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Prospective comparative study of extra-articular distal tibia fractures-intramedullary nailing versus medial minimally invasive percutaneous plating

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ABSTRACT

Background: The distal tibia extra-articular fractures are treated with both intramedullary nailing (IMN) and medial minimally invasive percutaneous plate osteosynthesis (MIPPO). The aim of this study was to compare the results of IMN and medial MIPPO in distal tibia fractures. The complications and secondary interventions in both groups were compared.
Methods: Fifty patients with distal tibia were randomly assigned to IMN (group 1) and medial MIPPO group (group 2). The functional outcomes were evaluated using American Orthopaedic Foot and Ankle Society (AOFAS) score. Complications like infection, delayed union, non-union, malunion, hardware prominence and secondary interventions were compared.
Results: The average union time was 21.12±6.93 weeks in group 1 and 23.56±6.96 weeks in group 2 (p=0.220). The mean AOFAS scoring was 90.76±7.9 in group 1 and 88.4±8.33 in group 2 (p=0.339). Five patients in group 1 and one in group 2 had malalignment. Deep infection was present in one and superficial infection was present in two cases in group 2. None of the patients in group 1 had infections. Three patients in group I developed anterior knee pain and six in group 2 had hardware prominence. Seven cases in IMN group required secondary interventions and fourteen in medial MIPPO group.
Conclusions: Extra-articular distal tibia fractures are successfully treated with IMN and medial MIPPO with comparable functional outcomes. Prevalence of malunion was higher in IMN group and hardware prominence was more prevalent in MIPPO group. Implant removal are more in medial MIPPO group mostly due to implant irritation.

Keywords: MIPPO, IMN, Distal tibia, Extra-articular

INTRODUCTION

Distal tibia fractures are notorious fractures among all tibia fractures due to precarious blood supply, inadequate soft tissue coverage and proximity to ankle joint.[1] Intramedullary nailing is standard treatment of tibia fractures but wide medullary canal with small distal fragment result in difficult reduction, inadequate stability and malalignment.[2-4] The expert tibia nails with multiple distal screw options and use of pollar screws have solved the issue of stability and alignment to greater extent.[5,6] Extramedullary fixation with the use of medial locking plate achieves good fixation and stability but prone to soft tissue complications and hardware prominence.[7,8] Minimal invasive percutaneous plating decreases the soft tissue complications associated with conventional plating with open approach.[9]

Both the methods of internal fixation (intramedullary nailing (IMN) and medial minimally invasive percutaneous plate osteosynthesis (MIPPO)) are in use for extrarticular distal tibial fractures. The purpose of this study is to compare the clinical and radiological outcome and the complications of the two methods. The need of secondary procedures in both these groups is evaluated.

METHODS

This is a prospective randomized study conducted from 2016 to 2017 in the department of orthopaedics, Institute for Medical Sciences and Research Centre, Jaipur National University. This study was approved by institutional review board and all patients gave written informed consent prior to their inclusion in their study. We received 108 patients of distal tibia fractures during this period. Among these, 74 patients in the age group 18 to 70 years with closed extrarticular fractures of tibia were included in the study after obtaining informed, written consent and randomized in the two groups (IMN group- group 1 and medial MIPPO group-group 2). All polytrauma patients, paediatric fractures, proximal and diaphyseal fractures, segmental fractures, open fractures, pathological fractures, associated compartment syndrome and intraarticular fractures were excluded from the study. All patients were randomized in two equal groups by means of permuted randomization. Twenty-four patients who were lost to follow-up were also excluded. So, we are left with 50 patients, were randomized into two equal groups of 25 patients each.

The fracture patterns (type A1, A2, A3) were classified based on AO/OTA classification of fractures of distal tibia.[10] In group 1, patients were managed by interlocking intramedullary nailing while in group 2, the medial MIPPO technique was used. Additional fibular fixation was done in both groups depending on the level of a simultaneous fibular fracture. All surgeries were performed by a senior surgeon in order to avoid bias. All surgeries were performed under spinal anaesthesia. The timing of surgery was decided on the basis of swelling and soft tissue component.

Surgical technique

IMN: An interlocked intramedullary reamed tibial nail was used in all fractures. Access to the proximal tibia was provided by a transtendinous approach. The starting point was made with an awl and the nail was inserted in an antegrade manner by hyperflexing the knee. Reduction of the fracture often was achieved with gentle manipulation and traction by an assistant. All 25 cases were fixed with two proximal and two distal static locking screws.

Medial MIPPO: An appropriate length of distal tibia locking plate was placed parallel to the tibia axial line and on the medial surface of the operated leg under fluoroscopy. Two 4 cm and 2 cm longitudinal incisions were made on the skin beneath the distal and proximal ends respectively of the plate based on the plate location. One incision was at the anterior aspect of the medial malleolus, and the other was along the medial aspect of the tibia located at the proximal end of the plate. An extra-periosteal, subcutaneous tunnel then was formed between these 2 incisions using blunt dissection. The great saphenous vein was protected, and the plate was inserted percutaneously from the distal to the proximal site. Closed reduction by manipulative traction was performed under fluoroscopy to restore the length and coronal alignment of the leg. The plate position was adjusted when reduction was achieved. The lag screw was inserted depending on fracture pattern. Four to five screws were inserted distally and 3 to 4 screws were inserted proximally.

A standard post-operative follow-up protocol was developed. Active knee and ankle range of movements were started on the first postoperative day. Patients were followed up three weekly till fracture union and then 3 monthly for one year and twice in the year after that. Radiographic assessment included malalignment, time to union and loss of reduction. Patients were allowed weight bearing when callus was seen in two cortices either on an AP (anteroposterior) or lateral view. At final follow-up, clinical and radiological examination was done and patients were assessed by the American Orthopaedic Foot and Ankle Society (AOFAS) score.[11] The maximum score was 100 points. A value greater than 90 points was considered an excellent result, 75 to 89 was considered good, 50 to 74 was considered fair, and less than 50 was considered poor. Coronal and sagittal alignment was assessed by AP and lateral radiographs as per Paley and Tetsworth method. These angles were calculated from immediate postoperative radiograph and the final follow up radiograph. Rotation was assessed clinically by foot thigh angle and the difference measured by goniometer. Union was defined as consolidation of three or more cortices on radiography and lack of pain on weight bearing without assistance.[12] Malunion was defined as a varus or valgus of more than 5 degrees in the coronal plane (AP X-ray) and procurvatum or recurvatum greater than 10 degrees in the sagittal plane (lateral X-ray) or external or internal rotation of greater than 10 degrees (foot thigh angle) and shortening of limb more than 1cm. Delayed union and non-union were defined as failure of fracture union after six and nine months of surgery respectively. Any complication during the surgery and follow-up period was recorded. Any secondary interventions like debridement, revision implant and bone grafting were also recorded.

Average, standard deviation, percentage and range were used for data descriptive statistics. The comparison of continuous variables was performed by using the Student t-test or Kruskale Wallis test or Mann-Whitney U test in accordance with normality testing. Chi-square test or Fischer's exact test was used for qualitative data analysis. A value of p less than 0.05 was considered statistically significant.

RESULTS

Overall, the complete study included 50 patients, excluding patients lost at follow-up. In group 1 (IMN group) was included 25 patients, and in group 2 (medial MIPPO) were allocated 25 patients. The IMN group was assessed at a mean of 28.4 months (range, 24-33 months); the medial MIPPO group was assessed at a mean of 27.8 months (range, 24-35 months). There were no statistically significant differences in follow-up times (p=0.178).

Demographic data of both groups were similar as reported in Table 1. A fibular fracture was associated in 20 cases in group 1 (surgical treatment with plate and screws in 7 cases, and with Kirschner wire in 3 cases) and in 22 cases in group 2 (surgical treatment with plate and screws in 10 cases, and with Kirschner wire in 4 cases). There were no statistically significant differences in fibular fracture (p=0.161) and fibular fixation (p=0.229) in both the groups.

The clinical and radiological outcome of the two groups is described in Table 2. The mean union time was 21.12±6.93 weeks for the IMN group (range, 12-48) and 23.56±6.96 weeks for the Medial MIPPO group (range, 16-50). This difference in union time was not statistically significant (p=0.220). At last follow-up, the average AOFAS scores were 90.76±7.9 (range, 70-100) in the IMN group, 88.4±8.33 (range, 68-100) in the medial MIPPO group (p=0.309). There were no significant differences in the excellent or good results of ankle function among both groups (p>0.05). In the IMN group, the final range of motion was 17.08°±1.65° (14 to 20) in ankle dorsiflexion and 33.04°±5.67° (25 to 45) in ankle plantar flexion. In the Medial MIPPO group, the final range of motion was 16.36°±1.38° (13-18) in ankle dorsiflexion and 32.04°±4.58° (25 to 38) in ankle plantar flexion. There were no significant differences in ankle range of motion among both groups (p>0.05). The full-weight bearing time in IMN group was 17.08±7.71 (10 to 48) weeks as compared to MIPPO group 19.29±8.05 (12 to 50) weeks. This difference was statistically not significant (p=0.325).

Table 1: Demographic and operative data of the two groups.

Parameters	IMN group (25 patients)	Medial MIPPO group (25 patients)	P value
Age (years), range (mean±SD)	21-70, 44.4±14.11	21-66, 41.96±15.81	0.567
Male	17 (68)	16 (64)	1
Female	8 (32)	9 (36)	
Mechanism of injury			0.829
Low energy fall (%)	4 (16)	6 (24)	
High energy fall (%)	9 (36)	8 (32)	
RTA (%)	10 (40)	8 (32)	
Others (%)	2 (8)	3 (12)	
AO classification			0.681
A1 (%)	10 (40)	12 (48)	
A2 (%)	11 (44)	8 (32)	
A3 (%)	4 (16)	5 (20)	
BMI (kg/m^2), mean±SD (range)	26.66±2.245, (23.5-31)	25.39±2.5048, (21-30.5)	0.69
Smoker (%)	12 (48%)	10 (40%)	0.578
Time, trauma/surgery (days)	2.12±1.09 (1-5)	2.64±1.70 (1-7)	0.205
Fibula fracture (%)	20 (80)	22 (88)	0.161
Fibula fixation	10/20	14/22	0.229

RTA: road traffic accident; BMI: body mass index (calculated as weight in kilograms divided by height in meters squared).

Table 2: Comparative analysis of results obtained for clinical and radiological outcome.

Parameters	IMN group	Medial MIPPO group	P value
Full weight bearing (weeks±SD, range)	17.08±7.71 (10-48)	19.29±8.05(12-50)	0.325
Bone union time (weeks±SD, range)	21.12±6.93 (12-48)	23.56±6.96 (16-50)	0.220
AOFAS score (±SD)	90.76±7.9	88.4±8.33	0.309
Ankle dorsiflexion (degrees±SD)	17.08±1.65	16.36±1.38	0.101
Ankle planter flexion (degrees±SD)	33.04±5.67	32.04±4.58	0.49

Table 3: Comparison between complications in IMN group and medial MIPPO group.

Complications	IMN group	Medial MIPPO group	P value
Varus	3	1	0.306
Valgus	2	0	0.155
Recurvatum	0	0	1
Rotation	0	0	1
Shortening	0	0	1
Total malunion (%)	5/25(20)	1/25(4)	0.084
Delayed union (%)	1/25(4)	1/ 25(4)	1
Non union (%)	1/25(4)	0 /25(0)	0.322
Implant breakage (%)	1/25(4)	1/25(4)	1
Wound complication (superficial infection) (%)	0/25(0)	2/25(8)	0.155
Deep infection (%)	0/25(0)	1/25(4)	0.322
Hardware prominence (%)	0/25(0)	6/25 (24)	0.008 (<0.05)
Anterior knee pain (%)	3/25(12)	0/25(0)	0.076

Table 4: Secondary procedures performed in both the groups.

Secondary interventions	IMN group	MIPPO group	P value
Debridement	0/25	2/25	0.155
Implant removal	3/25	9/25	0.048 (<0.05)
Implant revision	1/25	1/25	1
Bone grafting	3/25	2/25	0.645
Total secondary interventions (%)	7/25 (32%)	14/25 (48%)	0.343

Data related to complications are reported in Table 3. In group 1, 5 patients developed malunion: three varus deformities, two valgus deformities. Instead in group 2, one patients developed malunion: one varus deformity. There were no statistically significant differences in malunion in both the groups (p=0.084). The superficial infection rate was 0% in group 1 while in group 2 was 8% with two patients developed infection (p=0.155). Deep infection was 0% in group 1 while in group 2, one patient developed late deep infection (p=0.322) after union, treated by removing the implant and adequate antibiotic therapy. In IMN group no patient had hardware prominence while in medial MIPPO group, six patients (24%) had hardware prominence over the medial shin of tibia. So, there was statistically significant (p=0.008) difference in hardware prominence in the two groups. In group 1, three patients developed anterior knee pain (12%). Non-union was observed in one patient in group 1, treated with bone grafting and dynamization. Delayed union was observed in one patient in group 1, treated with bone grafting and dynamization. In group 1, implant breakage was seen in one patient treated with implant removal, revised nailing with bone grafting. Delayed union was observed in one case in group 2, treated with bone grafting. In group 2, Implant breakage was seen in one patient treated with implant removal, revised plating with bone grafting. There were no statistically significant differences in non-union and delayed union in both the groups.

Total number of secondary interventions (Table 4) required in seven cases in IMN group in comparison to fourteen cases in MIPPO group (p=0.08). Reoperation for nail due to anterior knee pain or screw prominence was reported in 3 cases in group 1. Reoperation for plate removal due to hardware prominence was reported in 9 cases in group 2. The implant removal surgery in MIPPO group is significantly higher than IMN group (P=0.048).

DISCUSSION

Extra-articular distal tibial fractures often poses a challenge to an orthopaedician due to limited soft tissue coverage, insufficient vascularity, and close proximity to the ankle joint. The goal of operative treatment is to obtain anatomical alignment and good stability to allow early mobilization and weight bearing. At the same time, fixation should be accomplished using techniques that minimize osseous and soft tissue complications resulting from treatment. Although both IMN and MIPPO have proven to be effective and widely accepted fixation methods for distal tibia extra-articular fractures, these both methods are associated with some bone or soft tissue complications.[13] IMN has an advantage over other methods because of its minimal invasive biological fixation with early weight bearing and union rate, lesser incidence of infections. With the development of locking plates, axial and angular stability is provided but soft tissue complications are associated. The introduction of percutaneous plating allow biological fixation that

preserve periosteal blood supply of the fracture with less soft tissue complications.[14]

In our study, the patients were in the range of 21 to 70 years, with mean age being 43.18 years. Of the 50 patients, 33 were males and 17 were females. IMN group had 17 males; 8 females while Medial MIPPO group had 16 males; 9 females. Predominant male patients in our study were due to more outdoor activities, more use of vehicles and heavy labor undertaken by males as compared to females in the Indian population. In our study, most common cause for these fractures was RTA followed by heavy energy fall. Our results were comparable to other studies for the gender involvement and the mechanism of injury.[15,16]

The mean time for starting full weight bearing in IMN group was 17.08±7.71 weeks as compared to 19.29±8.05 weeks in MIPPO group, which was not statistically significant difference. In our study, we allowed full weight bearing only after signs of the union in form of bridging callus on at least three cortices out of four cortices on radiograph and clinically as the absence of tenderness and movement at the fracture site which was usually by 12 to 20 weeks. The mean time of union in our study was 21.12±6.93 weeks for IMN and 23.56±6.96 weeks for MIPPO. Our results were not statistically significant for the union time between the two groups as shown in studies done by Shen et al and Barcak et al.[16,17] There are studies done by Guo et al, Pawar et al, Yao et al showed faster union rate in IMN group.[18-20]

With respect to secondary procedures to achieve union in group 1, we dynamized and bone grafting 2 cases (8%), one with delayed union and one with non-union. We achieved union in case of delayed union in 2 months and non-union case in 12 months. One case of broken nail required revision nailing with bone graft that achieved union in 7 months. Nork et al reported performing secondary procedures (bone-grafting or dynamization) to promote union in 19% of patients.[12] In our study, malalignment was found in 5 cases (20%) patients treated with IMN whereas MIPPO had one case (4%). Three cases had valgus and two cases had varus malunion which were primarily fixed with IMN, and one had varus in MIPPO group. This was comparable to studies by Janseen et al, Kumar et al, Vallier et al and Pawar et al.[4,15,18,21]

In our study, symptomatic hardware was a common problem in the medial MIPPO plating group but was unusual in the IMN group. Totally 24% (6 cases) of the patients treated with medial plating requested a secondary operation to remove the implants because of the discomfort produced by the medial plate placed under the skin over anteromedial tibia. Lau et al reported similar results; in their study, 52% of distal tibia fractures treated by MIPPO required plate removal due to skin impingement. In contrast, in the IMN group, 3 cases (12%) had anterior knee pain at the nail entry site. Residual anterior knee pain after nailing also has been commonly reported.[19,22,23] The most frequent causes of pain were the extent of soft tissue injury, particularly injury to the patellar tendon and retropatellar fat pad, the entry point of the nail, and the protrusion of the nail.[23] Implant removal surgery is significantly more in plating group as compared to IMN group in our study. 2 cases of superficial and one case deep infection occured in medial MIPPO group. Theoretically, medial plating increases skin tension of the anteromedial tibia. Although the risk of wound necrosis, infection are less in percutaneous plating as compared to conventional plating, but still it is higher than IMN group in our study.[13,24]

Ankle dorsiflexion and planter flexion in IMN group is marginally better, but statistically insignificant. Functional outcome according to AOFAS score was measured in our study which came out to mean score was 89.58. The results of our study showed that both MIPPO and intramedullary nailing are equally effective in terms of functional outcome as shown in previous studies.[4,19,21,25]

CONCLUSION

Extra-articular distal tibia fractures are successfully fixed with IMN and Medial MIPPO with comparable functional results and union rates. Both these methods provide biological fixation with few wound related complications. However, malunion was more common in the IMN group, and hardware prominence was more prevalent in the medial MIPPO group due to implant irritation. Secondary procedures like implant removal are more in medial MIPPO group mostly due to implant irritation.

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