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AO Tubular External Fixation vs. Unreamed Intramedullary Nailing in Open Grade IIIA-IIIB Tibial Shaft Fractures: A Single-center Randomized Clinical Trial

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Abstract: Although the intramedullary nailing is thought to be the method of choice for treatment of closed tibial shaft, there is ongoing debate on the optimal surgical approach in patients with open types of these fractures. In addition, choosing between the reamed and unreamed intramedullary nailing is still an issue for the orthopedic surgeons. In present study, we aimed to compare the outcome and consequences of OA tubular external fixation vs. unreamed intramedullary nailing in open grade IIIA-IIIB tibial shaft fractures. In a randomized clinical trial, 50 patients with open tibial shaft fractures (grades IIIA-IIIB) were recruited in Tabriz Shohada teaching centre in a 2-year period of time. They randomized in two equal groups underwent either AO tubular external fixation or unreamed intramedullary nailing. These 2 groups were matched for sex, age and fracture-grade. The follow-up time was one year. Union time, surgical outcome, postoperative complications and the ambulation time were compared between the two groups. Twenty five patients, 20 males and 5 females with a mean age of 30.80±5.24 years were allocated in unreamed intramedullary group and 25 other patients, 22 males and 3 females with a mean age of 28.92±8.88 years were studied in the external fixation group ($p = 0.70$ and 0.37, respectively). The two groups were matched for sex ($p = 0.70$) and age ($p = 0.37$). The time of union was 3, 4, 5 and 6≤ weeks after operation in 28, 12, 32 and 28% of the cases in unreamed intramedullary group vs. 4, 12, 48 and 36% of the cases in external fixation group, respectively ($p = 0.14$). Post-operative infection, soft tissue injury, malunion and nonunion were documented in 16, 8, 0 and 4% of the cases in unreamed intramedullary group vs. 32, 12, 24 and 8% of the cases in external fixation group, respectively ($p = 0.19$, 0.50, 0.02 and 0.50, respectively). The mean ambulation time after operation was 2.92±2.43 weeks in the unreamed intramedullary nailing group vs. 2.68±2.14 weeks in the external fixation group ($p = 0.71$). Our results are in favor of unreamed intramedullary nailing against external fixation in treatment of open tibial shaft fractures.

Key words: Tibial shaft fracture, unreamed intramedullary nailing, external fixation, ambulation time, fracture union

INTRODUCTION

Now-a-days, tibial fractures are very common, especially due to high frequency of traffic accidents. This is the most prevalent fracture of the long bones in the United States (Bucholz *et al*., 2005). Soft tissue lesions, vascular and neural injuries, compartment syndrome, infection (gangrene or osteomyelitis) and limb loss are possible complications. Delayed union, malunion and nonunion might be encountered frequently in tibial fractures (Saied and Mobarake, 2007). Surgeons use several strategies to manage tibial fractures-ranging from nonoperative to operative-as well as adjunctive strategies designed to accelerate healing and reduce rates of non-union (Busse *et al*., 2008). Choosing between the reamed and unreamed nailing methods is a basic discussion for treating tibial shaft fractures. In some studies, unreamed nailing has been advocated for open tibial fractures. However, some others have provided evidences that unreamed nailing may lead to a higher rate of delayed or non-union (Attal and Blauth, 2010; Hogel *et al*., 2010; Soleimanpour *et al*., 2008; Larsen *et al*., 2004). Although, external fixators and unreamed tibial nailing have been proposed as treatments of choice for severe open fractures of the tibia, the best and optimal techniques are still controversial and under debate (Atesalp *et al*., 2002; Hosny and Fadel, 2003; Finkemeier *et al*., 2000). By now, there have been plenty of studies basically aimed to compare external fixators and unreamed tibial nailing in open tibial shaft fractures; however majority of them have had significant limitation such as retrospective design, heterogeneity of groups compared and the mechanical disadvantages of using an external fixator (Inan *et al*., 2007). As a consequence, the

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available data are not conclusive in this regard (Sigurdsen *et al*., 2009; Penzkofer *et al*., 2008). This study aimed at comparing the results, complications and outcome of OA tubular external fixation and unreamed intramedullary nailing in types IIIA and IIIB tibial shaft fracture.

METHODS AND MATERIALS

Fifty patients with open tibial shaft fractures (grades IIIA or IIIB according to Gustillo and Anderson) and Saied and Mobarake (2007) were enrolled in a randomized clinical trial in a 2-year period of time (March 2009 to March 2011) in Shohada Teaching Hospital, a referral centre of orthopaedics in Tabriz City, north-western Iran. These patients were randomized in two sex, age and fracture-grade matched 25-patient groups underwent AO tubular external fixation (Germany) or unreamed intramedullary nailing (Germany). The unreamed intramedullary nail was inserted according to manufacturer's guidelines via a medial parapatellar approach. A four-pin unilateral frame configuration was used in patients treated with external fixation. Appropriate antibiotics were continued for 5 days postoperatively in all cases. Patients with diabetes mellitus, immunosuppressive conditions, malnutrition, active smoking, obesity (body mass index>27), concomitant fractures in other parts or multi-trauma were excluded. Controlling radiographs were obtained on week 3 and months 3 and 6 post-operation. All patients were followed up for one year after discharge. Union was determined according to radiographic (Bridging of the fracture by bone, callus or trabeculae) and clinical criteria (Absence of pain or tenderness when weight-bearing) (Dijkman *et al*., 2010). A nonunion was considered to be established when there was no bridging cortical bone on at least three of four cortices using antero-posterior and lateral radiographs and the fracture site did not show any visible progressive signs of healing within 6 months on serial radiographs. Delayed union was also taken into account when the fracture site did not show any visible progressive signs of healing within 3 months after the fracture. A malunion was defined as more than 5 degrees of varus/valgus; more than 10 degrees of anterior/posterior angulation; more than 15 degrees of rotation or shortening of more than 1 cm (Bucholz *et al*., 2005). All the operations were performed by a single skilled surgeon. Follow-up was done by an observer blind to grouping of the patients. Informed consent was obtained from all the participants. Present study was approved by the Ethics Committee of Tabriz University of Medical Sciences.

Statistical analysis was performed using Spss version 19.0 (IBM, USA). The Student's t test, Chi-square test or Fisher's exact test were used where appropriate. A p value of less than 0.05 was considered statistically significant.

RESULTS

Twenty five patients, 20 males (80%) and 5 females (20%) with a mean age of 30.80±5.24 (range: 23-39) years were allocated in unreamed intramedullary group and 25 other patients, 22 males (88%) and 3 females (12%) with a mean age of 28.92±8.88 (range: 12-49) years were studied in the external fixation group. The two groups were matched for sex (p = 0.70) and age (p = 0.37). Types of fracture were IIIA in 15 patients (60%) and IIIB in 10 patients (40%) in the unreamed intramedullary nailing group vs. 13 cases (52%) with type IIIA and 12 cases (48%) with type IIIB in the external fixator group. There was no significant difference between the two groups in this regard (p = 0.57). The time of union was 3, 4, 5 and 6≤ weeks after operation in 7 (28), 3 (12), 8 (32) and 7 (28%) cases in the unreamed intramedullary group vs. 1 (4), 3 (12), 12 (48) and 9 (36%) cases in the external fixation group, respectively (Fig. 1). There was no significant difference between the two groups in this regard (p = 0.14). Post-operative infection, soft tissue injury, malunion and nonunion were documented in 4 (16%), 2 (8), 0 (0) and 1 (4%) cases in the unreamed intramedullary group vs. 8 (32%), 3 (12%), 6 (24%) and 2 (8%) cases in the external fixation group, respectively (Fig. 2). The rates of infection (p = 0.19), soft tissue injury (p = 0.50) and nonunion (p = 0.50) were comparable between the two groups. Frequency of cases with

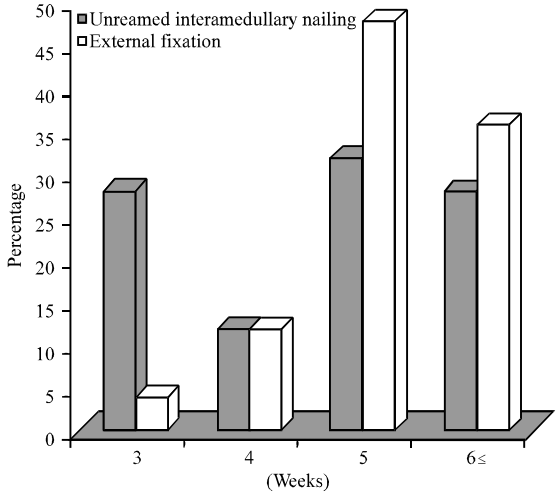

Fig. 1: Time of union after operation in the unreamed intramedullary nailing and external fixation groups

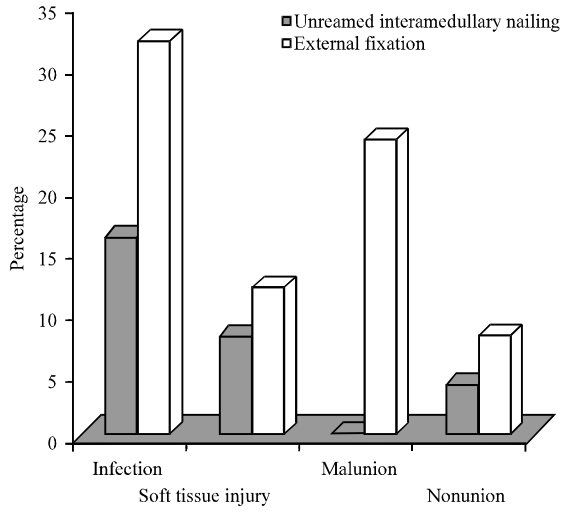

Fig. 2: Post-operative complications in the unreamed intramedullary nailing and external fixation groups

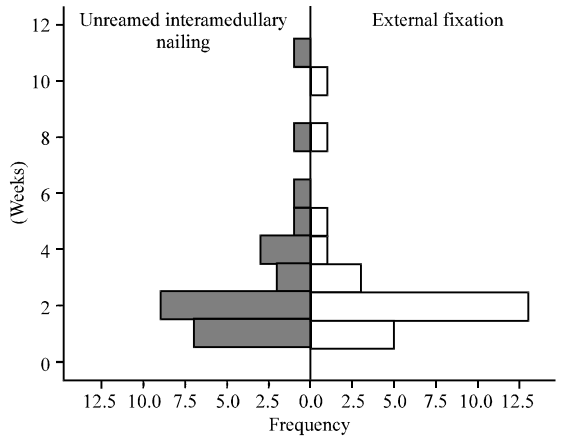

Fig. 3: Time of ambulation after operation in the unreamed intramedullary nailing and external fixation groups

malunion was significantly higher in the external fixation group ($p = 0.02$). The mean ambulation time after operation was 2.92±2.43 (range: 1-11) weeks in the unreamed intramedullary nailing group vs. 2.68±2.14 (range: 1-10) weeks in the external fixation group (Fig. 3). There was no significant difference between the two groups in this regard ($p = 0.71$).

DISCUSSION

In present study, outcome and complications of external fixation with tubular AO and unreamed licked nailing were compared in treatment of open tibial shaft fractures. Accordingly, the two methods were comparable with regard to time of fracture union, post-operative infection rate, frequency of malunion and soft tissue damage and the mean time gap between operation and ambulation. However, frequency of cases with malunion was significantly higher in the external fixation group. Although, the both techniques are not newly introduced and there are plenty of studies dealing with them in the literature, the available data are heterogeneous and inconclusive. In one the pioneer studies, Ostermann *et al*. (1993) evaluated 67 fractures of the tibial shaft with concomitant soft tissue injury underwent unreamed nailing (33 cases) or stabilization with external fixation (34 cases). Twenty fractures were closed. The mean time to union was 28 weeks in the external fixator group and 23.5 weeks in the unreamed nail group (statistically not significant). There was no significant difference between the two groups with regard to complications including infection, delayed union, nonunion and soft tissue damage. They concluded that the unreamed nail is a versatile implant for tibial shaft fractures with closed and open soft tissue compromise. The time to union was 3, 4, 5 and 6 months or over in 28, 12, 32 and 28% of the cases in the unreamed licked nailing group vs. 4, 12, 48 and 36% of the cases in the external fixator group, respectively ($p = 0.14$). Seemingly, this time is shorter in the first group but not statistically significant. This finding and other results are in line with the mentioned report. Mayr *et al*. (1994) compared outcome of unreamed tibial nailing in 15 cases with tibial shaft fractures with closed and open soft tissue damage with a 15-patient similar group underwent external fixation. Septic complications were only seen in the EF group. One malunion was seen in each group. Full weight-bearing was achieved after 1.8 months in the first group whereas it took 4.5 months in EF group. They showed an obvious advantage in comparison to fracture management by external fixation mainly due to a low complication rate and a much shorter over all surgical treatment period. For practical purposes, we compared the time gap between operation and ambulation of patients instead of full weight-bearing time. The average time was 2.92 weeks in the unreamed licked nailing vs. 2.68 weeks in the external fixation group ($p = 0.71$). In a study by Schandelmaier *et al*. (1995), 114 fresh tibial shaft fractures with severe soft tissue injury were operated either in unreamed tibial nailing group ($n = 48$) or external fixation ($n = 66$). There were a significantly higher number of reoperations in the external fixation group. In the external group, there was a 26% rate of pin tract infection. In the unreamed tibial nailing group, there were significantly fewer anteand recurvatum deformities of more than five degrees. They concluded that the treatment of tibial

fractures by unreamed tibial nailing, compared with external, gave a lower reoperation rate and better functional outcome. The results of this study are in conformity with ours regarding the higher infection rate, malunion and nonunion (need of reoperation) in the external fixator group. Tu *et al.* (1995) undertook a study comparing the unreamed interlocking nail to External Skeletal Fixation (ESF) in the treatment of 36 consecutive patients with open type IIIA and IIIB tibia fractures. They concluded that the unreamed interlocking nail is a good choice for the treatment of open type IIIA tibia fractures but not recommended for the treatment of open type IIIB tibia fractures because of the high infection rate. This is study very similar to ours regarding the studied population and fracture type. The types of fractures were comparable between the two groups in our study, so we did not performed a subgroup analysis in this regard. So we can not confirm the last part of their consequences dealing with the type of fracture and its effect on the final outcome of operation. Likewise, it should be mentioned that the type of nailing device (interlocking) was different from ours. Henley *et al.* (1998) compared unreamed intramedullary nailing (n = 104) with external fixation (n = 70) in patients with type II, IIIA and IIIB open fractures of the tibial shaft. Malunion (8% vs. 31%), nonunion (1.7% vs. 2.7% per fracture) and infection rate at the injury site (13% vs. 21%) and at surgical interfaces (2% vs. 50%) were significantly higher in the EF group. They suggested that unreamed interlocking intramedullary nails are more efficacious than half-pin external fixators, in particular with regard to maintenance of limb alignment. However, the severity of soft tissue injury rather than the choice of implant appears to be the predominant factor influencing rapidity of bone healing and rate of injury site infection. In our series, nonunion (4% vs. 8%) and infection rate (16% vs. 32%) were nonsignificantly and malunion (0% vs. 24%) was significantly higher in the external fixator group. These rates are almost similar to the results of Henley's study. It's noteworthy that we did report the infection rate as an overall incidence. As mentioned in their conclusion, the severity of soft tissue injury is an important determinant of consequences. We enrolled cases with types IIIA and IIIB fractures in our assessment and the two groups were matched in this regard. This ensures that the severity of injury as well as the soft tissue lesion is not a confounding factor for a precise concluding. Forty-six open tibial fractures (42 patients) were treated by primary unreamed intramedullary nailing, with debridement of open wounds and treatment of soft tissue in a series by Oh *et al.* (2001). There were two cases of superficial infection and one of deep infection. The mean time for union was 21.9 weeks and the rate of nonunion was 10.8%. They concluded that unreamed intramedullary nailing, with appropriate soft tissue treatment, gives good results in the treatment of open tibial fractures including grade III. Comparing with our results, the infection rate was lower in the above study; whereas, the union time and rate of nonunion are more than those ours. The type of fracture is not mentioned in Oh's series. It is shown that the grade of fracture and its close or open nature may influence the results of treatment with unreamed tibial nails (Gaebler *et al.*, 2001). This may lead to heterogeneous outcomes in different settings. Alberts *et al.* (1999) compared a series of 31 patients managed with unreamed nailing with a series of 31 managed by external fixation. Most fractures were grade I to III B injuries. The fracture wound infection rate was equal in both groups; 5 cases in the nail group and 16 cases in external fixation group. The mean time to union was five months in the nail group and eight months in the external fixation group. The incidence of delayed union was twice as high in the external fixation group as in the nail group. The rate of nonunion was three times higher in the external fixation group. The malunion rate did not differ between the groups. They concluded that intramedullary nailing was superior to external fixation in the treatment of most open tibial fractures. The rates of infection, delayed union (>3 months) and nonunion, as well as the mean time to union were similar to ours; however, we encountered a higher rate of malunion in our external fixation group. The main flaw of the above study is that the two groups were not fully matched. This may justify possible differences between the two studies. Shannon *et al.* (2002) compared the results of the AO unreamed tibial nail (n = 17) with external fixation (n = 13) in the treatment of patients with a grade III injury of the tibial shaft. Seven patients in the external fixation group required further surgery for nonunion versus two in the AO unreamed tibial nail group. This study supported the use of the AO unreamed tibial nail over external fixation in the treatment of severe open tibial fractures. The results of the mentioned study are similar to ours. Kutty *et al.* (2003) studied 45 patients underwent AO intramedullary nailing. Forty-four fractures united (97%). Complications included one non-union (2.2%), 15 delayed unions (33%), nine had either broken or bent interlocking screws (20%), six malunions (13%) and three patients underwent fasciotomy for compartment syndrome (7%). Twenty-one patients underwent at least one additional operation to obtain union (47%). They concluded that the AO intramedullary nailing does have a high complication rate and should it be used, we feel that early dynamisation or exchange nailing be considered to hasten union and

prevent screw breakage. This is one of the very rare studies against the use of unreamed intramedullary nailing in treatment of tibial shaft fractures. Many factors may influence the results and outcome of operation in these patients. Some factors such as grade of fracture and degree of soft tissue injury are discussed earlier. Other factors such as surgeon's experience, intra-and postoperative facilities and patients' characteristics are further contributing factors in this regard. In this study, all the patients were operated by a single skilled surgeon. So the inter-operator variability is omitted. Inan *et al.* (2007) compared the radiographic results and clinical outcome of unreamed tibial nailing (n = 29) and Ilizarov external fixation (n = 32) for the treatment of type IIIA open fractures of the tibia. The average time-to-bone healing was 19 weeks for external fixation and 21 weeks for unreamed tibial; significantly shorter in the first group. Malunion occurred in four patients for each group. Major infection occurred in two patients in the external fixation group and in three patients in the unreamed tibial nailing group. They showed a higher rate of major infection and delayed union in the unreamed tibial nailing vs. higher rate of limb abnormalities in the external fixator group. They believe that the decision to use either method should be made on a case-by-case basis. This is another study opposing the use of unreamed intramedullary nailing in patients with open tibial shaft fractures. These are in contrast with our findings. The same justification mentioned earlier may be proposed here, too. A study by Klein *et al.* (2004) was performed aimed to determine to what extent the mechanical conditions at the fracture site influence the healing process after unreamed tibial nailing compared to external fixation. They finally concluded that the unreamed nailing of a tibial diastasis did not provide rotational stability of the osteosynthesis and resulted in a significant delay in bone healing. This is also in contrast with our findings. We showed an earlier bone union in the group received unreamed nailing compared with that in the external fixation group. The above study was performed only to assess the mechanical condition without considering the clinical outcome, simultaneously. Thus, the results might be misleading. Further studies in this regard may help further elucidation of the issue. Joshi *et al.* (2004) assessed the clinical outcome of unreamed intramedullary interlocking nailing in open fractures of tibia. The patients were followed up for a mean period of 20 months. Results were good to excellent in 85.8% cases and poor in 10.7% cases. Only 2 of 8 patients with type-III fractures had good results. Two of 4 type-IIIA and all 4 type-IIIB fractures had chronic osteomyelitis. Of 56 patients, 6 had early infection, 6 had delayed union, 6 had infected non-union, 2 had nail breakage, 8 had screw breakage and 10 had anterior knee pain. They concluded that unreamed interlocking tibial nailing can be safely used for type-I and type-II open injuries even with delayed presentation. Use of unreamed nailing in those type-III fractures with delayed presentation was not recommended, because of high incidence of complications. It should be noticed that we did not recruited patients with delayed presentation. So another cause of heterogeneous results in different settings could be the time of presentation.

CONCLUSION

We compared the results of two common but still disputable techniques in treatment of open tibial shaft fractures in a single referral center of orthopedics. The results are in favor of unreamed intramedullary nailing against external fixation. Performing the operations by a single skilled surgeon, well-randomization and considering types IIIA and IIIB fractures as well as a comprehensive discussion enrolling almost all the related studies in the literature from the time of introducing these techniques are strengths of present study. Rather small sample size and medium follow-up might be the main limitations.

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