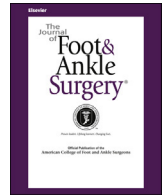




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Original Research

Why Fibular Nailing Can Be an Efficient Treatment Strategy for AO Type 44-B Ankle Fractures in the Elderly

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ABSTRACT

The reference standard treatment of unstable AO type 44-B ankle fractures is open reduction and internal fixation. However, delayed-staged surgery because of compromised soft tissues results in prolonged hospitalization and increased total healthcare costs in the elderly (age ≥ 65 years). The aim of the present study was to measure the efficiency of intramedullary fibular nailing (IMFN) in the elderly. A prospective series of 15 elderly patients with an AO type 44-B ankle fracture treated with IMFN were compared with a retrospective cohort of 97 elderly patients treated with plate and screw osteosynthesis (PSOS). Clinical and process-related variables and total healthcare costs, including 5 cost categories, were assessed. Functional outcomes, general health status, and quality of life were measured using the American Orthopaedic Foot and Ankle Society ankle-hindfoot and EuroQol 5-dimension 3-level visual analog scales. Although the preoperative length of stay was significantly shorter for the patients treated with IMFN, the total length of stay and total healthcare costs were not significantly different between the 2 groups. The complication and reintervention rates were similar in both groups, with improved American Orthopaedic Foot and Ankle Society scale scores in the IMFN group. Compared with delayed-staged surgery, early IMFN led to a significant reduction in total healthcare costs. We could not prove significant cost savings for IMFN compared with PSOS for the treatment of AO type 44-B ankle fractures. However, early IMFN was financially beneficial compared with a delayed-staged (IMFN and PSOS) surgery protocol. Because, ultimately, IMFN allows for early percutaneous fixation in most cases, IMFN is a potentially profitable treatment strategy for AO type 44-B ankle fractures in the elderly with good outcomes.

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The reference standard for the treatment of an unstable AO type 44-B ankle fracture is still open reduction and internal fixation with plate and screw osteosynthesis (PSOS). Because of compromised soft tissues, complications are not infrequent, with reported complication rates as great as 40% in elderly (1–4). Previously, we reported a complication rate of 29.3% in the elderly (5). In the same study, we conducted an explorative cost analysis and found that the healthcare costs for the treatment of AO type 44-B ankle fractures were mainly driven by the hospitalization costs (53%), which are determined by the length of stay (LOS). In turn, the LOS was driven mainly

by the use of delayed-staged surgery and patient age. Consequently, the healthcare costs were significantly greater for the elderly.

To reduce the preoperative LOS, we, therefore, have proposed the use of percutaneous intramedullary fibular nailing (IMFN) in the elderly, which allows for early operative treatment, regardless of the quality of the soft tissues. Subsequently, the crude initial costs were significantly lower with IMFN compared with delayed or delayed-staged surgery (6).

The primary goal of the present study was to determine the efficiency of the various treatments of AO type 44-B ankle fractures, comparing percutaneous IMFN in a prospective series of 15 elderly patients (age ≥ 65 years) and PSOS in a retrospective cohort of elderly patients. In addition, we compared the cost breakdown between patients treated with early IMFN and those treated in a delayed-staged surgery protocol, with either IMFN or PSOS. Furthermore, the clinical and functional outcomes, general health status, and quality of life were assessed. We hypothesized that the total healthcare costs would be decreased with early IMFN in the elderly owing to the decreased preoperative and total LOS, with maintenance of good outcomes.

Financial Disclosure: The fibular nails (Acumed, Hillsboro, OR) were provided free of charge from Hospital Innovations (Herzele, Belgium), distributor of Acumed in Belgium.

Conflict of Interest: None reported.

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Patients and Methods

Patients

A prospective series of 15 consecutive patients aged ≥ 65 years with an acute monotraumatic type AO-44B ankle fracture underwent IMFN (Acumed, Hillsboro, OR) from January 2015 to February 2016. These patients were compared with a retrospective cohort of 97 patients aged ≥ 65 years with an acute type AO-44B ankle fracture treated with PSOS from January 2009 to June 2014 selected from a retrospective database. Nonacute fractures (diagnosis >4 weeks after the incident), the presence of polytrauma, multiple traumatic events during the follow-up period, a nonfunctional ankle or leg before the incident, and severe neurologic dysfunction (i.e., dementia) were exclusion criteria. All the patients were treated at the trauma surgery department (University Hospitals Leuven). For the patients treated with IMFN, the follow-up visits were at ~ 6 weeks and 3, 6, and 12 months postoperatively. The follow-up protocol was completed using questionnaires at ~ 19 months postoperatively. The follow-up visits for the patients treated with PSOS were frequently irregular. The present study was conducted in compliance with national legislation and the guidelines of the ethics committee of the University Hospitals Leuven.

Study Variables

A total of 22 clinical and process-related variables were assessed between the first examination and the last clinical visit for the operatively treated ankle fracture. We grouped 16 clinical variables as 5 demographic variables (age, gender, American Society of Anesthesiologists score, body mass index, and other cardiovascular risk factors), 3 fracture-related variables (AO/OTA [Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association] classification, fracture side, and open fracture), and 8 treatment-related variables (interval to definitive surgery, surgery type, use of a syndesmotic screw, overall complication rate, infection, nonunion, other complications, and reintervention). Other cardiovascular risk factors included diabetes mellitus, hypercholesterolemia, dyslipidemia, arterial hypertension, smoking, alcohol abuse, obesity, and current cardiovascular diseases (e.g., cerebrovascular accident, myocardial infarction, peripheral artery disease). Radiographs or computed tomographic scans were used to identify and classify the fractures according to the AO/OTA classification system (7). The interval to definitive surgery was defined as the time from the first examination until PSOS or IMFN surgery in hours. The surgery type included immediate, delayed, and delayed-staged surgery. Immediate and delayed surgery were defined as operative treatment <24 and >24 hours after the first examination, respectively. Delayed-staged surgery was defined as the use of an external fixator before definitive surgery. The complication rate was defined as the number and percentage of patients who developed ≥ 1 ankle-related complication during the follow-up period. Surgical site infections, either superficial or deep, were defined in accordance with the Centers for Disease Control and Prevention guidelines (8). Nonunion was defined according to the U.S. Food and Drug Administration guidelines as an incomplete fracture healing within 9 months without radiographic progression toward healing during the previous 3 consecutive months (9). Other complications included wound necrosis, wound dehiscence, screw loosening, loss of reduction, intra-articular hardware, reflex sympathetic dystrophy syndrome, persistent pain at the level of the percutaneous introduction of the nail, and persistent nerve damage. All complications occurring during the entire follow-up period were considered.

We identified 6 process-related variables: LOS to definitive surgery, total LOS, number of operations, number of hospital admissions, number of surgical outpatient admissions, and number of ambulatory consultations.

Outcome Measures

The costs were calculated for all 15 IMFN and 97 PSOS patients from the first examination until the last follow-up visit. Within the study period, all healthcare costs incurred by the traumatology department were considered. These healthcare costs were divided into 5 main categories: honoraria, materials, hospitalization, outpatient admission, and pharmaceutical agents. Honoraria were fee-for-service-based costs related to different medical activities such as surgery, consultations, and imaging studies. The materials costs were the implants, including additional hardware and external fixation when required. Because the fibular nail was not a lump sum reimbursed in Belgium at the time of our study, Acumed sponsored the 15 nails. The cost for the fibular nail and screws was €524 and €27.03, respectively, and were included in our costing model. The hospitalization costs were calculated by the average national day-based care fee of €441, multiplied by the LOS (10). The pharmaceutical agents included all drugs and blood products the patient received during hospitalization. All costs were allocated according to the prices of 2016. The costs in Euros were converted to U.S. dollars using an exchange rate of 1 U.S. dollar to 0.93 Euro. Our focus was crude cost comparisons, and we did not compute quality-adjusted life-years or incremental cost differences.

The secondary endpoints included the clinical and functional outcomes, general state of health, and quality of life. The functional outcome of the ankle was measured using a Dutch version of the American Orthopaedic Foot and Ankle Society (AOFAS)

ankle-hindfoot questionnaire. This questionnaire focuses on pain, function, and alignment of the ankle, with a total high score of 100. The patients' general state of health was evaluated using a Dutch EuroQol 5-dimension 3-level (EQ-5D-3L) questionnaire. This questionnaire evaluates 5 domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each with 3 response levels (no problems, some problems, extreme problems). Additionally, the patients were asked to rate their current state of health, representing their quality of life at that moment, using the EuroQol visual analog scale (EQ-VAS), with a score range from 0 to 100, with 100 equaling the best state imaginable.

Statistical Analysis

SPSS, version 24.0 (IBM Corp., Armonk, NY) was used for all statistical analyses. Continuous variables were compared between groups using the Mann-Whitney *U* test. Nominal variables were compared using Pearson's χ^2 test. A *p* value of $< .05$ was considered to indicate statistical significance. Additionally, a subgroup analysis was performed of patients treated early with IMFN versus all patients treated using the delayed-staged approach, with either PSOS or IMFN as definitive surgery.

Results

Patient Characteristics

The clinical and process-related variables are summarized in Table 1. The time to definitive surgery is shown in Fig. 1. The median interval to definitive surgery for the patients treated with IMFN was less than one third that for the patients treated with PSOS and had minimal variability. One patient who underwent IMFN was treated with a delayed-staged surgery protocol, resulting in 140.6 hours (~ 6 days) to definitive surgery since the first examination. This patient was an 84-year-old obese female with severely compromised soft tissues and a trimalleolar ankle luxation fracture.

IMFN was complicated by 1 superficial wound infection. In contrast, in the PSOS group, 13 (14.0%) patients developed a superficial wound infection and 4 (4.3%) developed a deep infection postoperatively. Nonunion was diagnosed in 1 patient after treatment according to a delayed-staged surgery protocol, followed by PSOS. In the IMFN group, 2 patients required reintervention. In 1 patient, the syndesmotic screw was removed because of loosening within 3 months postoperatively, and in another IMFN patient, the nail was removed because of persistent pain at the level of the percutaneous introduction of the nail. Subsequently, owing to progressive talar tilt and high-grade osteoarthritis, tibiotalar fusion was performed in the same patient 15 months after the definitive surgery. Reintervention was required in 32 PSOS patients, including syndesmotic screw removal in 16 (15.1%), total hardware removal in 15 (15.5%), and revision surgery in 3 (3.1%).

No significant differences in the clinical variables were observed between the patients treated early with IMFN and those treated according to a delayed-staged surgery protocol. The following process-related variables differed significantly between the early IMFN and delayed-staged surgery: preoperative LOS, 1 (range 1 to 1) day versus 10 (range 6.5 to 17.5) days ($p < .001$); total LOS, 8 (range 4 to 9.3) days versus 21 (range 13.5 to 29.0) days ($p < .001$); and number of operations, 1 (range 1 to 1) versus 2 (range 2 to 3; $p < .001$), respectively.

Healthcare Costs

The results of a comparison of the total healthcare costs, 5 cost categories, and relative share between IMFN and PSOS are listed in Table 2. The distribution of total healthcare costs per patient for both IMFN and PSOS is visualized in Fig. 2. The distribution of total healthcare costs per patient for early IMFN, PSOS, and a delayed-staged surgery protocol is shown in Fig. 3. The total healthcare costs, cost categories, and their relative share for early IMFN and delayed-staged surgery were also compared (Table 3).

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