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Original Research Paper

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A PROSPECTIVE OBSERVATIONAL STUDY ON CLINICAL, FUNCTIONAL & RADIOLOGICAL OUTCOMES OF NAILING VS. PLATING IN PATIENTS HAVING FRACTURE DISTAL TIBIA.

Dr Anil Prakash — Professor & HOD , Department Of Orthopaedics, NAMO Medical Education & Research Institute, Shri Vinoba Bhave Civil Hospital, Silvassa, Dadra And Nagar Haveli UT.

Dr Dheeraj L Bhoi* — Senior Resident, Department Of Orthopaedics, NAMO Medical Education & Research Institute, Shri Vinova Bhave Civil Hospital, Silvassa, Dadra And Nagar Haveli UT. *Corresponding Author

Dr Gaurav Chaudhari — Senior Resident, Department Of Orthopaedics, NAMO Medical Education & Research Institute, Shri Vinova Bhave Civil Hospital, Silvassa, Dadra And Nagar Haveli UT.

ABSTRACT

Introduction: The treatment approach for meta diaphyseal fractures is distinct from that for articular impaction "pilon" fractures and mid-shaft diaphyseal injuries. The conservative management of distal diaphyseal or metaphyseal tibia fractures presents difficulties, and specialists still discuss the best surgical method. When surgery is necessary, surgeons must choose between plating and antegrade intramedullary nailing. **Objectives:** A comparative analysis of two series of patients operated with MIPO plating and ante-grade intra-medullary interlock nailing will be presented in this study, with a focus on their functional outcomes, complications, and other important parameters. **Methods:** A total of forty patients participated in the study and were subsequently divided into two groups, with twenty individuals in each group. Prior to this division, the patients were informed about the advantages and disadvantages of both surgical techniques: Group A underwent plating, while Group B received intramedullary nailing (IMN). Patients were advised to engage in partial weight bearing, with full weight bearing permitted upon the observation of calcified callus formation. Follow-up assessments were conducted at six weeks, three months, six months, and nine months post-surgery. **Results:** Every patient was monitored for a year. In both groups, the time it took for callus to form was equal. In our series, one case of plating had malunion. In the nailing group, non-union was more prevalent. Both groups had OMAS score. **Conclusion:** When treating distal tibial extra-particular fractures, MIPO and intramedullary nailing are both efficient therapeutic strategies with similar functional results.

KEYWORDS : MIPO (Minimally invasive Plate Osteosynthesis, Distal tibia Fracture, Intra Medullary Nailing.

INTRODUCTION

Meta diaphyseal fractures require a different approach than articular impaction "Pilon" fractures or middle third diaphyseal injuries[1].Distal extra-articular tibial fractures, which are seen 4–12 cm from the tibial plafond, are frequently included in distal tibial fractures (AO 42A1 and 43A1). Subdivisions 43-A1 into non-comminuted extra-articular fractures, 43-A2 into wedge fractures, and 43-A3 into comminuted extra-articular fractures are further classified according to morphology and degree of comminution. 43-B1 fractures, which are frequently treated similarly to 43-A fractures, are defined as those that extend into the joint without causing a depression in the joint surface[2-4].

Distal tibia fractures are difficult to manage due to their specific anatomical characteristics, such as proximity to the skin on the anterior medial side, minimal soft tissue coverage, and poor blood flow[5]. At present, intramedullary nailing (IMN) and plate fixation represent the predominant therapeutic approaches for managing fractures of the distal tibia[6].The technique of intramedullary nailing is characterized by its minimally invasive nature, whereby small incisions in the skin are implemented, the nails can be effortlessly extracted, a greater preservation of extraosseous blood supply is achieved, and the extent of soft tissue injury is significantly reduced[7]. The prompt initiation of the process of union, coupled with the early implementation of weight-bearing activities, significantly contributes to the enhancement of the healing process while simultaneously mitigating the likelihood of encountering a diverse array of potential complications that may arise during the recovery phase[8-11]. Plate fixation is accomplished by open reduction and internal fixation (ORIF) or minimally invasive percutaneous plate osteosynthesis (MIPO). The ORIF approach, which requires more extensive wound exposure and soft tissue dissection, increases the risk of wound complications and delayed union[12].MIPO has the potential to offset the disadvantages of ORIF by using an indirect bridge reduction strategy that causes less blood supply damage[13,14].There is little consensus on whether IMN or plate fixation is superior for distal tibia fractures, making the ideal surgical method a questionable decision. Numerous retrospective studies comparing both surgical procedures yield low levels of evidence due to their design[15-17].Several randomized controlled trials (RCTs) have addressed this issue, but the sample sizes are generally limited, limiting their statistical power to identify differences in complication rates[18-20].

Aim

This study will compare the clinical and radiological effects of intramedullary nailing and MIPO Plating in individuals with a distal tibia fracture.

MATERIALS AND METHOD

A Prospective cohort study was carried out at the Department of Orthopaedics, Shri Vinoba Bhave Civil Hospital, Silvassa. Informed consents were obtained from the patients, as well as approval from the hospital's ethical committee, to undertake a comparative analysis of the two methodologies employed in fracture fixation. The study was for one year duration.

40 patients with fracture distal tibia were treated with 20 patients with Minimally Invasive Plating and 20 patients with intra medullary nail in our study.

Inclusion Criteria

(1) Fractures of the distal tibial metadiaphysis
(2) Fractures that are closed or Gustilo grade-I or grade-II open fractures.
(3) Skeletally mature adult patients

Exclusion Criteria

1) proximal intra-articular or distal intra-articular fractures of the tibia
2) Limb having vascular injury fractures due to pathology
3) previous fractures of the same leg
4) open fractures Gustilo grade 3a,3b,3c.

Treatment Protocol –

All these patients were treated according to protocol which consists of the following;

Standard anteroposterior and lateral radiographs Fracture classification is done according to AO classification system Open wound fractures were classified with Gustilo Anderson system and posted at operation theatre for proper wound management and debridement Radiographs were used to decide the appropriate plate length, length of interlocking nail and planning of surgery All patients were operated within 3 to 7 days of injury 4.5mm distal tibia anatomical plate and tibia interlocking nail was used. The fibula was initially stabilized utilizing either a 3.5 mm one-third semi-tubular plate or an elastic nail, with its stabilization being autonomous from the fixation technique employed for the tibia. knee and ankle range of movement exercises post operatively Advised B/K slab and patient discharged Patients were followed up for routinely for wound care mobility and union status.

Surgical Technique

For tibia ILN

The surgical intervention was performed with patients under spinal anesthesia, positioned supine on a standard radiolucent table. Intravenous antibiotics were administered prophylactically 15 minutes before the skin was incised. An image intensifier provided fluoroscopic guidance throughout all procedures. The patient's hip was flexed to 45° and knees to 90° on the radiolucent table. A 5-cm incision was created along the patellar tendon's medial border, extending proximally from the tibial tubercle. Lateral retraction of the patellar tendon exposed the insertion site and protected it during the process. The awl was introduced at the junction of the anterior tibia and the joint. Particular attention was paid to maintaining an extra-articular position to prevent potential impingement of the nail's posterior aspect on the femoral condyle. The nailing procedure followed established protocols, with each fracture secured using two proximal and two distal locking screws.

For MIPO

The leg was prepared from toes to mid-thigh and draped freely in a circumferential manner. A 3–4 cm long, bone-deep longitudinal incision was made over the medial malleolus, long enough to accommodate screws in the distal fragment. Both the saphenous vein and nerve were anteriorly retracted and preserved. Next, using the plate's blunt tip, an epiperiosteal space tunneling was created toward the diaphysis. Traction and manipulation by hand were used to accomplish the reduction. A precontoured plate was used anatomically, and it was passed through the subperiosteal tunnel to be placed on the anteromedial aspect of the distal tibia. After the plate was inserted and the reduction was achieved, one locking screw was used to secure the proximal fragment and K-wires were used to temporarily fix the plate to the bone. Cortical screws and locking screws were used in tandem to fix the distal fragment. Placing the lag screw was decided upon based on the quality of the bone and the fracture pattern. Screws were inserted into the proximal fragment using tiny stab incisions.

Post Opertive Care

After surgery, all patients were placed in a long leg plaster splint. All patients under the physiotherapist's supervision were encouraged to mobilize their ankle joints as soon as the swelling from the wound decreased. Depending on the development of the bony union, decisions regarding weight bearing were made individually. Patients with intraarticular fractures that were only slightly displaced were placed in a short leg cast for three weeks. Patients were evaluated every two weeks until the third month following surgery, and then every month for one year.

Assessment Of Outcome

After the fracture union, the patients were reviewed annually after the operation. Standardized anteroposterior and lateral roentgenographs were taken at the time of the evaluation. Fracture healing was defined as the time when the patient had no pain or tenderness on the fracture site, walking painless with full weight bearing, and the bridging callus was seen to cross the fracture on three of four roentgenographic views. Nonunion was defined as a fracture that failed to unite by the ninth month after the operation. The range of the motion from maximum active dorsiflexion to neutral position was determined with the use of a goniometer. The functional ankle scores as described by Olerud and Molander was recorded.[17] To limit the bias inherent in all clinical examinations and manual tests, the final follow-up examination, 1 years after the operation, was performed by an independent physician who had not been involved in the actual treatment of any of the patient. The final findings after a one-year follow-up were evaluated using the "Johner and Wruhs' Criteria"[(21)] of excellent, good, fair, and poor.

Statistical Analysis

A statistical analysis was undertaken to assess the relationships between positive predictive variables and clinical outcomes.

For qualitative data comparison, the chi-square test was utilized. The demographic factors were compared between treatment groups using the student t-test. Statistical significance was determined for all cases at $P < 0.05$. GraphPad InStat 3 statistical software was used to conduct the analysis.

RESULTS

Table 1 (Demographic Data)

Age	Number of patients	
	ILN	PLATING
<25	2	1
25-34	5	3
35-44	8	11
45-54	4	3
>55	1	2
Sex	Number of patients	
	ILN	PLATING
Male	15	12
Female	5	8
Mode of Injury	Number of patients	
	ILN	PLATING
Road traffic Accident	14	12
Direct Blow/Assault	3	3
Fall	3	5
FRACTURE CLASSIFICATION(AO)	Number of Patients	
	ILN	PLATING
43-A1	7	6
43-A2	8	8
43-A3	5	6

Table 2 (Clinical & Functional Outcome)

	ILN	PLATING
Time for Union(weeks)	16.9	17.2
Malunion	0	1
Nonunion	1	0

Table 3 (Radiological Outcome)

	ILN	PLATING
Surgery time (In minutes)	62.2	71.9
Time for Partial Weight Bearing	6.1	6.2
Time for Full Weight Bearing	17.1	17.5
Superficial Infection	1	1
Deep Infection	0	1
OMAS score	86.8+/-7.8	76.4+/- 6.5

A total of 27 men and 13 women with an average age of 38.4 years (18–72 years) were assessed. Both the groups were similar with respect to mode of injury, radiological type of fracture (P value > 0.05; Table 1).

There were no statistically significant differences be- tween the two techniques with respect to time to partial weight bearing, time to full weight bearing. the mean operating time was longer in plating group but no statistical significance. There were only 1 case of superficial infection which healed with local wound care and antibiotics. Early Implant removal was not needed. The implant was removed, PTB applied and antibiotics started to treat the one deep infected case. functional results evaluated according to the OMAS score in both groups. In the analysis with the Fisher two-sided exact test, no significant difference was found between the groups. (table 2). According to Johner and Wruh's criteria, the majority (56.28%) of the study's participants had outstanding functional results (IMLN: 58.35%; MIPO: 53.54%), whereas 23.68% had good results (IMLN: 16.54%; MIPO: 26.93%). These differences were not statistically significant, according to the Chi-square test (P = 0.6355).

Fracture healing and nonunion were assessed according to the definition of Im and Tae. The mean time to tibia fracture union for all patients was 17.05 weeks (16.1–17.8). one patient has malunion. That fractures were initially stabilized in a malaligned position. one patient had nonunion which occurred after plating. He underwent bone grafting at 32 weeks. The fractures united without further surgery.

DISCUSSION

In the context of distal tibial fractures, surrounding soft tissues often suffer damage; therefore, it is very important to employ a treatment that respects these tissues.

Extra-articular distal tibial fractures might be difficult for the surgeon to treat because of the soft tissue condition and degree of comminution. Achieving anatomical alignment of the joint surface while maintaining sufficient stability to permit early motion is the aim of surgical treatment. In an effort to reduce treatment-related problems, this should be achieved by employing methods that reduce osseous and soft tissue devascularization.

For distal tibial fractures in a group of 64 patients, Im et al. prospectively compared open reduction and plate and screw fixation with closed reduction with IMN. Despite reporting same functional ankle ratings, participants in the IMN group had superior ankle dorsiflexion.

The advancement of minimally invasive surgical techniques has led to percutaneous plating emerging as a competitor to interlocking nailing. This is due to the fact that locked plate designs function as fixed-angle devices, offering stability through axial and angular support at the screw-plate interface, rather than depending on the frictional force between the plate and the bone. This mechanism is believed to help maintain the periosteal blood supply surrounding the fracture site.(doi https://doi.org/10.1007/s00068-008-8049-1)

In our study, the patients were in the range of 21-57 years, with mean age being 36.7 years. Of the 40 patients, 27 were males and 13 were females. Males probably had predominant involvement in our study due to undertaking more outdoor activities and heavier labor compared to females in the Indian set up. The result was comparable to that of J.J. Guo et al[19]., N. Ali et al.[21], Y. Li et al[22].

In our study, most common cause for these fractures was RTA followed by fall. Our results were comparable to other studies by N. Ali et al[21]., E. Vaienti et al[23]., H. A. Vallier et al[24]. Kumar et al(25). conducted a study involving 52 patients who underwent surgical treatment for distal tibia fractures. Among these cases, 32 patients (61.5%) sustained their injuries due to road traffic accidents, while 17 patients (32.6%) experienced fractures from self-falls.

In our study, the operating time in the intramedullary nailing group ranged from 50 to 75 min (mean 62.24 ± 9.40 min), while in case of lock plate it ranged from 65 to 85 min (mean 71.89 ± 6.48 min). This was comparable to studies done by Guo et al[19]., Li et al[22]., In our study, time for partial weight bearing in the intramedullary nailing group ranged from 6 weeks to 7 weeks (mean 6.1 weeks), while in case of lock plate it ranged from 6 weeks to 8 weeks (mean 6.2 weeks). This was comparable to studies done by Janssen et al.[27], Ali N. et al.[21], In terms of union time, we did not achieve any noteworthy outcomes. Union was likely advanced by a shorter bearing time in the IMN group and a more anatomical reduction in the LP group.

superficial infections were reported in 5% of plating cases & 5% of nailing group cases, while deep infection was reported 5% in plating group and not in nailing group. Superficial infection was seen in distal locking screw which was debrided and 2 weeks of antibiotic treatment healed the site. At the end of the fourth month, one patient in the MIPO group showed clinical symptoms of an infection related to the implant. The wound was debrided and the implants were taken out. Following the collection of deep tissue samples for bacterial culture, methicillin-resistant Staphylococcus aureus (MRSA) was identified. The patient used a patellar tendon-bearing (PTB) brace for the duration of his four weeks of antibiotic treatment. He was fully recovered at the last follow-up, showing no symptoms of osteomyelitis in the lab, radiography, or clinical settings.

Malunion was 5% in plating group and non-union was 5% in nailing group. case with malunion that was noticeable right after surgery recovered in the same position at the one-year follow-up, with no discernible changes. This finding shed light on the challenge of precisely reducing the distal fragment and raises the possibility that intraoperative error may be the primary cause of malunion. Nonunion was treated with bone grafting at 32 weeks. This was comparable to studies by Kumar et al(25).,10 Ram et al(28).,11 Vallier et al(24). and Pawar et al.(29)

After applying functional score of Olerud and Molander after 1 year, it was found that the average score in the Nailing group was 86.8% and 76.4% in Plating group which is comparable to k. NH et al(30)

CONCLUSION

After one year of follow-up, there was no significant difference in clinical or radiological outcomes between intramedullary nailing and locking plate fixation. The above-mentioned parameters, fracture pattern, and soft tissue status must all be considered while selecting the proper surgical approach. There were no predictors of a negative outcome discovered.

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