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Comparing the Effects of Two Tourniquet Times on Pain and Knee Range of Motion after Internal Plate Fixation of Tibia Fractures

Maryam Khodabakhshi[1*], Gholamhossein Mahmoudirad[1] and Reza Bahador[2]

[1]Department of Nursing and Midwifery, Birjand University of Medical Sciences, Birjand, Iran

[2]Department of Medicine, Birjand University of Medical Sciences, Birjand, Iran

[*]**Corresponding author:** Maryam Khodabakhshi, Department of Nursing and Midwifery, Birjand University of Medical Sciences, Birjand, Iran, Tel: 989371638928; E-mail: khodabakhshim2013@gmail.com

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Abstract

Background: Tourniquet is used in limb surgeries in order to create a clear blood-free surgical filed. Despite its considerable benefits, tourniquet has potential risks such as neuromuscular injuries, decreased joint range of motion, and pain. Present study was made to compare the effects of two tourniquet times on pain and knee range of motion after internal plate fixation of tibia fractures.

Methods: This randomized controlled trial was performed on forty patients with acute closed extra-articular tibia fractures who were candidates for internal plate fixation. The patients were conveniently recruited and randomly allocated to groups A and B. In group A, tourniquet was deflated after tibial fixation and before wound closure while in group B, it was deflated after wound closure and compression dressing. The level of pain as well as knee range of motion were measured before, 24 hours after, and fourteen days after the surgery using a 30 cm goniometer and a 0-10 visual analogue scale, respectively.

Results: Pain intensity score in group A was significantly lower than group B both at 24 hours and fourteen days after the surgery. Knee range of motion in group A was also significantly greater than group B at 24 hours after the surgery. However, fourteen days after the surgery, there was no significant difference between the groups regarding knee range of motion.

Conclusion: Tourniquet deflation before wound closure is associated with lower levels of postoperative pain and greater postoperative knee range of motion among patients undergoing internal plate fixation of tibia fractures. Possible explanations for these findings are faster reperfusion, reduced duration of ischemia, and slighter ischemic and mechanical injuries to nerves, muscles, and the skin.

Keywords: Tourniquet; Tibia fracture; Internal plate fixation; Pain; Range of motion

Introduction

Fracture is among the most common occupational and road accidents injuries. It incurs considerable direct and indirect costs for both patients and healthcare systems [1]. Tibia fracture (TF) is the most common fracture among people younger than 60 [2]. According to the American National Center for Health Statistics, 490000 cases of TF happen each year in the United States, resulting in an annual incidence rate of one TF per 2000 persons [3].

Compared with other types of fractures, more considerable controversies exist over TF treatment. Previously, surgeons preferred to treat TF non-surgically [3] while currently, TF is mostly managed by surgical procedures such as internal plate fixation, intramedullary nailing, and external fixation [3]. Intramedullary nailing necessitates advanced techniques and sophisticated equipment. External fixation is also indicated mostly for open peri-articular fractures [4]. Thus, the treatment of choice for TF is internal fixation using plates and screws.

Internal plate fixation of tibia fractures requires a large surgical incision and the separation of periosteum, both of which can be associated with massive intraoperative bleeding, increased risk for infection, and delayed union of fractured bones [5]. Bleeding is one of the main concerns during surgeries. Intraoperative bleeding is usually managed using different techniques such as chemical, thermal, and mechanical hemostasis. Chemical hemostasis is achieved through using medications while thermal hemostasis is achieved by burning the bleeding tissues through electrocauterization [6]. On the other hand, mechanical hemostasis is mainly achieved using tourniquet [7], i.e. an electrical or mechanical device which prevents or stops bleeding through exerting pressure on the proximal portion of extremities and blocking blood flow to distal portions.

There are two types of tourniquet namely pneumatic and non-pneumatic. An extension of non-pneumatic tourniquet is Esmarch bandage. It is an elastic band which is tied around the proximal portion of an extremity. Due to exerting extremely high pressure and shearing force, Esmarch bandage can cause injuries

to the skin and nerves and even life-threatening complications such as pulmonary embolism. In order to minimize the complications and adverse effects of Esmarch bandage, Harvey Cushing invented pneumatic tourniquet in 1904 [8]. Cushing's inspiration for pneumatic tourniquet came from sphygmomanometer system. It is now more than a century that surgeons use pneumatic tourniquet to manage intraoperative bleeding [9].

Tourniquet minimizes intraoperative bleeding, provides a clear blood-free surgical filed, gives surgeons a better view to the surgical site and anatomical structures, facilitates cement fixation through providing dry bone surfaces, reduces surgery time, and diminishes the risk of infection [10]. Nonetheless, like other surgical techniques, tourniquet can also cause different complications [11] such as neurovascular injuries, deep vein thrombosis, edema, bruising, rhabdomyolysis, pulmonary embolism, acute pulmonary edema, cardiac arrest, increased postoperative bleeding, hypoxia of skin flaps, delayed wound healing, muscular ischemia, delayed reversal of muscular strength due to microscopic alterations of myofibrils [12], limited range of motion (ROM), and high levels of postoperative pain [10]. Ischemic or compressive effects of tourniquet can alter neural conduction and muscular function and cause a wide spectrum of complications from mild transient dysfunction to irreversible damages [13]. Fan et al. [14] found that postoperative pain was more severe among patients who were treated with tourniquet. Liu et al. [15], Nagpal et al. [16] and Saied et al. [17] also reported the same finding while Nakayama and Yoshiya found no significant difference between the postoperative pain intensity of patients in tourniquet and no-tourniquet groups.

Tourniquet can also limit ROM and hinder recovery through inflicting microscopic damages to muscles, affecting the viability of muscular cells, and causing edema and pain [14]. Ledin et al. [18] made a study to assess the effects of using tourniquet in cemented total knee arthroplasty and found that ROM in tourniquet group was 11° less than patients in no-tourniquet group. Ejaz et al. [19] also reported the same finding. However, Liu et al. [14] and Tarwala et al. [20] found that although patients who were treated with tourniquet had better muscular function and shorter hospital stay, their twelve-month ROM was not significantly different from that of patients who underwent tourniquet-assisted surgery. On the other hand, electromyographic alterations in the quadriceps muscle were also reported after using tourniquet for knee surgeries [10]. In addition, Lohmann-Jensen et al. reported that patients who underwent no-tourniquet total knee arthroplasty were able to start rehabilitation exercises faster than patients who received tourniquet-assisted total knee arthroplasty and thus, they were able to use their newly-transplanted knee more confidently, experienced fewer immobility-related complications, and expressed higher satisfaction with medical and care services [9].

There are considerable controversies over the safest tourniquet time [21] and the complications of tourniquet use [17]. The most widely used tourniquet techniques include tourniquet deflation either before or after wound closure. The results of a meta-analysis and illustrated that tourniquet deflation before wound closure is associated with lower levels of postoperative pain [22], less postoperative bleeding [23], faster functional recovery [22,23], and reduced risk for complications [24,25]. However, some scholars reported that tourniquet deflation before wound closure is unessential and has no priority over tourniquet deflation after wound closure regarding the amount of bleeding [26-30], recovery rate [31,32], and risk for complications [30,32].

The results of previous studies in the area of tourniquet time are conflicting. Moreover, most studies into the tourniquet time were conducted on the candidates for elective knee surgeries such as arthroplasty or arthroscopy. Consequently, the present study was made to compare the effects of two tourniquet times on pain and knee ROM after internal plate fixation of tibia fractures.

Methods

This randomized controlled trial was carried out on forty patients with tibia fracture who were candidates for internal plate fixation of tibia. The patients were conveniently recruited from the orthopedic care ward of Imam Reza (PBUH) teaching hospital, Birjand, Iran. Sample size was calculated based on the findings of Fan et al. [14]. They reported that the means and standard deviations of pain intensity in their two groups were 5.0 ± 0.91 and 3.83 ± 0.59 [33]. Accordingly, with a confidence interval of 0.95 and a power of 0.80, the sample size calculation formula ($n = (((z_{(1 - \alpha/2)} + z_{(1 - \beta/2)})^2 \times (S_1^2 + S_2^2))) / (\mu_1 - \mu_2)^2$) revealed that ten patients were needed for each study group. In order to enhance the credibility of the findings, we recruited twenty patients to each group. Patients were included if they

- aged 18-55 years;
- suffered from closed extra-articular tibia fracture;
- were going to undergo internal plate fixation surgery during the first week after fracture;
- had no history of previous surgeries on the extremities;
- had no other fracture in the extremities;
- suffered from no trauma to the chest, head, or abdomen;
- did not suffered from neurovascular injuries or compartment syndrome;
- had no history of coagulation disorders, peripheral vascular diseases, peripheral neuropathy, or deep vein thrombosis;
- were not receiving any steroidal or non-steroidal anti-inflammatory drugs, anticoagulant medications, chemotherapeutic agents, or opioid drugs;
- did not smoke cigarette;
- had a knee ROM of 135°, a body mass index of less than 30, and a systolic blood pressure of less than 200 mmHg; and
- were in class I or II of the American Society of Anesthesiologists Physical Status Classification System;

Exclusion criteria were a tourniquet time of longer than 90 minutes, the need for another surgery of any type, death, or voluntarily withdrawal from the study. Sampling was performed from February 2015 to August 2016.

Eligible patients were visited the day before their surgery, informed about the study, and allocated to groups A or B by using permuted block randomization. During the surgery, a 75 × 15 cm cuff of a pneumatic tourniquet (MICROBACE; Raeensanat Co., Iran) was placed on the most muscular area of the intended patient's thigh. Three layers of padding bandage were placed under the cuff. Then, the diastolic and systolic blood pressures of the patient were measured and documented and the pressure of tourniquet was set at 150 mmHg greater than his/her systolic blood pressure. After prepping and draping, the afflicted leg was elevated for three minutes for the purpose of exsanguination. After that, tourniquet cuff was inflated. All patients got open reduction and internal plate fixation of tibia by a same surgeon and through standard techniques and plates. In group A, tourniquet was deflated after plate fixation and before wound closure while in group B, it was deflated after wound closure and compression dressing. Hemostasis was achieved for all patients using an electrocauterization device (Matin; MEG1; Kavandish system Co., Iran). Subcutaneous tissue and the skin were sutured by using absorbable polyglycolate-coated polyglycolic acid (1 USP; SUPA Co., Iran) and non-absorbable nylon (2/0; SUPA Co., Iran) sutures, respectively. Surgical site was bandaged by padding and elastic bandages. A hemovac drain was placed in the site in order to drain secretions. The drain was removed 24 h after the surgery.

Active and passive ROM of the knee was measured using a 30-centimeter standard goniometer at three measurement time points namely before, 24 hours after, and fourteen days after the surgery (T1, T2, and T3, respectively). Pain intensity was also measured trice at the aforementioned time points using a 0-10 visual analogue scale. Scores 1 and 10 on the scale represented "Slight tolerable pain" and "Severe pain", respectively. Visual analogue scale is a standard tool for pain measurement. All patients received the same analgesics both before and after their surgeries and did not receive any analgesic during the last six hours before pain measurements.

This study obtained the ethical approval of the Ethics Committee of Birjand University of Medical Sciences, Birjand, Iran, and was registered in the Iranian Registry of Clinical Trials. The approval and registry codes were IR.BUMS.1394.84 and IRCT2015092824252N1, respectively. The patients were provided with adequate explanations about the methods of the study and then, their written informed consent was secured.

Collected data were entered into the SPSS software (v. 22.0) and frequency tables were used to present the data. Between-group comparisons with regard to knee ROM and pain intensity were done through running the independent-sample t and the Mann-Whitney U tests while within-group comparisons respecting knee ROM and pain intensity across the three measurement time points were performed using the repeated measures analysis of variance (RM ANOVA) and the Friedman's test. The correlation of pain and ROM was also examined through Spearman correlation analysis. The level of confidence for all statistical tests was set at greater than 0.95.

Results

From forty participating patients, 34 (85%) were male and six (15%) were female. The means of patients' age in groups A and B were 31.85 ± 2.65 and 29.35 ± 2.7 years, respectively. In these two groups, respectively thirteen and sixteen patients had a normal body mass index and ten (50%) and eight (40%) patients had right tibia fracture. In group A, the frequency distribution of the tibia fracture site was as follows: proximal: 1 (5%); shaft: 12 (60%); distal: 7 (35%). These values in group B were 1 (5%), 13 (65%), and 6 (30%), respectively. The means of systolic blood pressure in groups A and B were 119.7 and 118.2 mmHg while the means of tourniquet pressure were 269.7 and 268.8 mmHg, respectively. There were no significant differences between the groups regarding the participants' gender, age, body mass index, tibia fracture site, systolic blood pressure, and tourniquet pressure (P>0.05).

The means of tourniquet time in groups A and B were 53.2 (25-90) and 55.5 (20-90) minutes, respectively. Moreover, the means of operation time in these groups were 77.5 (45-120) and 64.7 (30-120) minutes, respectively. The independent-sample t test revealed no significant difference between the groups regarding the means of tourniquet and operation times (P>0.05). Moreover, tourniquet time was not significantly correlated with ROM and pain intensity (P>0.05).

The Mann-Whitney U test showed that the level of pain in group A at T2 and T3 was significantly lower than group B (P<0.05; **Table 1**). The results of the Friedman's test also indicated that pain intensity variations across the three measurement time points were statistically significant in both groups (P<0.001; **Table 1**).

Table 1 Pain intensity in both groups at different measurement time points.

Time	Groups	Before	24 hours after	14 days after	Friedman's test
Pain intensity score	A	8.6 ± 0.2	4.1 ± 0.4	1.00.2	<0.001
	B	6.8 ± 0.6	8.5 ± 0.4	1.90.2	<0.001
Mann-Whitney U test	P value	0.012	<0.001	0.007	

The independent-sample t test revealed that at T2, knee ROM in group A was significantly greater than group B (P=0.019); however, the between-group difference regarding knee ROM at T3 was not statistically significant (P=0.379; **Table 2**). The RM ANOVA also illustrated that knee ROM variations across three measurement time points were statistically significant in both groups (P<0.001; **Table 2**). In addition, the T2-T1 mean difference of ROM in group B was significantly greater than

group A (P=0.017, **Table 3**), denoting larger decline in knee ROM in group B.

Table 2 Knee ROM in both groups at different measurement time points.

Time	Groups	Before	24 hours after	14 days after	RM ANOVA
Knee ROM	A	140.9 ± 0.5	90.7 ± 3.3	128.8 ± 3.1	<0.001
	B	141.2 ± 0.5	77.8 ± 4.0	125.0 ± 2.9	<0.001
Independent-sample t test	P value	0.682	0.019	0.379	
ROM: Range of motion					

Table 3 Pairwise comparisons of measurement time points regarding knee ROM.

Variable	Groups	T1-T2 mean difference	T1-T3 mean difference	T1-T3 mean difference
Knee ROM	A	14.8 ± 3.3	12.9 ± 2.9	14.2 ± 3.1
	B	18.3 ± 4.1	12.4 ± 2.7	18.5 ± 4.1
Independent-sample t test	P value	0.017	0.314	0.091
ROM: Range of motion; T1: Before surgery; T2: 24 hours after the surgery; T3: fourteen days after the surgery				

Finally, Spearman correlation analysis illustrated a significant correlation between pain intensity and ROM so much so that higher levels of pain intensity were associated with lower ROM both at T2 and T3 (P=0.008 and 0.003; respectively; **Table 4**).

Table 4 Correlation between pain and knee ROM.

Variables	Pain at T2		Pain at T3	
	Correlation coefficient	P value	Correlation coefficient	P value
Knee ROM at T2	-0.4	0.003	-0.1	0.347
Knee ROM at T3	-0.3	0.022	-0.4	0.008

Discussion

The present study was made to compare the effects of two tourniquet times on pain and knee ROM after internal plate fixation of tibia fractures. Findings revealed that the level of pain among patients whose tourniquet was deflated immediately after fixation and before wound closure was significantly lower than the patients whose tourniquet was deflated after wound closure and compression dressing.

There are only few studies into the effects of tourniquet time on pain and ROM after internal plate fixation of tibia even though some studies assessed the effects of tourniquet use on postoperative pain. For instance, Saied and Zyaei assessed the effects of tourniquet use during plate fixation of acute extra-articular tibia fractures and found that tourniquet use was associated with significantly higher levels of postoperative pain [16]. Besides, Konrad et al. [33] reported that tourniquet use increased postoperative pain after open reduction and internal fixation of ankle fractures. Kumar et al. [34], Liu et al. [15], Ejaz et al. [19], and Ledin et al. [18] also reported that tourniquet use was associated with significantly higher levels of postoperative pain after knee surgeries. Although these studies assessed the effects of using or not using tourniquet, their findings are in line with our findings in that shorter length of tourniquet use is associated with lower level of postoperative pain. Fan et al. [14] also assessed the effects of tourniquet time on postoperative pain. They randomly allocated sixty candidates for total knee arthroplasty to two 30-person groups namely groups A and B. They used tourniquet for the patients in group B from the beginning to the end of the surgery while for the patients in group A, they used tourniquet just from cementing to the end of surgery. In line with our findings, their findings also revealed significantly lower levels of postoperative pain in group A compared with group B [14]. All these findings indicate that more limited tourniquet use is associated with lower levels of postoperative pain. Tourniquet-related pain can be due to mechanical pressure on the limb and ischemia-reperfusion mechanism. The central nervous system can also contribute to the pain [8]. Thus, reducing tourniquet time during surgeries can minimize mechanical pressure on tissues, the severity of tissue ischemia and injury, and the level of postoperative pain.

Contrary to our findings, Tarwala et al. [20] found no significant difference between the level of postoperative pain of patients treated with extended tourniquet use (i.e. throughout knee arthroplasty) and patients treated with limited tourniquet use (i.e. just during cementing). A plausible reason for such

conflicting findings can be the differences in the amount of tourniquet pressure and the type of analgesics administered to patients in these two studies. In other words, tourniquet pressure in Tarwala and colleagues' study was 250 mmHg for all patients while in our study, the pressure was set based on each patient's systolic blood pressure and was 270 mmHg, on average. Moreover, Tarwala et al. [20] gave their patients an intra-articular injection of Ketorolac (15 mg), morphine sulphate (4 mg), and ropivacaine (100 mg) while we did not administer any analgesic to the surgical sites.

Our findings also revealed no significant difference between the groups regarding knee ROM at T3; however, at T2, knee ROM in group A was statistically greater than group B. Fan et al. also assessed knee ROM at days 3,5,7 and 14 after surgery. In agreement with our findings, they reported that at days 3 and 5, ROM in group A (tourniquet use just from cementing to the end of surgery) was significantly higher than group B (tourniquet use throughout surgery). However, they found no between-group difference regarding ROM at days 7 and 14. A possible explanation for significant between-group difference regarding knee ROM at first days after surgery and non-significant between-group difference at subsequent days may be tissue repair and regeneration and pain relief over time. It is believed that tourniquet use reduces ROM of joints through inflicting microscopic injuries to muscles, affecting cellular viability, and increasing postoperative pain and edema [16]. Dennis et al. [35] also assessed the effects of tourniquet use on the function of lower extremities after knee arthroplasty and found that quadriceps strength in their no-tourniquet group was significantly higher than the tourniquet group. They observed this difference even three months after the surgery [36].

Contrary to our findings, Tarwala et al. [20] found no significant difference between tourniquet and no-tourniquet groups regarding ROM. This contradiction may be due to the difference in measurement time points in the studies in that while we measured ROM before, 24 hours after, and fourteen days after surgery, they did ROM measurements three weeks after surgery. Moreover, they gave all their patients intra-articular injection of analgesics. Such practice might have reduced pain and improved ROM in both groups of their study.

The findings of the present study also showed a significant negative correlation between pain and knee ROM both at T2 and T3. Silver et al. [36] also reported that higher levels of postoperative pain were associated with lower ability to perform postoperative self-care activities and lower knee ROM [37]. Besides, postoperative pain may be a sign of muscular injury-inflicted by mechanical pressure and altered reperfusion-which can limit ROM [18]. Thus, patients in group B whose tourniquet was deflated after wound closure and compression dressing might have experienced more severe muscular injury and pain and thus, they showed more limited ROM compared with patients in group A. This finding denotes that limited tourniquet use can reduce the length of ischemia time, decrease the level of postoperative pain, and improve postoperative ROM.

Conclusion

Tourniquet deflation before wound closure is associated with lower levels of postoperative pain and greater postoperative knee ROM after internal plate fixation of tibia fractures probably due to faster reperfusion, shorter duration of ischemia, and slighter ischemic and mechanical injuries to the nerves, muscles, and the skin. Because of limited evidence regarding the effects of tourniquet use on patient outcomes after surgeries for tibia fractures, further investigations are recommended.

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