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Assessment of rate of infection in open tibial shaft fractures in adults treated with IMIL nail

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Abstract
Aim: Toestablish super ficial and deep in fection rate sand time to unionofo penti bial shaft fractures treated with primary debridement and intramedullary inter locking nails.
Materials and Methods: The clinical and radio graphs out comes were Pro spectively analyzed following treatment of 54 Gustilo-Ander son grades 1 to 3 A open tibial shaft fractures by initial debride mentand intra medullary inter locking nail fixation over a three-year period. Forty- seven men and seven women with a meanage of 35 years (range 17–68) were included in the study. They were followed up for a mean period of 18 months (range7–32).
Results: Twelve fractures (22.2%) were classifiedas grade 1, Twenty-seven fractures (50%) asgrade 2 and fifteen fractures (27.8%) asGustilo-Andersongrade3Aopenfractures. The mean time to surgery was 29 hours (range 10–110). The overall infection rate was 16.7%. Superficialinfectiondevelopedin11.1%anddeepinfectionoccurredin5.6%.Time to surgery was found notto be associated with in fection rate (p=0.819). No association was found between typeo fclo sureand sepsis (p=0.405). Them eantimetounionwas17weeks (range 12–50). Two patients (3.7%) had delaye dunionand one patient showed non-union which was managed through secondary procedures.
Conclusion: Primary wound debridement, intramedullary interlocking nailing and primary flap cover for management of Gustilo-Anderson grade 1to3 a open tibial shaft fractures shows good short-term results with low in fection and non-union rate seven when surgical management was delayed.

Keywords: open fractures, tibial shaft fractures, union, infection, intramedullary nailing, lower limb

Introduction

"The primary objective in the management of anopen fracture is union with prevention orera dication of wound sepsis."-Gustillo et al [1]. Tibia and fib ula shaft fracture sare the
Most common long bone fractures. The subcutaneous nature of the medial border as well as the delicate blood supply increases the vulnerability to open injuries, deep infection, malunion and non-union [2].
The management of open fractures is regarded as an orthopedic emergency [3]. The various modalities of treatment are-Conservative gentle man ipulation and use of long leg cast (Sarmiento'stechnique), Open reduction and internal fixation with plate sand screws, intramedullary fixation (including Enders nail, intra medullary non-locked V-nails, and inter locking intra medullary nails with or without reaming), external fixation techniques.The surgeon should be capable of using all these techniques and must weigh advantages and disadvantage so feach one and adapt the best possible treatment. The surge on should deter- mine the best treatment option should by a thorough analysis of morphology of the fracture, the quality of bone, the amount of energy imparted to the extremity, the age and general conditionsofthepatientandmostimportantlythestatusofthesofttiss ues. [4]. It is believed that the eventual solution to the tibial fractures would be an intramedullary nail. [5].
The goals of surgical management include-correction and Maintenance of sagittal and coronal alignment, restoration of length and rotation, early functional knee and anklerange of motion, the prevention of infection, the achievement of bony union. [4]. in the past plaster cast has been used to immobilize the limb but it does not always maintain the length of the limb and the wound becomes inaccessible. Unacceptably high infection rates are associated with open reduction and internal fixation with plates and screws. Severe or local injuries, associated displace dintra- articular fractures of knee and ankle can be treated by this method. Whereas, external fixation, considered the treatment of choice by many Orthopedic surgeons, has the disadvantages like-1) bulky frames, 2) frequent pin track infections, 3) nonunion and 4) malunion.
Interlocked intramedullary nails addressed all these above said goals and complications. Naili salo ad sharing device and isstiff to both axial and torsional forces. Least damageto so fttissues, fracture haemato maand natural process of bone healing was associated with close dnailing as compared too the rform so finter nal fixation.The locking of intramedullary nails to the major proximal and distal fragments decreases theincidence of malunion of comminuted fractures [4]. The fear of osteomyelitis has previously precluded any form of internal fixation especially

in the immune-compromised host and delays in operative management greater than six hours. [6]. With the improvement inanti bioticuse and surgical technique, the use of intra medullary nail shasevol ved from lowener gyopen Gustilo grade1and grade 2 fractu resto more severe Gustilo grade 3 injuries, with excellent long-term results. [7, 8]. The use of locked intramedullary y nail sinthe acute settings for openti bial fractures has been wide lyre porte din the international literature. [9]. There are however nou niversally accepted guide lines to suggest inter locked intra medullary nail in gas treatment of choice for open tibial shaft fractures. This study aims to establish infection rates and time to union of open tibial shaft fractures treated with primary debride ment and locked intra medullary nails in order to suggest the same.

2. Materials and Methods

This study was done at the Department of Orthopedic Surgery, K.V.G. Medical College and Hospital during the course period of July 2018 till July 2020. It is a prospective study. 57 opentibial shaft fracture as es were analyze dout of which 3lost follow up.Of the 54 cases 7 were female and 47 were male. The study population was chosen by using convenience sampling. The average follow up was for 18 months. Ethical approval was obtained from the in stitutional ethics committee priortoe mbarking on the study.

2.1 Inclusion criteria

IIIC
ExtraarticularOpentibiafractureswith/withoutfibulafractureexcep tgrade-IIIB& Age above

- 18years
- Grade I, II, IIIA.
- Open tibial fractures with associated injuries
- Headinjury
- Otherfractures
- Other soft tissueinjuries

2.2 Exclusion criteria

- Open Tibial fracture treated primarily with external fixation.
- Non-union of tibial fractures.
- Intra-articular fractures.
- Closed tibial fractures. Grade
- IIIB & IIIC fractures.

A standard protocol was followed to manage all the patients. A stat dose of tetanus toxoid and a first-generation cephalosporin was given to the patients in the emergency department patients. Wounds were cleaned and dressed, and the limbs plinted after which a surgical debridement was done immediately. A locked intramedullary nail was used to stabilize the fracture. Each patient's injury was classified intra-operatively according to GustiloandAnderson.Woundswereeitherapposedwithnyloninterr uptedsutures, closed by vacuum-assisted closure, left open, or delayed closure was performed. Post-operative antibiotics were prescribed based on the severity of injury and advised to be continued for a period of 24 to 72 hours. Follow up inspection of the wounds were done at 48 hours in the ward and are debridement was performed if deemed necessary. Sutures were removed at two weeks and wounds were cleaned and dressed appropriately. Outpatient follow-up was schedule dat monthly inter vals. Wounds were in spected for signs of infection and the ery thro cytese dimentation rate (ESR) and C-reactive protein (CRP) was take nifthere was any clinical suspicion of infection.
IBM SPSS for Windows version 22 (Armok, New York: IBM Corp) was used for statistical analysis. A p value of <0.05 was considered to be statistically significant. ANOVA tests were used to compare normally distributed continuous variables between the grades. Categorical variables were compared between the three grades by means of Pearson' schi- squaretests. Time to surgery data were compared between the three grades using log-rank tests.

3. Results

Fifty-seven patients with 57 tibial fractures met the inclusion criteria. Three patients were excluded from the study. One patient shifted to another district, 2 patients died of causes other than the tibial fracture. The final sample comprised of 47 men and 7 women with 54 open tibia fractures. The mean age was 35 years (range 16-68). Mean follow-up was 18 months (range7-32).
In total, 12 fractures (22.2%) were classified as grade 1, 27 fractures (50 %) as grade 2 and 15 fractures (27.8%) as Gustilo-Anderson grade 3A open fractures.
The fracture morphology included comminuted (41.3%), oblique (36%), transverse (9.3%), segmental (6.7%) and spiral (6.7%) fractures *(Table 1*).
Middle third fractures (59.8%) of the tibial diaphysis comprised the majority of fractures followed by distal third (32.7%) and proximal third (7.5%).
Pedestrian accidents accounted for 35% of the injuries while 27.5% were occupants ofthe vehicle. There were 14.3% of patients who were assaulted, 12.3% with sports injuriesand 10.9% fractures from accidental fall. Three patients sustained polytrauma. (*Figure 1*)Systemic comorbidities were identified in eight patients like diabetes, hypertension, pep-tic ulcer disease, schizophrenia and a history of drug abuse. 18 patients (33.3%) were smokers. The average time to surgery was 28 hours (range 8-112). The time to surgery for grade 1, grade 2 and grade 3A fractures were 28 hours, 35 hours and 22 hours respectively. The mean operating time was 78 minutes. The average length of stay in hospital was nine days (range4-30).

Table 1: Different fracture pattern for allgrades

Fracture pattern	Gustilo Grade 1(no. of patients)	2(no.	of patients)	3A (no.	of patients)	Total (%)
Transverse	1	4		0		9.3
Oblique	4	11		4		35.2
Spiral	1	2		1		7.4
Segmental	0	0		4		7.4
Comminuted	6	10		6		40.7

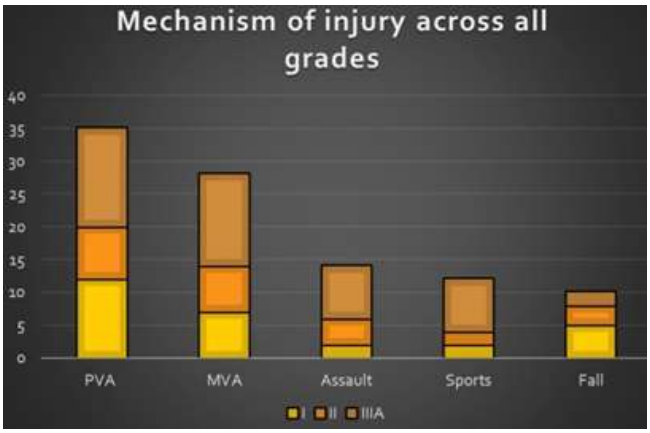

Fig 1: Mechanism of injury across allgrades

Systemic comorbidities were identified in eight patients like diabetes, hypertension, peptic ulcer disease, schizophrenia and a history of drug abuse. 18 patients (33.3%) were smokers. he overall infection rate was 16.7%. Superficial infection developed in 11.1% and deep infection occurred in 5.6% (Table 2). The average time taken for union was 15 weeks in the grade 1, 17.1 weeks in the grade 2 *(Figure 2*), and 17.3 weeks in grade 3A fractures *(Figure 3*). The mean time to union for all grades was 17 weeks (range 12-50) *(*Table 3*).*

Table 2: Sepsis Gustilo grade

	1	2	3A	Total
Superficial	8.3%	11.1%	13.3%	11.1%
Deep	0.0%	7.4%	6.7%	5.6%
No Sepsis	91.7%	81.5%	80%	83.3%

Association between time to surgery and development of sepsis within the different grades and overall was assessed using non-parametric Mann-Whitney tests. There was no difference in the time to surgery between those with and without sepsis, either within grades or across grades. This indicated that time to surgery was not associated with the development of sepsis (p= 0.819).

Patients with Gustilo-Anderson grade 1 injuries had an infection rate of 8.3%. One patient developed superficial wound infection that resolved following local wound care and oral antibiotics, (ESR 15, CRP <10). No patients with grade 1 injuries developed chronic osteomyelitis or deep infection.

Patients with Gustilo-Anderson grade 2 injuries had an infection rate of 18.6%. Three patients (11.1%) developed superficial infection, (average ESR 7, CRP <10). Local wound care and oral antibiotics were sufficient for the three patients. Two patients (7.4%) developed deep infections, (average ESR 45, CRP <15). One patient had chronic draining sinuses at the distal locking screw that resolved after screw removal but did not necessitate nail removal. One patient developed chronic osteomyelitis with a chronic draining sinus on the anterior medial cortex that resolved with nail removal after union. Pus swab showed no growth in all cases.

Patients with Gustilo-Anderson grade 3 injuries had infection rate of 20%. Two patients (13.3%) had superficial sepsis (average ESR 23, CRP 32). Both patients were managed with local wound care and oral antibiotics. One patient (6.7%) developed deep infection, (average ESR 85, CRP 20).

The patient had an abscess collection that underwent incision and drainage with implant retention while the second patient required nail removal and application of a circular external fixator.

Wounds were managed by suturing with nylon interrupted sutures in 64.2% of cases; left open in 27.8% of cases; vacuum-assisted closure/ split skin graft was used in 4% of cases and delayed closure in 4% of cases. No association was found between type of closure and sepsis (p=0.405). Apposition with nylon was associated with the highest deep sepsis rate (6%) followed by vacuum assisted closure. The values are too small to reach any definitive conclusion.

Fig 2: (A, B) AP and Lateral radiographs of a grade II fracture, treated with locked intramedullary nail (C) AP and lateral radiograph is of 17 weeks after the nail.

Fig 3: AP and lateral radiographs of grade 3A tibial fracture (A) treated with an intramedullary nail (B). Intra medullary nail was removed and (C) a simple ortho fix external fix at or applied. (D) A Pand lateral showing valgus malunion after 1year.

The average time taken for union was 15 weeks in the grade 1, 17.1 weeks in the grade 2 (Figure 2), and 17.3 weeks in grade 3A fractures (Figure 3). The mean time to union for all grades was 17 weeks (range 12-50) (Table 3). Two patients showed delayed union but united with full weight bearing. Dynamization was done for two patients before union could be achieved. Statistically significant difference in time to union between the grades was found (p=0.011). The survival curve shows that grade 1 required the shortest time to union while grade 2 and 3A required longer time on average. There was no difference (p=0.405) in time to union between grade 2 and 3A injuries. One patient who sustained a grade 3A injury developed a septic non-union and united by 50 weeks after nail removal, debridement, bone grafting and application of a circular fixator with fibular osteotomy.

Table 3: Time to union for all grades

Time to union	Gustilo grade			
(weeks)	1	2	3A	Total
Median	15.0	17.1	17.9	17.0
25th percentile	14.5	16.3	14.5	15.1
75th percentile	16.9	19.0	19.0	18.9
Minimum	13.3	14.2	12.0	12.0
Maximum	20.0	24.0	50.0	50.0

4. Discussion

The treatment of open tibial fractures is complex and successful outcomes are dependent on multiple factors.Some of the long-term complications include non-

union, chronic osteomyelitis and amputation. Despite multiple publications the optimal management of these injuries is still unclear. The successful treatment of open tibial fractures with intramedullary nailing has been well documented but few studies have been published on this topic in India and Asia.

This study reports the outcomes of our local experience of open tibial fractures in the acute setting, in our unique patient population by comparing the infection rates and union time with other similar studies to suggest why intramedullary nailing is a practicable treatment option for open tibial fracture patients.

Study	Infection Rate (%)	Union Time (Weeks)	Non- Union rate (%)
Our study (54 fractures)	16.7	17	1.8
B. Chowdhury et. al. (34 Fractures)	11.6	24.1	11.8
Seron et. al. (74 fractures)	17	18	2.7
Court Brown et. al. (41 Fractures)	50.1	38.2	15

Fig 4: Comparison with other similar studies

In our study infection rates were found to be directly proportional to the severity of injury as defined by the Gustilo-Anderson classification as well as the host comorbidities similar to other studies. [11, 12] A infection rate of 16.7 % was seen in our study which is slight better when compared to international literature. (Figure 4) Superficial infection usually resolved with minimal intervention; however, deep infection warranted multiple additional surgical procedures. Chowdhury et al. and Brown et al. reported union times that ranged from 11.6 weeks to 50 weeks. Average time to union in our study was 17 weeks (range 12–50) which is comparable toot her studies. [13, 14, 15] Even non-union rate sinour study is quitter educed as compared to international studies.

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