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**Single center experience in treatment of tibial shaft fractures
using Ilizarov technique**

Искуство једног центра у третману прелома дијафизе тибиге
Илизаровљевом методом

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Single center experience in treatment of tibial shaft fractures using Ilizarov technique

Искуство једног центра у третману прелома дијафизе тибије Илизаровљевом методом

SUMMARY

Introduction Since tibial shaft is a common location of opened and closed tibial fractures, it is very important to determine the best method of treating those fractures.

Our goal was to assess whether the Ilizarov technique is appropriate in terms of complications, outcomes, and pain reduction in treatment of patients with tibial shaft fracture.

Methods Retrospective analysis included all consecutive patients with tibial shaft fracture treated with Ilizarov technique in the period from January 2013 to June 2017 at the Banjica Institute for Orthopaedic Surgery, Belgrade, Serbia. Demographic and clinical data on patients were collected. Pain was assessed using visual-analogue scale of pain. Two models of uni- and multi-variate linear regression analysis were performed.

Results The study showed that overall rate of complications was low. It is shown that hypertension, administration of antibiotics, and reoperation prolong fixation. Also, severe fractures and longer procedure time delay mobilization. Significant reduction of pain was observed.

Conclusion Ilizarov technique is safe and reliable method in treatment of patients with tibial shaft fractures and is followed by pain reduction, overall improvement of functioning, good outcomes, and is not commonly associated with complications.

Keywords: Ilizarov technique; tibial shaft fracture; disability; functionality; satisfaction; outcome

САЖЕТАК

Увод Дијафиза тибије је често место настанка отворених и затворених прелома тибије, те је веома важно изабрати најбољи метод за третман ових повреда.

Циља рада је био да се процени да ли је Илизаровљева техника прикладна у смислу компликација, исхода лечења и редуције бола, у третману пацијената са преломом дијафизе тибије.

Метод Ретроспективна анализа је укључила све пацијенте са преломом дијафизе тибије који су третирани Илизаровљевом методом, у периоду од јануара 2013 до јуна 2017 године на Институту за Ортопедско Хируршке болести „Бањица“ у Београду. Демографски и клинички подаци о пацијентима су анализирани. Бол је процењен коришћењем визуелно-аналогне скале за бол. Коришћена су два модела уни- и мулти-варијантне линеарне регресије за анализу података.

Резултати Резултати студије су показали мали број укупних компликација. Показано је да високе вредности крвног притиска, употреба антибиотика и реинтервенције, пролонгирају фиксацију. Такође, тежина прелома и дужина интервенције, пролонгирају фиксацију. Показано је значајно смањење нивоа бола након интервенције.

Закључак: Илизаровљева метода је сигурна и поуздана у третману пацијената са преломом дијафизе тибије, и праћена је смањењем јачине бола, свеукупним побољшањем функционалности и добрим исходом, и није праћена честим компликацијама.

Кључне речи: Илизаровљева метода; прелом дијафизе тибије; исход лечења; задовољство пацијента лечењем

INTRODUCTION

Tibial shaft is a common location of opened and closed tibial fractures. Opened tibial fractures develop in a consequence of strong force effects, usually seen intratraffic accidents [1, 2]. Along with the increased use of motor vehicles and consequential increase of trauma, it is very important to determine the best method and timing of treating tibial shaft fractures [3, 4].

Segmental fractures of tibia are rare, accounting for only 12% of all tibial fractures. It is not unusual for them to be associated with different complications such as malunion and

infections. In this case, it is also inconclusive which treatment option to choose and this issue stays unclear and undefined [5, 6].

The generally used treatment method for tibial shaft fractures is still an interlocking nail (IL). This therapeutic approach has its advantages in terms of good mobilization of patient and prompt return to usual activities. However, some cohort studies have shown that this approach may be associated with high rate of complications after the insertion of IL [7, 8, 9]. The alternative method primarily for opened and complicated fractures is external Ilizarov fixation. This is considered to be an efficient and safe method [6, 8, 10]. Its unique biomechanical characteristics provide the formation of elastic wires under the tension and maintain stable fixation of bone fragments, while allowing dynamization at the place of fracture. For successful treatment, it is necessary to put the wires under the certain tension which should be maintained during the whole period of treatment [11]. The weakening of tension, losing or even breaking of wires bring to the instability which further causes deformities and delayed healing of fracture.

External fixation using Ilizarov fixator is used for treatment of tibial plateau fractures as well. The majority of literature data indicate that it is an equally efficient, if not an even more efficient method, in treatment of tibial plateau fractures, compared to internal fixation [12, 13].

However, treatment of tibial fractures using Ilizarov fixator can be associated with certain complications, especially in cases involving large bone and surrounding soft tissue defects. The most common complications include the infection of surgical region, osteomyelitis, axial deviation, delayed union or malunion [14, 15].

Considering the fact that there is no consensus concerning the best surgical approach for tibial shaft fractures and the lack of studies investigating the long-term prognosis in patients treated with Ilizarov fixator, the aim of our study was to retrospectively analyze patients with tibial shaft fractures in terms of pain, complications, and to determine which characteristics represented the significant predictors of postoperative course.

METHODS

In this retrospective analysis we aimed to review the postoperative course in terms of complications, pain, and to determine which demographic and clinical characteristics of patients represented significant predictors of postoperative course.

The study was conducted at the Banjica Institute for orthopedic surgery, Belgrade, Serbia, in the period from January 2013 to June 2017 and included all consecutive patients with radiographically confirmed tibial shaft fracture which were treated with Ilizarov technique. Classification of tibial fractures was according to the Orthopedic Trauma Association (OTA) classification system. All fractures were classified as A, B, or C type, in accordance with the radiological finding.

Demographic and clinical characteristics of patients were obtained from their medical records. The following characteristics were analyzed: age, gender, chronic diseases, duration of hospitalization (in days), duration of waiting for the procedure (in days), duration of surgical procedure (in minutes), type of anesthesia, type of fracture, the manner of injury, prophylaxis (antibiotics, nadroparin calcium), complications after the procedure, as well as the duration of fixation. Complications that were analyzed included superficial and deep infection, nonunion, pseudo-arthrosis, compartment syndrome, and reoperation.

Intensity of pain at the moment of admission and after period of recovery, that is, when Ilizarov fixator was removed, was assessed using visual analog scale (VAS). VAS is consisted of a continuous scale that can be horizontal or vertical and is 100 mm of length. It is marked with two perpendicular labels at the end of the 100 mm line that represent the extreme values, that is, minimal and maximal possible pain in the last 24 hours. VAS is designed to be fulfilled by the participants themselves. Scoring is performed using the ruler that measures the length from the beginning of the line to the label the participants gave, which represents the intensity of pain from 0 to 100, higher scores indicate higher pain intensity [16].

In order to describe the study sample, measures of descriptive statistics were used: mean values, standard deviation (SD) and relative numbers (percentages). The normality of distribution was assessed using Kolmogorov–Smirnov test. The differences between groups were evaluated using Student t test. To estimate which characteristics of participants represent significant predictors of pain, complications and duration of fixation, we performed two models of linear regression analysis. In the first model independent variables were

clinical end demographic characteristics of patients, while the independent variable was the duration of fixation. In the second model the independent variables were the same as in the first one, while the dependent variable was the mobilization in days. P values less than 0.05 were considered statistically significant. Statistical analysis was performed using SPSS (Statistical Package for Social Sciences), version 22.0 (SPSS Inc, Chicago, IL, USA).

This research was approved by the Council of the Banjica Institute for Orthopedic Surgery and the Ethical Committee of the Faculty of Medicine, University of Belgrade, with the decision that this type of study (retrospective study) does not need any written consent from the patients since it covers period of time before the research has been initiated. However, the investigators are under obligation to keep all personal information on study subjects strictly confidential. All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

RESULTS

The average age at admission to the hospital was 47.8 ± 16.0 years. 63.5% of patients were men and 36.5% were women. Diabetes mellitus was present in 12.2%, hypertension in 28.4%, while coronary artery disease in only 2.7% of patients.

The average duration of hospitalization was 26.5 ± 13.3 days (range 13–85 days), while patients waited for the procedure for 7.5 ± 8.1 days, (range 1–61), since the day of admission.

Most of the patients received spinal anesthesia (75.7%), block anesthesia (16.2%), while the least number of them undergone to total anesthesia (8.1%).

The average duration of surgical procedure was 68.2 ± 25.8 minutes (range 30–165 minutes). None of the patients received blood transfusion during the procedure.

In the majority of patients (70.3%), A type of fracture occurred. However, one significant proportion of patients (20.3%) had complicated C type of fracture, while B type of fracture occurred in 9.5% of patients. The most frequent manner of injury was the fall on the

flat (67.6%), while the fall from the height was the rarest manner of injuring (8.1%). Direct force caused trauma in 10.8%, while traffic accidents caused trauma in 13.5% of patients.

The antibiotic was administered in 24.3% of patients, while nadroparin calcium (fraxiparine®, Aspen Notre Dame de Bondeville, France) was administered in the majority of patients in the aim of thrombosis prevention (97.3% of cases).

Considering the rate of complications, the overall rate was low. 5.4% of patients underwent the repeated surgical procedure and only 2.7% of patients had pseudo-arthritis.

The highest value on VAS was observed at the place of fracture which was expected. That high score remained even after removing the Ilizarov fixator. However, there was a significant difference in pain intensity before and after the procedure, and for each location where pain was assessed (knee, ankle joint, place of fracture). These results are given in Table 1 and Table 2.

Table 3 shows the results of uni- and multi-variate linear regression analysis with the duration of fixation, as independent variable. The average duration of fixation was 6.2 ± 1.9 months. Univariate model showed that significant predictors of duration of therapy, that is, duration of fixation, were the presence of hypertension ($p = 0.057$), antibiotic prophylaxis ($p = 0.029$), repeated surgical procedure ($p < 0.001$) and the presence of pseudo-arthritis ($p = 0.002$). These variables entered the model of multivariate linear regression analysis where all variables, except pseudo-arthritis, remained the significant predictors of the duration of fixation. Patients with hypertension ($p = 0.040$) were at greater risk of longer therapy duration, as well as those who were on the antibiotic therapy ($p = 0.012$) and those who undergone the repeated surgical procedure ($p = 0.021$).

The results of uni- and multi-variate linear regression analysis with the mobilization as dependent variable are shown in Table 4. The average time of mobilization was 1.3 ± 0.5 days. Univariate linear regression analysis has shown that the duration of procedure, type of fracture and manner of injury are significant predictors for mobilization time ($p < 0.001$, $p < 0.001$ and $p = 0.037$, respectively). These three variables entered the model of multivariate linear regression analysis which showed that the duration of procedure and type of fracture were independent predictors of mobilization, while the manner of injury has not remained significant ($p = 0.952$). Patients with more severe fractures ($p < 0.001$) and those who

underwent longer procedures could lean on their feet later, compared to those with shorter procedure times ($p < 0.001$).

DISCUSSION

We observed that the overall rate of complications in our study was low, with only 5% of patients undergoing repeated surgical procedure and about 2% with pseudo-arthrosis. There were no other complications observed. In the study of Lan et al. [17], which investigated the outcomes after the lengthening procedure, and compared the Ilizarov technique with nailing, one of the outcome measures after the Ilizarov technique was also the complications rate. They followed the rate of pin-site infections and deep infections. The rate of pin-site or superficial infections was about 2%, and there were no deep infections observed. Our results are in concordance with this study. Pin sites may become colonized with bacteria and much shorter time needed for external fixation may be the possible explanation for low rate of infections in this group of patients. In other studies, the rates of infections were between 1.7% and even 21%, but bony union rates were high only when the nail was inserted after the initial external fixation, for high energy and opened tibial fractures [18, 19, 20]. But, in the study of Lan et al, all tibiae were well vascularized and that could also be an explanation for low rate of infections. In our sample, the majority of cases were non complicated fractures, so that is the possible explanation for our findings. However, we had a significant percentage of complicated fractures without any infection as complication and this goes in favor of Ilizarov technique, in terms of safety and good outcomes.

Some authors found that the nonunion represented a relatively frequent complication. Surgery to treat pseudo-arthrosis and nonunion is difficult and can be a serious problem, followed by severe complications [21, 22]. In their study, Gulabi et al. [23] described that the nonunions were the result of closed fractures in two patients and opened fractures in three patients. Our results are in accordance with these studies, considering the fact that in our sample nonunion was a result of complicated fracture.

In the study of Sen et al, the rate of complications was 2.08% per patient [24]. Other studies reported the rate of 2.2 complications per patient [25] and 2.5 complications per patient [26]. The study of Gulabi et al. [23] reported the rate of 2.6 complications per patient, but most of them were minor and could be resolved without any additional surgical

procedure. Only one patient had chronic deep, bone infection, so he had to be reoperated. Although in our study the rate of complications was not calculated per patient, the overall rate was presented so the results could not be adequately compared. We can conclude that in all these studies using Ilizarov external fixation the rate of complications was low and our results are in accordance to theirs. This further implicates that Ilizarov fixation method is safe and gives good results. Also, the results of Meleppuram and Ibrahim [27] showed the similar rate of complications per patient which was 1.6.

Tibial fractures range from low energy injures, like in women with osteoporosis, to high energy injures with severe soft tissue damage, along with bone trauma. The most common clinical finding associated with tibial fracture is soft tissue damage. This injury is particularly serious when there is metaphysio-diaphyseal dissociation. The treatment of such injures with external fixation dramatically improved results. The advantage of Ilizarov fixator over closed fixation is that it allows closed reduction, minimal soft tissue damage, early mobilization, and a minor procedure of removal of Ilizarov fixator [28]. Our results are in concordance with these particular findings. We have also shown that complicated fractures and longer duration of the procedure postponed mobilization time. However, we could not compare our results with previously mentioned study since the authors have not investigated the predictors of faster mobilization.

Early removal of external fixation reduces the risk of complications, that is, the risk of infections and allows earlier rehabilitation [23]. One of the aims of our study was to show how certain demographic and clinical characteristics of patients influence the length of fixator carrying, that is, the time of fixator removing. We have shown that patients with hypertension, those who received antibiotic therapy, and those who underwent repeated surgical procedures were at greater risk of later removal of fixation. In other words, we may say that complications (repeated procedure in our sample) delay the removal of fixation and that further leads to other complications, like infections.

Ilizarov technique offers an effective and safe manner of treating some of the most challenging conditions in orthopedics, such as complicated fractures, infected fractures, or nonunions of tibia. In our study the average duration of fixation was about 6 months and that is slightly shorter than in the study of Meleppuram and Ibrahim [27], who showed that the average duration of fixation was 8 – 10 months. Some studies have shown that smoking had negative effects on fixation, in terms of lengthening the time of fixation, as well as on bone

lengthening index [29]. We have not investigated the influence of smoking status on the duration of fixation, but, as it is already mentioned, we have shown that hypertension, repeated procedure, and use of antibiotics were independent predictors of fixation duration.

We have investigated the functionality after the procedure, that is, the pain and reduction of pain after fixation. We have observed that the reduction of pain was significant, even in those with complicated fractures. The other authors also measured functionality after procedure. Meleppuram and Ibrahim [27] showed good bone results in 60% of patients, but functional results were worse than bone results. It shows that excellent bone results do not guarantee good functionality. Functional results, as well as the pain reduction, are affected by damage of soft tissue and neurovascular structures. There are many published papers investigating long bone defect managing and describing complications, but pain, long treatment process, and prolonged external fixation are the main shortcomings. This could be a significant physical and mental burden for the patient. The study of Wang et al., which investigated the overall wellbeing and pain after the Ilizarov fixation, showed that treatment deteriorated physical and emotional wellbeing and patients experienced severe pain for a long time. At the end of follow up, although with severe pain, the overall functioning was significantly improved [30]. Our results differ significantly from these findings. This study included only patients with infected tibial nonunions, unlike our sample which involved the patients with less complicated fractures as well, which could be the possible explanation for the different results.

Our study has some limitations. First of all, although we analyzed the representative sample of all consecutive patients with tibial shaft fractures in given period of time, sample size is still small and that could be a problem that can disable generalization of results. Also, we used only VAS without analyzing overall physical and mental condition of patients, so we cannot have the comprehensive view on the situation. Furthermore, this is a retrospective analysis that relied on medical records of the patients, but not prospective design where we could further follow the outpatients. Clinical data are undertaken from medical history of patient that was administered partly by anesthesiologist and partly by orthopedic surgeon, so it can affect the consistency of data and further results. Also, the small number of studies investigating this medical problem in the manner we did make the comparison difficult.

CONCLUSION

In conclusion, we may say that Ilizarov technique in treatment of tibial shaft fractures is a safe and reliable method, not commonly associated with complications, and is followed by pain reduction, overall improvement of functioning and good outcomes. It is important for surgeons to consider the factors influencing the outcome, such as duration of fixation, pain and mobilization time, so that they could better cope with the problem of their patient at an individual level.

Conflict of interest: None declared.

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1. **Table 1.** The average pain scores on visual analogue scale (VAS) at admission and after treatment

Pain (VAS)	On admission		At the end of the treatment	
	Mean	SD	Mean	SD
Knee	64.52	10.15	20.27	8.97
Ankle joint	69.25	13.09	20.27	8.97
Place of fracture	81.64	10.38	23.90	10.52

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Table 2. The reduction of pain during the treatment (fixation)

Differences in pain intensity (VAS)	Mean	SD	t test	p
Knee	44.26	13.79	27.606	< 0.001
Ankle joint	48.11	16.97	24.379	< 0.001
Place of fracture	57.63	16.14	30.723	< 0.001

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Table 3. Uni- and multi-variate regression analysis with the duration of fixation as an independent variable

Independent variable	Univariate linear regression analysis			Multivariate linear regression analysis		
	β coefficient	IR*	p	β coefficient	IR*	p
Sex	-0.049	-1.115–0.735	0.683			
Age	0.214	-0.002–0.053	0.069			
Diabetes mellitus	0.167	-0.379–2.302	0.157			
Hypertension	0.225	-0.023–1.901	0.057	0.220	0.045–1.792	0.040
Coronary vascular disease	-0.130	-4.219–1.211	0.273			
Other	0.047	-0.911–1.357	0.696			
Total duration of hospitalization	0.165	-0.010–0.057	0.162			
Waiting for the intervention	-0.036	-0.071–0.041	0.594			
Type of anaesthesia	0.081	-0.472–0.964	0.497			
Duration of procedure	1.023	-0.008–0.026	0.310			
Type of fracture	0.140	-0.220–0.869	0.239			
Manner of injury	0.061	-0.296–0.504	0.606			
Antibiotics	0.255	0.117–2.122	0.029	0.261	0.258–2.034	0.012
Fraxiparine	-0.137	-4.294–1.132	0.249			
Reoperation	0.451	1.190–5.496	<0.001	0.345	0.447–5.237	0.021
Pseudo-arthrosis	0.359	1.595–6.707	0.002	0,79	-2.030–4.721	0.429

Table 4. Uni- and multi-variate linear regression analysis with mobilization as independent variable

Independent variable	Univariate linear regression analysis			Multivariate linear regression analysis		
	β coefficient	IR*	p	β coefficient	IR*	p
Sex	0.171	-0.060–0.395	0.146			
Age	-0.180	-0.112–0.001	0.124			
Diabetes mellitus	-0.178	-0.593–0.076	0.128			
Hypertension	-0.069	-0.319–0.173	0.557			
Coronary vascular disease	-0.119	-1.028–0.333	0.312			
Other	0.020	-0.260–0.307	0.868			
Total duration of hospitalization	0.956	-0.004–0.012	0.324			
Waiting for the intervention	0.158	-0.004–0.023	0.178			
Type of anaesthesia	-0.098	-0.254–0.104	0.408			
Duration of procedure	0.445	0.004–0.012	< 0.001	0.385	0.004–0.011	< 0.001
Type of fracture	0.512	0.181–0.417	< 0.001	4.113	0.004–0.011	< 0.001
Manner of injury	0.242	0.006–0.200	0.037	0.061	-0.082–0.087	0.952
Antibiotics	0.061	-0.191–0.326	0.605			
Fraxiparine®	0.119	-0.333–1.028	0.312			
Reoperation	-0.044	-0.548–0.398	0.707			
Pseudo-arthritis	-0.119	-1.028–0.333	0.312			