REOPERATION RATES FOLLOWING INTRAMEDULLARY NAILING VERSUS EXTERNAL FIXATION OF GUSTILO TYPE 3A OPEN TIBIA SHAFT FRACTURES

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ABSTRACT

Background: Open tibia fractures are among the most difficult to manage due to the lack of soft tissue coverage and poor blood supply. This is especially true in developing settings primarily due to a lack of resources. Both locked Intramedullary Nailing (IM) and External Fixation (EF) are two possible modalities for surgical treatment of open tibia fractures. However, it is unknown at this time which one is most suitable in low resource regions especially with regards to the risk of serious complications requiring reoperation. This study was conducted to identify which method is safest and minimizes this risk in patients with open tibia fractures.

Methodology: A prospective cohort study of Gustilo 3A open tibia shaft factures treated either by intramedullary nailing or external fixation was conducted from March 2013 to February 2014 at Muhimbili Orthopaedic Institute (Dar es Salaam, Tanzania). Follow-up was conducted at 2, 6 10, 14, and 18 weeks postoperatively. The primary outcome assessed was all-cause reoperation.

Results: Fifty patients were enrolled and completed follow-up at all-time points; twenty-six were treated with IM nail and twenty-four were treated by EF. There were 9 (37.5%) EF patients who required reoperation compared to 1(3.8%) IM nail patient (p=0.004). Reasons for reoperation among EF patients were infection (2 patients), malalignment (3 patients), and delayed union (4 patients). The one IM nail patient presented with signs of infection and wound dehiscence at 14 weeks postoperatively. No patients presented with hardware failure or malrotation.

Conclusion: Treatment of Gustilo Type 3A open tibia shaft fractures with interlocking intramedullary nailing results in lower reoperation rate in the early stages of treatment compared to uniplanar external fixation.

Keywords: Orthopaedic surgery, Tanzania, Intramedullary nail, External fixation, Open tibia fracture

INTRODUCTION

The most common type of open fracture in long bones as a result of road traffic accidents occurs in the tibia (1,2). Open tibia fractures are among the most difficult to manage due to the lack of soft tissue coverage and poor blood supply. This conundrum is exacerbated in developing countries by resource-limitations (3-5). In Tanzania, controversy over the best treatment method for these fractures remain, as complication rates have been reported as high as 30% at referral trauma centers following surgical fixation (5,6).

Intramedullary (IM) nailing or External Fixation (EF) of the tibia after surgical debridement are the two most common modalities for treatment and have frequently been compared with respect to infection rates, malalignment, callus formation and leg shortening (1,7-11). Previous studies suggest that EF may lead to higher rates of infection and less bridging callus compared to IM nailing (12,13).

However, notably absent in the literature is a comparison of reoperation rates and aetiologies for reoperation, which is one of the most salient indicators of a successful treatment (14). Given that reoperation or revision surgery is often associated with higher complication rates and significantly lower patient reported outcomes compared to primary procedures (14,15), the likelihood of reoperation with IM nail compared to EF is important for both surgeon and patient to be cognizant of. However, reoperation is uniquely difficult to report given the need for adequate, prospective follow-up, which is particularly challenging in settings where research capacity is limited (14). Thus, very few studies have been conducted in health

settings comparable to those in Tanzania that have examined reoperation rates, and none were conducted prospectively.

Retrospective studies have suggested that reoperation for EF-treated tibial shaft fractures range from 20-41% within one year postoperatively compared to a 5-25% rate for open fracture patients treated by IM nail (13,16,17). While one study suggested that patients treated by EF may have a reoperation rate three times higher than those treated by IM nail, the patient demographics for the two cohorts of that study were not comparable (17). Thus, it still remains unclear how the reoperation rates of locked IM nailing and EF compare with one another with respect to treatment of tibial open fractures.

The purpose of this study was to prospectively compare IM nailing to EF in the treatment of Gustilo type 3A tibial shaft open fractures with respect to safety, using reoperation rate as the primary outcome. Based on the existing literature, we hypothesize that open tibia shaft fractures treated by IM nail will have significantly lower rates of patients who require reoperation.

MATERIALS AND METHODS

Study design and location: A prospective cohort study was conducted from March 2013 to February 2014 at Muhimbili Orthopaedic Institute (MOI) (Dar es Salaam, Tanzania). Ethical clearance was obtained from Muhimbili University of Health and Allied Sciences (Dar es Salaam, Tanzania). Skeletally mature patients over 18 years with Gustilo Type 3A open tibia shaft fractures who presented within 24 hours of injury and received either SIGN intramedullary nailing (SIGN Fracture Care International, USA) or external fixation (Samay Surgical, USA) were consented and invited to enroll in the study. Exclusion criteria included the following: bilateral open tibia fractures, comminuted femur fractures, significant medical comorbidities, and prior ipsilateral lower limb injury or deformity.

Demographic data included age, gender, and region of residency in Tanzania. Preoperative Anteroposterior (AP) and lateral radiographs were taken to categorize fracture location as proximal, middle, or distal diaphyseal. Tetanus booster was provided if necessary. Ceftriaxone (Rocephine) was administered preoperatively and continued postoperatively for five days. Intra-operative confirmation of fracture type and wound classification was performed following surgical debridement.

Patients were surgically treated with either intramedullary nailing or external fixation based on the discretion of the treating surgeon. External fixation was performed using an AO single bar uniplanar device with two proximal and two distal screws. These patients were placed in a cast as soon as their wounds healed satisfactorily. The time in which this transition occurred differed from patient to patient. This is considered the standard of treatment at our facility due to a limited supply of external fixator devices. For those who received IM nailing, the Surgical Implant Generation Network (SIGN) reamed intramedullary nail was used with two proximal and two distal interlocking screws without the aid of an image intensifier. Those who received temporary stabilization with external fixation and later treated by intramedullary nailing were not included in this study.

Postoperative AP and lateral radiographs were done to assess the quality of fracture reduction. Patients were discharged without a cast or brace after their conditions were stable and no signs of infection were visible in the wound. Patients were instructed to perform daily wound dressing changes. Early weight-bearing was recommended if the fixation device was stable and could be tolerated by the patient. No uniform weight-bearing timeline was implemented in order to account for differences in healing rates between individuals. Those with external fixators were instructed to conduct pin care with methylated spirit three times a day; these patients were placed in a cast as soon as their wounds healed satisfactorily.

Follow-up visits were performed at 2, 6, 10, 14, and 18 weeks postoperatively. Clinical exam was conducted to assess for wound healing/infection, malalignment, malrotation, malunion/delayed union, limb length discrepancy, hardware failure, and any other medical or surgical complications. Limb length discrepancy was present if there was greater than 1cm of difference between the two limbs. Malunion was defined as more than 5 degrees of angular deformity in the coronal or sagittal planes. Malrotation was defined as greater than 10 degrees of rotational deviation between the femur and tibia.

The primary outcome measured was all-cause reoperation rate. Patients who had early signs of infection (<6 weeks) were given high dose antibiotics. Those with delayed or persistent signs of infection (>6

weeks) or wound necrosis were taken to the operating room for debridement. Any complications requiring reoperation were done at the same study center as soon as possible. The fracture was deemed united when both clinical and the radiological criteria were met.

Sample size calculation: From January 2012 to June 2012, 238 open tibia shaft fractures presented to the study center's emergency room (Mcharo *et al*, 2005; MOI registry 2012). Among these patients, 119 (50%) were Gustilo Type 3A open fractures, indicating a prevalence of p=119/3812=0.031. Sample size was estimated using the formula $n=Z^2*p(1-p)/m^2$. Using a Z Score of 1.96 (Confidence Interval of 95%) and m of 0.05 (standard value of 0.05), we obtained an expected sample size of 46 patients. Assuming a 10% lose to follow-up rate, we aimed for 50 patients.

Data management: A research coordinator assisted with data collection. Data was stored on a password-protected laptop. Descriptive statistics, Fisher exact, and Student T-Test were performed on SPSS 20.

RESULTS

A total of 54 patients were enrolled in the study. There were four patients (2 IM, 2 EF) who were lost to follow-up, resulting in a final sample size of 50 (26 IM, 24 EF). The majority of patients (80%) were males. Road traffic accident was the most common mechanism of injury (96.2%). Most patients (76.9%) presented to the hospital within 8 hours post-injury.

After 18 weeks of follow-up, there were 9 (37.5%) EF patients who required reoperation compared to 1 (3.8%) in the IM nail group (p=0.004) (Table 1). Among the re-operated EF patients, two (8.3%) were due to infection; three (12.5%) had malalignment that required osteotomy and conversion to IM nail; four (16.7%) had delayed union which was treated by conversion to IM nail. The one IM nail patient presented with signs of infection and wound dehiscence at 14 weeks postoperatively. Surgical debridement and drilling of exposed bone was performed.

Table 1

Summary of reasons for reoperation in IM nail versus EF groups

	Reoperation reason					
Arm	Total	Infection	Malalignment	Delayed union	Malrotation	Hardware failure
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
IM Nail	1 (3.8)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EF	9 (37.5)	2 (8.3)	3 (12.5)	4 (16.7)	0 (0.0)	0 (0.0)

* Percentages reflect proportion of patients within each treatment arm

There were no patients in either group who presented with hardware failure or malrotation while limb shortening greater than 1cm was seen in four EF patients. Thus, these patients were not re-operated and did not count towards the overall reoperation rate.

DISCUSSION

In this series, the rate of reoperation was significantly, higher in the EF group (37.5%) compared to the IM nail group (3.8%, p=0.004). These data suggest that IM nailing is a safer option for the treatment of Gustilo Type 3A open tibia shaft fractures than external fixation.

The results that we obtained in this study are similar to those that have been previously reported (18). One study by Shannon *et al*. (20), for instance, found that 41% of EF patients required reoperation compared to 15% in the IM nail group. Additionally, another study by Alberts *et al.* (16) found that EF patients required approximately three times more procedures than IM nail patients to correct surgical complications. It would appear that the evidence in the literature supporting the use of IM nailing to external fixation is growing.

There are a number of factors in this study which temper with our findings. One major consideration is that study participants treated with external fixators were placed in a cast as soon as their wounds healed satisfactorily. In contrast, most centers in High-Income Countries (HICs) keep patients on the device for longer period (20, 21). Additionally, we compared single-bar, four-pin external fixators to intramedullary nailing; in contrast, most HICs use double-bar systems. While results from HICs may not necessarily be applicable in developing settings, EF patients may have outcomes more comparable to IM nailing if treatment protocols were similar to those used in HICs. Indeed, malalignment and delayed union were the underlying cause of 78% of reoperations in the EF group in this

series; these may not have been necessary had they been placed in an external fixator for longer.

On the other hand, there were four EF patients who had limb shortening greater than 1cm. Since our study center does not have the capability to correct limb length discrepancy, these patients did not receive reoperations and thus did not contribute to the total reoperation rate. Therefore, the reoperation rate we presented in the EF group would have been higher had our study center been able to manage these patients.

Another important aspect of this study was the relatively short follow-up period of 18 weeks. One of the most significant complications that can arise in patients with intramedullary nail implants is deep infections. As defined by the Center for Disease Control (CDC), deep infections can occur within a one-year period postoperatively (22). It may be that with longer follow-up, reoperation rates in the IM nail group will increase due to cases of deep infection.

CONCLUSIONS

The findings in this study show that locked intramedullary nailing is more suitable than external fixation for the treatment of Gustilo Type 3A open tibia shaft fractures. However, future studies done in a randomized fashion with larger sample sizes are warranted in order to more definitively identify the most appropriate modality.

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