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Original Article

Open diaphyseal fracture of the tibia in Pakistani adults: A comparative study of Plaster of Paris cast vs. Naseer Awais external fixator.

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Abstract

Background: The management of open tibial diaphyseal fractures is the most challenging glitch faced by orthopedic surgeons. For open or comminuted fractures, external fixation remains the gold standard. This study aimed to assess the treatment response of fixators by comparing the results of open diaphyseal tibial fracture stabilization in adults by Plaster of Paris (POP) cast versus Naseer Awais External Fixator (NAEF).

Methodology: A single-center, prospective study was conducted at the leading teaching institute and tertiary care hospital of Jamshoro and Hyderabad, Pakistan. A total of 30 patients having an open diaphyseal fracture of the tibia were randomly assigned to two groups (Group A-POP cast and Group B to NAEF; n=15 each). Duration of hospital stay and postoperative complications (like wound infection, union rate, and functional outcome) were compared between groups.

Results: On average, group A patients stayed in the hospital for 3.65 weeks, while group B patients stayed for 2.49 weeks (p=0.004). Wound infections were observed in 26.7% and 53.3% of the patients in group A and B, respectively. No significant difference in the adequate callus formation (i.e. union) and good functional outcome was observed among patients of group A and B (p>0.05).

Conclusion: The use of NAEF for open diaphyseal fractures of the tibia has a significant advantage over POP cast in reducing the duration of hospital stay. However, no significant differences were observed in wound infection, union rate and time, and functional outcome.

Keywords

Open Fracture, Naseer Awais External Fixator, Plaster of Paris, Tibia.

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Introduction

Tibia is the commonest long bone fractured, and 94% of open tibial fractures in adults result from a motor vehicle accident when a patient sustains high-velocity injury[1]. Open tibial diaphyseal fractures account for around 25% of all open fractures; out of which 28.7% are Gustillo type I, 25.3% Gustillo type II, and 46% are Gustillo type III injuries[2]. Generally, type I open diaphyseal fractures are treated by conservative measures whereas, type II and III are often managed with osteosynthesis[3].

A tibial fracture is often resulting in extensive damage to the soft tissue and bone[1,2]. With high infection rates and frequent injury to neurovascular structures, they have a high incidence of complications and poor treatment outcome[4]. Treating these injuries requires experience judgment and remains one of the most challenging problems facing the orthopedic surgeon5. Nonetheless, the management of open diaphyseal fractures depends upon the type of fracture and soft tissue damage. Manipulation and casting is a reliable treatment for type I open tibial fractures in adults. External fixation remains the gold standard for high-grade open fractures (Gustillo type III) or comminuted fractures[5,6].

The majority of isolated open tibial fractures in young adults can be treated by wound debridement and plaster cast immobilization[2,7,8]. There is still a role for using an external fixator, especially where there is a grossly unstable fracture or extensive soft tissue injury requiring a flap procedure[2,9]. External fixation is a method of immobilization that uses percutaneous pins placed in the bone and linked with external connectors to maintain the fracture segments in a desired spatial relationship. The ease and speed of application, adjustability of the frame, and minimization of blood loss with preservation of blood supply at the cutaneous and osseous levels are advantages of the external fixation technique[10].

The NAEF is a locally made, cheap and uni-planar external fixator, which has performed the desired function. The first NAEF was developed and used in the Department of Orthopaedic Surgery King Edward Medical College and Mayo Hospital Lahore in early 1981. Since then, based on the local experience, different types of NAEFs have been developed and used to manage different problems like fractures and leg lengthening[11]. The NA Fixator for leg lengthening and segment transport was introduced in 1988 and used for segment transport in a girl of 8 years[11]. The system has been successfully used for the treatment of open fractures, segmental fractures, open fractures with segmental loss of bone, infected fractures, and leg-lengthening in case of segmental bone defects and post-polio paralysis[11,12].

It is cost-effective and well tolerated by patients compared to other sophisticated dynamic axial fixators because most patients belong to poor socio-economic conditions and easy to apply, especially in developing countries like Pakistan. Application of alternative compression and distraction helps enhance healing of the fracture in the open fractures of the tibia, which is permissible and easy with NAEF[11]. As NAEF is associated with less duration of hospital stay, quick union, less infection rate and good fracture outcome, therefore; the purpose of this study was to compare the results of open diaphyseal tibial fractures stabilization adults by POP cast vs. NAEF.

Methodology

It was a single-center, prospective study conducted at the Department of Orthopaedics Surgery and Traumatology (DOST), Jamshoro and Hyderabad, Pakistan. The study duration was 18 months, from Jul 1, 2018, to Jan 15, 2020. The study was compiled as per International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP-E6). Before initiation, the ethics review committee approved the study, and informed consent was taken from all recruited subjects.

A total of 30 patients who fulfilled the inclusion criteria were enrolled and then randomly assigned into two groups (Group A and B) by the lottery method. Each group comprised 15 patients. The POP cast was applied in group A patients, whereas NAEF was carried out in patients of group B.

After receiving the patients in the emergency room, proper resuscitation was done, i.e. Airway, Breathing and Circulation were checked. Fracture grades were assessed according to Gustillo-Anderson classification (i.e. grade I/II/IIIA/IIIB). Intravenous opioids analgesics were given to all patients, and the fracture site became temporarily immobilized. Tetanus toxoid (IM) and intravenous antibiotics (penicillin G and gentamycin) were administered to all patients. Later, antibiotics were changed according to the culture and sensitivity report. Baseline investigations (like CBC, U/C/E, PT and INR, and Chest X-ray) were carried out, and blood was sent for grouping and cross-matching. Then X-ray of the fracture site was performed. After initial stabilization, patients were shifted to the emergency operation theatre, where the primary procedure was performed.

The software program SPSS for Windows (version 10; SPSS Incorporated, Chicago, Illinois, USA) was utilized for all statistical analyses. Frequencies and percentages were used to summarize categorical variables, whereas mean and standard deviation (SD) were computed for numerical variables. The Unpaired Student t-test and Fischer-exact test were used to compare the results of open diaphyseal fracture stabilization. The p-value < 0.05 was considered statistically significant.

Results

The age range of patients was between 17 to 49 years, with the mean age of 30.97±9.80 years. The majority (66.7%) of cases had age ≤ 35 years {09 (60%) in group A and 11 (73.3%) in group B. The difference between the two means was statistically insignificant (p=0.968). Out of 30 patients, 80% were male making an overall, male to female ratio of 4:1. The details mentioned in table 1.

Table 1: Demographic Distribution of the studied population.

Characteristics		Group A (POP cast group) (n=15)	Group B (NAEF group) (n=15)	Total (n=30)	p-value
Age (Years)		32.0±10.01	29.93±9.82	30.97±9.80	0.968
Age Group	< 35 years	9(60)	11(73)	20(66.7)	
	> 35 years	06(40)	04(26.7)	10(33.3)	
Gender	Male	12(50)	12(50)	24(80)	0.456
	Female	03(50)	03(50)	6(20)	

POP = Plaster of Paris, NAEF = Naseer Awais External Fixator

The common mode of injury was road traffic accidents, i.e. in 50% patients. Firearms caused 06(20%), 05(16.6%) had a history of assault, and 02(6.7%) patients had both histories of fall and bomb blast. In this study, both grade II and grade IIIA fractures were encountered in 30% patients, 23.3% had grade IIIB, and 16.7% had grade I fracture according to Gustillo-Anderson classification. Further analyses revealed that most of the grade I fractures were observed due to fall and assault; however, severe fractures were noticed as a consequence of high-velocity injuries like a bomb blast, road traffic accidents, and firearms. The relationship of the mode of injury to the grade of fracture is mentioned in table 2.

Table 2: Relationship of mode of injury to grade of fracture.

Mode of Injury	Grade of Fracture n(%)			
	I	II	IIIA	IIIB
Fall	2(40)	-	-	-
Road traffic accident	-	5(55.6)	6(66.7)	4(57.1)
Firearms	1(20)	2(22.2)	2(22.2)	1(14.3)
Assault	2(40)	2(22.2)	1(11.1)	-
Bomb blast	-	-	-	2(28.6)

The time-lapse between injury and arrival at the hospital ranged between 01 to 17 hours, with a mean time of 5.60 ± 4.64 hours. The time between admission in hospital and primary procedure ranged from 01 to 07 hours, and the mean time being 3.0 ± 1.55 hours. The time-lapse between admission and definitive treatment varied from 04 to 33 days and mean of 12.13 ± 8.18 days. The difference between mean time lapse between injury and arrival at the hospital and time between admission in hospital and primary procedure of both groups were statistically insignificant (p=0.448 and 0.457 respectively). However, the difference between the mean time lapse between admission and the definitive procedure was statistically significant in both groups (p=0.000) (Table 3). This significant difference was because of the early application of external fixator compared to POP cast due to wound condition. NAEF was applied early in the course, whatever the status of the wound, whereas POP cast was employed in patients only when the satisfactory condition of the wound was achieved.

Table 3: Distributions of time lapse in both groups.

Time Lapse	Group A (POP Cast)	Group B (NAEF)	p-value
	Mean±SD		
Between injury and arrival at hospital (hours)	6.27±5.06	4.93±4.23	0.448
Between admission & primary procedure (hours)	2.93±1.48	3.07±1.67	0.457
Between admission & definitive treatment (days)	16.53±7.73	9.56±2.40	0.000*

Primary Procedure

Out of 30 patients, wound debridement and the application of POP back-slab were performed in 76.7% patients, whereas 23.3% patients were subjected to wound debridement and soft tissue coverage and POP back-slab application.

Duration of hospital stay

Patients of group B were discharged home early as a result of early stabilization of the fracture. The mean duration of hospital stay scores was 3.65 ± 1.51 weeks in group A and 2.49 ± 0.73 weeks in group B. Hence, in group A, the mean length of hospital stay was statistically high (p=0.004).

Postoperative Complications

Postoperative complications were assessed in the follow-up period. These included wound infection, union rates (with time duration of the union) and functional outcome.

a. Wound Infection:

Wound infection was statistically insignificant in both groups (p=0.264). It was noticed in 26.7% patients who underwent POP cast application and 53.3% patients in whom NAEF was employed.

b. Union (i.e. Callus Formation):

Out of 30 cases, 86.7% were united (i.e. radiologically demonstrated adequate callus formation) by the end of the 24th week of follow-up visits (Graph 6). In group A, 20% patients demonstrated non-union (i.e. absent callus radiologically), whereas 6.7%) patient of group B showed non-union. Despite this clinical difference, the statistical union rate (i.e. callus formation) was insignificant in this study (p=0.598). Excluding 04 patients who demonstrated non-union, the mean time duration of the union in the rest of 26 patients were 17.50 ± 4.36 weeks and 15.75 ± 3.60 weeks in group A and B, respectively.

c. Functional Outcome:

This study showed a statistically insignificant difference in functional outcomes after both procedures (p=0.330). In group A, 26.7% cases showed poor outcomes, whereas 6.7% patients of group B revealed poor outcomes in this study.

Table 4: Postoperative Complication.

Complication	Group A (POP Cast) n(%)	Group B (NAEF) n(%)	p-value
Wound infection (n=12)	4(26.7)	8(53.3)	0.26
Union by the end of 24th week (Callus Formation) (n=26)	12(46.1)	14(56)	0.59
Functional Poor Outcome (n=05)	04(80)	1(20)	0.30

Discussion

The current study showed a significant difference in hospital stays in patients of the NAEF group compared to the POP cast group. However, postoperative wound infection, union rate, and functional outcome were statistically insignificant.

The most common cause of morbidity and mortality in the most productive period of life worldwide is road traffic accidents causing fractures[13]. Therefore, it is not surprising that these fractures occur mostly in people aged between 20 and 50 years. In this study, most patients were <35 years of age group with an average age of 30.97 years. This result is comparable to the study conducted by Masood and Qaymn[14] at Shaikh Zayed Postgraduate Medical Institute. Correspondingly, Pollak et al. reported 190 patients with ages ranged from 16 to 69 years, and the average age is 36 years[15].

The sex ratio distribution in this study was also in keeping with other reports and further emphasized the greater vulnerability of males to trauma[16]. Males in our population play major holding financial matters of family, and for that, they have to remain outside of their homes most of the time, predisposing to trauma. In this study, 80% of males sustained an open fracture of the tibia. Tornetta et al. also showed the involvement of 20 men and 09 women in their study of management of open fractures of the tibia[17].

In this study, the majority (50%) of open fractures of the tibia were afflicted as a consequence of road traffic accidents. This was followed by firearms (20%), assault (16.6%), fall (6.7%), and bomb blast (6.7%). The fairly high incidence of road traffic accidents and firearms was explained due to the civilization and law-and-order situation in our society. Joshi et al. observed traffic accidents as a major mode of injury in open tibial shaft fracture in their case series[18]. Siddiqui et al. reported 79 patients, 38 (55.88%) were injured in road traffic accidents, and 14 (20.58%) were the victims of firearms[11].

Gustillo-Anderson classification was utilized to grade open diaphyseal fracture of the tibia in this study. According to this, grade II and IIIA (both) were encountered in 30% of cases, grade IIIB in 23.3%, and grade I in 16.7% of patients. Closer analyses further revealed grade I fracture mostly resulted from falls and assaults, whereas grade II and III were the consequence of high-velocity injuries. Leong et al. also noticed high-grade open fractures due to the severe mode of injuries in their case study of management of 80 open tibial fractures[19].

In this study, the time lapse between injury and arrival at hospital ranged between 01 to 17 hours (average 5.60 hours). The time between admission in hospital and primary procedure ranged from 01 to 07 hours (average 3.0 hours). However, the time-lapse between admission and definitive treatment of open diaphyseal fracture varied from 04 to 33 days (average 12.13 days overall; 16.53 days in POP cast group versus 9.56 days in NAEF group, p=0.000). This delay was attributed to preoperative management of wound in patients of POP cast group compared to NAEF group patients in whom fixator was applied earlier irrespective of the wound status. These results are comparable to the study conducted by Siddiqui et al[11].

Open fractures of the tibia in adults are challenging injuries for orthopedic surgeons. Frequently, they are associated with multiple injuries[20], and initial

management requires general assessment, resuscitation of the patient if required, temporary fracture stabilization via POP back-slab, wound debridement, soft tissue coverage in grade IIIB and IIIC fractures, along with appropriate broad-spectrum antibiotic coverage[21,22]. Definitive management of fracture includes early skeletal stabilization. Various techniques have been described for skeletal stabilization in literature, like cast bracing[23,24], external fixator[17,25,26], plating[27] and intramedullary nailing[18]. All these techniques have their own merits and demerits.

Compression plating in the management of open diaphyseal tibial fracture has been associated with poor outcomes in the literature. Jensen and colleagues[28] encountered significant non-union rates after application of compression plates in the management of open diaphyseal fractures of the tibia. Similarly, van den Linden and Larsson[29], in their study of management of 100 displaced fractures of the tibia, encountered more complications and longer duration of stay with the usage of compression plates. Hence, non-union was twice as common and infection five times more likely when open fractures were treated with plating, as previously mentioned by Clifford and associates[27].

Various authors have advocated intramedullary nailing, but it is associated with significant postoperative knee pain[30]. Moreover, Bhandari et al. [31], in their case series, showed that more than 88% of surgeons use an intramedullary nail for open type I and II tibial shaft fractures. Interestingly, this number decreases to 68% for type IIIA and 48% for type IIIB fractures.

Traditionally, POP cast bracing has been employed for skeletal stabilization and good functional outcome in managing diaphyseal fracture of the tibia[23]. In the study of 780 fractures of tibia; Sarmiento et al.[24] observed an overall 97.5% union rate, 90% of patients had less than 10 mm of shortening, 2% had varus or valgus angulation of greater than 110, 2% had anterior or posterior angulation of greater than 100, and 4% of patients needed to have bracing discontinued. However, these satisfactory results were encountered in closed and low energy type tibial fractures. High energy or Gustillo type II and III fractures required an external fixator in this study.

External fixation has long been proposed for provisional soft tissues care. A growing number of reports advocate for definitive fracture care, especially for high-energy fractures with significant diastases or dissociation of the tibia and fibula and little intrinsic instability[32,33] Similarly, Sarmiento et al.[24] also recommended external fixator application in Gustillo grade II and III fractures.

In this study, 30 patients with open diaphyseal fracture of the tibia were randomly assigned in two groups (A and B). Group A was treated with POP cast immobilization, whereas NAEF was applied in group B patients. Results were compared in terms of duration of hospital stay and postoperative complications (i.e. wound infection, union rates, and functional outcome). The results showed a statistically significant difference in duration of hospital stay, i.e. average of 3.65 weeks in a POP cast versus 2.49 weeks in the NAEF group; p=0.004). However, statistically insignificant results were obtained regarding postoperative wound infection, union rate and time, and functional outcome.

Khan et al. in their case series, recommended that an external fixator provides skeletal stability and allows early mobilization and thus reduces the hospital stay of the patient in the management of high velocity, contaminated open fractures of the tibia[34].

Siddiqui et al. in their study of the outcome of distal tibia fractures treated by Ilizarov External Fixator versus T-Clamp NAEF, demonstrated an average hospital stay duration of 12.93 days which is nearly comparable to the results of this study[11].

The major determinants of open diaphyseal fracture of tibia management are postoperative wound infection, healing rate and time, and functional outcome. Although these parameters were statistically insignificant in this study but

clinically wound, infection was more encountered in the NAEF group versus the POP cast group (53.3% versus 26.7%, respectively). The high infection rate in the NAEF group was due to the early application of this fixator irrespective of wound status. Contrary to this, the POP cast was only applied when the wound condition became satisfactory in this study.

The union rate was 80% in the POP cast and 93.3% in the NAEF group. However, after both the procedures, union time was nearly the same (17.50 weeks in a POP cast versus 15.75 weeks in the NAEF group). Sarmiento et al.[24] observed an average union time of 18.7 weeks after functional cast bracing of open diaphyseal fractures of the tibia. Siddiqui et al. [11], in their case study, observed that out of 68 cases, 66 were united (97.1%) after NAEF. Time to union ranged between 12 to 28 weeks (19.87 weeks). The results of these studies were comparable to this study.

Clinically 93.3% good functional outcome was associated with usage of NAEF as compared to 73.3% with POP cast group. In contrast, Shoaib et al. in their 30 patient series of closed reduction and POP casting, noticed 50% excellent and 33.33% good functional outcome[35]. This difference in results is due to the inclusion of closed diaphyseal fractures by them. Sahibzada et al. reported 35% excellent, 40% good, 20% fair and 5% poor functional outcome in the management of tibial bone defects due to high energy trauma using the locally manufactured external fixator by segmental bone transport[26].

As this study is distinctive in approach, it has several limitations. Firstly, it has a relatively small sample size for the conclusion of overall postoperative complications (i.e. wound infection, union rate and functional outcome) of these commonly performed procedures in managing open diaphyseal fracture of the tibia. Moreover, due to this small sample size, we cannot finally figure out whether the difference in postoperative complications was true or just a sampling error. Secondly, common complications of both POP cast (like skin maceration, compartment syndrome) and NAEF (pin-track infections) were not included in this study.

Conclusion

The local study results indicate that the use of NAEF for open diaphyseal fractures of the tibia has a significant advantage over POP cast in reducing the duration of hospital stay. Although union rate and time, and functional outcome are statistically insignificant in this study, clinically these outcome parameters are satisfactory with the usage of NAEF compared to POP cast application.

Conflicts of Interest

The authors have declared that no competing interests exist.

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