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Comparison Study of Therapeutic Results of Closed Tibial Shaft Fracture with Intramedullary Nails Inserted with and without Reaming

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Abstract: Tibia fractures are the most common type of long bone fractures in US. This study aimed at comparing the therapeutic results of closed tibial shaft fracture with intramedullary nails inserted with and without reaming. In this randomized clinical trial study, 60 patients with a fracture of the tibia were examined. The patients were randomly divided into two groups. Thirty patients treated through inserting intramedullary nail with reaming technique (group A). The other 30 patients treated through inserting intramedullary nail without reaming technique (group B). After operation physical examination and control radiography were taken up to 6 month and results were compared. Sixty patients suffering from closed tibial diaphysis fractures were studied. Mean age of the group A and B were 40.24±12.32 and 38.42±14.28, respectively. Group A consisted of 24 (80%) males and 6 (20%) females while group B consisted of 24% females and 76% males. Considering fracture based on OTA criteria ($p = 0.4$) and severity of soft tissue damage based on Tscherne classification ($p = 0.6$), there was no statistically meamingful difference between groups A and B. The study demonstrated that degree of horizontal displacement, mean time of surgery, post-operation infection, organ shortness at the end of the follow-up period, organ deviation in patients of the group A was significantly more than that of the group B. Time required for callus formation (mean time of union), mean time of full weight bearing time and mean time of return to normal activities in group B was significantly more than that of the group A.

Key words: Tibia fractures, intramedullary nail, reaming

INTRODUCTION

The tibia is the major bone of the lower leg, commonly referred to as the shin bone. Tibia fractures can occur from many types of injuries. These fractures are the most common type of long bone fractures in US (Lam *et al*., 2010). Due to increase of motor vehicle crashes, tibial shaft fractures are one of the most common and important fractures observed in therapeutic centers during recent years (Bhandari *et al*., 2008; Busse *et al*., 2005). Damage of soft tissue, vessels and nerves of the fractured area, compartment syndrome, infection (gangrene, osteomyelitis) and lose of the organ is possible (Broos and Sermon, 2004). There are many difference of opinion among surgeons regarding how to treat tibial shaft fractures (Angliss *et al*., 1996; Bhandari *et al*., 2008). When determining treatment of a tibia fracture, the following factors must be considered: (1) Location of the fracture, (2) Displacement of the fracture, (3) Alignment of the fracture, (4) Associated injuries, (5) Soft-tissue condition around the fracture and Patient general health (Krettek *et al*., 1991; Wu and Chen, 1997). Several methods including treating through dressing with plaster cast and pin and plaster technique, open setting and inserting plate, using intraosseous channel materials of intramedulary nailing and plate inserting technique with the least manipulation and invasion (MIPO) are used in this regard (Krettek *et al*., 1996; Wu and Chen, 1997). Opening the fractured area are common in most of these methods but it leads to more tissues damages. These factors are involved in complications including nonunion, delayed union and also increase of probability of infection (Gregory and Sanders, 1995). Use of intramedulary nail has recently been accepted as the selected method to fix closed and instable fractures of tibial shaft. Placing pin leads to successful stabilizing of tibial shaft and puts it in one direction (Nag *et al*., 2010). The most successful, closed intramedullary (IM) nailing, has been associated with shorter time to union and a shorter period of disability before working compared with closed reduction and fixation with a cast (Hansen *et al*., 2009). IM nails have been greatly improved in recent years and indications for their use have been extended to fractures closer to the ankle joint (Crist and Wolinsky, 2009). This

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study aimed at therapeutic comparison considering union time, prevalence of infection, weight bearing degree and stability of fractured area in every method. It is tried to evaluate priority of each method and present required criteria affecting the selected method considering facilities of therapeutic centers and physician's experience in using each method.

MATERIALS AND METHODS

In this randomized clinical trial study From January 2009 to March 2011, 60 patients with a fracture of the tibia received operative treatment at the departments of orthopaedic and general surgery of the Tabriz University of Medical sciences, Tabriz, Iran. The patients were randomly divided into two groups. Thirty patients treated through inserting intramedullary nail with reaming technique (group A). The other 30 patients treated through inserting intramedullary nail without reaming technique (group B). Written consent was obtained from all the patients. Exclusion criteria were earlier fractures of the tibial shaft on the same side, proximal intra-articular or distal intra-articular fractures of the tibia, fractures within 6 cm of the ankle joint and temporary treatment with an external fixator. After operation physical examination and control radiography were taken up to 6 month and results were compared regarding to age, sex, classification of fractures based on OTA criteria, classification of soft tissue damage (Tscerne), vessel damage, union, infection stability. Radiographs were used to determine the time to union of the fractures. Radiographic union was defined as the presence of bridging callus in 3 of the 4 cortices as seen on anteroposterior and lateral radiographs. There was no standardisation of the radiographs. Delayed union was defined as radiographic union after >24 weeks. At follow-up all patients were interviewed according to protocol and examined by the first author Statistical analyses were performed in SPSS with use of the paired t test to compare differences between the two groups with regard to the time to union, time to weight-bearing, the time patients were unable to work, the hospital stay and the operating time and ... McNemar's test was used to compare the difference in malalignment between the two groups. For all tests significance was defined as $p<0.05$.

RESULTS

In this study, 60 patients suffering from closed tibial diaphysis fractures were studied. In both understudy groups, all fractures were closed and located at the middle one third of tibial diaphysis. Mean age of the group A was 40.24±12.32. In group B, the mean age was 38.42±14.28. Group A consisted of 24 (80%) males and 6 (20%) females while group B consisted of 24% females and 76% males. Considering fracture based on OTA criteria, in group A, C_2 and C_3 types of fracture were observed in 20 and 80% of patients, respectively. While it was 15 and 85% in group B (Table 1). There was no statistically significant difference between groups A and B ($p = 0.4$). Considering severity of soft tissue damage based on Tscherne classification, following results were obtained: In group A, Class II: 14 patients (46.7%) and Class III: 16 patients (53.3%). In group B, Class II: 10 patients (33.3%) and Class III: 20 patients (66.7%) Considering damage of soft tissue, there was no statistically meaningful difference between groups A and B ($p = 0.6$). Mean of partial weight bearing starting time was 4 weeks in group A and 6 weeks in the group B. Weight bearing in group A was started quickly but its difference with the group B was not statistically meaningful ($p = 0.2$). Considering final range of motion of knee (end of the follow-up period), following results were obtained: group A, partial (90-0): 3 cases (10%), well (110-0): 15 cases (50%) and perfect (130-0): 12 cases (40%). In group B, Partial: 5 cases (16.7%), well: 17 cases (56.6%) and perfect: 8 cases (26.7%). Considering final range of motion, there was no significant difference between these two groups ($p = 0.2$). During follow-up period, post-operation infection was observed in 3 cases (10%) of group A. There was no post-operation infection in group B. considering post-operation infection, there was statistically meaningful difference between two groups ($p = 0.03$). After surgery, all patients suffered from surface infection but appropriately responded to antibiotic short-term (3-5 days) treatments. No vascular or nervous complications were observed in patients after surgery. Device failure and delayed union was not observed in patients of the group A. This is while, one patient (3.3%) suffered from device failure and one patient (3.3%) suffered from delayed union in group B. In this regard, there was no statistically meaningful difference between groups A and B ($p = 0.15$). Mean time of return to normal activities was 8.5 weeks in group A and 10 weeks in group B (Table 2).

Table 1: Demographic characteristics of the study population

Characterstic	Intramedullary nail with reaming (n = 30)	Intramedullary nail with reaming (n = 30)
Age	40.24±12.32	38.42±14.28
Sex		
Male	24 (80%)	22 (76%)
Female	6 (20%)	8 (24%)
Height (cm)	160±12.32	166±11.48
Weight (kg)	62.32±8.14	68.28±7.64

Table 2: Comparison of intramedullary nailing with and without reaming

Index	With reaming N (%)	Without reaming N (%)	p-value
OTA classification			0.40
C_3	24 (80)	25 (83.4)	
C_2	6 (20)	5 (16.6)	
Tscherne classification			0.60
II	14 (46.7)	10 (33.3)	
III	16 (53.3)	20 (66.6)	
Partial weight bearing time (week)	4	5	0.25
Full weight bearing time (week)	6.5	9	0.01
Range of motion			0.20
Partial (0-90)	3 (10)	5 (16.7)	
Well (0-110)	15 (50)	17 (56.6)	
Perfect (0-130)	12 (40)	8 (26.7)	
Post-operation infection	3 (10)	0 (0)	0.03
Device failure	0 (0)	1 (3.3)	0.15
Delayed union	0 (0)	1 (3.3)	0.15
Callus formation time (month)	5	6	0.60
Organ deviation	5 (16.7)	0 (0)	0.035

DISCUSSION

This study considered 60 patients suffering from diaphysis closed tibial fracture. Out of them, 30 patients treated through intramedulary nailing with reaming technique (group A) and the next 30 ones treated with the same method but without reaming technique (group B). Tibia shaft fracture is one of the most common fractures and has very problems considering type and complications of the chosen therapeutic method and costs for the patient in addition to physical and functional problems. The study demonstrated that degree of horizontal displacement, mean time of surgery, post-operation infection, organ shortness at the end of the follow-up period, organ deviation in patients f the group A was significantly more than that of the group B. On the contrary, time required for callus formation (mean time of union), mean time of full weight bearing time and mean time of return to normal activities in group B was significantly more than that of the group A. Robinson *et al.* (1995) demonstrated that use of intramedulary nail is generally the best and preferred surgical treatment method in tibial diaphysis fractures. (Robinson *et al*., 1995). In present study, post-operation infection in group A was 10% (3 cases). Redfern *et al.* (2004) reported that infection was not observed in the group treated by intramedulary nail. Redfern *et al.* (2004) There are several reasons for wide range of post-operation infection including difference observed in understudy sample volume, type of fracture and its severity, conditions of local soft tissue, quality of the broken bone, patients' age, background condition and consumption of different drugs by patients, type of used implant, skills of surgeon, etc. In our study, the amount of infection is satisfactory because the studied fractures were severe ones. In our study, mean time required for callus formation in group A was quicker than that of the group Baumgaertel *et al.* (1998) demonstrated that callus formation in intramedulary nailing method is quicker that reaming technique. In this study, mean of union starting time (observing of callus formation in radiography) was 5 months in group A and 6 months in the group B. According to Oh *et al.* (2005), study mean time required for callus recovery was 16.5 weeks. In a study conducted by Redfern *et al.* (2004) partial weight bearing was observed at 12th week. In this study, full weight bearing in groups A and B was observed after 6.5 and 9 weeks, respectively. Delayed union was not observed in group A, but it was seen just in one patient (3.3%) of group B. In another study, on 40 patients suffering from tibial shaft fracture, 5.5% of patients suffered from delayed union at the end of the six-month follow up period (Sie *et al*., 2006). Slight, fair and severe damages were respectively observed in 14, 64 and 22% of the group A's patients. In our study, organ deviation was observed in 5 (16.7%) cases of group A, out of which two cases were toward inside and 3 cases were toward outside. Organ deviation was not seen in any patients of the group B. In the study of Bassi *et al.* (2001), organ deviation and malunion was reported in 10%. It was 6% in the study conducted by Bassi *et al.* (2001) Device failure was reported just in one patient (3.3%) of the group B which was due to breaking of distal locking screw. In a study conducted by Keating *et al.* (1997) device failure was reported in 32.2% of patients. Screw breaking and intramedulary nail breaking were responsible for 29 and 2.2% of device failure, respectively (Keating *et al*., 1997).

CONCLUSION

Post-operation infection in patients treated with reaming technique was significantly more than those treated without reaming technique. Horizontal displacement and surgery mean time in patients treated

with reaming technique was significantly more than those treated without reaming technique. In our study, organ shortness at the end of follow-up period an organ deviation in reaming technique was significantly more than technique used without reaming. On the other hand, time required for soft callus formation, mean of full weight bearing starting time and mean time of return to normal activity in patients treated by without reaming technique was significantly quicker than that of reaming technique.

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