A study designed to determine optimal ratio of intramedullary nail diameter to tibial canal diameter that leads to reliable and timely healing in tibial shaft fractures

Dr. Rohit Kavishwar[1§], Dr. Ravinder Lamoria[2], Dr. Mahesh C. Bansal[3], Dr. Girdhar Gopal Goyal[4]

[1]3rd Year Resident, Department of Orthopaedics, SMS Medical College, Jaipur (Rajasthan) India
[2]Assistant Professor, Department of Orthopaedics, SMS Medical College, Jaipur (Rajasthan) India
[3]Senior Professor, Department of Orthopaedics, SMS Medical College, Jaipur (Rajasthan) India
[4]Senior Specialist, MO/IC Trauma Hospital, SMS Medical College, Jaipur (Rajasthan) India
§Corresponding author's Email: rkavishwar26@gmail.com

Abstract— *Tibial fracture is quite common. There are various modalities to manage tibial fracture, one of them is intra-medullary nailing. This study was conducted on 100 tibial fracture patients undergoing intramedullary nailing. After operation they were followed at 3 months, 6 months , 9 months and 12 months. For 12 month followup, 90 patients were available. So 90 patients were used to determine optimal ratio of intramedullary nail diameter to tibial canal diameter at the isthmus that leads to reliable and timely healing in tibial shaft fractures. It can be concluded from this study that non union rate was significantly less in the patients having optimal ratio(0.8 to 0.99mm) of tibia nail to medullary cavity width at the isthmus than the other group having ratio less than 0.8mm or more than 0.99mm. So optimal ratio of tibia nail to medullary cavity width at the isthmus was found 0.8 mm to 0.99mm.*

Keywords: Tibial fracture, intramedullary nailing, RUST, Functional Outcome.

I. INTRODUCTION

Fractures of the leg bones are the most common long bone fracture. In an average population, there are about 26 tibial diaphyseal fractures per 100,000 population per year.[1] Men are more commonly affected than women, with the male incidence about 41 per 100,000 per year and the female incidence about 12 per 100,000 per year. The average age of patients sustaining a tibia shaft fractures is 37 years with men having an average age of 31 years and women 54 years.[1]

The management of tibial diaphyseal fractures has always held a particular interest for orthopaedic surgeons.[2] Fractures of the shaft of the tibia cannot be treated by following a simple set of rules. Most fractures of tibia will heal if treated by non-operative means — this fact is undeniable.[3]

The shaft of tibia is subcutaneous throughout its length and may have a diminished blood supply, severe complications and major disability are common outcomes.[4] Fractures of the tibia and fibula can range from completely undisplaced fractures with minimal soft tissue damage to traumatic amputations. The treatment modalities described for tibia and fibula fractures range from simple cast immobilization to complex surgical procedures[4]

Operative treatment is indicated for most tibial fractures caused by high-energy trauma. These fractures usually are unstable, comminuted, and associated with varying degrees of soft-tissue trauma. Operative treatment allows early motion, provides soft-tissue access, and avoids complications associated with immobilization. The goals of treatment are to obtain a healed, well-aligned fracture; pain-free weight bearing; and functional range of motion of the knee and ankle joints. The optimal treatment method should assist in meeting these goals, while minimizing complications, especially infection. These goals may not be attainable in severely injured limbs.[3]

Locked intramedullary nailing currently is considered the treatment of choice for most type I, type II, and type IIIA open and closed tibial shaft fractures and is especially useful for segmental and bilateral tibial fractures.[3]

Anterior knee pain is the most commonly reported complication after intramedullary nailing of the tibia. A significant number of patients have some degree of chronic knee pain, and more have difficulty on kneeling.

Suggested contributing factors include younger, more active patients, nail prominence above the proximal tibial cortex, meniscal tear, unrecognized articular injury, increased contact pressure in the patellofemoral articulation, damage to the infrapatellar nerve, and surgically induced scar formation.[5,6]

Some authors have suggested that a transtendinous approach is associated with more frequent anterior knee pain than is a medial paratendinous approach. (20,21) The cause of this knee pain is still unclear.[3]

Intramedullary nailing is the favoured fixation technique for diaphyseal fractures of the tibia. Nails are categorized as reamed and non-reamed depending on whether enlargement of the medullary canal with power reamers is an intended part of the nail insertion procedure.

Nails for which reaming is generally required have outside diameters of 11 mm or more, whereas those intended for insertion without reaming may be as small as mm in outside diameter. Tibial intramedullary nails have holes in various configurations for locking screws at both the proximal and distal ends.

So this study was conducted to determine optimal ratio of intramedullary nail diameter to tibial canal diameter at the isthmus that leads to reliable and timely healing in tibial shaft fractures.

II. METHODOLOGY

This prospective study was conducted from January 2016 to December 2017 at Trauma Centre of the department of Orthopaedics, SMS Medical College and attached Hospital Jaipur (Rajasthan) India. This study was done on 90 patients with displaced diaphyseal fractures of the tibia treated with intramedullary interlocking nail. Ethical clearance was obtained before starting the study. An informed, bilingual and written consent was obtained from all the patients.

For this study, 18-50 years aged patients with tibial shaft fracture of AO/OTA42 Type with less than 50% cortical contact & more than 5 degrees varus/valgus angulation and Gustilo Anderson Type 1 and Type 2 were included. Out of these patients, patients having with peripheral neuropathy, peripheral vascular disorders, arthritis, any systemic disease, previous tibial fractures were excluded from study. Patients denied for giving written informed consent were also excluded from study.

After taking baseline data, all the patients underwent primary survey and hemodynamic stabilization in the emergency department. The presence of other fractures, neurovascular status of the limb and systemic evaluation was done subsequently on secondary survey.

Appropriate anteroposterior and lateral radiographs were taken and limb was immobilized in GT Slab(Groin to toe). Fractures pattern of AO/OTA42 type were taken in account.

Patient was managed initially by splinting with GT slab, analgesics, antibiotics and debridement for open wound, anaesthetic preop evaluation and physician fitness if advised by the anesthetist. In all the eligible cases, tibial fracture was fixed with interlocking intramedullary nail within 24 hrs of patient reporting to the hospital after pre-anaesthetic checkup.

X ray of the involved leg was taken post operatively including knee and ankle joints in the same film. Limb was elevated in the immediate postoperative period.

Nail diameter used for fixing the tibia was mentioned on the discharge card of the patient from the operative notes. Also the preoperative X rays were taken and diameter of medullary cavity at the isthmus was taken and mentioned on the discharge card. For this true size X rays of the tibia were taken. Average of diameter on anteriorposterior and lateral Xrays were taken. Ratio was then obtained by dividing the nail diameter by diameter of medullary cavity at the isthmus.

Post operatively all the patients were mobilized with 25% weight-bearing with crutches or walker as per the motivation of the patient. Weight bearing was gradually increased, 25% per week in the patients showing good improvement clinically. Mobilization of knee and ankle, also the hip was started immediately in postoperative period. Continuous static quadriceps exercise was recommended to the patient.

Sutures were removed on 14^{th} day of surgery. Patient was counseled for regular and adequate physiotherapy and proper nutrition. Patient was counseled against excess weight bearing.

Patients were followed up clinically and radiologically at 3 months, 6 months, 9 months, 12 months. Data was collected by verbal communication, clinical examination and radiographic features. RUST scale has been shown to be highly reliable for evaluation of radiological consolidation of tibial shaft fractures. For functional outcome, Karlstrom-Olerud functional score was used. Functional outcome was divided into five categories -Excellent(36 points), Good(33-35), Acceptable(30-32), Moderate(27-29) , Poor(24-26).

The data thus obtained was complied and analysed using Statistical Package for Social services. (SPSS trial version 18). Measured data was analysed by using student unpaired ‘t’ test. Categral data was analysed using Chi – Square test. A 'p value' of less than 0.05 was considered as statistically significant.

III. RESULTS

This study was done on 100 patients but full follow up could be done in only 90 patients. So these 90 cases were taken into account for evaluation.

A total of 90 patients of tibial fracture, 49% of the cases were in the age group of 31-40 years of age followed by 37 % cases were in the age group of 18-30 years of age. Leg bone fractures were mostly seen in the younger age group. The mean age was observed to be 32.87±7.06 (years) in this study group. Males were with slight predominance i.e. 89 % of the cases in this study group were male and 11 % of the cases were females. Out of 90 cases 48 were left sided tibia and 42 were right sided. (Table 1)

Table 1
Characteristics of Study Population

S. No.	Variable		Number	Percentage (%)
1	**Age in years**	**18-30**	33	36.67
		31-40	44	48.89
		41-50	13	14.44
2	**Sex**	**Male**	80	88.89
		Female	10	11.11
3	**Side of Tibia**	**Left**	48	53.33
		Right	42	46.67

The mean of all the nail sizes (available sizes 8 mm,8.5mm,9 mm, 10mm,11 mm 11.5mm,12 mm) was 8.76±0.66 mm. Medullary cavity diameter mean was found to be 10.27±1.35 mm. (Table 2)

Table 2
Mean Nail and Medullary Cavity Diameter of Study Population

Diameter	Mean	SD
Nail Diameter	8.76	0.66
Medullary Cavity Diameter	10.27	1.35

Out of 90 cases, study group was divided into two, one having the ratio of nail diameter to medullary cavity diameter at the isthmus 0.8-0.99 and the other having ratio less than 0.8 and more than 0.99. RUST (Radiographic Union Sale for Tibial Fracture) Criteria was used for radiological assessment of postoperative union. As per RUST criteria the maximum score was 12 and the minimum score was 4. Radiologically fracture having RUST score equal to or greater than 7 was considered to be consolidated. It was found that RUST score was significantly more with ratio of nail diameter to medullary cavity diameter at the isthmus 0.8-0.99 than the other having ratio less than 0.8 and more than 0.9 at every follow up. (Table 3 & 4)

Table 3
Association of RUST with Ratio of Nail and Medullary Cavity Diameter

Ratio	RUST at Post -operative Follow ups			
	3 months	6 months	9 months	12 months
0.8-0.99	5.21±0.99	6.32±1.37	7.68±2.04	9.44±2.12
Other (<0.8->0.99)	4.78±0.80	5.67±0.92	6.48±1.45	7.37±1.94
P* Value LS	0.04 **S**	0.026 **S**	0.006 **S**	<0.001 **S**

Unpaired 't' test

Regarding nonunion of cases, although there was no difference in consolidation in both the group at every followup but proportion of cases with non union was found significantly less in patients with ratio of nail diameter to medullary cavity diameter at the isthmus 0.8-0.99 than the other having ratio less than 0.8 and more than 0.9. (Table 4)

Table 4
Association of Fracture consolidation with Ratio of Nail and Medullary Cavity Diameter

Ratio	Consolidated at Post -operative Follow ups				Non-Union
	3 months	6 months	9 months	12 months	
0.8-0.99 (N=62)	**6**	**9**	**15**	**22**	12
Other (<0.8->0.99) (N=28)	**1**	**3**	**2**	**5**	16
P* Value LS	0.564 NS	0.876 NS	0.105 NS	0.150 NS	<0.001 **S**

Chi-square test

Regarding functional outcome of cases, significantly better outcome was observed in patients with ratio of nail diameter to medullary cavity diameter at the isthmus 0.8-0.99 than the other having ratio less than 0.8 and more than 0.9. (Table 5)

Table 5
Association of Functional outcome with Ratio of Nail and Medullary Cavity Diameter

Ratio	Functional outcome Grading				
	Acceptable	Excellent	Good	Moderate	Poor
0.8-0.99 (N=62)	**10**	**7**	**26**	**9**	10
Other (<0.8->0.99) (N=28)	**2**	**1**	**2**	**10**	13

Chi-square test = 21.002 with 4 degrees of freedom; P < 0.001 LS= Significant

IV. DISCUSSION

All 90 patients of tibia nail are operated in emergency OT at our institution. The tibia nail size is determined intra operatively by the surgeon perceived as cortical chatter during reaming. Tibia nail size was recorded and mentioned on the discharge card of the patient. True size X ray of the patient gave the medullary canal width at the isthmus.

Pre-operative decision of the size of nail was never perfect. Hence it could only be decided intraoperatively. Extreme proximal fractures of tibia and extreme distal fractures of tibia were not included in the study. They were subject to plating/Nailing according to Surgeon choice.

In this study, follow up clearly showed the difference in time to union between two groups. Retrospective charting gave us two groups of patients. One with having optimal ratio of tibia nail to medullary cavity 0.8 to 0.99 and the other having less than 0.8 or more than 0.99. Using RUST criteria we evaluated the follow up X rays. At the 3 months, 6 months, 9 months and 12 months the difference shown was statistically significant. RUST criteria at 3 months , 6 months ,9 months and 12 months clearly showed difference of time to radiological union in these two groups.

In this study as per Karlstrom-Olerud functional score criteria, 52% of the patients in optimal ratio group had functional scoring in Excellent and Good category. The statistical difference between the two groups on the basis of Karlstrom-Olerud functional score was found significant (P <0.001). Functional scoring had no relation with RUST criteria. Even a fracture with poor RUST criteria clinically showed good Karlstrom-Olerud functional scoring. Radiological union is all together a different aspect. So a fracture having poor RUST scoring doesn't necessitate poor Karlstrom-Olerud functional scoring.

Conversely, several studies have shown that smaller diameter tibial nails can lead to failure with nail breakage and screw failure rates, ranging between 3%-20%.[7, 8] Biomechanical studies have shown that tibia shaft fractures without bony defects treated with solid small diameter tibial nails can be made full weight bearing immediately, while those with segmental defects that fully weight bear may lead to implant failure.[9] Ina series by Whittle et al,[7] 3% of nails broke and 16% of screws failed in small diameter,solid body nails; however, all nail failures were in open, unstable fracture patterns that hadbeen dynamically locked.[7] Sanders et al[10] showed that small diameter nails in openfractures can lead to delayed union, especially with increasing Gustilo-Anderson type.[10]

Augat et al,[11] in a biomechanical cadaveric study, showed that even when overreaming by1mm greater than the diameter of the nail, there is increased clearance between the nail andthe cortex, leading to significant displacement, especially with shear forces[11] .Balance between adequate strength and stability, necessary for interfragmentary motion,and preservation of biology to promote healing must be considered in any tibial shaft fracture. Historically, there has been some debate as to whether a larger implant is beneficial or even necessary during intramedullary fixation of tibial shaft fractures.

In this series, a negative clinical impact with respect to time to union and nonunion rate was seen if a suboptimal ratio between implant diameter and canal diameter was created when treating extra-articular tibial shaft fractures with intramedullary nails.

It was clearly seen that the ratio of tibia nail diameter to medullary canal width diameter exceeding 0.99 was also not favourable for time to radiological union. Only when the ratio of tibia nail to medullary canal width was optimal, time to radiological union was less.

V. CONCLUSION

It can be concluded from this study that non union rate was significantly less in the patients having optimal ratio (0.8 to 0.99) of tibia nail to medullary cavity width at the isthmus than the other group having ratio less than 0.8 or more than 0.99. So optimal ratio of tibia nail to medullary cavity width at the isthmus was found 0.8 mm to 0.99mm.

CONFLICT OF INTEREST

None declared till now.

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