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Original Article

Orthopaedics Section

Factors Determining the Functional and Radiological Outcome after Secondary Nailing in Open Fractures of Lower Extremity- A Prospective Cohort Study

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ABSTRACT

Introduction: Open long bone fractures of lower limb are cumbersome to treat. Because of the increased chances of infection, wound debridement and external fixation is the primary procedure followed by a secondary intramedullary nailing when the wound improves. Pin tract infection, loss of fixation, non union is the most frequently encountered complications of external fixation. These complications have discouraged surgeons all over the world in accepting external fixation as a definitive method of fracture treatment. Secondary intramedullary interlocking nailing provides intramedullary input of cancellous tissue at the fracture site due to reaming and nailing.

Aim: To evaluate the factors determining the outcome after secondary nailing in open fractures of lower extremity.

Materials and Methods: The prospective cohort study was conducted from October 2017 to April 2020 at Pondicherry Institute of Medical Sciences, Puducherry, India, with 33 patients who had open long bone fractures of lower limb and underwent secondary nailing following external fixation, were evaluated. The patients were followed-up for a period of six months. Factors such as age, bone involved, grade of injury, timing of debridement, time interval between external fixation and secondary nailing were analysed to see whether they affect the outcome of secondary nailing of open fractures of long bones. All patients underwent an initial thorough wound debridement and external fixation application. A secondary nailing was done once wound had settled down. Age, gender, bone involved, grade of injury, timing of debridement and timing of secondary nailing were noted for all the patients and patients were followed-up at six weeks, three months and six months. Final functional outcome (end of six months) was calculated using Lower Extremity Functional Scale (LEFS) and radiological union (end of six months) was calculated using Radiological Union Scale in Tibial fractures score (RUST).

Results: There were no statistically significant differences in RUST/LEFS score at the end of six months, with respect to age (p-value=0.825/0.847), gender (p-value=0.235/0.348), bone involvement (p-value=0.726/0.757), grade of injury (p-value=0.107/0.546) and timing of debridement (p-value=0.117/0.374). The mean RUST scores at six weeks, three months and six months were 4.39, 6.57 and 9.28, respectively. The mean LEFS scores at six weeks, three months and six months were 20.96, 34.92, 49.5, respectively. The radiological union rate in this study was 60.61% at the final follow-up. But patients who underwent secondary nailing with 10 days of primary debridement and external fixation had a statistically significant (p-value) better outcome in terms of RUST (p-value at 3 months=0.045)/LEFS (p-value at 6 months=0.030).

Conclusion: The interval between external fixation and secondary nailing was found to be a significant determinant of radiological outcome at three months (p-value at 3 months=0.045) and better functional outcome at six months (p-value at 6 months=0.030) with patients undergoing secondary nailing within 10 days of external fixation having a good final outcome. However, the radiological outcome between the two groups was comparable at six months follow-up.

Keywords: External fixation, Intramedullary nailing, Wound debridement

INTRODUCTION

One in every 120 persons, under the age of 65 years, is estimated to have fracture and 3% of these fractures are open fractures [1,2]. Open fractures of the lower limb are challenging injuries for surgeons to treat. There has been a fear of increased chances of infection that has the potential of resulting in amputation or sometimes even death [3]. In olden days, open tibial fractures were treated by closed reduction and casting, with a window created at the fracture/wound site for care of the soft tissue. The introduction of external fixator revolutionised the management of open fracture and this was particularly true with regard to the high velocity trauma sustained in road traffic accidents and firearm injuries [4].

Since open fractures have increased chances of infection, many surgeons prefer to initially do a wound debridement and external fixation as a primary procedure followed by a secondary intramedullary nailing when the wound condition improves [5]. The actual principles for treating an open fracture include resuscitation as the first priority, analgesia, anti-tetanus and antibiotics therapy, debridement and rigid stabilisation. Use of adjuncts such as antibiotic beads, vaccum therapy and early soft tissue coverage with well vascularised tissue help to promote revascularisation which prevents late infections and nonunion that may occurs secondary to persistent bone ischaemia. The use of antibiotic beads and vacuum therapy are not mandatory, but are an important part of the armamentarium for those caring for such fractures [3].

External fixation is associated with a number of complications [6] like pin tract infection, loss of fixation, non union of 10%-41% [7,8] delayed union and malunion. These complications have discouraged the surgeons all over the world in accepting external fixation as a definitive method of fracture treatment. The aim of the present study was to evaluate the factors that determine the outcome after secondary nailing in open fractures of lower extremity.

MATERIALS AND METHODS

The prospective cohort study was conducted from October 2017 to April 2020, at Pondicherry Institute of Medical Sciences,

Puducherry, India. Total 47 patients were initially recruited after obtaining approval from Institutional review board and the Ethical Committee (IEC: RC /17/82).

Sample size calculation: Assuming the union rate as 85.7% [9], with 10% precision and 95% confidence level, the estimated sample size was 47. Eight patients were lost during the follow-up, five withdrew from the study and one patient died at five months due to cardiac arrest. At the final follow-up, 33 patients were included in the present study.

Inclusion criteria: All patients presenting to the Institution with open long bone fractures of lower limb, who were treated with wound debridement and external fixator application and then converted to secondary intramedullary nail fixation were included in the study.

Exclusion criteria: Patients less than 18 years of age, polytrauma patients and those patients with associated neurovascular injury were excluded from the study.

Study Procedure

Patients with open fractures of long bones of lower limbs presenting to casualty were initially resuscitated (airway, breathing and circulation). After the stabilisation of general condition, the wounds were photographed and documented. Triple antibiotics (cephalosporin, aminoglycoside, metronidazole) were started as soon as possible.

Under aseptic precautions, thorough debridement of the wound was done and fractures were graded according to Gustilo Anderson classification [5]. The fractures were reduced and stabilised with AO external fixator. In cases with wounds which can be approximated, wounds were sutured with a suction drain and in cases with soft tissue defect i.e., Gustilo Anderson grade 3B fractures were left open and saline dressing applied. Postoperatively, for grade 1, 2 and 3A fractures, regular dressing and pin tracts were taken care. For grade 3B, soft tissue procedures like skin grafting/flap, depending on the extent and nature of the wound was done by plastic surgery team.

If the pin tracts/wound got infected, antibiotics were given according to culture sensitivity and regular dressing was done till the infection subsided. After the infection subsided or wound/Split Skin Graft (SSG)/flap condition improved, external fixators were removed and patients were given slab or skeletal traction according to the fracture. After the granulation of pin tracts, patients were planned for definitive fracture fixation. After nailing, patients were followed-up at six weeks, three months, six months and on every visit RUST [10] and LEFS [11] scores were calculated. Factors such as age, bone involved, grade of injury, timing of debridement, time interval between debridement and nailing were noted and the relationship between these factors and the final functional outcome (RUST and LEFS scores) were calculated.

- According to the age, the patients were grouped into three groups. Group 1 included less than or equal to 30 years of age, group 2 included 31 to 50 years of age and group 3 included patients of age more than or equal to 51 years.
- According to the bone involvement the patients were classified into two groups: group 1- Tibia fractures and group 2- Femur fractures.
- According to the grade of injury, the patients were classified into three groups based on Gustilo Anderson classification into three grades {Grade 1, 2 and 3 (A and B)}.
- Based on time interval between injury and external fixation, patients were classified into two groups. Group 1 with time interval less than five hours and group 2 with time interval more than five hours.
- Based on time interval between debridement and nailing, patients were divided into two groups: group 1- less than 10 days and Group 2- more than 10 days.

STATISTICAL ANALYSIS

The data were entered in MS excel sheet and data analysis done by SPSS version 21.0. Mann-Whitney U test was used for analysis of gender, grading of injury, bone involvement, time interval between injury and debridement, time interval between external fixation and secondary nailing. Kruskal-Wallis test was used for age analysis.

RESULTS

In the present study, 33 patients with open fractures of long bones of lower limbs were evaluated. Age of the patients ranged from 19 to 72 years with a mean of 38.94 years and majority of them belonging to 30 to 50 years. There were 30 males and three female patients, in the ratio of 10:1. Out of 33 patients, majority of the patients (23 patients) belonged to grade 3A and 3B, mostly involving tibia (tibia-25, femur-8). The minimum time interval between injury and intervention was two hours and the maximum time interval was 52 hours. The mean time was 13.94 hours. The mean interval between external fixation and secondary nailing was found to be 37.9 days. The median RUST scores at six weeks, three months and six months were 4, 6 and 9, respectively. The median LEFS scores at six weeks, three months and six months were 20, 31, 50, respectively [Table/Fig-1].

Time interval		Minimum	Maximum	Median	Inter-quartile range value
6 weeks	RUST	4	6	4.00	1
	LEFS	9	32	20.00	9
3 months	RUST	4	9	6.00	1
	LEFS	22	55	31.00	15
6 months	RUST	5	11	9.00	2
	LEFS	29	64	50.00	16

[Table/Fig-1]: RUST and LEFS scores at each follow-up (N=33).

There was no statistically significant difference in RUST and LEFS scores among the three groups at the end of six months follow-up based on age. This shows that age did not play a significant factor in the outcome [Table/Fig-2].

Age group	6 weeks		3 months		6 months	
	RUST	LEFS	RUST	LEFS	RUST	LEFS
≤30 years	4	19	6	29.5	9	50
31 to 50 years	4	20	6	35	9	49.5
≥51 years	4	21	7	32	9	49
p-value (Kruskal-Waliis test)	0.603	0.489	0.950	0.337	0.825	0.847

[Table/Fig-2]: Median RUST and LEFS according to age distribution.

There was no statistically significant difference between the two groups (male and female) in terms of functional and radiological outcome [Table/Fig-3].

Gender	6 weeks		3 months		6 months	
	RUST	LEFS	RUST	LEFS	RUST	LEFS
Male (n=30)	4	20	6	31	9	49.5
Female (n=3)	4	19	7	41	9	50
p-value (Mann-Whitney U test)	0.701	1.000	0.131	0.211	0.235	0.348

[Table/Fig-3]: Median RUST and LEFS according to gender.

There was no statistically significant difference between the grades of open fracture in terms of functional and radiological outcome [Table/Fig-4]. Eight patients had femoral fracture and 25 had tibial fracture. There was no significant difference in outcome (RUST and LEFS) when either of the bone was fractured [Table/Fig-5]. There was no statistically significant difference of RUST and LEFS between the femoral and tibial groups [Table/Fig-5].

Grade	6 weeks		3 months		6 months	
	RUST	LEFS	RUST	LEFS	RUST	LEFS
Grade 1 n=2	4	18.5	6	35	7.5	52.5
Grade 2 n=8	4	22.5	6	30	8.5	44
Grade 3 n=23	4	20	7	31	9	50
p-value (Mann-Whitney U test)	0.542	0.482	0.627	0.720	0.107	0.546

[Table/Fig-4]: Median RUST and LEFS according to Gustilo Anderson grading.

Bone involvement	6 weeks		3 months		6 months	
	RUST	LEFS	RUST	LEFS	RUST	LEFS
Femur (n=8)	4	21	6	34.5	9	50
Tibia (n=25)	4	20	6	31	9	49
p-value (Mann-Whitney U test)	0.578	0.636	0.496	0.470	0.726	0.757

[Table/Fig-5]: Median RUST and LEFS according to bone involvement.

With respect to timing of debridement, patients were classified into two groups. Group 1 (eight patients) underwent a primary debridement and external fixation within five hours of injury and group 2 (23 patients) underwent the same after five hours of injury. At the end of six weeks, three months and six months, there was no statistically significant difference in RUST and LEFS scores between the groups [Table/Fig-6].

Time interval	6 weeks		3 months		6 months	
	RUST	LEFS	RUST	LEFS	RUST	LEFS
<5 hours (n=8)	4	20	7	39.5	9	50
>5 hours (n=25)	4	20	6	31	9	49
p-value (Mann-Whitney U test)	0.853	0.726	0.190	0.127	0.117	0.374

[Table/Fig-6]: Median RUST and LEFS according to time interval between injury and debridement.

There was no statistically significant difference in functional and radiological outcome in terms of the time interval between injury and debridement [Table/Fig-6]. According to the time interval between external fixation and secondary nailing, patients were grouped into group 1 (five patients) with those undergoing nailing within 10 days of primary debridement with external fixation, and group 2 (28 patients) who underwent the same after 10 days of external fixation. A statistically significant difference was found (p-value=0.045) in RUST score between the two groups at the end of three months, but by six months they were similar. Furthermore, there was a statistically significant difference (p-value=0.03) in LEFS score between the two groups at the end of six months [Table/Fig-7].

Time interval	6 weeks		3 months		6 months	
	RUST	LEFS	RUST	LEFS	RUST	LEFS
<10 days (n=5)	6	27	8	55	9	64
>10 days (n=28)	4	20	6	31	9	49
p-value (Mann-Whitney U test)	0.074	0.247	0.045	0.066	0.364	0.030

[Table/Fig-7]: Median RUST and LEFS scores according to time interval between external fixation and secondary nailing.

DISCUSSION

The treatment of Gustilo and Anderson grade 3A and 3B femoral and tibial fractures has traditionally been emergency wound debridement and external fixation. Though in the past many surgeons preferred to use the external fixator as a definite management, there has been a trend in converting the external fixation into intramedullary device after adequate wound healing in recent times [5]. This has mainly been due to the complications arising from having the external fixators for a long time namely, pin tract infection, delayed union, non union and malunion [10]. The timing of conversion of external fixator into an intramedullary device, initial wound status, pin tract infection and various other factors play an important role in achieving a good outcome after secondary nailing [11]. This was a prospective observational study involving 33 patients, in whom secondary intramedullary nailing was done as a definite procedure after an initial temporary fixation with an AO unilateral external fixator. Of the 33 patients, the youngest was 19-year-old and the oldest was 72 years with the mean being 38.94 years. Although one would expect a good functional outcome in the younger age group, in the present study there was no statistically significant difference in RUST and LEFS scores at the end of six months with respect to age.

The union rate of open fractures of tibia and femur at the end of six months of secondary nailing was only 60.6% (20 patients). The remaining 13 patients were followed-up further after the study. Although this was much lower than the union rates achieved by Wu CC and Shih CH, Blachut PA et al., and Malik MHA et al., which were 95%, 96% and 94%, respectively, all of these authors were able to achieve such high union rates only at the end of one year, whereas the index patients have been followed-up only for six months [9,12,13]. Of the 33 patients in this series, 25 had open tibial fractures and eight had open femoral fractures, and at the end of six months both the tibial and femoral group had uniform RUST and LEFS scores with no statistical significant difference. A study done by Wu CC and Shih CH also showed that there was a union rate of 96% in tibia and 93.3% in femoral fractures after secondary nailing [14].

Only 8 (24.2%) out of the 33 patients underwent an initial wound debridement and external fixation within five hours of injury. The remaining 23 patients had an initial debridement more than five hours after the injury. The time span ranged from a minimum of two hours to a maximum of 52 hours. According to the present study, there was no statistically significant difference in RUST and LEFS scores in groups which has been treated within and after five hours of injury.

This is in accordance with studies by Singh A et al., Reuss BL and Cole JD, and Li J et al., who have also said that there is no association between the timing of initial debridement and the final functional and radiological outcome [15-17]. This is further emphasised by a study made by British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) and British Orthopaedic Association (BOA) [18] wherein, there was found to be no advantage of debridement of open fractures within six hours of injury or after six hours of injury.

The time interval between external fixation and secondary nailing played a significant role in the final functional and radiological outcome at the end of six months. Of the 33 patients, only five underwent definite nailing within 10 days of wound debridement and external fixation and the remaining 28 patients were taken for nailing after 10 days. At the end of three months, RUST score was found to be statistically significant in those who underwent nailing within 10 days, whereas, LEFS was found to be statistically significant in the same group by six months. These results were comparable with studies made by Wu CC and Shih CH, Blauchut PA et al., where more than 90% union rates were achieved in patients nailed within 10 days of external fixation. This may be due to the fact that we were able to avoid the known complications of having the external fixator for a long time [9,12].

Limitation(s)

The sample size (47 patients) was limited, and the study participants were not operated by the same surgeon. The patients were followed-up for a short period of time (six months). The number of patients in grade 1, 2 and 3 (A/B) were not comparable to comment on the significance.

CONCLUSION(S)

Age, gender, grade of open injury, bone involved, interval between injury and debridement were not the determinants of functional and radiological outcome of secondary nailing of open fractures of long bones of lower limbs. Furthermore, the interval between external fixation and secondary nailing was found to be a significant determinant of radiological outcome and functional outcome with patients undergoing secondary nailing within 10 days of external fixation having a good final outcome. The notion that opens fractures should be debrided within six hours of injury does not hold true anymore. Debridement can be carried out within 24 hours of injury on scheduled trauma lists, combining plastic and orthopaedic surgeons whenever possible. Operating an open fracture in the middle of the night with untrained theatre staff and a junior surgeon has been found to be much more harmful than the delay in surgery itself. However, further studies with higher sample size are suggested to generalise the results obtained from the present study.

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