ORIGINAL RESEARCH

A randomised trial comparing outcome of expert tibial nail versus proximal tibial plate in management of fractures of proximal tibia in adults

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ABSTRACT

Background: As the major weight-bearing area of the proximal part of the tibia is involved, the fracture is likely to result in functional impairment. Later, any treatment method must achieve the desired anatomical reduction and stable fixation in order to permit early weight bearing and early joint motion. This kind of fracture can be treated using a range of treatments, from conservative casting to major surgery. It is still up for debate which surgical procedure is best for treating proximal tibia fractures, especially extra-articular fractures. **Aim:**To compare the FUNCTIONAL and RADIOLOGICAL outcome of Expert tibia Nailing and Proximal tibia plating in Proximal tibia Extraarticular fractures. **Methods:** This study was carried out in Rajendra InstituteofMedicalSciences,Ranchi. The study was a randomized trial in which patients were randomized in both the groups using Random lottery method by an independent observer. According to the prevalence of patients with proximal tibia fractures admitted in RIMS in the years 2018-20, 40 patients, 20 Expert ILN group and 20 in Plating group were selected for our study after approval from Institutional Ethics Committee. **Results:**Both the groups had excellent outcome and no statistically significant difference was found between both the groups in terms of functional outcome assessment using the Oxford Knee Score. **Conclusions:**The use of PTLCP and ILN produces effects that are almost equal in treating proximal tibia extra articular fractures, according to this prospective randomized trial. While using Expert ILN is related with higher risks of malunion, using PTLCP is associated with more intraoperative blood loss, a higher rate of postoperative infection, and a longer length ofhospital stay.

INTRODUCTION

The tibia, which articulates proximally with the femur at the knee and distally with the talus at the ankle, is a significant weight-bearing bone in the lower limb. In comparison to injuries to the middle part of the skeleton, these meta-diaphyseal fractures require different treatment.

The most frequent fracture of a long bone is a tibia shaft fracture. About 5% to 11% of all tibial injuries are proximal tibia fractures, which typically impair knee stability and function. These fractures are especially troublesome due to an increase in related comorbidities. It is still unclear which surgical procedure is best for treating fractures in the proximal portion of the tibial shaft.[1]

Proximal tibia fractures are frequent intra-articular fractures. High energy fractures and low energy fractures are two major categories into which these injuries can be categorized. The majority of these fractures result from high-speed collisions or falls from great heights. either a valgus (more common) or varus moment and indirect shear pressures are present, and fractures are caused by direct axial compression. Depressed type fractures are more prone to occur in elderly adults with osteoporotic bone.[2]

Complex tissue damage of the bone and encircling soft tissues result from extra- articular proximal tibial fractures. The conservative treatment of these fractures has led to surrounding joint stiffness, rotational deformity, malunion, or nonunion. Therefore, there has been a recent shift toward the surgical therapy of these fractures. However, it is still disputed whether to operate on these fractures.[3]

Approximately 10% of shaft tibia fractures are extra-articular proximal fractures, which are typically caused by high-velocity trauma. For these fractures,

there are alternatives for both conservative and surgical care, however conservative management has led to problems like non-union, malunion, joint stiffness, or rotational instability. Therefore, in these individuals, surgical intervention is favoured over conservative management. For operative treatment, there are several alternatives, including Intramedullary nailing (IM) nailing, external fixation, plating, or a combination of these. The preferred methods of surgical therapy now available are intramedullary nailing and minimally invasive plating. The advantage of one of the two strategies is not sufficiently supported by the available data.[4]

As the major weight-bearing area of the proximal part of the tibia is involved, the fracture is likely to result in functional impairment. Later, any treatment method must achieve the desired anatomical reduction and stable fixation in order to permit early weight bearing and early joint motion. This kind of fracture can be treated using a range of treatments, from conservative casting to major surgery. It is still up for debate which surgical procedure is best for treating proximal tibia fractures, especially extra-articular fractures.

AIM

To compare the FUNCTIONAL and RADIOLOGICAL outcome of Expert tibia Nailing and Proximal tibia plating in Proximal tibia Extraarticular fractures.

METHODOLOGY

This study was carried out in Rajendra InstituteofMedicalSciences,Ranchi. The study was a randomized trial in which patients were randomized in both the groups using Random lottery method by an independent observer. According to the prevalence of patients with proximal tibia fractures admitted in RIMS in the years 2018-20, 40 patients, 20 Expert ILN group and 20 in Plating group were selected for our study after approval from Institutional Ethics Committee.

INCLUSION CRITERIA

1) Adult patients of Age more than 18 years and less than 70 years of age.
2) Closed fracture and Grade I open proximal tibia fractures without intraarticular extensions.

EXCLUSION CRITERIA

1) Age less than 18 years and more than 70 years
2) Grade II and III open fracture of proximal tibia.
3) Fracture with intra articular extensions.
4) Polytrauma patients with any other fracture of lower extremity
5) Severe head injury and medical comorbidities precluding surgical intervention.
6) Pathological fractures.

METHODOLOGY

All patients were followed up at 2 and 6 weeks, 3 and 6 months postoperatively. Both the immediate postoperative and the final follow-up radiographs werecompared to assess the accuracy of reduction and final alignment. Functional outcome was assessed using Oxford Knee Score.

SURGICAL TECHNIQUES

PLATING IN PROXIMAL TIBIA FRACTURES

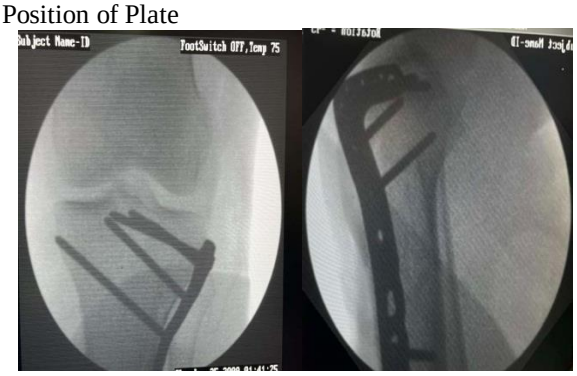
The patients were operated in supine positionunder general anaesthesia on a radiolucent table, with a sandbag underneath the ipsilateral hip joint with pneumatic tourniquet over the proximal thigh. Under all aseptic precautions, a curvilinear incision (s-shaped) was made over the proximal tibia on the lateral side. The skin incision was approximately 5-6 cm in length.

Dissection was extended distally through the fascia of tibialis anterior muscle. The submuscular tunnel was made with a periosteal elevator.

All was confirmed under fluoroscopic guidance (High Frequency 50Khz Microprocessor controlled portable C-arm machine). Internal fixation with a proximal tibia lateral locking compression plate 4.5 mm/5 mm was achieved. Principles of bridging plate fixation were followed. Fracture reduction was obtained before the screw placement. Cortical screws flushed the plate to the bone. Locking screws were fixed distally and proximally. A submuscular drain was inserted and closure done in layers.

Reduction being confirmed using fluoroscopy

Position of Plate



Position of plate and screws bring confirmed using fluoroscopy

EXPERT TIBIA NAILING IN PROXIMAL TIBIA FRACTURES

Position the patient supine on the radiolucent table. Ensure that the knee of the injured leg can be flexed at least 90°. Position the image intensifier such that visualization of the tibia including the articular surface proximally and distally is possible in anteroposterior and lateral views. Semi-extended position was used in few cases.

Patient on table with skin markings done for Patella, Patellar tendon and Tibial tuberosity. Poller screw insertion/unicortical plating/pin fixator

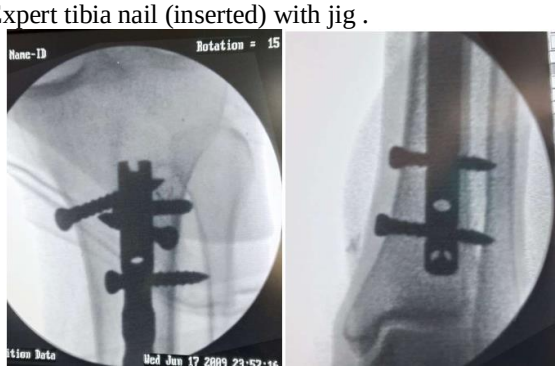
Poller screw insertion if planned is done before nail entry under fluoroscopic guidance. Unicortical plating or Temporary external fixation if planned is done as per routine techniques with the knee fully extended and the fracture reduced perform closed reduction manually by axial traction under image intensifier before applying large distractor or external fixator.

The incision starts proximally at the distal third of the patella along the patellar ligament down to the tibial tuberosity. The infrapatellar corpus adiposum is mobilized laterally and dorsally without opening the synovia. A free access of the nail to the insertion point must be guaranteed. the entry site of the nail is prepared on the ventral edge of the tibial plateau. Closed reduction of fracture done and guide wire passed.

Guidewire insertion with Pollar screws in situ.

Depending upon the availability of the medullary canal after Poller screw insertion, serial reaming with flexible reamers done. Insertion of the appropriate size nail after connecting securely to the proximal jig is done with the knee semi extended and holding the reduction under image guidance.

Expert tibia nail (inserted) with jig .



Fluroscopic confirmation of proximal and distal locking.

POST-OPERATIVE-PROTOCOL

All patients were given third generation cephalosporin intravenously during induction which was continued for 3 days post operatively. Post-operatively the leg was initially placed in a compressive dressing extending from foot to above knee and elevated for 48 to 72 hours to decrease swelling. Postoperative antero-posterior and lateral X-rays were taken and analyzed for alignment, position of implant and stability of the fixation. All patients were encouraged to begin an early active range of motion of the knee and ankle as tolerated. Sutures were removed on the 12^{TH}post-operative day. Patients were not permitted to bear full weight for four weeks.

RESULTS

The statistical analysis of data was performed using the computer program, statistical package for social sciences (SPSS for windows, version 20.0 Chicago, SPSS Inc.) And Microsoft Excel 2010.

In the present study, there were 6 (30%) patients in Expert ILN group and 7 (35%) patients were in PTP group who belonged to 20-30 years age group. In 31-40 years age group, 7 (35%) patients in Expert ILN and 6 (30%) in PTP group were present. 7 (35%) patients from Expert ILN group and 6 (30%) patients from PTP group belonged to 31-40 years age group. 2 (10%) patients from Expert ILN group and 3 (15%) patients from PTP group. In this study, in Expert ILN group, there were 3 (15%) females and 17 (85%) females. In PTP group , there were 5 (25%) females and 15 (75%) males. In this study, as per etiology, 1 (5%) had Assault, 2 (10%) had Fall from height (FFH) and 17 (85%) had Road traffic accident (RTA) in Expert ILN group. In PTP group, 1 (5%) had Assault, 3 (15%) had Fall from height (FFH) and 16 (80%) had RTA. In this study, as per coronal, 0^0valgus was seen in 3 (15%) Ex ILN and 6 (30%) PTP. 2^0valgus seen in 2 (10%) Ex ILN and 1 (5%) PTP. 3^0valgus in 9 (45%) Ex ILN and 8 (40%) PTP. 4^0valgus in 5 (25%) Ex ILN and 4 (20%) PTP. 7^0valgus in 1 (5%) Ex ILN. 8^0valgus in 1 (5%) PTP. In this study, on sagittal, 0^0procurvatum was seen in 7 (35%) Ex ILN and 9 (45%) PTP patients. 3^0procurvatum in 4 (20%) Ex ILN and 1 (5%) PTP. 3^0recurvatum in 2 (10%) Ex ILN and 3 (15%) PTP. 4^0procurvatum in 2 (10%) Ex ILN and 3 (15%) PTP. 4^0recurvatum in 3 (15%) Ex ILN and 3 (15%) PTP. 6^0procurvatum in 2 (10%) Expert ILN. 7^0procurvatum in 1 (5%) PTP group. In this study, Infection was present in 1 (5%) Expert ILN patient and 3 (15%) PTP patients. In this study, in Expert ILN group, complications occurred were delayed union in 2 (10%), malunion in 4 (20%), superficial infection in 1 (5%). In PTP group, delayed union was seen in 1 (5%), malunion in 2 (10%) and superficial infection in 3 (15%) patients. In this study, 1 (5%)patientin ExpertILN group and 3 (15%) patients in PTP group had superficial infection and required debridement andsecondary suturing which led to healing of the wound. Dynamization was done at 10 weeks in 2 (10%) Expert ILN patients who did not show adequate signs of healing which then eventually led to union at 30 weeks and 28 weeks. There is statistically significant difference present in Mean operative time in both groups compared, with lesser operative time in Expert ILN group (p=0.001) There is statistically significant difference present in Mean hospital stay in both groups compared, with longer duration of stay in PTP group (p<0.001). There is statistically significant difference present in Mean union time (in weeks) with lesser duration in Ex ILN Group (p=0.012)

OXFORD KNEE SCORE

Group	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	P value
Ex ILN	20	41.75	2.95	0.66	0.05	0.955
PTLCP	20	41.80	2.67	0.60		NS

Both the groups had excellent outcome and no statistically significant difference was found between

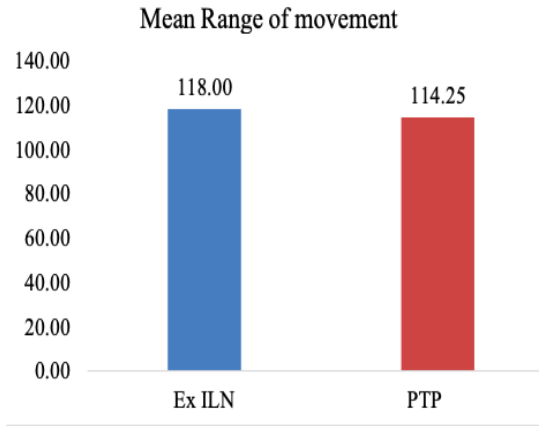
both the groups in terms of functional outcome assessment using the Oxford Knee Score.

Mean Range of movement

Group	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	P value
Ex ILN	20	118.00	11.74	2.63	3.75	0.284
PTLCP	20	114.25	10.04	2.24		NS

Both the groups had good final knee range of motion and was no statistically significant difference between both the groups in mean range of movement.

Bar chart showing Mean oxford knee score



DISCUSSION

Mean age of participants was 38.6 years in a similar study done by Jain S et al. [5], Schultz M. et al. [6] has shown mean age of 42 years in their study. Cole PA et al [7] have shown mean age of 45 years in their study. As a result, the findings of the current study and those of earlier investigations were very comparable. In this study, Infection was present in 1 (5%) Ex ILN patient and 3 (15%) PTLCP patients. But Lindvell et al [8] reported noticeably higher infection rates in their study: 28% in the nailing group and 24% in the plating group. The greater percentage (42.8%) of patients with open fractures in their study is the most likely cause of this. The infection rates were 2.5% in the nailing group and 14% in the plating group in the systemic review by Bhandari et al. [9].

In this study, 1 (5%) Ex-ILN and 3 (15%) PTLCP patients required debridement and secondary suturing. Dynamisation at 10 weeks was done in 2 (10%) Ex ILN patients. Due to the extensive dissection required for plating and the fact that high velocity injuries are the sort of fractures for which plating is employed, there is a higher risk of skin infection and superficial necrosis. Two patients in the Plating group, according to a related investigation by Sharma AK et al [10], experienced profound infection. Debridement and intravenous antibiotics were used to treat them, and the infection was managed. One patient required implant removal due to a late postoperative infection, or infection that appeared after 12 months. One patient in the nail group experienced a superficial infection that was treated for three weeks with intravenous antibiotics and day-by-day bandages. In the Pandey Aet al study [11], the rate of malunion was greater in Group I treated with IMN as compared to Group II treated with plating 14.8% (1/7) instances develop malunion in follow-up.. The plating group also had 5 patients with malunion (16%) in the study by Patel Z et al [12], but the difference was not statistically significant. Gross oedema around the fracture site is a key characteristic of proximal tibia fractures. It is one of the characteristics that 90 percent of proximal tibia fractures show.

The clinical efficacy of the blocking screw was supported by Ricci et al [13] and Krettak et al [14]. These patients only received mediolateral blocking screws; none of the instances involved antero-posterior blocking screws. Because there are sofew IMN fixation cases in which blocking screws are utilized, its effectiveness cannot bestatistically demonstrated. Use of transfixation pin distracter, percutaneous clamps, temporary pinning for fracture management, and the use of a nail with a more proximally positioned Herzogcurve are further approaches. Oh C.W. et al. [9] recommendations of double plating in severely unstable fractures helped prevent these problems with PTLCP fixation. With different degrees of open and closed soft tissue injury, Bolhofner et al. [15] recommendations for composite fixation (lateral plate with medial external fixator) in patients with extraarticular proximal tibia fractures was made in 1980.

Our findings supported the findings of the aforementioned research that patients in the ILN group recovered more quickly than those in the PTLCP group. Further supporting our findings was the finding by Meena et al[16] that the ILN group had a considerably shorter average hospital stay (4.1 days vs. 5.3 days) and time to fracture union (18.26 weeks vs. 22.84 weeks) than the PTLCP group. Morwood et al [17] found that patients treated with ILN fixation had a quicker time to complete weight-bearing than those who received plate fixation, which was consistent with our finding.

CONCLUSION

The use of PTLCP and ILN produces effects that are almost equal in treating proximal tibia extra articular fractures, according to this prospective randomized trial. While using Expert ILN is related with higher risks of malunion, using PTLCP is associated with more intraoperative blood loss, a higher rate of postoperative infection, and a longer length ofhospital stay. However, there is no distinction between Expert ILN and PTLCP in terms of functional result. The proximal one third extraarticular tibia fracture is a challenging fracture to treat and is frequently

accompanied by severe soft tissue injury. Repair of proximal one third extraarticular tibia fracture is technically challenging surgery regardless of the implant, high level surgical abilities are essential to cope with these fractures.

LIMITATION

Follow-up is very short. Long term complications may be missed. Small sample size. To validate this issue further, a large sample size multicentric randomized study is recommended.

CASE ILLUSTRATIONS

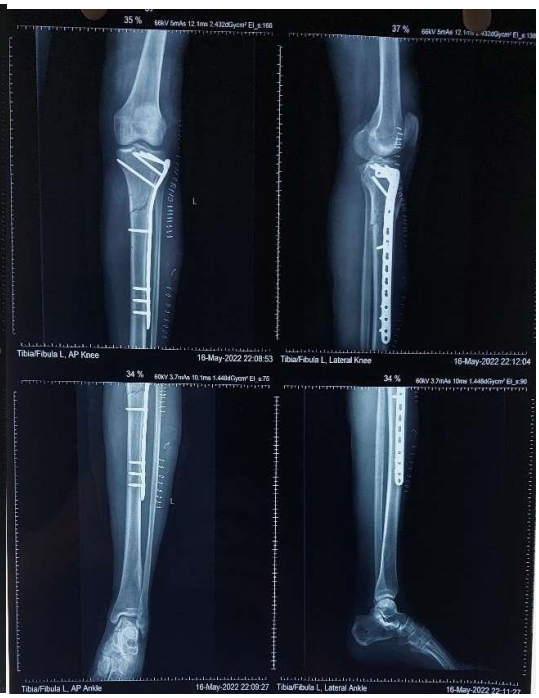
CASE NO-1:CRIF with Expert ILN Tibia

PRE OP RADIOGRAPH **POST OP RADIOGRAPH**

KNEE RANGE OF MOTION **POST OP WOUND**

CASE NO-2: ORIF with PTLCP

PRE OP RADIOGRAPH



POST OP RADIOGRAPH

POST OP KNEE RANGE OF MOTION

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