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Comparative study of functional outcome of distal one-third shaft tibia fractures treated with tip locking tibia nailing versus precontoured anatomical locking plate

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ABSTRACT

Background: The distal 1/3rd shaft tibia extra-articular fractures are treated with both tip locking intra-medullary nailing (TLIMN) and precontoured anatomical locking plates (PCALP). The aim of this study was to compare the results of TLIMN and PCALP in distal tibia fractures and to determine dominant strategies. The complications and functional outcome in both groups were compared.
Methods: Forty patients with distal 1/3rd shaft tibia were randomly assigned to TLIMN (group 1) and PCALP 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 15.05±3.33 weeks in group 1 and 13.4±2.46 weeks in group 2 (p=0.045). The mean AOFAS score at 1 year follow up was 89.8±6.13 in group 1 and 89.1±6.15 in group 2 (p=0.262). Five patients in group 1 and one in group 2 had mal-alignment. Deep infection was present in one and superficial infection was present in two cases in group 2. Four patients in group 1 developed anterior knee pain and five patients in group 2 had hardware prominence.
Conclusions: We conclude that tip locking intra-medullary nail is a reliable and satisfactory method for treatment of fractures of distal 1/3rd shaft tibia AO type 42A, 42B and 42C fractures with good functional outcomes and high union rates with comparatively low complications. Prevalence of malunion was higher in TLIMN group and hardware prominence was more prevalent in PCALP group. Implant removal are more in PCALP group mostly due to implant irritation.

Keywords: PCALP, TLIMN, Distal one-third shaft tibia, Extra-articular

INTRODUCTION

As the civilization proceeds towards industrialization more and more accidents have been experienced. In almost all lower limb fractures over the world, the incidence of road traffic and industrial accidents are growing up, in addition to twisting injuries, fall from height and other high energy injuries tibia fractures accounting for 2 per 1000 individuals.[1] If we scrutinize the statistics of fractures in body parts, The fractures of the distal tibia diaphysio-metaphyseal region comes at the top because it is the most distal part of the body and actively involves in locomotive system.[2] As these fractures occur in proximity of weight bearing surface of ankle joint, a slight misalignment in inclination of ankle joint may lead to permanent disability which affects patient's daily living. The fractures of the distal 1/3rd shaft of tibia diaphysio-metaphyseal region are complex injuries with high complication rate.[3]

Traditionally, a variety of methods of management have been described with a reportedly high rate of associated complications where orthopaedic surgeon must be aware of the advantages, disadvantages and limitation of each treatment modalities. The age of patient, social and economic status, the type of fracture and degree of communition may influence the method of treatment. Intervention modalities of treatment include close reduction and above knee cast to external fixation like ilizarov external fixator to closed reduction internal fixation with intramedullary devices to open reduction internal fixation with plate and screws for the fractures of the distal 1/3rd shaft of tibial region is available.

Intramedullary nailing (IMN) is the most accepted surgical treatment modality.[4] Since these are load sharing devices, implant induced osteolysis is not encountered and healing is rapid with abundant callus. In 1937, the Rush brothers began to use long thin flexible steel wires to stabilize long bone fractures. Küntscher's first nailing procedure in a human was in 1939. IM nails, such as Lottes and Ender nails, used without reaming in the treatment of open tibial fractures and have been associated with low rates of postoperative infection as they are intramedullary devices and no direct manipulation of fracture site is taking place. The locking of intramedullary nails to the major proximal and distal fragments decreases the prevalence of malunion of communited fractures. Until recently, however, all interlocking intramedullary nailing involved reaming, which destroys the endosteal blood supply. The rate of infection after treatment of open tibial fractures with intramedullary nailing with reaming has been relatively high, causing most investigators to discourage the use of this technique for grade III open tibial fractures as per the gustilo-anderson classification.

Modern tibial nail designs like tip locking tibia nail or expert tibia nail have interlocking holes that enable distal placement of screws in close proximity to tip of nail have solved issue of stability and alignment to a greater extent.[5] The closed intramedullary nailing also has been associated with significantly shorter operative time and fewer wound infection (AO/ASIF).[2] Locking compression plate (LCP) of tibial fractures was first described in the 1880's by Hansmann in Germany. Karlstrom in 1972, in treating 135 tibial fractures showed 90% good results with plating. It has been accepted since then but gained popularity with introduction of dynamic compression plate by AO group.[6] To obtain maximal mechanical stability in order to achieve primary (endosteal) bone healing, exact anatomical reduction and strict rigid fixation were emphasized in the beginning.

In recent years, plates have been developed as that they have less periosteal contact. They undoubtedly provide superior fixation in osteoporotic bone, as all the screws must loosen for the plate to fail. They are therefore particularly useful in treating distal 1/3rd shaft tibial fractures in the older patients. The plates can be used with unicortical or bicortical screws and is more useful in elderly patients.[6] Well-known complications like infection and delayed or non-union are frequently attributed to the devitalisation of bony fragments and additional damage to the soft tissues. In order to improve fracture healing, more 'biological' methods have been developed over the last decades, to lessen the surgical dissection, preserving the blood supply to the bony fragments. More and more new insights in reduction techniques and fracture healing are leading to the development of a 'minimally invasive osteosynthesis' promoted by the AO group and others.[7] The emphasis now lies for percutaneous plate on indirect reduction (MIPPO), axial alignment and stable fixation without disturbing the fracture environment and thus preserving most of the vascularization and fracture hematoma, containing all necessary growth factors for bony healing. There has been an increasing trend towards the use of the locking compression plate (LCP) for fracture fixation. The device allows the screws to lock to the plate, therefore creating a stable, fixed angle device. Precise anatomical contour of this plate is therefor necessary because the plate does not need to be pressed on the bone to achieve stability, thus preventing the loss of primary reduction of fracture fragments caused by inadequate contouring of the plate The objective of the current study is to compare both these modalities of management in closed distal third extra-articular tibia fractures in terms of radiological and functional outcomes.

Aim and objectives

To study the management of extra-articular distal 1/3rd shaft diaphysio-metaphyseal fracture of tibia using tip locking intra-medullary nailing and precontoured anatomical locking plate fixation. To assess and compare the functional outcome of above procedure in terms of time taken for clinical union, radiological callus formation and regain of daily living and functions using AOFAS score.

METHODS

This is a prospective study where in 40 consecutive cases of skeletally mature distal 1/3rd shaft tibia fractures, which presented to the department of orthopaedics, Krishna institute of medical science and research centre, between the period from september 2020 to november 2022. This study was approved by krishna institute of medical science ethical committee board and all patients gave written informed consent prior to their inclusion in their study.

Patients were treated with surgical methods either by close interlocking intramedullary nailing or with open/percutaneous reduction and internal fixation with PCALP plating. In the study percutaneous reduction and plating through minimal invasive technique (MIPPO) was preferred and open reduction was done in those cases where acceptable reduction was not achieved with minimal invasive technique. All cases were followed up for a minimum period of 1 year at regular interval at one and half months, and on every month till 6 months, at 9 months and at one year post-operatively.

Sample size

For the purpose of sample size calculation, time to union was taken as the primary outcome. Assuming a pooled standard deviation of 2.49 weeks for time to union in both the groups, the study would require a sample size of 15 in each group to achieve a power of 80% and a level of significance of 5% (two sides) for detecting a difference to heal of 3 weeks. By expert advice a final sample of 20 in each group was taken to compensate for drop outs. Group A is designated for patients those are operated with tip locking intramedullary nailing. Group B is designated for patients those are operated with distal tibia pre-contoured anatomical locking plate.

Inclusion criteria

All closed extra-articular distal 1/3rd shaft tibia fractures as per AO Classification 42A1, 42A2, 42A3 of all skeletally mature patients (age ≥18 years) of either sexes who are willing to participate in the study were included.

Exclusion criteria

Exclusion criteria for current study were; age below 18 years. intra-articular extension of fractures, all open fractures according to Gustillo and Anderson, all pathological fractures, earlier fracture of tibia on same side, unfit for surgery and lost follow up.

Selection of implant for particular fracture was entirely based on operating surgeon's discretion and no other factors were taken into consideration. The fractures were classified according to the orthopaedic trauma association (AO-OTA) classification. The associated fibular fracture was fixed either with plate or intra-medullary rush nail, only if it was at or below the level of syndesmosis. Fibula fracture, if in distal third was fixed first with either 3.5 mm one-third semitubular plate or with rush nail and its fixation is independent of tibial method of fixation. Initial management consisted of splinting with above knee slab for immobilization. Intravenous antibiotics consisting of ceftriaxone sulbactam, were administered preoperatively and ceftriaxone sulbactam, metronidazole and tobramicin for 3 days post-operatively for both the groups. Non-weight bearing was recommended for 2 weeks post-operatively for both groups. Partial weight wearing was initiated from third week after suture removal and gradual transition to full weight bearing at the end of six weeks post operatively. Patients were evaluated with radiographs in both anteroposterior and lateral views of ankle joint and leg. Clinical union was defined as no pain or mobility at the fracture site and radiologically as healing of at least three of four cortices on bi-planar plain radiographs. Mal-union was defined as >5 degree of varus/valgus angular deformity or >10 degree of anterior/posterior angulations or translation/shortening of 10 mm.

Delayed union was defined as lack of any healing on plain radiographs within 3 months. Non-union was defined as lack of any healing on plain radiographs within 6 months. Superficial infection was confined to dermal and subcutaneous tissue whereas deep infection was defined as those below the deep investing muscular fascia. At the end of follow-up functional outcome was evaluated according to the American orthopaedic foot and ankle score (AOFAS) as excellent (90-100), good (75-89), fair (50-74) and poor (<50). The Microsoft Excel software was used for data entry. SPSS 16.0 and SYSTAT 12.0 software packages were used for data analysis.

RESULTS

The mean age of the patient in the group of tip locking IM nailing and PCALP was 35 and 38.25 respectively. Amongst 13 in tip locking IM nailing group and 14 in PCALP group were male and remaining were female which was statistically insignificant. The road traffic accident was the major mode of injury in both groups causing distal 1/3rd shaft of diaphysio-metaphyseal fractures of tibia. Fracture type was based on AO fracture classification- 12 cases classified to 42A (11 in TLIMN group and 1 in PCALP), 13 cases classified to 42B (06 in TLIMN group and 07 in PCALP) and 15 cases classified to 42C (only 03 in TLIMN group and 12 in PCALP).

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

Parameters	TLIMN group (N=20)	PCALP group (20 patients)	P value
Age, range (mean±SD) (years)	22-53, 35±9.330	28-58, 38.25±8.607	0.1568
Gender, N (%)			
Male	13 (65)	14 (70)	-
Female	7 (35)	6 (30)	
Mechanism of injury, N (%)			
Low energy fall	2 (10)	2 (10)	-
High energy fall	4 (20)	5 (25)	
RTA	11 (55)	12 (60)	
Others	3 (15)	1 (5)	
AO classification. N (%)			
42A	11 (55)	1 (5)	0.500
42B	6 (30)	7 (35)	
42C	3 (15)	12 (60)	

Interval from injury to surgery among the patients of tip locking IM nailing was 2.8 days and was significantly lower in comparison to the patients of group of PCALP was 4.65 days.

Mean operative time among the patients of tip locking IM nailing was 71.2 minutes and was significantly lower in comparison to the patients of group of PCALP where mean operative time was 93.7 minutes. Mean intra-operative

blood loss among the patients of tip locking IM nailing was 53.5 ml and was significantly lower in comparison to the patients of group of PCALP where mean intra-operative blood loss was 139.8 ml.

Table 2: comparison of mean operative time in minutes.

Groups	Mean operative time (minutes)	SD	P value
TLIMN	71.2	16.28	0.000003125
PCALP	93.7	13.55	

Table 3: comparison of mean intra-operative blood loss in ml.

Groups	Mean intra-op blood loss (ml)	SD	P value
TLIMN	53.5	15.05	0.0000000678
PCALP	139.8	44.60	

Table 4: Time taken for clinical union.

Time for clinical union (weeks)	TLIMN group		PCALP group		P value
	N	%	N	%	
<3	1	5	0	0	0.0052
3-6	16	80	10	50	
7-10	3	15	9	45	
>10	0	0	1	5	
Total	20		20		
Mean time	4.5		6.6		
SD	1.670		2.542		

Table 5: Time taken for radiological union (appearance of callus on X-rays).

Time for radiological union (weeks)	TLIMN group		PCALP group		P value
	N	%	N	%	
10-15	13	65	16	80	0.04554
16-20	5	25	4	20	
21-30	2	10	0	0	
Total	20		20		
Mean time	15.05		13.4		
SD	3.3320		2.436		

Mean time taken for clinical union among the patients of tip locking IM nailing was 4.5 weeks and was significantly lower in comparison to the patient of group pf PCALP where mean time taken for clinical union was 6.6 weeks.

Mean time taken for radiological union among the patients of tip locking IM nailing was 15.05 weeks and was significantly higher in comparison to the patient of group pf PCALP where mean time taken for radiological union was 13.4 weeks. Mean time taken for partial weight bearing among the patients of tip locking IM nailing was 7.05 weeks and was significantly lower in comparison to the patient of group of PCALP where mean time taken for partial weight bearing was 10 weeks.

Table 6: Time taken to partial weight bear in weeks.

Time for partial weight bearing (weeks)	TLIMN group		PCALP group		P value
	N	%	N	%	
4-6	9	45	0	0	0.0000063
7-10	8	40	11	55	
11-14	3	15	9	45	
Total	20		20		
Mean time	7.05		10		
SD	2.012		1.891		

Table 7: Time taken to full weight bear in weeks.

Time for full weight bearing (weeks)	TLIMN group		PCALP group		P value
	N	%	N	%	
10-15	19	45	9	0	0.0000234
16-20	1	40	9	55	
21-25	0	15	2	45	
Total	20		20		
Mean time	12.05		16.20		
SD	1.848		3.334		

Table 8: Comparative analysis of results obtained for clinical, radiological and functional outcome.

Parameters (weeks)	TLIMN group	PCALP group	P values
Clinical union time (mean±SD)	4.5±1.670	6.6±2.542	0.0052
Radiological union time (mean±SD)	15.05±3.332	13.4±2.436	0.04554
Partial weight bearing (mean±SD)	7.05±2.012	10±1.891	0.0000063
Full weight bearing (mean±SD)	12.05±1.848	16.2±3.334	0.0000234

Mean time taken for full weight bearing among the patients of tip locking IM nailing was 12.05 weeks and was significantly lower in comparison to the patient of group of PCALP where mean time taken for full weight bearing was 16.2 weeks. There was no significant differences and in the outcome of ankle function as in range of motion (dorsi-flexion and plantar-flexion) among both groups.

Table 9: Comparison of the AOFAS between the groups at 3 months, 6 months and 1 year follow up.

Time Interval	Groups	Min	Max	Mean	SD	P value
3 months	TLIMN	55	82	69	9.171	0.212
	PCALP	52	80	67.4	6.908	
6 months	TLIMN	68	88	79.3	6.896	0.249
	PCALP	64	88	78.15	6.345	
1 year	TLIMN	76	96	89.8	6.131	0.262
	PCALP	68	96	89.1	6.152	

DISCUSSION

Extra-articular diaphyseo-metaphyseal distal tibia fractures are often challenging to an orthopaedic surgeon as it poses a limitation due to inadequate soft tissue coverage, proximity to ankle joint and vascular compromise. The goal of operative intervention is to achieve better stability while maintaining anatomical alignment and to aid in early mobilization and weight bearing. At the same time appropriate treatment should also target to rectify union and to minimize soft tissue and hardware complications.[5]

In the present study, the mean age of the patient in the group of tip locking IM nailing and PCALP was 35 years and 38.25 years respectively which ranges from 22 to 58 years of age. The majority of the patients in both groups belonged to the age group of 18-35 years. Singla et al in study of 40 patients, mean age were 48.12 years in expert tibia nailing group and 49.71 years in distal tibia plating group.[8] Meena et al the patients were in the range of 21 to 70 years, with mean age being 43.18 years. Study by Prakashappa et al mean age of the patients was 42 years for plating and 49 years for nailing.[5-8] Thus, both the study and groups were comparable in terms of age wise distribution of the patients. Thus, we concluded that distal 1/3rd shaft tibia fractures are more common in middle age. These groups are more common as they were engaged in outdoor activities and are physically active person among which most were sustained high velocity injuries. Amongst 13 patients in tip locking IM nailing group and 14 patients in PCALP group were male and remaining were female which was statistically insignificant. These injuries are also gender dominant as in both study groups 65-70% patient was male. Our results were in concordance with the previous authors who also reported male preponderance in their respective studies. Such predominant involvement of male gender in both groups can be explained as males are prone to outdoor activities, industrial accidents, road traffic accidents and active involvement in cases of assaults. This type of distal tibia fracture is frequently associated with high velocity trauma. As in our both present study groups major mode of injury was road traffic accidents which accounts for 57.5% of patients as our institute is situated at a prime location with proximity to highways as most of commutators are travelling at high speed which makes them more prone to high velocity trauma. Followed by high energy fall from height or staircase which is commonly seen in household women or construction site working men accounting for 20% of patients in our study group. Study by Prakashappa et al the mode of injury was RTA for 17 (85%) cases, 3 (15%) cases had history of self-fall in plating group and RTA for 19 (95%) cases, 1 (5%) case had history of self-fall in nailing group which is in concordance with other studies.[6] As in present time, widely accepted AO fracture classification was used in our current study as extra-articular diaphyseo-metaphysial distal 1/3rd shaft tibia fractures classified under AO fracture classification type 42 under subsection type 42A, 42B and 42C. In our study, 12 cases were classified to 42A among which 11 patients in TLIMN group and 1 patient in PCALP group. 13 cases were classified to 42B among which 06 patients were from TLIMN group and 07 patients from PCALP group. And 15 cases were classified under 42C among which only 03 patients from TLIMN group and 12 patients were from PCALP group.

Patient in PCALP group was kept for average 4-7 days in wards for relieving of swelling and inflammation for which those patients were treated by medications and limb elevation. The time interval from injury to surgery among the patients of tip locking IM nailing was 2.8 days and was significantly lower in comparison to the patients of group of PCALP was 4.65 days. Mean operative time is statistically significant parameter as mean operative time for the patients of tip locking IM nailing group was 71.2 minutes and was significantly lower in comparison to the patients of group of PCALP where mean operative time was 93.7 minutes. In Prakashappa et al average surgical timing was 96 minutes for plating group and 69 minutes for nailing group. Providing that plating involves greater size of incision, dissection, implant handling and closure is a time-consuming process in comparison to tip locking IM nailing group.[6] Mean intra-operative blood loss is also a statistically significant parameter as among the patients of tip locking IM nailing was 53.5 ml and was significantly lower in comparison to the patients of group of PCALP where mean intra-operative blood loss was 139.8 ml. Providing greater size of incision, greater amount of dissection of soft tissue and muscle prone to loss blood in PCALP group. Whereas relatively smaller incision and subcutaneous handling gives less blood loss.

Clinical union was assessed by pain over leg, mobility at a fracture site and subsiding signs of inflammation. Mean time taken for clinical union among the patients of tip locking IM nailing was 4.5 weeks and was significantly lower in comparison to the patient of group pf PCALP where mean time taken for clinical union was 6.6 weeks. Clinical union also shows patients wellbeing with undergoing clinical condition and emerging out of it on day-to-day basis. Radiological union was stated with appearing of a calus formation on X-rays films on antero-posteior and lateral views on atleast 3 cortices out of 4 cortices. Mean time taken for radiological union among the patients of tip locking IM nailing was 15.05 weeks and was significantly higher in comparison to the patient of group of PCALP where mean time taken for radiological union was 13.4 weeks. Study by Prakashappa et al the average time for radiological fracture union in study was 15.95 weeks in plating group and 15.60 weeks in nailing group.[6] Allowing post-operative outcome where fracture were allowing cortical touch and amount of comminution which also plays role in addition to time to mobilization and weight bear. Mean time taken for partial weight bearing among the patients of tip locking IM nailing was 7.05 weeks and was significantly lower in comparison to the patient of group of PCALP where mean time taken for partial weight bearing was 10 weeks. In our study, we allowed full weight bearing only after signs of union in form of callus formation on at least three cortices out of four cortices on radiograph and clinically as absence of tenderness and movement at the fracture site which was usually by time period of 6 to 18 weeks. Mean time taken for full weight bearing among the patients of tip locking IM nailing was 12.05 weeks and was significantly lower in comparison to the patient of group of PCALP where mean time taken for full weight bearing was 16.2 weeks. In study of Lakhotia et al (2020) 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.[5] Similar outcome was also seen in concomitant studies Sreen et al, Jain et al and Rabari et al suggesting early full weight bearing and union among nailing group.[11-18]

On post-operatively malunion was stated when bone was united in abnormal position disturbing ankle movement and delayed weight bearing. Non-union was stated when there was no briging callus formation on any of cortice even at 9 months postoperatively. In our study, these nonunion, malunion and delayed union was seen in 15% and 5% patient in tip locking IM nailing and PCALP respectively. Rate of superficial and deep infection was taken as a part of operative complications accounting for 15% in PCALP and 5% in tip locking IM nailing group is statistically significant. Anterior knee pain was seen in 20% patient of tip locking IM nailing group and no patient in PCALP group had knee pain as a part of complication and is statistically significant. Hardware prominence as a implant or part of it being felt over skin or seen upon through clinical examination and it was observed in 5 patients (25%) of PCALP group and no patient in TLIMN group had hardware prominence. In study Chittan et al observed complication rate of 12.5% each in both the nailing and the MIPO groups.[3] While the nailing group had two mal-unions, the plating group had one implant irritation and one superficial infection. Lakhotia et al[5] with respect to secondary procedures to achieve union in nailing group one case had to dynamized and bone grafting was done in 2 cases (8%) where in one with delayed union and one with non-union.[5] Ankle dorsiflexion and plantarflexion in tip locking IM nailing group was marginally better but statistically insignificant in comparison to PCALP group, as early mobilization was kept a target in both groups allowing early callus formation and early regain of functions. AOFAS anke-hindfoot scoring system is widely used for trauma around ankle and was used to assess the functional outcome and to assess pain in our present study. In our study mean AOFAS score for the TLIMN group at 3 months, 6 months and one year was 69, 79.3 and 89.8 respectively and for PCALP group was 67.4, 78.15 and 89.1 respectively. Prakashappa et al showed mean AOFAS score improved from 75.35 (at 3 month) to 79.05 (at 6 month) and 83.7 (at 1 year) for plating group and for nailing group it was 77.35 (at 3 month) to 82.5 (at 6 month) and 88.5 (at 1 year).[6] Sonnet et al AOFAS score at 1 year was 87.5, Chen et al mean AOFAS score at the end of 1 year 87.8 and Bhat et al 143-study showed 83.6. Duckworth et al study had showed 76.2 at the end of 1 year.[19,20] The final AOFAS score at the end of 1 year was similar with the previous studies. These outcomes suggest that both TLIMN and PCALP treatment modalities can be used for extra-articular distal 1/3rd shaft tibia fractures and both have good functional outcome. Overall results were comparable to our study, and majority of the patients had good outcomes.

Limitations

Limitations of current study were; study sample size is small. Expert tibia nail design with multidirectional locking system may also be compared with precontoured anatomical locking plate for distal 1/3rd shaft of tibia fractures and to compare difficulties in implant removal, a longer follow up is required.

CONCLUSION

Extra-articular distal tibia fractures are successfully fixed both surgical modalities with TLIML and PCALP with comparable functional outcomes and union rates. Both treatment modalities provide biological fixation with observed complications. However, malunion was more common in TLIMN along with knee pain and hardware prominence along with superficial infections was more prevalent in PCALP group.

Thus, we conclude that tip locking intra-medullary nail is a reliable and satisfactory method for treatment of fractures of distal 1/3rd shaft tibia AO type 42A, 42B and 42C fractures with good functional outcomes and high union rates with comparatively low complications.

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