary external fixation (EF) and reaming.

Results: Initial fracture stabilization was performed by IMN in 161 (64.9%) and by EF in 87 (35.1%) fractures. There were no documented cases of deep infection. Nonunion was diagnosed in 27 patients with 28 fractures (11.3%). Factors affecting nonunion in the univariate analysis were Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) fracture type (odds ratio [OR] 25.0; $p < 0.0001$), Gustilo type (OR 0.64; $p = 0.0358$), and EF (OR 0.42; $p = 0.0401$). Multiple logistic regression analysis only identified AO/OTA fracture type (OR 22.0; $p < 0.0001$) as a risk factor for nonunion. Fracture reaming did not change the outcome (OR 0.80; $p = 0.6073$). A separate analysis showed that damage control EF was not a risk factor in polytrauma patients (OR 0.76; $p = 0.5825$).

Conclusions: Fracture stabilisation with IMN is a good treatment option for femoral shaft fractures in adults. The purpose of this study was to evaluate risk factors of poor outcome after IMN of femoral shaft fractures. The present analysis revealed that there was no difference in the outcome whether the fracture was reamed or not. Univariate and multivariate analysis could only correlate AO/OTA fracture type with the occurrence of nonunion. Therefore, in this study, unreamed nailing and damage control EF were not associated with a negative outcome.

Introduction

The current standard treatment for femoral shaft fractures in adults is intramedullary nailing (IMN) [1]. Since its description by Kuntscher in 1939 [2], IMN has been reported to have healing rates up to 99% and low complication rates [3,4]. Despite these good outcomes, some controversies remain. One example is the necessity to ream the fracture site. Although previous studies have addressed this issue [3,5–7], a clear consensus is still lacking [1]. The timing of IMN and the safety of reaming in polytrauma patients have also been debated in recent years [1,8]. Several detrimental effects of acute IMN in these patients, especially those with pulmonary compromise, have led to the current practice of damage control orthopaedics (DCO) [9]. Additional trauma due to IMN could push the 'borderline' stable patient towards decompensation [8]. Other open questions are the influence of injury severity and damage control external fixation (EF) on the outcome of femoral shaft fracture treatment [10–12].

The current study addresses these remaining controversies. We performed a retrospective evaluation of a large cohort of patients treated at a single centre. The studied patient population is one of

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the largest to study the impacts of reaming and damage control EF [6,12,13]. We also critically evaluated our treatment protocol and identified factors influencing outcomes after IMN to treat femoral shaft fractures.

Materials and methods

Study design

The study protocol was conducted following good clinical practice guidelines. The University Hopstals Leuven is a designated trauma referral centre in Belgium. Patients were identified based upon their International Classification of Disease (ICD)-9 coding as having suffered a femoral fracture. Of the identified patients, the injury data were retrieved from the hospital electronic patient file system and included in the study's database.

Between July 1998 and July 2013, the Department of Trauma Surgery treated 5740 patients with femoral fractures, and 420 underwent IMN for femoral shaft fractures. Patients were identified from the operating theatre logbooks, and all case notes were retrieved.

Inclusion criteria included skeletal maturity and femoral shaft fractures treated with IMN. The definition and classification of shaft fractures were based on the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification [14]. Open fractures were subdivided by the Gustilo-Anderson classification [15], 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, or the presence of metaphyseal or pathological fractures.

Patient demographics including age, sex, smoking, obesity (body mass index [BMI]: $\geq$30), diabetes, polytrauma (Injury Severity Score [ISS]: $>$16) [16,17], fracture type, Gustilo type, primary EF, reaming, length of hospital stay, and length of intensive care unit (ICU) stay were recorded.

The minimum follow-up period was 12 months, and follow-up was continued until there was evidence of union. The results were retrospectively reviewed using the patients' hospital and operation charts. The clinical records and radiographs were independently reviewed by three of the authors (WJM, NR, SN).

Treatment protocol

Surgery was undertaken on closed fractures within 24 h after the injury. Open fractures were treated within 6 h with sterile wound irrigation, debridement, and stabilization of the fracture in the operating room. If appropriate, plastic and reconstructive surgeon involvement occurred early in the treatment process. In severe open fracture cases, definitive skeletal stabilization and wound coverage were preferably achieved within 72 h and did not exceed 7 days. Systemic prophylactic antibiotics were administered once before surgery for closed fractures and continued in case of open fractures until wound closure, for a maximum of 5 days. Surgical fixation was performed using four types of nails (DepuySynthes; Johnson & Johnson Co. Inc., New Brunswick, NJ, USA): unreamed femoral nail (UFN), reamed femoral nail (RFN), lateral femoral nail (LFN), and retrograde femoral nail (DFN). These were all Titanium – (6%) Aluminium – (7%) Niobium (TAN) implants. Another surgical treatment option was the external fixator (DepuySynthes; Johnson & Johnson Co., Inc.). The fixation type was selected at the surgeon's discretion. Conversion from EF to IMN was performed between days 5 and 10 after the initial surgery. General indications for DFN placement were: distal femoral shaft fractures, ipsilateral pelvic or tibia fractures, and pregnancy [1]. Fracture dynamizations were not standard and were performed as planned procedures 6–8 weeks after IMN.

Postoperative mobilization started on day 1 under the 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 evaluations. Thereafter, scheduled appointments were made at 3-month intervals until clinical and radiological healing occurred. Nail removal was not planned as a standard procedure.

Outcomes

Outcome measures such as infection and nonunion were retrospectively assessed. Infection was classified into two groups: superficial or deep infections, which were defined according to Dellinger et al. and Centre for Disease Control (CDC) guidelines [18,19]. 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 clinically defined as no pain or tenderness over the fracture zone and radiographically as three solid bridging callus ridges connecting the fracture fragment on both anteroposterior (AP) and lateral views. We followed the US Food and Drug Administration (FDA) guidelines defining nonunion as a fractured bone that has not completely healed within 9 months of injury and that has not shown progression towards healing over the past 3 consecutive months on serial radiographs [20].

Statistical analysis

Categorical data were described using observed frequencies and percentages, and continuous variables were summarized by their means and standard deviations (or medians and interquartile ranges in case of serious deviations from normality).

The primary outcome was the occurrence of nonunion. The following set of predictive variables was selected based on our speculation that they would contribute: sex (male or female), smoking, obesity (BMI $\geq$ 30), polytrauma (ISS $>$ 16), fracture type, open fractures, Gustilo type, primary EF and reaming. The univariate association of each predictor with outcome was assessed using a generalized estimating equation (GEE) [21] logistic regression using an unstructured variance/covariance matrix to account for multiple fractures per patient. In addition, a multivariable GEE logistic regression was performed that included all of the above variables.

Time to union was assessed using Kaplan–Meier curves. To account for the repeated nature of the data, the robust sandwich estimators of Lin and Wei [21] were used for the variance. Differences between groups were assessed using robust Wald tests.

All analyses were performed with SAS software (version 9.3; SAS Institute, Cary, NC, USA) by L-Biostat University of Leuven. All tests were two-sided and assessed at a significance level of 5%.

Results

Clinical characteristics

During the 15-year study period, 251 patients with 269 fractures met the inclusion criteria. Of these, 9 patients were lost to follow-up, 4 died from trauma-related causes within the first 30 days after the injury, and 8 died within 5 months from other causes (cardiovascular disease and cancer), leaving 230 patients with 248 fractures for inclusion in this retrospective study (Figure 1). The