
ORIGINAL ARTICLE**Functional Outcome and Complications in Fracture Tibia Operated with Intramedullary Interlocking Nail: A Prospective Study in a Tertiary Care Hospital***Sayaji V. Bhamre¹ and Khairnar G²,**Associate Professor¹, Assistant Professor², Department of Orthopedics,
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Abstract:**Introduction:**

Treatment of open tibia fracture is controversial. Complication like infection, re-operation, and non-union are more common after these fractures. While grade II and III fractures are mostly treated with detriment and external fixator, grade I fractures are a matter of controversy. It is essential to evaluate factors affecting deep infections and fracture healing of closed and grade I open fracture of the tibial shaft treated with immediate or delayed interlocking intramedullary nail, and to study the functional outcome of the surgical procedure in a set up of a tertiary health care centre.

Objectives:

Study of functional outcome and complications in closed and grade I open tibia fracture operated with intramedullary interlocking nail in a tertiary health care centre.

Material and Methods:

Sixty patients admitted to hospital from May 2015 to December 2017 with diagnosis of closed or grade-I open tibia shaft fracture and aged more than 18 years, were included in the study. After initial evaluation and investigation, they were posted for surgery. Closed reduction and fixation with intramedullary nailing was done under spinal anesthesia. After discharge, patients were followed up at an interval of 3 weeks, 3 months and 6 months and were evaluated using Johner and Wruhs Criteria.

Results:

In this study, 90% patients had excellent, 5% good and 1.67% poor results according to Johner and Wruhs Criteria.

Conclusion:

Closed and grade-1 open fractures of the tibia shaft, managed with interlocking intramedullary nailing involves minimal surgical trauma and negligible blood loss while provides the advantages of early ambulation, lower rate of infection, delayed union, non union and mal-union.

Keywords:

Tibia fracture, Diaphysial fracture, Intramedullary Nail, Interlocking Nail.

Introduction:

The long bone fractures most frequently occur in the tibial shaft¹. Fractures of the tibia shaft are important for the reason that they are common and controversial. Because of the high prevalence of complications associated with these fractures, especially when it is an open fracture, management is often difficult, and the optimum method of treatment remains a subject of controversy².

There are various modalities of treatment such as conservative gentle manipulation and use of long leg cast with a window^{3,4}, open reduction and internal fixation with plates and screws, intramedullary fixation (including ender pins, intramedullary nails and interlocking intramedullary nails) and external fixation techniques. Best possible treatment should be

determined by a thoughtful analysis of morphology of the fracture, the amount of energy imparted to the extremity, mechanical characteristics of the bone, age and general conditions of the patient, and most importantly the status of the soft tissues⁵. The goals of infection prevention, the achievement of bony union, and the restoration of function are interdependent and are achieved in the chronological order given.

Open reduction and internal fixation with plates and screws has yielded unacceptably high rates of infection⁶. External fixation, considered the treatment of choice by many traumatologists, has the disadvantages of bulky frames and frequent pin track infections, non-union, and malunion.

The intramedullary nailing, locked or unlocked has become an attractive option since image intensifier has made closed intramedullary nailing possible. Interlocking nail is stiff to both axial and torsional forces and load sharing device. Closed nailing has less disturbances of fracture hematoma and soft tissue as compared to other forms of internal fixation^{7,8,9}. The locking of intramedullary nails to the major proximal and distal fragments decreases the prevalence of malunion of comminuted fractures.

Materials and Methods:

Study population:

In this study, 60 cases of closed and grade-I open fracture shaft tibia, admitted under Orthopaedics department in our institute, treated with intramedullary interlocking nail were studied during the period from May 2015 to December 2017.

Case selection was done according to the history, clinical examination and radiological (X-ray) findings. Soon after admission, clinical data was recorded as per the case record form. Age, sex, mode of trauma, type of injury and all other vital parameters were noted. After all initial evaluation to rule out other associated fracture and pre-operative investigation they were posted for surgery.

The average interval between admission and surgery was 6 hours. An intramedullary nailing was done using image intensifier guidance under anesthesia (Fig-1 a-e). The wound, where present, were closed after proper debridement over a corrugated rubber drain. Next day, full weight bearing mobilization was started for most of the patients and they were discharged after 3 days of intravenous antibiotics. Oral antibiotics were administered for two weeks after discharge.

Patients were followed up after 3 weeks, 3 months and 6 months. In every follow up, the patients were assessed both clinically and radiologically for the signs of infections, bony union and the range of motion at the knee and the ankle. Dynamization was done only in those cases where the fractures did not show good signs of union between 6-10 weeks. Final outcome was evaluated by Johner and Wruh's criteria (Table-1)¹⁰.

Sample size calculation:

The sample size was calculated using the method described for assessment of clinical outcome from a single group interventional study. The data used in the calculation is based on the previously published literature of findings on clinical outcomes of intramedullary nailing in open fractures of tibia and their complications, in patients presenting to a tertiary care hospital in India.

The proportion of patients showing good to excellent outcome (responder rate) based on the Johner and Wruh's criteria was reported to be around 86% (proportion of 0.86). To achieve the success rate of 80% for the said study, intervention with 95% level of significance ($\alpha=0.05$) and if a difference of <10% in responder rate is considered to be of no clinical significance, the required sample size giving a 90 % power ($\beta=0.1$) comes to 54. Presuming a 10 % drop out, the minimum sample size for this study was finalized to 60 subjects (N=60).

Table No 1: Johner and Wruh’s Criteria

Sr. No.	CRITERIA	EXCELLENT	GOOD	FAIR	POOR
1	Non-union	None	None	None	Yes
2	Neurovascular injury	None	Minimal	Moderate	Severe
3	Deformity (in degree)				
	Varus / valgus	None	2-5	6-10 degree	>10
	Pro / recurvatum	0-5	6-10 degree	10-20 degree	>20
	Rotation	0-5	6-10 degree	10-20 degree	>20
	Shortening (in mm)	0-5	6-10	10-20	>20
4	MOBILITY (in percentage)				
	Knee	Full	>80	>75	<75
	Ankle	Full	>75	>50	<50
	Subtalar	>75	>50	<50	
5	Pain	None	Occasional	Moderate	Severe
6	Gait	Normal	Normal	Minimal limp	Significant
7	Strenuous activities	Possible	Limited	Severely limited	Impossible

$$n = \frac{(z_{\alpha} + z_{\beta})^2 \theta(1-\theta)}{(\theta - \theta_0 - \delta)^2}$$

Where,

- $\alpha = 0.05$
- $1-\beta=0.9$
- $\theta = 0.80$
- $\theta_0 = 0.86$
- $\delta = 0.1$

Variables Description

- α : One-sided significance level
- $1-\beta$: Power of the test
- θ : Expected success proportion of sample
- θ_0 : Known success proportion
- δ : True difference of mean response rates, $\delta > 0$, the superiority margin or value of $\delta < 0$, the non-inferiority margin
- N: Required sample size

Statistical analysis:

Qualitative data are represented in form of frequency and percentage. Association between qualitative variables is assessed using the chi-square test with continuity correction for all 2x2 tables and without continuity correction in rest. Fischer exact test was done for all 2x2 tables where p-value of chi-square test is not valid due to small count. Analysis of quantitative data between a qualitative variable with two subgroups was done using unpaired t-test, if data passes “Normality test” and by Mann-Whitney test if data fails ‘Normality test’. SPSS version 17 is used for most analysis. Significance levels of P Value less than 0.05 are considered as significant.

Inclusion criteria:

1. Patients of either sex, age 18 years and above.
2. Fracture tibia or tibia and fibula both in same leg.
3. Closed and open Gustilo-Anderson grade-I fractures.
4. All those fractures of tibia which are in the diaphysis (7-8 cm distal to knee and 4-5 cm proximal to the ankle joint).
5. Unilateral or bilateral tibia fractures.

Exclusion criteria:

1. Patient less than 18 years of age.
2. Any associated fracture (other than fibula) in the same limb.

3. Fractures other than diaphysial one.
4. Open fractures of tibia which are Gustilo grade II and III.
5. Patient having arthritis involving knee and ankle.
6. Pathological tibia fracture.

The study was conducted as per national and international guidelines for conducting research in human subjects. The protocol was submitted to institutional ethics committee for review and study was initiated only after obtaining approval from the committee.

Table No 2: Distribution of Functional activity level

Parameters for classification	Number	Percentage
Knee pain		
Occasional	2	3.33
Moderate	2	3.33
Nil	56	93.34
Non union	1	1.67
Neuromuscular injury	0	0
Deformity	1	1.67
Gait		
Minimal limp	2	6.67
Significant Limp	1	1.67
Normal	57	95.00
Strenuous activity		
Impossible	1	1.67
Limited	2	3.33
Severely limited	2	3.33
Normal	55	91.67

Table No 3: Mobility of knee joint

Mobility of knee	Number	Percentage
<75%	1	1.67
>75%	2	3.33
>80%	3	5.00
Full	54	90.00
Total	60	100

Results:

The present study consists of 60 patients having tibia fracture treated by closed intramedullary interlock nailing. The functional outcome of the patients treated with intramedullary interlock nailing was studied. The age of the patients ranged from >18 years to 70 years. Majority of the patients were in age group 30-50 years (50%). Average age in our series was 45 years. The present study had 46 male (76.67%) and 14 female (23.33%) patients. The male:female ratio was approximately 3:1.

Mode of injury:

In our study, 54 patients had a history of road traffic accident (90%) and 6 patient had history of fall from height (10%). Thirty-eight patients had right side involvement and 22 patients had left side involvement. The Results show non-significant involvement of right side. In our study, we had 56 (93.33%) cases of closed fractures and 4 (6.67%) cases of grade-I open fractures (Table-2).

Type of fracture:

According to AO-OTA classification, TYPE-A accounted for 59.99%, TYPE-B for 33.34% and TYPE-C for 6.67%. In our study Type-A i.e. simple type of fracture were most common.

Follow up of patients:

After discharge, patients were followed up at 3 weeks, 3 months and 6 months. The time of return to work and full activities were noted. Taking into consideration the Indian life style and working pattern, we had given much importance to knee range of motion which is necessary for squatting and sitting cross legged. The possible causes of restriction of movement were associated trauma at the time of injury, wasting of quadriceps tendon due to prolonged immobilization in cast and lack of physiotherapy due to less patient compliance. In this study, 90.00 % of the patients had good range of movement, while remaining 8.33 % developed slight restriction in range of motion (Table-3).

Discussion:

The present study involved 60 cases of tibia shaft fracture, which were operated with closed intramedullary interlocking nailing. In the present study, majority of the patients were in age group 30-50 years (50%) with mean age of 45 years. This is little higher than earlier reports, 35 yrs by Ekland A et al¹¹ and 37 yrs by Court Brown et al.¹² Middle aged people between ages of 30-50 years are more prone to accident due to their increased vehicular usage¹². Most of the study population was of middle age between 30- 50 years with male preponderance. The preponderance of males could be attributed to (1) Males are more outgoing,

hence more vulnerable to vehicular accidents. (2) Due to usual society practice, certain tasks, which involve high risk, are performed by males. e.g. working at height, driving, labor and travelling. Union problem with this technique was negligible. The rate and type of complication such as implant failure, wound gapping has not been observed. Acceptable range of movement with going back to activities of daily living was observed in this study.

Court Brown et al¹² in their study noted male incidence to be around 81.3%, while the female around 18.7%. Whereas, in the present study, 46 males (76.67%) and 14 females (23.33%) were recorded. Study by Radhakrishna et al¹³ reported that 86.7% of the patients with tibia fractures were due to road traffic accidents, which is comparable to 90% in the present study. Simple transverse tibia fracture were 23.33%, spiral 16.66%, and 20% oblique type. Court brown et al¹² reported 37.2% transverse and oblique fractures and Ekeland et al¹¹ reported 42% transverse and oblique fractures. Radhakrishna et al¹³ reported 30% transverse and oblique fractures.

In majority of the patients, right side was predominantly affected; mostly was closed fracture with only 4 open fractures (Grade 1). According to AO classification, TYPE-A accounted for 59.99%, TYPE-B for 33.34% and TYPE-C for 6.67%.

After discharge patients were followed up at 3 weeks, 3 months and 6 months. The time of return to work and full activities were noted. The average union time was 22 weeks. It was observed that 91.67% of the patients developed no post-operative restriction of movement while 8.33% developed restriction in range of motion.

Final assessment of the patients was done at 6 months using the Johner and Wruh's criteria, which takes into account of the objective and subjective symptoms of gait, pain, deformity, range of motion of knee, ankle and subtalar joints shortening. The patients were reviewed in respect of neurovascular

disturbances, ability to do strenuous activities, radiological union and presence or absence of non-union. Functional outcome was graded into Excellent, Good, Fair and poor. In the present study, 90% patients had excellent, 5% good, 3.33% had fair and only 1.67% had poor grades (Fig-2). In comparison with study by Ekeland et al¹¹ which reported 64.4% excellent, 28.8% good, 4.4% as fair and 2.4% poor results, present study achieved significant better outcomes using the Johner and Wruh's criteria.

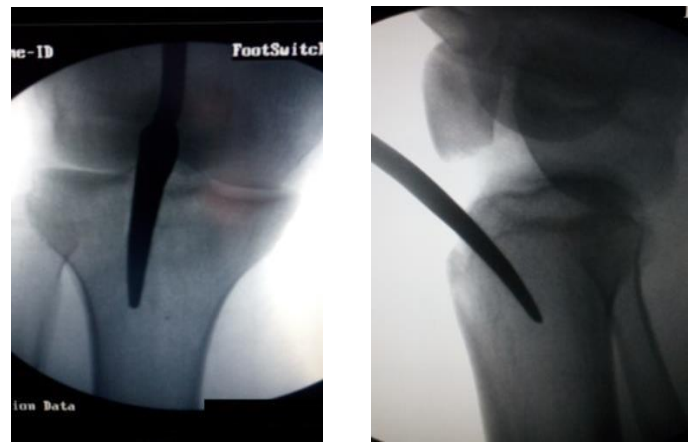


Figure 1a: Entry taken under c-arm image intensifier

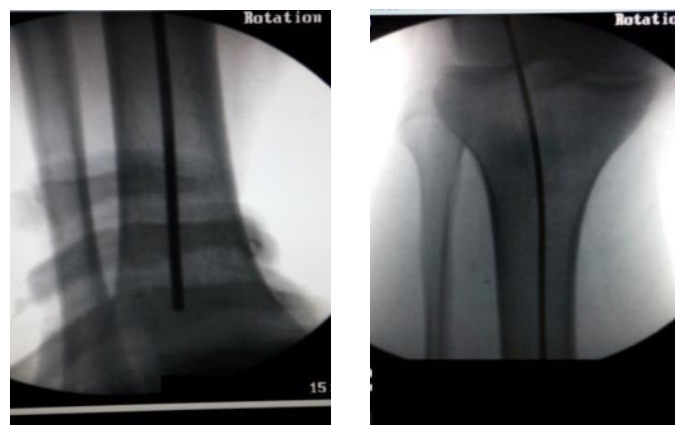


Figure 1b: Guide-wire inserted and position confirmed



Figure 1c: Nail inserted and distal locking done in free-hand technique.



Figure 1d: Proximal locking done through zig



Figure 1e: Immediate post-operative X-rays

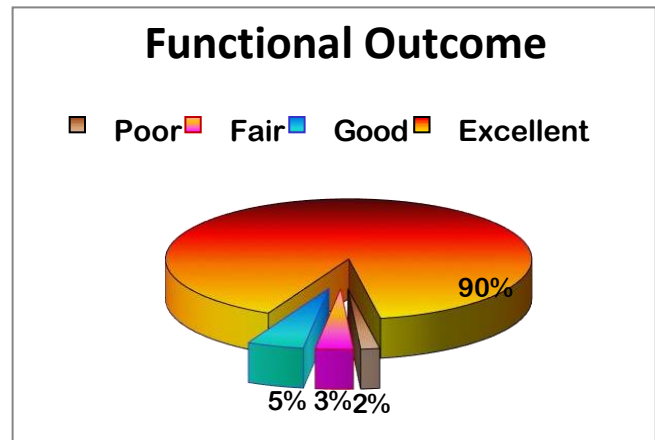


Figure 2: Distribution of Functional Outcome

Conclusion:

The present study shows that closed fractures and Grade 1 open fractures of the tibia shaft; managed with interlocking intramedullary nailing involves minimal surgical trauma and negligible blood loss. It provides the advantages of early ambulation, lower rate of infection, delayed union, non-union and malunion. It is a viable option for managing fracture of the tibia in public hospital set up as it is cheaper, causes minimal morbidity, shortens operative time and hospital stay.

Conflict of Interest - Nil

Sources of Support - Nil

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