Injury, Int. J. Care Injured 49 (2018) 1330–1335

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Predictors of lower health-related quality of life after operative repair of diaphyseal femur fractures in a low-resource setting☆

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ARTICLE INFO

Keywords:
Femur fractures
Quality of life
Orthopaedic trauma
Predictors
Low-income
Africa
Tanzania

ABSTRACT

Background: Little data exists on the negative impact of orthopaedic trauma on quality of life (QOL) in low- and middle-income countries (LMICs). The goal of this study is to investigate the factors associated with lower QOL after operative fixation of femoral shaft fractures in adult patients in a low-resource setting.
Methods: This prospective cohort study followed 272 factures in adults undergoing operative fixation for diaphyseal femur fractures at Tanzania. Patient demographics, injury characteristics, treatment modalities, and functional outcomes up to 1-year post-operatively were evaluated for association with 1-year post-operative EQ-5D QOL scores via univariate linear regression analysis.
Results: EQ-5D values were significantly lower at 1 year than at baseline (0.941 vs 0.991, $p < 0.0005$).
Conclusions: Operative fixation of femoral shaft fractures in LMICs results in return to near baseline QOL. Demographic and treatment factors were not significantly associated with EQ-5D. and several markers of recovery were associated with lower 1 year QOL, including pain, knee stiffness, delayed radiographic healing, complications requiring reoperation. Efforts to reduce perioperative complications may help improve post-operative QOL.

Introduction

Traumatic musculoskeletal injury accounts for a significant proportion of disease in the developing world [1–5]. The calculated disability resulting from injury is 11% of total disability-adjusted life years (DALYs) [1], a quantification of years of life lost and years lived with a disability due to trauma, as compared with all other diseases. In developing nations, musculoskeletal injury often occurs from road traffic injuries, and as these nations experience an increase in urbanization – with minimal traffic regulations – rates of road traffic accidents and traumatic injury continue to rise [1,2,6].

Rates of extremity injury are also higher in developing nations [6]. Comparing injuries in Sub-Saharan Africa with developed countries, 219 versus 161 extremity injuries per 100,000 males occurs from road traffic accidents [6]. Specifically, femoral shaft fractures are a common extremity injury treated in Sub-Saharan hospitals [7,8]. The preferred method of treatment for these injuries is operative fixation with an intramedullary nail, and has been associated with low complication rates and high union rates in both high and low income countries [8–10]. Femoral shaft fractures and other musculoskeletal injuries often have a significant impact on the function and health-related quality of life (HRQOL) of patients [1–13]. Some studies have shown that post-operative HRQOL can be associated with patient characteristics, comorbidities, and mental health [12,14,15], but these studies include patients from high-income countries (HICs). Little is known about the patient, injury, and treatment factors that are associated with the HRQOL of patients from low- and middle-income countries (LMICs).

☆ This work was performed at the Muhimbili Orthopaedic Institute, Dar es Salaam, Tanzania and at the Institute for Global Orthopaedics and Traumatology, University of California, San Francisco, San Francisco, CA.

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[1] Each author certifies that he has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

https://doi.org/10.1016/j.injury.2018.05.021
0020-1383/

The goal of this study is to investigate the factors associated with lower health-related quality of life after operative fixation for femoral shaft fracture in adult patients in a low resource setting.

Methods

We conducted a prospective observational study, enrolling skeletally mature patients with diaphyseal femoral fractures (OTA/AO type 32 [16]) managed surgically at a high-volume tertiary referral hospital in Tanzania in collaboration with an academic orthopaedic department in the United States. The study was approved by the National Institute for Medical Research (NIMR) in Tanzania and the Committee for Human Research at the partnering U.S. institution. It was registered at ClinicalTrials.Gov (NCT01548456).

All patients admitted over a 12-month period from July 2012 to July 2013 with fractures involving the femur were evaluated for inclusion. Each potential participant underwent screening using the injury radiographs. Eligible for inclusion were patients with a diaphyseal femoral fracture (OTA/AO type 32 [16]). Exclusion criteria were (1) skeletal immaturity, (2) pathologic fracture, and (3) prior surgery involving the affected femur. The following clinical exclusion criteria were subsequently applied: (1) delayed presentation ($\geq$6 weeks from injury), (2) active infection at the surgical site, (3) severe traumatic brain injury, (4) severe burns, and (5) the inability to participate in follow-up (Fig. 1).

All patients meeting the above criteria who provided written informed consent were included. Participants were treated at the discretion of the surgeons at Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania. Treatment could include use of the SIGN IMN (intramedullary nail) system (SIGN Fracture Care International), the AO Universal femoral nail (DePuy Synthes), plate fixation, or external fixation. Both the standard SIGN IMN with 1 or 2 distal interlocking screws and the SIGN Fin nail, which relies on interference fit for distal fixation, were used. Other potentially predictive variables recorded at baseline were age, sex, body mass index (BMI), employment status, comorbidities, fracture pattern (OTA/AO type, Winquist classification [17]), open versus closed injury, time from injury to presentation, time from presentation to surgery, and the Injury Severity Score (ISS) [18,19]. Open reduction of the fracture through a lateral approach was performed for all nail and plate cases. Intraoperative fluoroscopy was not used for any case. The primary outcome was health-related quality of life as measured by the EuroQol (EQ)-5D [20] (Swahili version). Secondary outcomes were a complication requiring reoperation for any reason, radiographic union as defined by the radiographic union score for tibial fractures (RUST score) [21,22], the visual analog scale for pain (VAS pain), and a functional test. The test involves asking the patient to perform a deep squat and smile for a photograph. The test was judged on a scale from 1 to 4, where 1 is unable to perform, 2 is a partial squat (<90° knee bend), 3 is a full squat with difficulty, and 4 is a full squat without difficulty. For simplicity, we report the percentage that achieved the highest level (full squat without difficulty). The test has not been clinically validated but was thought to be relevant, particularly in low-resource settings, where patients are required to perform a deep squat regularly for activities of daily living. For the RUST score, in cases with inadequate lateral imaging, we used a modified score by assessing callus on the anteroposterior view only and doubling the score for comparison with complete cases.

This study was powered to detect a difference in the rate of reoperation, comparing intramedullary nailing with plate fixation. We used data available from the SIGN database to estimate the appropriate sample size [23–25]. From unpublished data, there were >400 femoral shaft fractures treated annually with the SIGN IMN at the study center (SIGN database accessed August 27, 2011). No data regarding other implants were available, but co-investigators estimated that 20% of femoral shaft fractures were treated using plates. We therefore estimated an annual volume of 500 femoral shaft fractures treated operatively per year. Assuming two-thirds of the patients would meet the inclusion criteria, there would be 333 patients enrolled in the study. With 80% follow-up, a total of 267 patients would be included in the final analysis. On the basis of a prior study using the SIGN database, the reoperation rate for intramedullary nailing was estimated to be 3% [25]. Using these values, the study would have 80% power to detect a difference in the rate of reoperation of 12%. After enrollment, however, there were only 4 plate cases with complete follow-up yielding an allocation ratio of 67:1. Post-hoc power analysis indicated that 3468 patients would be required to achieve 80% power for the same effect size. Because this sample size was not considered feasible, the decision was made to shift the aim of the study to a study evaluating risk factors for lower health-related quality of life.

Data were collected by local study coordinators using REDCap electronic data capture tools hosted at the U.S. institution [26]. The injury and post-operative radiographs were photographed with a

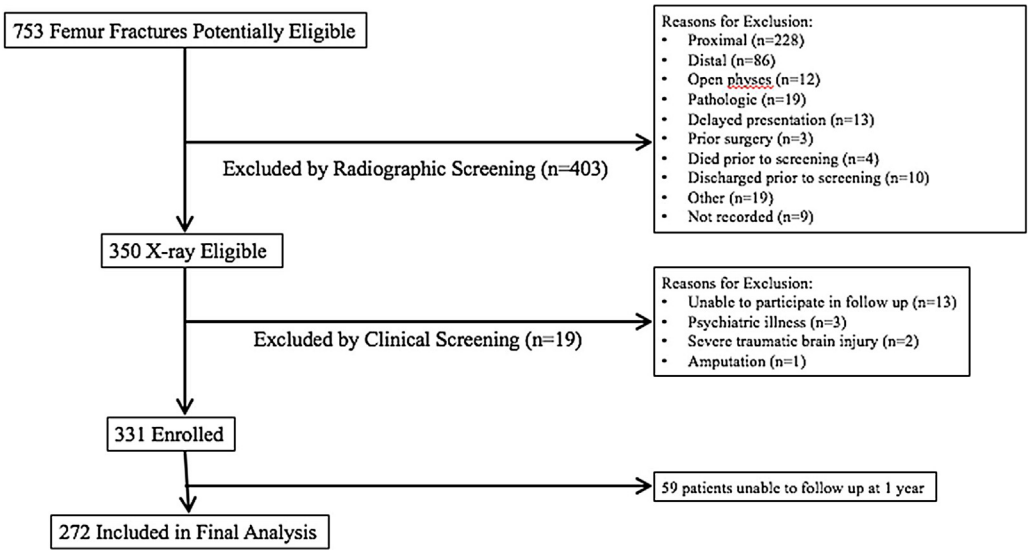

Fig. 1. Flowchart illustrating screening, enrollment, and follow up.