



RANDOMISED CONTROLLED TRIAL TO DETERMINE THE ROLE OF FIBULAR FIXATION IN BOTH DISTAL THIRD TIBIAL DIAPHYSIS AND FIBULAR FRACTURES

Orthopaedics

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ABSTRACT

Fixation of Distal third tibial diaphysis fractures poses unique challenges in terms of selection of appropriate implants and reduction of the fracture. Distal tibial diaphyseal fractures associated with fibular fractures produce valgus malalignment at the fracture site. Fibular plating has been classically recommended before tibial fixation citing improved alignment of the fracture along with maintenance of length, ensuring proper reduction of the tibial fracture. However, it is not exempt from complications of surgical procedure and recent literatures have equally favoured tibial fixations without fibular plating in such distal third diaphyseal fractures. So, we have tried to compare the outcome of tibia fixation with or without fibular plating in distal third diaphyseal fractures. This is a randomized controlled trial involving 66 cases treated with (group A) or without (group B) fibular fixations. Tibial fixation was done with distal tibial metaphyseal locking plate or intramedullary interlocking nail system. Patients were followed up at 6 weeks, 12 weeks and 6 months. Clinical and radiological union was assessed at 6 months follow up, and Johner and Wruhs score was calculated. 11 patients were lost to follow up. In both groups, there was no excellent or poor result. Group A had good results in 22 out of 26 patients (84.6%) and 4 had fair results (15.3%). Group B had good results in 20 out of 29 patients (68.9%) and fair in 9 out of 29 patients (31%). There was no significant difference in tibial malalignment (valgus angulation) between the two groups.

KEYWORDS

Fibula fixation, Fibular fractures, Tibial diaphysis, Johner and Wruhs scoring system.

Introduction:

Tibial diaphyseal fractures are the most common type of long-bone fracture encountered by most orthopaedic surgeons. In an average population, there are about 26 tibial diaphyseal fractures per 100,000 of the population per year.^[1] Of all tibial fractures 37.8% are distal tibial fractures and associated fractures of fibula are encountered in 77.7% of all cases.^[2] Subsequent malalignment and unequal distribution of articular surface pressures in the distal tibial fracture is a common concern as it leads to post traumatic arthritis of both the ankle and knee.^[2,4-7,8,9] More distal the deformity, more symptomatic is the patient.^[2,10,11]

Fractures of the tibia and fibula can range from completely undisplaced fractures with minimal soft-tissue damage, to traumatic amputations. This is the reason why making a decision for treatment is a complex process. It must take into account many factors, including the patient's overall health, associated injuries of the thigh, knee, foot, and the pattern of injury to the bone itself. Treatment is equally varied, ranging from simple walking-cast immobilization through complex procedures required to replace lost bone, soft tissues, and neurovascular structures.^[3]

The clinical impact of fibular fixation as an adjuvant to the treatment of tibial distal fractures treated with intramedullary nail or plates is still unknown. Some authors believe that fibular fixation would help to reduce rotational and sagittal alignment, which may be difficult to achieve with intramedullary nails alone. When a bridge plate is used on the tibia, fibular fixation would help to restore length and angular and rotational deformities, thus reducing the risk of vicious union.^[3,6,12-14]

The need for fibular fixation in such fractures is controversial. Many agree that fibular fractures associated with syndesmotic or ankle mortise instability should be stabilized as malreduction of the ankle mortise has been shown to be a factor in poor functional outcomes, but there is no consensus over the role of fibular fixation in extra-articular fractures of the distal tibial metaphysis. In general, adjunctive fibular fixation seems to lessen the risk of distal tibial malalignment, but only a few clinical reports have specifically evaluated this clinical impression. Presently there are no studies in Nepal which have explored the role of fibula fixation in fractures of distal third tibia and fibula. The aim for doing this study is to attempt to find a definitive answer as to whether to fix or not to fix fractures of the fibula in associated fractures of distal tibia and fibula and to measure its functional outcome using ankle scoring systems like Johner and Wruhs.

Materials and methods:

The study was conducted in the Department of Orthopaedics, B.P.

Koirala Institute of Health Sciences, a tertiary care hospital in Eastern Nepal, from March 2014 to February 2015. After Ethical approval was obtained from Institutional Review Committee (IRC) of B.P. Koirala Institute of Health Sciences, Dharan, Nepal work was started. Patients were informed of all the procedures, its complications and advantages. Patients who provided written consent for the surgical approaches were included in the study. Confidentiality and anonymity were maintained throughout the study and will be maintained in the future. The data were used only for study purpose.

All patients were included in this who have fracture of lower one third of shaft of tibia and fibula. Cases of lower third leg fractures which are less than 2 weeks old, Skeletally mature patient with closed physis as assessed radiographically and who have Closed and Gustilo grade I and II open lower one third diaphyseal fractures of the leg. Patients are Exclusion from study who have Segmental fracture of tibia, skeletally immature patients as assessed radiographically, single bone fracture and Open fracture (Gustillo Type III). All patients were randomly allocated using Excel random number generation technique into two treatment groups. Group A (Both tibia and fibula were fixed) and Group B (Where tibia only fixed).

Intervention:

All the eligible patients were evaluated clinically and radiologically in Orthopaedic OPD/Emergency of BPKIHS. Following the fitness for anaesthesia, patients were posted for surgical intervention as per their respective groups. All the cases were operated with appropriate anaesthesia in supine position. Fixation device used were either intramedullary nail or plate for tibia and either one third tubular plate or rush pin for fibula.

Group A: All cases of tibia fracture were fixed with plate or intramedullary nail and some selected case of fibula were fixed with one third tubular plate with minimum of three screws on each side of fracture. **Group B:** Only the tibia was fixed with plate or intramedullary nail and fibula was not fixed. **Follow up:** Patients were admitted to ward after surgery and monitored for immediate postoperative complications. They were discharged after two days of antibiotics as per department protocol. After discharge patients were reviewed after two weeks for suture removal and to assess signs of wound infection and at the end of 6 weeks, 12 weeks and 6 months Johner and Wruhs score [Table: 1] was calculated.^[15] Radiological assessment was done using plain x ray of leg in AP and lateral view and degree of valgus/varus was calculated. Clinical and radiological union was calculated at 6 months follow up. Complications were looked for during all follow ups.

Table 1: Criteria for evaluation of final results [Johner & Wruhs score^[16]]

	Excellent	Good	Fair	Poor
Non union	None	None	None	Yes
Deformity : Varus / Vagus	None	2 – 5°	6 – 10°	>10°
Mobility at ankle (%)	Normal	> 75%	> 50%	<50%
Gait	Normal	Normal	Insignificant limp	Significant limp

The sample size was 33 in each group and total sample size was 66. On the basis of literature review and study by Prasad et al., 66 patients were randomised into two groups: patients with fibular fixation (Group A) and without fibular fixation (Group B) For inferential statistics: Chi square test, T- test or Mann Whitney U test were applied to the data to look for significant differences between the two groups. The study was done at 95% confidence interval with p=0.05.

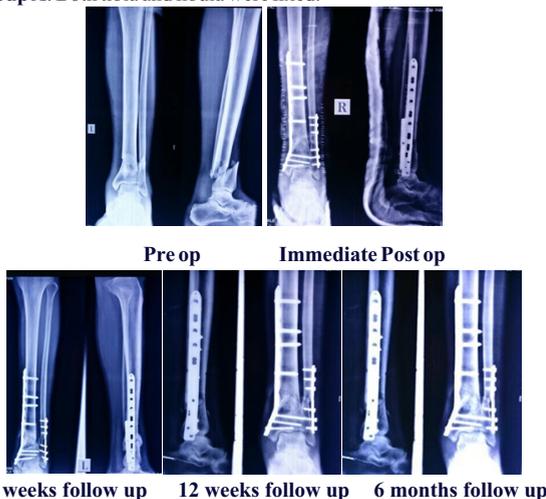
RESULTS

Sixty six patients with fracture of both bones distal third leg fulfilling the inclusion criteria were taken as the study population. Thirty three patients were randomized into group A in which patients underwent fixation of both bones and thirty three in group B in which patient's fibula was not fixed. Of these, total 11 patients did not follow up (because they belonged to remote areas of Nepal) of which 7 were from fibula fixed group (Group A) and 4 was from the fibula unfixed group (Group B). All patients failed to attend scheduled follow up. Total of 26 cases of group A and 29 cases of group B were included in the final analysis.

The study population consisted of 66 patients of whom 11 were lost to follow up. The age range of population included in the study was 22-72 years. The mean age in fibula fixed group was 41.38 years and in unfixed group was 45.45 years. Of the 55 patients there were 40 (72.7%) males and 15 (27.2%) females. Gender ratio was 2.6:1 (M:F). The right side (30/55) was more commonly involved than left side (25/55) but there was no significant difference between the two groups. None of the patients showed varus deformity. The average valgus deformity for all patients of the tibia in was 6.92°. For fibula fixed group the average valgus was found to be 6.15°. For fibula not fixed group the average valgus was found to be 7.62°. The mean range of movement at 6 months in patients with fibula fixation was 76.92% and that in whom fibula is not fixed was 74.93%. Mean time of union in patients with fibula was fixed were 5.88 months and those in which fibula was not fixed was 5.96 months after radiographical assessment. Four out of the 26 patients in whom fibula was fixed developed wound infections at the fibular wound site. When calculating the Johner and Wruhs score for both fixed and unfixed groups, there were no excellent or poor results. In the fixed group out of 26 patients 22 (84.6%) had good results and 4 had fair results (15.3%). Among the 29 patient in whom the fibula fixation was not done 20 (68.9%) had good results and 9 (31%) had fair results.

X-rays Pre op and Post op x rays distal third both bones fracture fixed with tibia IMILN and 1/3 tubular plate

Group A: Both tibia and fibula were fixed.



Group B: Fibula not fixed



DISCUSSION

The role of fibula fixation in distal third fractures of the shaft of tibia and fibula has not been clearly defined.^[6,7,17] This study was conducted in 55 patients to analyze the results of fixing the fibula fracture in fractures of the lower third of shaft of tibia and fibula when compared with cases in which fibula is not fixed. In all of the cases, the fracture tibia was treated with interlocking intramedullary nailing or plating. The longest duration of follow up was nine months and shortest duration was six months.

The mean age of the patient in fibula fixed group was 41.38 ± 13.4 and not fixed group was 45.45 ± 10.9. In a study performed by Rouhani et al.^[18] mean age in fibula fixed group was 24.2 ± 7.8 and unfixed group was 28.6 ± 10.3. This is not consistent with our study due to wide range of age group. This study showed a high incidence of fractures in males than females in fixed group, gender ratio was 3.3:1 (M:F) and in unfixed group the 2.22:1 (M:F) in unfixed group. Rouhani et al.^[18] gender ratio was 11:1 (M:F) in fixed group and 3.8:1 (M:F) in unfixed group. We find that both studies show a higher incidence of fractures in males due to cultural differences. In our study the right side (30/55) was more commonly involved than left side (25/55) but there was no significant difference between the two groups. This is correlating to the study by Prasad et al^[16] where right side (34/60) and left side (26/60) were involved but were not statistically significant. The injuries sustained are mostly by RTA or fall from height. In fibula fixed group RTA was 26.9% and fall from height was also 26.9%. In unfixed group RTA was 34.5% and fall from height was 31%. This data does not correlate to a study conducted by Prasad et al. in which most cases were due to RTA in both groups (90%). This difference in groups among the two studies can be due to the fact that many patients in our study come from a rural and hill region where incidence of RTA is less.

In all of the 55 patients, irrespective of whether fibula was fixed or not, there was valgus angulation at the fracture site. In our study none of the patients showed varus deformity. The average valgus deformity for all patients of the tibia in was 6.92°. For fibula fixed group the average valgus was found to be 6.15°. For fibula not fixed group the average valgus was found to be 7.62°.

The results correlated with the study performed by Ehlinger et al. and Prasad et al.^[19,16] In the study conducted by Prasad et. al. the average valgus deformity in fixed group was 5.06° and unfixed group was 7.86° and showed no significant difference in the two groups.^[16] These findings co-relate with results of this study. Of the patients undergoing fibular fixation 84.6% had good results, 15.3% of patients had fair results. Among the patients in whom fibula was not fixed 68.9% had good results, 31% had fair. In both groups no patient had excellent or poor results. In the study by Prasad et al. in the fixed group 80% had good results and 20% had fair results. In unfixed group all patients had fair results. They also found a significant difference in the two groups. These findings are not concurrent with our study as we have found no statistical difference between fibula fixed and unfixed group. The probable reasons for such an outcome could be: (1) the relatively wider diameter of the medullary canal of the distal fragment decreases the

amount of fixation with less contact surface between the nail and the bone.^[15] This in turn can result in the distal fragment going for valgus/varus angulation (2) the short distal tibial segment (3) the most important factor in avoiding malreduction of distal fragment is ensuring that the guidewire is placed in the exact middle of the medullary canal and that it is perpendicular to the tibial plafond. Any variation from this can result in the distal segment going for valgus/varus angulation^[1,2,3,4] (4) comminution at the fracture site. The fixation of the fibula establishes the length of the lateral column. When the fixation of the fibula is done prior to nailing of the tibia, it helps to restore the alignment of proximal and distal tibial fragments.^[20] This may be the reason for less valgus angulation in cases where fibula was fixed. This result correlates with the study performed by Buzzi et al.^[21]

Range of motion at the ankle at 6 months was statistically not significant in patients with and without fixation of the fibula. The mean range of movements in patients with fibula fixation was 76.92% and that in whom fibula is not fixed was 74.93%. In patients with fibula fixed, 21 had good results, 5 had fair results. In patients without fibula fixation 19 had good results and 10 had fair results. In both groups there were no excellent or poor results. In a study conducted by Prasad et al. in fibula fixed group the mean ROM was found to be 78.33% and unfixed group was found to be 74.66%. The ROM score for fixed group 22 patients (73.33%) had good results and 8 patients (26.66 %) had fair results. In unfixed group 20 patient (66.67%) had good results and 10 (33.3%) had fair results. there was no significant difference in range of motion between the two group in this study was well. Mean time of union in patients with fibula was fixed were 5.88 months and those in which fibula was not fixed was 5.96 months after radiographical assessment. In a study conducted by Prasad et al. found that average time of union in fixed group was 4.93 months and unfixed group was 5 months. Both results are show no significant difference between the two groups.^[16] Patients treated with fixation of fibula had comparatively higher rate of complications than those without fibula fixation. Four out of the 26 patients in whom fibula was fixed developed wound infections at the fibular wound site. All the three infections were controlled by appropriate dressing and antibiotics which correlates with the study done by Gupta et al.^[22] Prasad et al. in their study showed that 6 out of 30 developed superficial wound infection at fibula surgical site.^[16]

In our study according to Johner & Wruhs criteria showed that the distribution of results were statistically insignificant between patients with and without fibula fixation. We found that in both fixed and unfixed groups there were no excellent or poor results. In the fixed group out of 26 patients 22 (84.6%) had good results and 4 had fair results (15.3%). Among the 29 patient in whom the fibula fixation was not done 20 (68.9%) had good results and 9 (31%) had fair results. Prasad et al. found that in fixed group 24 patients (80%) had good result and 6 (20%) had fair results. In unfixed group 20 out of 30 patients (66.66%) had good results and 10 (33.33%) had fair results their study also showed no significant difference in scores between the two groups.^[16]

Conclusion:

There was no statistical difference in the tibial malalignment [valgus angulation] in patients in whom fibula was fixed in lower third tibia and fibula fractures compared to those in whom fibula was not fixed. The functional score after 6 months follow up between patients with and without fibula fixation were statistically insignificant. There was no significant statistical difference in the time of union of the tibial fracture between the two groups of patients. There was no significant difference in the rate of complications between the two groups

Declaration of patient consent:

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest:

There are no conflicts of interest.

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