

The Role of Fibular Fixation in the Treatment of Combined Distal Tibia and Fibula Fracture: A Randomized, Control Trial

Abstract

Background: This randomized, parallel-group, non-blinded study was designed to determine the role of fibular fixation in the treatment outcomes of combined distal tibia and fibula fractures. **Materials and Methods:** Sixty patients with distal tibial and fibular fractures were randomly divided in two groups of case and controls. In the case group, fibula was fixed prior to the fixation of tibia. In the control group, tibia was fixed without fibular fixation. Primary outcomes were varus–valgus angulation, anterior–posterior angulation, union and side effects. Follow-up visit and radiographs were taken 2 and 4 weeks as well as 3, 6 and 9 months after surgery. **Results:** During the follow-up, 11 out of 60 patients in case and control groups were excluded. We recruited 24 and 25 patients in the case and control group, respectively. Intramedullary nailing was used in 8 patients of case and 11 patients of control group. Plate and screw were used in 16 patients in the case and 14 patients in the control group. Varus/valgus and anterior–posterior angulation were not statistically significant between two groups ($P \geq 0.05$). The frequency of tibial and fibula union after 1, 3, 6 and 9 months in case and controls groups were not statistically significant ($P \geq 0.05$). The frequency of nonunion of tibia and fibula, infection and nerve injury in studied groups were not statistically significant ($P \geq 0.05$). **Conclusion:** We did not observe any significant improvement using fibular fixation in the treatment outcomes of tibia distal fractures.

Keywords: *Fibula fracture, fibula union, nonunion of fibula, nonunion of tibia, tibia fracture, tibia union*

Introduction

Multiple factors such as systemic and soft-tissue injury, device stability and host factors like diabetes, immunodeficiency, and nicotine abuse affect tibial fracture healing.^[1] Distal tibial fractures account for 37.8% of all tibial fractures,^[2] and the fractures of the distal tibia typically occur as a result of axial and rotational forces on the lower extremity and represent approximately 10% of fractures of the distal end of the tibia.^[3,4] Delayed union and nonunion could be complications of tibial fractures.^[5] Treatments of distal tibial fractures are frequently associated with worse results and complications, leading to the poor outcome measurements in tibia diaphyseal fractures. Management of distal injuries is often different and more complex.^[6,7] Although different treatment methods have been developed for distal tibia fractures and external fixation, plate and intramedullary nailing are the surgical options for tibial fractures, there is currently

no consensus on the optimal mode of management.^[3,8]

Fibular fractures in 77.7% of the cases are common with tibial fractures.^[2] Fibula fixation as an adjunct method was proposed by Morrison *et al.*, to manage the fractures of the tibia and fibula.^[9] In both clinical and laboratory settings the role of fibular fracture fixation in cases of distal tibia-fibula fractures has been examined, and particularly in the setting of distal tibia fractures, has been shown to help maintaining the tibia fracture reduction.^[10] Previously, studies have reported that effective plating of the fibula fracture improves alignment and the ability of the tibial fracture fixation to resist motion across the defect and prevents loss of reduction.^[6,11,12] On the other hand, fibular fixation may result in delayed union or nonunion because it inhibits the cyclic loading on the tibial fracture site.^[13]

There seems to be a controversy about fibular fixation in the treatment of distal

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tibial fractures and data about the impact of fibular fixation in distal tibia-fibula fractures are limited. So, the present study was aimed to determine the role of fibular fixation in combined distal tibia and fibula fractures. We hypothesized that fixation of the fibula increases the stability of fixation in distal tibial and fibular fractures without increasing other complications, such as nonunion or delayed union.

Materials and Methods

This randomized, parallel-group, non-blind study was conducted between Sep, 2013, and May, 2014, on 60 patients with distal tibial and fibular fractures who were referred to Al-Zahra and Kashani hospitals in Isfahan, Iran. The ethics committee of Isfahan University of Medical Sciences approved this study, and written informed consent was obtained from all studied patients.

Patients older than 18 years old in both genders with combined distal tibia and fibular fractures AO/OTA 43 A1-3, who had fractures less than 2 weeks old, were eligible if they had no evidence of syndesmotic injury or open fractures. Also, exclusion criteria included refractures, pathologic fractures, articular involvement, vascular and soft tissue injuries, multiple fractures and chronic systemic or infective disease with interaction by healing process such as DM.

Sixty eligible patients were randomly divided into two groups with 30 patients using random-maker software “Random Allocation”. In the case group, fibula was fixed by a 3.5 mm DCP or one-third tubular plate through lateral approach prior to the fixation of tibia. Patients who received fixation of the tibia without fibular fixation were allocated in the control group. All procedures were performed under spinal or general anesthesia. Reamed intramedullary nail or plate and screw was placed in tibia in all of the patients according to type and location of fracture. Patients had locking nail placed in tibia and were statically locked with distal locking bolt configuration two medial to lateral bolts or DCP or LCP plating.

Between first day and 13th days from the time of the injury, surgery was performed by different surgeons. Range of motion of the ankle and knee was allowed immediately after operation. We also allowed partial weight-bearing immediately after surgery and progressively after that depending on radiographic signs of union in the first 3 months.

Primary outcomes were varus-valgus angulation, ant/pos angulation, union and side effects, which were recorded for each group during the 9-month follow-up. Union was defined as when patients could tolerate unprotected weight bearing accompanied by radiographic criteria of union. Malunion was defined as a varus–valgus angulation of more than 5° and an anterior-posterior angulation of more than 10°. Malrotation was assessed clinically. Follow-up visit and radiographs were taken 2, 4 weeks, 3, 6 and 9 months after surgery. Due to the nature of the intervention it is not possible to blind participants or the immediate research team to the allocated intervention.

The sample size was calculated using the comparison of proportions formula with two-sided log-rank test, $\alpha = 0.05$, and 80% power. All statistical analyses were done using SPSS software for Windows, version 20. Descriptive data are reported as mean \pm SD or number (percent) as appropriate. Independent sample *t*-test and Chi-square test or fisher exact test were used to compare all studied variables between groups as indicated. *P* less than 0.05 were considered as statistically significant.

Results

Figure 1 shows the flowchart of the study. Twelve out of 72 patients were not eligible or refused informed consent and were not recruited to the study. Sixty eligible patients were randomly assigned in two groups of study, which received treatment and followed for 9 months. During follow-up, 11 patients (six in case group and five in control group) were excluded from the study. Finally, 49 patients (24 in case group and 25 in control group) completed the study and their data were analyzed.

The mean age of the studied patients was 35.4 ± 4.8 years. Baseline characteristics of patients between studied groups are shown in Table 1. No significant differences were observed between groups in the mean of age,

Table 1: Baseline characteristics of 49 studied patients by groups

	Case group (n=24)	Control group (n=25)	<i>P</i> value
Age (year)	36.9 \pm 13.1	34.8 \pm 12.5	<i>P</i> \geq 0.05
Sex, male/female	21 (87)/3 (13)	24 (96)/1 (4)	<i>P</i> \geq 0.05
Mechanism of injury			
Falling	1 (4.2)	1 (4)	<i>P</i> \geq 0.05
Vehicle accident	22 (91.6)	24 (96)	
Torsion	1 (4.2)	0	
Type of tibia fracture			
Simple	2 (8)	3 (12)	<i>P</i> \geq 0.05
Wedge	12 (50)	14 (56)	
Complex	10 (42)	8 (32)	
Type of fibular fracture			
Transverse	6 (25)	8 (32)	<i>P</i> \geq 0.05
Oblique	5 (21)	3 (12)	
Comminuted	12 (50)	10 (40)	
Distance from ankle joint	5.28 \pm 1.28	6.2 \pm 1.63	<i>P</i> \geq 0.05
Location of fibular fracture			
Proximal to tibia fracture	9 (37)	11 (44)	<i>P</i> \geq 0.05
Distal to tibia fracture	15 (63)	14 (56)	
Distance between tibia and fibula fracture	1.58 \pm 1.3	1.88 \pm 1.76	<i>P</i> \geq 0.05
Varus–valgus angulation <5	4 (16)	6 (24)	<i>P</i> \geq 0.05
Varus–valgus angulation >5	20 (84)	19 (76)	
Ant/pos angulation <10	11 (46)	18 (72)	<i>P</i> \geq 0.05
Ant/pos angulation >10	13 (54)	7 (28)	

Data expressed as mean \pm SD or number (percent). *P* values calculated by Independent sample *t*-test, and Chi-square test

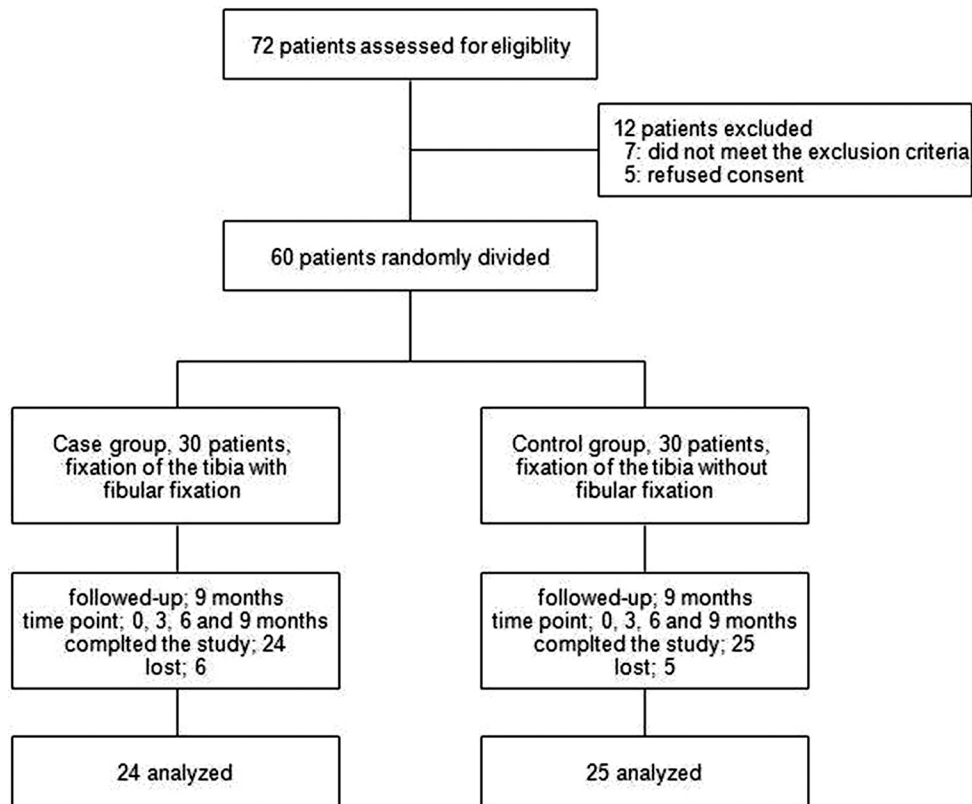


Figure 1: Patients who entered to the study, divided into the study groups and analyzed

sex combination, mechanism of injury, type of tibia and fibular fracture, distance from ankle joint, location of fibular fracture, distance between tibia and fibula fracture, and varus–valgus angulation, anterior–posterior angulation ($P \geq 0.05$).

Eight patients in the case group and 11 patients in the control group were treated by intramedullary nailing. Sixteen patients in the case group and 14 patients in the control group were treated by plate and screw ($P = 0.44$).

Figures 2 and 3 show variation of varus/valgus and anterior–posterior angulation between studied groups during the follow-up period. As shown, varus/valgus angulation during follow-up period in case group showed an increase compared to the control group but this difference was not statistically significant. Anterior–posterior angulation in the control group showed an increase compared to the case group but this difference was not statistically different.

The frequencies of tibial and fibula union at different time points are shown in Table 2 in percentage. Tibial and fibula union at 3, 6 and 9 months after surgery increased in the case group compared to the control group but the differences did not reach significance ($P \geq 0.05$).

Table 3 shows the frequency of tibia and fibula nonunion as well as infection and nerve injury in the studied groups. Nonunion of tibia occurred in 1 out of 24 patients in case group and 2 out of 25 patients in the control group

(4.2% and 8% respectively, $P = 0.99$). Nonunion of fibula occurred in 1 out of 24 patients in case group and 4 out of 25 patients of control group (4.2% and 16% respectively, $P = 0.35$). Nerve injury occurred in none of the patients, infection occurred in one of patients in case group and two patients in the control group, ($P > 0.05$).

Discussion

A common orthopedic injury is the combined fractures of the distal of tibia and fibula.^[14] There is an ongoing debate about the necessity of fibular fixation in distal tibia and fibula fractures. The possibility of a better control over the length and rotation of the limb and better anatomical alignment are the theoretical benefits of fibular fixation, but delayed union or nonunion because it inhibits the cyclic loading on the tibial fracture site because of fibular fixation.^[13,15] In the present study we assessed the role of fibular fixation in distal tibial and fibula fractures. Two groups of cases (with fibula fixation) and controls (without fibula fixation) were treated by intramedullary nailing or plate and screw and outcomes were compared between groups. Varus/valgus and anterior–posterior angulation between studied groups during follow-up period were similar. Frequency percentages of tibial and fibula union after 1, 3, 6 and 9 months between groups were not significantly different. The frequencies of nonunion of tibia and fibula were comparable in both groups. Incidence of

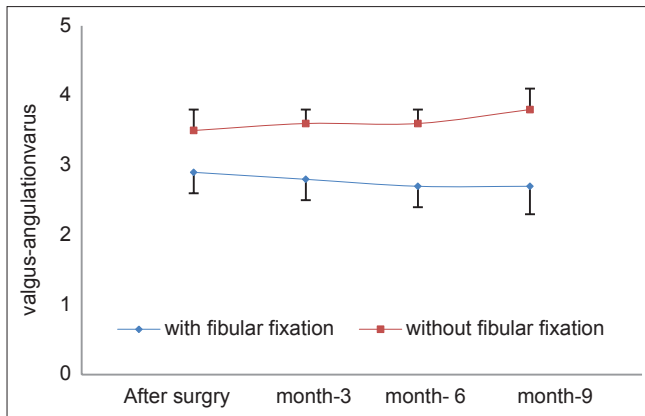


Figure 2: Comparison of varus/valgus angulation among study groups by repeated measurements of ANOVA. The difference of the trend of was not statistically significant between groups (P -values < 0.05)

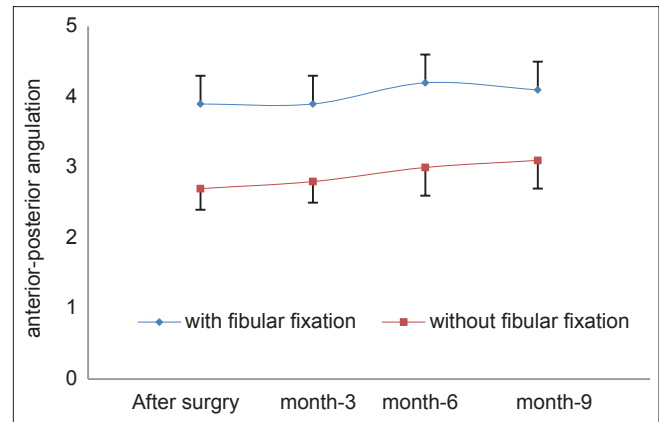


Figure 3: Comparison of anterior-posterior angulation among study groups by repeated measurements of ANOVA. The difference of the trend of was not statistically significant between groups (P -values < 0.05)

Table 2: Comparison of the frequency percentage of tibial and fibula union in studied groups

	Case group (n=24)	Control group (n=25)	P value
Tibial union			
Month-3	1 (4.2)	0	$P>0.05$
Month-6	5 (20.8)	2 (8)	$P>0.05$
Month-9	23 (95.8)	23 (92)	$P>0.05$
Fibula union			
Month-3	6 (25)	2 (8)	$P>0.05$
Month-6	13 (54.2)	12 (48)	$P>0.05$
Month-9	23 (95.8)	21 (84)	$P>0.05$

Data expressed as number (percent). P values calculated by Chi-square test or fisher exact test

Table 3: Comparison of the frequency percentage of nonunion of tibia and fibula, infection and nerve injury in studied groups

	Case group (n=24)	Control group (n=25)	P value
Nonunion of tibia	1 (4.2)	2 (8)	$P=0.99$
Nonunion of fibula	1 (4.2)	4 (16)	$P=0.35$
Infection	0	2 (8)	$P>0.05$
Nerve injury	0	0	$P>0.05$

Data expressed as number (percent). P -values calculated by fisher exact test

nerve injury and infection were not significantly different between groups.

In a randomized clinical trial by Rouhani *et al.*,^[16] during a 23-month period, a total of 53 patients with concomitant fractures of tibia and ipsilateral fibula at distal third level were assessed to investigate the effect of the fixation of fibula in the treatment of tibia distal fractures. Results in this study showed that frequency of varus/valgus angulation and anterior-posterior angulation during the follow-up period was comparable in both studied groups.

Also, they did not found any differences between case and control groups for the frequency of Infection and nonunion. Authors in this study concluded that fixation of fibula did not improve the treatment outcome of distal third of tibia diaphysis fractures. In agreement to Rouhani *et al.* study, there was no significant difference in the frequency of infection as an adverse effect of fibular fixation in our study, and we did not find any advantage of using fibula fixation to treat distal of tibia diaphysis.

Several studies showed different results in comparison to our study, however, most of these studies are not similar to the present study because have been done in tibial plafond fractures. One of these studies was done by Marsh *et al.*^[13] showed an increasing risk of infection after using the fibular fixation method. In another study by Williams *et al.*^[17] the effect of fibular fixation in the tibial fracture treatment was assessed and they reported that clinical outcomes of tibial plafond fractures with associated fibula fractures were stabilized using monolateral external fixators spanning the ankle joint. Their results also showed an increase of nonunion and infection rate in case group with fibular fixation. They concluded that favorable clinical outcomes may be achieved without fibular fixation in such cases. These contrasts to a retrospective study by Berlusconi *et al.*,^[18] in which a total of 60 patients with distal shaft fracture of the tibia with associated fracture of the fibula were assessed in two groups of patients who had their fibula fixed and patients who did not. The infection rate was not difference among the three groups and investigators recommend fibular fixation in all distal fractures when both fractures lie on the same plane and the tibial fracture is relatively stabilized. Another study by Teitz *et al.*^[19] showed that sparing the fibula may result in rapid union of the fracture because of the inhibiting cyclic compression theory.

Some studies reported that fibular fixation does not affect tibial fracture treatment; one of them reported no benefit

of fibular fixation on extra-articular fractures of combined tibia and fibula, and did not recommended it.^[20,21] Other two studies reported no effect of fibular fixation on the treatment outcome of patients with tibial fractures.^[22,23]

Some studies have suggested concurrent fibular fixation and reported some beneficial effects of fibular fixation in same level combined tibial and fibular fractures. One study reported that fibular fixation would preserve reduction of tibia.^[9] Other studies showed that fibular plate fixation increased the initial rotational stability after distal tibial fracture in comparison with patients that had tibial intramedullary nailing alone.^[11] Others reported more complications in fibula distal fractures without fibular additional plating compare to fibular additional plating and recommended fibular fixation in combined tibial and fibular fractures.^[24-26]

In agreement with some studies, results of the present research did not show any significant difference in treatment outcomes between groups with or without fibular fixation and we did not found any beneficial effect of fibular fixation. But some studies have different results than our results and reported advantages or disadvantages of fibular fixation in the treatment outcomes. The difference among these results and our results could be explained by the difference in the design of the studies, the difference in surgery procedure and the duration of follow-up.

One limitation of this study is the small number of samples especially after losses of 11 patients in both groups during the follow-up period. Another limitation is that surgeries were done by different surgeons. Additionally, we did not perform any bone density measurements in the participant and this factor may be introducing a bias in patient selection.

In conclusion, according to the results of the present study, there was no any advantage of the fixation of fibula fracture associated to distal of tibia fracture. And also it did not show an increase in the frequency of complications after fibula open reduction and internal fixation. However, future studies with appropriate sample size are recommended to further our understanding of this effect.

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Conflicts of interest

There are no conflicts of interest.

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