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Research Article

A prospective randomized control trial between immediate undreamed nailing versus delayed nailing in compound tibial shaft fracture

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Abstract

Objective: To assess the outcome of results in compound tibial fractures in terms of immediate and delayed nailing.
Methods: A prospective randomized, double blind, control trial regarding immediate nailing in 30 patients and delayed nailing in another 30 patients and the outcome is measured in GA Type II, IIIA and IIIB fractures, with 10 patients in each Sub-Group.

Results: In Open Type II fractures in immediate and delayed nailing Groups union occurred after 18.09 and 26.5 weeks respectively. We obtained excellent results in 73.07% patients after immediate nailing and 53.84% after delayed nailing in Group II, p Value 0.001.

Conclusion: The immediate nailing in GA Type II gives better result but equivalent results with GA Type IIIA and IIIB.

Keywords: Unreamed nailing, Delayed nailing, Compound fracture, Tibia fracture

INTRODUCTION

Evidence favors the use of interlocking nails in fixation of fractures of tibia. This procedure has revolutionized the treatment of tibial diaphyseal fractures with less hospital stay, early mobilization and better functional outcome. The loss of soft tissue covers over a fracture, particularly when interrupted with endosteal blood supply is combined with periosteal damage, demands coverage of exposed bone with vascularized tissue after thorough debridement of devitalized tissue. Soft tissue coverage of Type III open fractures of leg diminishes the rate of infection, non-union and secondary amputation when it is performed early. With this background, we undertook this single blinded Randomized control trial with Grade II, IIIA and IIIB open fractures of the diaphysis of the tibia, who were treated with either immediate un-reamed tibial interlocking nail (here after immediate nailing) or external fixator followed by un-reamed tibial interlocking nail (here after delayed nailing). Sincere efforts were made to evaluate the effect of these treatment modalities in tibial diaphyseal fractures with regards to treatment outcomes such as union rate and time and functional results.

The aim of my study was to analyze and compare the results of immediate un-reamed intramedullary locking nail versus delayed intramedullary locking nail in treatment of compound tibia shaft fracture as per defined outcome variables.

Our Objective was to evaluate radiological union time in both groups, to evaluate clinical outcome in both groups in terms of early mobilization and weight bearing. To evaluate complications in both groups in terms of infection, implant failure and non-union.

It is our sincere hope that this work would throw some light on this controversial and resource consuming problem as well as its management in our setup.

METHODS

A prospective randomized, double blind, control trial regarding immediate nailing in 30 patients and delayed nailing in another 30 patients and the outcome is measured in GA Type II, IIIA and IIIB fractures, with 10 patients in each Sub-Group. Results of 60 patients suffering from tibial diaphyseal fractures after their written informed consent were selected for the study. Fixator was applied until wound healing, which depends upon the severity of wound and types of Fracture. Mean of 10 days was required for GA Type II, 25 days for GA Type IIIA and 32 days for GA Type IIIB. Time to weight bearing included the time of External Fixator applied.

Inclusion criteria

Only those patients who gave consent were included in the study, adult patients (>18 years), fracture type Grade II, IIIA and IIIB open tibial diaphyseal fractures (4 cm distal to tibial tuberosity and 4 cm proximal to ankle joint), duration of injury <24 hrs, competent neurological and vascular status of the affected limb, ipsilateral hip, knee, ankle and contralateral lower limb in functionally good enough so as not to exert a serious adverse effect on the rehabilitation process, only patients with a near normal daily activities of life and patients who meet the medical standards for routine elective surgery.

Exclusion criteria

Patients who do not give consent, inability to take part in post-operative rehabilitation, Grade IIIC open fractures, medical contraindications to surgery, previous tibial abnormalities (infection, tumour), patients with multiple major bone fractures, duration of injury >24 hrs, associated ipsilateral or contralateral major limb injury affecting treatment. Initial care and work up of the patient was done regarding pre-operative preparation, antibiotic and anaesthesia. Surgical technique started with patient positioning,

skin preparation and draping, debridement. Entry point was done as per the standard protocol, reduction of fracture was done with proximal and distal locking. Closure of wound was done with the help of plastic surgeon as and when required. In another group external fixator was applied with thorough debridement followed by un-reamed solid intra-medullary nailing done later, when the wound healed. Standard post-operative protocol was done with early mobilization in both group and follow up as per our protocol.

Criteria for union

Union at fracture site was defined as bridging callus in a minimum of three cortices on anteroposterior and lateral radiographs combined with a lack of tenderness at the fracture site or unassisted weight bearing. Delayed union was defined when the fracture did not show any signs of healing for 2 months even after dynamisation was performed along with clinical symptoms like pain and difficulty on bearing weight [1]. Non-union was defined when 9 months had passed after the surgery and no progressive signs of union were seen for 3 consecutive months (Food and drug Administration, USA). The functional results were evaluated using the criteria of Johner and Wruh criteria [2]. Statistical analysis was done using suitable bio-statistical technique on each variable in the same patient and between two treatment groups. Statistical screening of treatment effect was measured by relative risk reduction, absolute risk reduction with adjustment for a small sample size and confounders in the study. Paired t test and other appropriate tests were applied to check for presence of significant difference in outcome variable in two groups.

The software InStat Graph pad was used in the analysis. P-value less than 0.5% was considered significant.

RESULTS

60 patients of type GA Type II, IIIA and IIIB compound tibial shaft fractures were randomly allocated into two groups of treatment.

I. Immediate un-reamed interlocking Tibia Nail (n=30)

II. Delayed interlocking Tibia Nail (n=30).

30 patients were allocated in each treatment group as per randomization seed no 5233.

Table 1. Treatment methods used in various cases.

Open grade (GA)	Immediate nailing	Delayed nailing
Type II	14	10
Type IIIA	08	12
Type IIIB	08	08
Total	30	30

In immediate nailing group all skeletal fixation was done within 24 hrs. The average time for full weight bearing in the immediate nailing group (n=3) was 11 weeks (range 5 - 28 weeks). In delayed nailing group, full weight bearing started at an average of 24 weeks (range 14 - 45 weeks), which included the days of External Fixator applied (Table 1).

Table 2. Average full weight bearing time in immediate and delayed nailing group.

Open grade(GA)	Immediate nailing (in weeks)	Delayed nailing (in weeks)
II	7(5-8)	21(14-28)
IIIA	13(8-28)	28(20-32)
IIIB	16(12-20)	38(24-45)

Early ambulation in immediate nailing is quite striking and statistical difference too comes out to be very significant (p value=0.011).

The average time of union in the immediate nailing group (n=26) was 23 weeks (range 14 weeks to 40 weeks). In delayed nailing group, union occurred at an average of 35 weeks (range 24 weeks to 48 weeks), which included the days of external fixation application.

The statistical difference between immediate and delayed nailing comes out to be very significant (p-value=0.0001) (Table 2).

The functional results, as assessed by Johner and Wruh’s criteria, showed that majority (n=45, 75%) of the patients in the immediate nailing group had excellent to good functional results (Table 2).

Table 3. Functional results in all open grade separately.

Open grade(GA)	Immediate nailing		Delayed nailing	
II	E	12	E	2
	G	2	G	7
	F	0	F	1
	P	0	P	0
IIIA	E	5	E	7
	G	1	G	4
	F	2	F	0
	P	0	P	1
IIIB	E	4	E	5
	G	1	G	2
	F	2	F	0
	P	1	P	1

E: Excellent, G: Good, F: Fair, P- Poor.

In open grade II we have 12 excellent functional result after immediate nailing (n=12/14) and 2 in delayed nailing (n=2/10). The p-value is 0.002, which is quite significant. In open grade IIIA 5 excellent functional results in immediate nailing (5/8) and 7 in delayed nailing (n=7/12), the p-value is 0.732, which is not significant. In open grade IIIB occurrence of excellent functional result was 4 and 5 respectively (4/8 and 5/8) in immediate and delayed nailing group. The p-value=0.280 statistically which is not significant (Table 3).

DISCUSSION

Fracture of the tibial diaphysis is a very common injury and it continues to pose a difficult challenge for the orthopaedics surgeon. With an eventful history of both non-operative and operative treatment, the current opinion is still controversial. Davis [3] performed the first immediate internal fixation following timely initial debridement of open fractures. McGraw et al. [4] noted high rate of infection if nailing was done after removal of fixator. Katzenian [5], Riemer [6] and Yokoyama et al. [7] believed there are definitive advantages of primary internal fixation provided infection could be prevented by careful and radical debridement and use of antibiotics. All immediately closed cases went for uneventful healing in immediate nailing except one which was open grade II

which got superficial infection (8.33%) while 4 cases got infected in open grade III (28.2%). This shows trend towards primary closure of compound wound. Yokoyama et al. [7] concluded that early skin closure within 1 week is the most important factor in preventing deep infections when treating open tibial fractures. Fischer et al. [8], Yaremchuk [9], Hohmann et al. [10], Levin et al. [11], Osterman et al. [12], Gopal et al. [13] have also documented significantly better outcomes with early closure (within 7 days). Siebenrock et al. [14] reported average full weight bearing time in delayed nailing group to be 27, 27, and 41 weeks respectively in open type II, IIIA, IIIB fractures, which is comparable to our study. Our study showed that immediate nailing led to faster union compared to delay nailing. Results of Reimer et al. [15] union rate 7.6 months, Singer and Kellam [16] union rate 6.1 months, Schandelmaier et al. [17] union rate 25.8 ± 14 weeks, Hasse et al. [18] 6 months and Osterman et al. [12] -23.5 weeks were also comparable to our study. Singh et al. [19] found delayed union rate of 26.6% in their study concluded that un-reamed interlocking with solid nail is a good mode of immediate internal fixation of compound fractures of tibia (grade I - IIIB) as it allows early weight bearing, minimizes the chances of infection and delayed union and has led to union in almost all the cases. We believe that the un-reamed smaller diameter nails failed to provide sufficient rotational stability. We agree with Blachut et al. [20] that the nails inserted without reaming are usually smaller diameter nails which provide less stability. The weak link are the locking screws, that too the distal ones. Other authors have also reported similar problems in patients who were not allowed early weight-bearing.

CONCLUSION

Achievement of length, apposition, axial and rotational alignment provides excellent functional results following interlock nailing of fractures of tibial diaphysis. A proper pre-operative planning as well as intra-operative observance of basic surgical principles is essential for treating these fractures. A thorough knowledge of the concept features and procedure of intra-medullary interlocking nails as well as soft tissue coverage is required. Un-reamed solid Intra-medullary interlocked nailing provides excellent results in function as well as union, especially in GA Type II fracture. Immediate nailing led to earlier union in this study. Statistically significant differences were found in case of union rate and full weight bearing in favor of immediate nailing. A multi-centric randomized control trial, possibly triple blinded in nature, involving a large number of patients with long term follow-up is clearly needed to bring the differences between the two techniques and making the study more significant.

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