

Original Research Article

Comparative study of minimally invasive plate osteosynthesis and interlocking nailing in the management of closed distal tibia fracture: A randomised controlled trial**Banikanta Sharma^{1*}, Chingshubam Imobi Singh², Heisnam Kulabidhu Singh³**¹*Associate Professor, Department of Orthopedics, JNIMS, Imphal, Manipur, India*²*Assistant Professor, Department of Orthopedics, JNIMS, Imphal, Manipur, India*³*Associate Professor, Department of Community Medicine, JNIMS, Imphal, Manipur, India***Received: 04-10-2021 / Revised: 13-11-2021 / Accepted: 22-12-2021****Abstract**

Introduction: Distal tibia fractures constitute 10-13% of all tibia fractures. There are two well accepted ways of surgical management of such fractures viz. minimally invasive plate osteosynthesis (MIPO) and intramedullary interlocking nailing (ILN). Earlier studies have shown that both have their inherent complications. **Aims & objectives:** The current study was done to compare the functional recovery among patients who had distal extra-articular fracture AO type 43A treated with ILN and MIPO technique. **Material & methods:** An RCT was done in the Orthopedics Department, JNIMS during Sept. 2018-Aug. 2020 among 62 adult patients who had closed distal tibia fractures and were medically fit for surgery. Demographic profiles and pre-operative findings were recorded. They were randomly allocated to two groups (ILN and MIPO). The intra-operative details were noted. Patients were then followed up every 4 weekly for 7-9 months until union occurred. Results were interpreted on the basis of AOFAS score for a minimum period of 5 months after surgery. **Results:** 60 adult patients (30 in each of the two intervention arms) could be followed up for the desired period. There was no significant difference in the time taken for surgery in both the two groups. The mean hospital stay in ILN group (6.4; SD-0.81 days) was found to be significantly shorter while compared to MIPO group (7.47; SD-2.67 days) ($p=0.001$). Otherwise, there were no significant differences regarding time taken for partial and full weight-bearing and time taken for union. Functional outcome was excellent in both arms (MIPO=90%; ILN-93.3%). The remaining cases had good scores. Anterior knee pain and mal-alignment were the main complications in ILN group (8; 23.8% each) whereas, ankle stiffness (8; 23.8%) and superficial infection (6; 20%) were the common complications in MIPO group. **Conclusion:** Both minimally invasive plate osteosynthesis with a medial distal tibial locking plate and closed reduction with intramedullary nailing are almost comparable in terms of the intra-operative and post-operative outcomes. Hence, both are viable options for management of extra-articular fractures of the distal tibia, with each having its own merits and demerits.

Keywords: Distal tibia fracture, Intramedullary interlocking nail (ILN), Minimally invasive plate osteosynthesis (MIPO)

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Introduction

In this fast moving era, vehicular accidents and other forms of accidents are encountered more often. High energy motor vehicle trauma, falls, direct blows and sports injuries can cause tibial fractures[1]. All tibial fractures are usually associated with soft tissue injury. If they are not properly treated, they may cause substantial disability to the patient. Distal tibia fractures constitute 10-13% of all tibial fractures[2]. Better understanding of the injury patterns, availability of better implants, the concept of early surgical fixation and early post-operative mobilization of joints have convincingly improved the functional outcome of the patients to a large extent. Minimally Invasive Plate Osteosynthesis (MIPO) and Intramedullary Interlocking Nail (ILN) are two well-accepted and effective methods. But each method has its inherent complications. Mal-alignment and knee pain are frequently reported after ILN whereas, wound complications and implant prominence have been associated with tibial plating. Hence, it was felt important to compare the outcomes between the two methods.

Aim

The present study was done to compare the functional recovery among patients who had distal extra articular fracture AO type 43A treated with ILN and MIPO technique.

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E-mail: sharmabanikanta@gmail.com**Material & methods**

A Randomized Controlled Trial was taken up in the Orthopedics Department of the Jawaharlal Nehru Institute of Medical Sciences (JNIMS), Imphal during the period September 2018 – August 2020. All adult patients aged ≥ 18 years with closed distal tibia fractures in the ward and found medically fit for surgery included. Patients with pathological fractures, fractures extending to ankle joint and those not willing to undergo surgery were excluded.

A sample size of 28 in each arm of the study was scientifically calculated by considering 6.6% good functional outcome by using American Orthopedics Foot and Ankle Surgery (AOFAS) score-group A and 40% good functional outcome by using AOFAS score-group B[3], 95% Confidence interval and a power of 90%. To this estimated sample size, 10% was added for possible drop-outs during follow-ups giving a final sample size of 31 in each arm. After getting informed consent, eligible patients were allocated into Group A (MIPO technique) and Group B (ILN) using simple randomization technique. Demographic profiles of the patients were collected by using an interview schedule. All pre-operative assessment details and necessary basic and advanced investigative findings were also recorded systematically by using a *pro forma*.

For patients allocated to ILN, in the operation theater, under spinal anesthesia, a 3 inches-long incision was made along the medial border of the patellar tendon, extending from the tibial tubercle in a proximal direction. The patellar tendon was retracted laterally to expose insertion site which was made with a diamond awl and a window was tunneled to the medullary canal. Reduction was achieved by traction and closed manipulation or by making an incision at fracture site for open reduction. Then, reaming was done by inserting a guide wire

which was later replaced with a smooth tip for nail insertion. Solid nails were inserted without guide wire. When the nail has passed into the distal fragment, the guide-wire was removed and during seating of the nail traction was released to allow impaction of fracture. Proximal locking screws using jig attached to the nail insertion device were inserted after tightening all connections between the insertion device, drill guide and the nail. Distal locking was performed by using free-hand technique after perfect circle was obtained by fluoroscopy. Alignment was improved by small movements of the nail. Then, the hole was tapped and 4.5mm screws insertion was done which was repeated for all other holes. Lastly, after skin closure compression bandaging was done and above knee slab was applied.

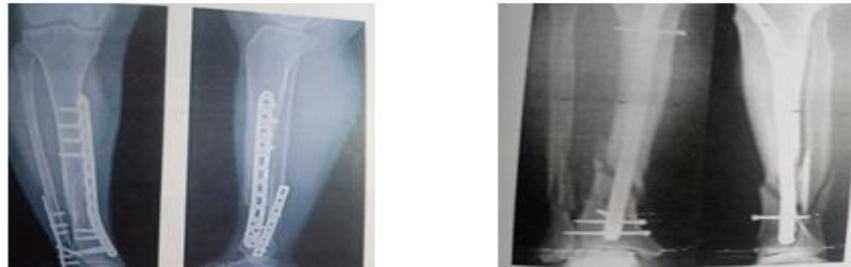


Fig. 1: Post-operative x-rays in MIPO and ILN

Patients were followed up every 4 weekly for 7-9 months until union occurred. Results were interpreted on the basis of AOFAS score for a minimum period of 5 months after surgery. The score was categorized as (i) Excellent (90-100 points) (ii) Good (80-90 points) (iii) Fair (60-79 points) and (iv) Poor (<60 points).

Data collected were entered and analysed by using SPSSv22 software (IBM). Both descriptive and analytical (χ^2 test) statistics were used. A p value of <0.05 was considered as statistically significant.

Ethical approval for the study was obtained from the Institutional Ethics Committee, JNIMS. Strict confidentiality was maintained for the data.

For MIPO, a 3-4 cm long longitudinal incision was made bone-deep over the medial malleolus. The saphenous nerve and vein were retracted anteriorly. Then an epiperiosteal space tunneling towards the diaphysis was made using periosteal surfer. Reduction was achieved with manual traction and manipulation. Anatomically, precontoured plate was centered on the tibia which was confirmed radiologically through AP and lateral views. Cortical screws were inserted first depending on the need of reduction in proximal or distal fragment. After reduction was confirmed, locking screws were inserted with the aim of achieving a minimum of 6-8 cortices on either side of the fracture. Lastly, after closing wound in layers it was immobilized with an above-knee slab.

Results

Of the 62 patients included in the study, two patients, one each from the two intervention groups) were lost in the follow-up. The age-group analysis between the two groups showed that they were comparable. Majority of the patients in both the groups were males (MIPO – 86.7% and ILN – 80 %). Road traffic accident was the commonest cause leading to the fracture (80% in both groups). Most of the MIPO group had comminuted fracture (26; 87.6%) whereas most of the ILN group patients had transverse fractures (26; 87.6%). In MIPO group, duration of surgery lasted for 55-125 (mean; SD =79.9; 20.49) minutes, whereas, for ILN group, it lasted for 51-128 (mean; SD=69.5; 22.12) minutes. The difference was not statistically significant ($p=0.52$). (Table 1)

Table 1: Comparison of Intra- and post-operative outcome between MIPO and ILN groups

Variable	Group	Mean (SD)	P value
Duration of surgery (min)	MIPO	79.9 (20.49)	0.52
	ILN	69.5 (22.12)	
Hospital stay (days)	MIPO	7.47 (2.67)	0.001
	ILN	6.4 (0.81)	
Time for partial weight-bearing (week)	MIPO	5.87 (2.52)	0.18
	ILN	5.07 (2.33)	
Time for full weight-bearing (week)	MIPO	17.87 (2.52)	0.18
	ILN	17.07 (2.33)	
Time for union (week)	MIPO	20.4 (3.84)	0.288
	ILN	18.93 (2.96)	

The mean (SD) hospital stay in the two groups were MIPO - 7.47 (2.67) and ILN - 6.4 (0.81) days. The difference was found to be statistically significant ($p=0.001$). Otherwise, there were no statistically significant differences when compared for time taken for partial and full weight bearing and union.

Regarding clinical functional and radiological outcome, 27 (90%) patients in MIPO group and 28 (93.3%) of patients in ILN group had excellent score while the remaining 3 patients in MIPO group and 2 patients in ILN group had good score.

A few complications occurred in both the groups. Anterior knee pain (8; 23.8%), mal-alignment (8; 23.8%), angulation $> 5^\circ$, knee/ankle stiffness etc. were reported in ILN group while ankle stiffness (8; 23.8%), superficial infection (6; 20%), implant irritation, mal-alignment etc. were seen in the MIPO group. All the cases which had mal-alignment evident on immediate post-operative period healed in the same position at follow-up of one year and no significant change was noted.

Discussion

Male predominance among patients having distal tibia fractures have been observed by other scholars both from the country as well as from abroad[4-8]. This can be attributed to more outdoor activities and heavier labor undertaken by males as compared to females in the Indian set-up. The most common cause of the fracture being RTA followed by fall and assault was also observed by Guo JJ et al and Yang Li et al[7,9].

Hospital stay in ILN group was found to be significantly shorter than in MIPO group in the present study while other parameters were comparable. The mean time of union in MIPO group was found to be 20.4 weeks while that of ILN group was 18.9 weeks which was almost similar without any statistically significant difference. Similar observations were made by Eknath PD et al, Kasper W et al and Bahari S et al[10-12].

The mal-alignment seen in 23.8% in ILN group and 14.3% in MIPO group could be due to intra-operative error. Occurrence some mal-

alignment in a few cases both in ILN and MIPO groups were also reported by other researchers[5,6].

Anterior knee pain and valgus angulations were the most common complications seen in ILN group, whereas implant irritation and ankle stiffness were the most common complications in MIPO group. Studies done earlier by Guo JJ et al, Bahari S et al and Redfern DJ et al all showed similar complication patterns[9,12,13].

Conclusion

Based on our present study findings, it is concluded that both minimally invasive plate osteosynthesis with a medial distal tibial locking plate and closed reduction with intramedullary nailing are almost comparable in terms of the intra-operative and post-operative outcomes. Both give excellent results in terms of functional outcome in most of the cases. Hence, both are viable options for management of extra-articular fractures of the distal tibia, with each having its own merits and demerits.

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