

# The effect of limited versus no tourniquet use on rapid recovery in total knee replacement—a randomized controlled trial

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## Research article

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# Abstract

**Background:** Tourniquets are widely used in TKA, but few articles state the difference in postoperative effects between restricting tourniquet use and not. **Objective:** We hoping that this experiment will look at the effect of limited tourniquet use on enhanced recovery in TKA.

**Methods:** 150 patients who received TKA in the Affiliated Hospital of Chengdu University of TCM from June 2018 to December 2019 were randomly selected and randomly divided into 3 groups: ①limited use tourniquet group: after the completion of osteotomy, tourniquet was applied only when the prosthesis was installed, ②second half tourniquet group: Install prosthesis until suture is complete ③ no tourniquet group: no tourniquet was used throughout. The postoperative venous blood hemoglobin, C-reactive protein, visual analogue scale and HSS score were compared among the three groups.

**Results:** Compared with the restricted use of tourniquet group, the visual analogue scale of knee joint pain and venous blood C-reactive protein level at 1 and 3 d after operation and hemoglobin level at 1 d after operation in the second half of tourniquet group increased and the HSS score at 3 and 7 d after operation decreased ( $P < 0.05$ ). No significant differences in visual analogue scale, HSS score, C-reactive, and hemoglobin between the restricted tourniquet and the no tourniquet.

**Conclusion:** The results confirmed that the use of tourniquet in the second half of TKA would aggravate the early postoperative pain. In the effect of early rehabilitation, there is no significant between limited use of tourniquet or no use.

## 1. Background

Tourniquet is widely used in total knee arthroplasty. It can effectively reduce intraoperative bleeding, provide a clean and clear surgical field, and also facilitate the application of bone cement technology. However, the postoperative complications caused by tourniquet, such as postoperative lower limb pain, stiffness, high wound inflammatory response, etc., significantly reduce the use value of tourniquet and delay the postoperative rehabilitation of patients [1]. The use of tourniquet in total knee arthroplasty has been controversial in recent years. To address the negative effects of tourniquets, more and more scholars have turned their attention to the timing of tourniquet use and put forward the view of restrictive use of tourniquets [2– 4]. Therefore, the authors wanted to verify with this trial the effects of different timing of tourniquet use versus no tourniquet use on rapid postoperative recovery.

## 2. Methods

2.1 Design: Randomized controlled clinical trial.

2.2 Time and venue: Completed in the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine from June 2018 to December 2019. Trial Registration: Chinese Clinical Trial Registry, ChiCTR1900026573. Registered on May 12, 2018.

2.3 Subjects were randomly selected from 150 patients who underwent primary unilateral total knee arthroplasty in the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine from June 2018 to December 2019.

The study was approved by the Ethics Committee of the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine on May 17, 2018 (NT-5324). Any protocol modifications will be submitted to the Ethics Committee for review and participants will be informed. After eligibility screening, we will request signed consent from participants. Participants are also informed that their choice to participate or not participate in the study will not affect their access to health services or treatment, and that there is no penalty for not participating in the study.

2.3.1 Inclusion criteria Referring to the 2018 edition of the Guidelines for the Diagnosis of Osteoarthritis[5] Patients with knee osteoarthritis who need unilateral total knee arthroplasty due to ineffective conservative treatment General conditions can tolerate surgery Mental status is normal and can cooperate with functional exercise Patients have informed consent for the treatment and trial program.

2.3.2 Exclusion Criteria Osteoarthritis caused by other reasons, such as rheumatoid arthritis, traumatic arthritis, etc. Severe varus and valgus deformity and ankylosis of the knee Patients with severe femoral and tibial defects Revision surgery History of thromboembolism Patients with liver and kidney dysfunction Patients with severe anemia before surgery Patients with hemorrhagic hematological diseases and patients receiving anticoagulant therapy Patients with tranexamic acid allergy Previous history of lower limb venous thrombosis, cardiovascular and cerebrovascular thrombosis and other peripheral vascular disease, combined with malignant tumors.

150 patients were treated according to SPSS software was randomly divided into 3 groups: limited tourniquet group, Second half tourniquet group and no tourniquet group, 50 cases for each group.

## 2.4 Experimental methods

2.4.1 Preoperative preparation After admission, blood routine, biochemical and coagulation related examinations were perfected, and anteroposterior and lateral X-ray films of both knees and full-length anteroposterior X-ray films of both lower limbs in standing position were taken. The patient's surgical procedure was explained before surgery to relieve anxiety. Preemptive analgesia with oral seloxifene 200 mg was routinely administered 3 days before surgery twice daily, local skin disinfection was performed with local diluted iodophor wet compress of the affected knee, diet was prohibited 6 h before surgery, drinking was prohibited 2 h before surgery, and urinary catheters were routinely not placed.

2.4.2 Replacement methods: All operations were performed by the same senior joint surgeon in the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine and assisted by the same group of assistants. General anesthesia was used for anesthesia. Cefuroxime Sodium 2 g was intravenously infused 30 min before operation to prevent infection, and aminocyclic acid 1 g was intravenously infused

15 min before skin incision to stop bleeding. Controlled hypotension was routinely performed during the operation, mean arterial pressure was controlled at two-thirds of the basal blood pressure, and a tourniquet was tied at the root of all thighs. The anterior midline medial patellar approach was used. The posterior cruciate ligament substituting bone cement was used to fix the total knee prosthesis. The osteophyte was only removed without patellar replacement followed by peripheral denervation.

2.4.3 Method of tourniquet use  
Restricted tourniquet group: after the completion of osteotomy, tourniquet was applied only when the prosthesis was installed, and ended when the knee prosthesis was successfully placed and the bone cement hardened, that is, limited tourniquet was used;  
Tourniquet group was used in the second half (after the completion of osteotomy, tourniquet was started when the prosthesis was installed, until the incision was sutured and pressurized, that is, tourniquet was used in the second half);  
No tourniquet group: no tourniquet was used throughout. All patients were given "cocktail" [formula: lidocaine, betamethasone infiltration injection through the surgical incision and surrounding soft tissues, routine placement of drainage tube, injection of aminocyclic acid into the joint cavity through the drainage tube, elastic bandage compression bandaging.

2.4.4 Postoperative treatment  
All patients were given Parecoxib for Injection for analgesia 3 d after operation, Tramadol for symptomatic analgesia, Estazolam for sleep assistance, and Mosapride for relieving nausea and vomiting. After the patient returned to the ward, ice compress was started. The drainage tube was clamped for 3 h and then opened. Additional tranexamic acid 1 g was intravenously infused. The drainage tube was removed within 24 h. On the first postoperative day, the patient was instructed to perform quadriceps strength and active and passive flexion and extension functional exercises of the knee. 6 h after operation, 4000u of enoxaparin was subcutaneously injected for routine anticoagulation. From the first day after operation to 2 weeks after operation, if the patient did not tolerate acupuncture, switch to oral rivaroxaban, 10 mg/d. If there was bleeding tendency, the anticoagulation was immediately stopped; venous blood C-reactive protein, hemoglobin levels and visual analogue scale and HSS score were reexamined on the 1st, 3rd, and 7th day after operation.

## 2.5 Primary outcome measures

2.5.1 Pain: The visual analogue scale of knee joint pain was measured at 1, 3, 7 d and 1 month after operation, and the score represented the degree of knee joint postoperative pain.

2.5.2 Knee function  
The HSS score of the patients' knees was measured at 3, 7 d and 1 month after surgery, and the score represented the better the functional activity of the knee joint.

2.5.3 Inflammatory Index  
The concentration of C-reactive protein (CRP) in upper limb veins was measured by immunonephelometry at 1, 3 and 7 d after operation.

2.5.4 Blood loss  
The hemoglobin level of the upper limb veins of the patients was measured by colorimetry at 1, 3, and 7 d after surgery, and the lower the hemoglobin level, the greater the overall blood loss of the operation.

2.6 Statistical analysis was performed using SPSS 25.0 statistical software for data analysis. Measurement data conformed to normal distribution and were expressed as  $x \pm s$ . One-way analysis of variance was used for comparison. LSD-t test was used for comparison of measurement data between the two groups.  $X^2$  test was used for comparison of enumeration data.  $P < 0.05$  was considered significant.

### 3. Results

3.1 The number of subjects analyzed was finally counted in the number of results analyzed as 150. Figure 1.

3.2 There was no significant difference in age, body mass index and gender between the two groups at baseline, Table 1.

3.3 Comparison of visual analogue scale of knee joint pain in the second half showed that the visual analogue scale of knee joint pain at 1 and 3 d after operation in the group using tourniquet was greater than that in the group not using tourniquet ( $P < 0.05$ ); there was no significant difference in the visual analogue scale of knee joint pain at 1 and 3 d after operation in the group using tourniquet ( $P > 0.05$ ); there was no significant difference in the visual analogue scale before operation, 7 d after operation and 1 month after operation in each group ( $P > 0.05$ ), Table 2.

3.4 Comparison of HSS score of knee joint before and after operation: The HSS score of knee joint at 3 and 7 d after operation in the second half of tourniquet group was lower than that in the restrictive tourniquet group ( $P < 0.05$ ); there was no significant difference in HSS score at 3 and 7 d after operation in the restrictive tourniquet group ( $P > 0.05$ ). There was no significant difference in HSS score before operation and 1 month after operation in each group ( $P > 0.05$ ), Table 3.

3.5 Comparison of venous blood C-reactive protein and hemoglobin levels in each group: C-reactive protein at 1 and 3 d after operation and hemoglobin at 1 d after operation in the group using tourniquet in the second half were higher than those in the group not using tourniquet ( $P < 0.05$ ); there was no significant difference in C-reactive protein hemoglobin level at 1 and 3 d after operation in the group not using tourniquet ( $P > 0.05$ ); there was no significant difference in C-reactive protein and hemoglobin level before operation and 7 d after operation in each group ( $P > 0.05$ ), Tables 4 and 5.

### 4. Discussion

The application of tourniquet in total knee arthroplasty can effectively reduce intraoperative bleeding, provide a clean and clear surgical field, and also facilitate the application of bone cement technology [6], but its postoperative complications such as early postoperative pain, lower limb swelling, and tension blisters make its use value controversial[7, 8]. As the concept of enhanced recovery was put forward [9–

11], more and more scholars proposed the restrictive use of tourniquets as well as the optimal use of tourniquets [12–14]. There are a wide variety of studies on tourniquets, such as the timing of tourniquet release [15, 16], the location of tourniquet installation and the pressure of tourniquet [17], and the timely and long timing of tourniquet use [18], and most scholars agree that the length of tourniquet use has a significant correlation with postoperative complications: Barker, T et al. [19] concluded that the use of tourniquets for more than 100 min in total knee arthroplasty will increase the risk of postoperative wound infection, deep vein thrombosis, pulmonary embolism, and nerve injury. Jawhar et al. [20] found that surgery longer than 120 min with a tourniquet increased the risk of deep vein thrombosis. Therefore, there was a significant negative correlation between the length of tourniquet use and postoperative complications. The latest opinion on whether to use tourniquet in total knee arthroplasty: By comparing the postoperative rehabilitation of patients in the group with and without tourniquet, it has been found that the non-use of tourniquet in total knee arthroplasty can reduce the postoperative pain and limb swelling, without increasing the risk of postoperative complications, and without affecting the quality of prosthesis installation and fixation [21, 22]. It has been suggested that long-term use of tourniquet can reduce intraoperative and intraoperative total blood loss, while short-term use of tourniquet can reduce postoperative and postoperative hidden blood loss without increasing the rate of allogeneic blood transfusion [23]. Interestingly, some studies found that 48 h after total knee arthroplasty, the strength of knee extension was not superior in the group without tourniquet, but tourniquet caused lower limb pain [24, 25]; others suggested that the use of tourniquet had no significant correlation with postoperative rehabilitation [26]. In summary, studies on tourniquet use or not have been reported, but there is little literature comparing postoperative rehabilitation with limited tourniquet use versus no tourniquet use. The purpose of this trial was to evaluate more precisely the clinical effects and optimal timing of tourniquet use by phasing the duration of tourniquet use in the second half of surgery and comparing the effects of limited use versus no tourniquet use on early postoperative biochemical parameters and functional rehabilitation.

It is well-known that pain is an important influencing factor for patients' satisfaction with surgery. In the trial, the same enhanced recovery after surgery and postoperative rehabilitation training were used in all groups [27, 28]. The analysis of the results showed that the visual analogue scale at 1, 3 and 7 d after the second half of tourniquet application was significantly greater than that in the other two groups. These results suggest that prolonged tourniquet time does increase early postoperative pain, which may be closely related to prolonged local soft tissue and nerve compression and ischemia-reperfusion injury during tourniquet release [29]. However, there was no significant difference in visual analogue scale among the three groups 1 month after surgery, suggesting that the injury caused by the tourniquet was reversible. Therefore, the length of tourniquet time is mainly positively correlated with pain in the early postoperative period.

C-reactive protein can reflect the inflammatory response of the body to surgery to a certain extent [24]. The trial comparison found that C-reactive protein was significantly increased in all three groups after surgery. The comparison at 1 d after surgery found that C-reactive protein was higher in the tourniquet group than in the other two groups in the second half, which may be related to prolonged ischemic

anaerobic metabolism and release of tourniquet inflammatory factors into the blood. Hemoglobin can show operative blood loss to some extent[21]. The test found that all patients in the 3 groups had different degrees of postoperative hemoglobin loss, but the hemoglobin loss 1 d after the surgery with tourniquet in the second half was significantly lower than that in the restrictive use group without tourniquet, but there was no significant difference 3 d after the surgery, suggesting that the tourniquet in the second half could reduce the intraoperative blood loss, but there was no significant difference in the total blood loss 3 d after the surgery with the other two groups possibly due to the increase of invisible blood loss[30], which was consistent with the study results of Charalambides et al. [23]. Analysis of trial results showed no significant differences in postoperative visual analogue scores, HSS scores, C-reactive protein, and hemoglobin levels between the limited and no tourniquet use, suggesting that the limited use of a tourniquet can achieve the same effect as no tourniquet use in early postoperative rehabilitation. However, the trial only focuses on the study of various indicators in the early postoperative period. The long-term follow-up results of patients have not been further studied, and there are still limitations.

## 5. Conclusion

In conclusion, there was no significant difference in the effect of early postoperative rehabilitation between the limited use and no use of tourniquet, and the use of tourniquet in the second half would aggravate the early postoperative pain.

## 6. Abbreviations

TKA

Total Knee Arthroplasty.

HSS Score

Hospital for special surgery knee score

TCM

Traditional Chinese Medicine

## 7. Declarations

## 7. Declarations

All Authors Commit to the following points: Our study adheres to CONSORT guidelines, This manuscript been original and not published elsewhere, All authors acted without misconduct during the research and writing of the paper and assumed the relevant responsibilities.

## 8. Consent for publication:

All authors agree to the publication of this article.

## 9. Authors' Contributions

The first author,JDY and WXL, was esponsible for the experimental design. The second author,BZ and FC, was responsible for data collection and collation. The corresponding author, YY, was responsible for article writing. Simultaneous,all authors agree to submit the manuscript

## 10. Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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## 13. Competing Interests

Conflicts of interest: All authors of the article declare that there is no report on the article views and data results due to their post role in the process of topic research and article writing, and there is no conflict of interest.

## 14. Ethics approval and consent to participate

Institutional ethical issues: The trial protocol has been discussed and approved by the Ethics Committee of the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine, informed consent has been obtained from the patients and relevant family members, and informed consent has been signed.

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## Tables

Due to technical limitations, the tables are provided in the Supplementary Files section.

# Figures

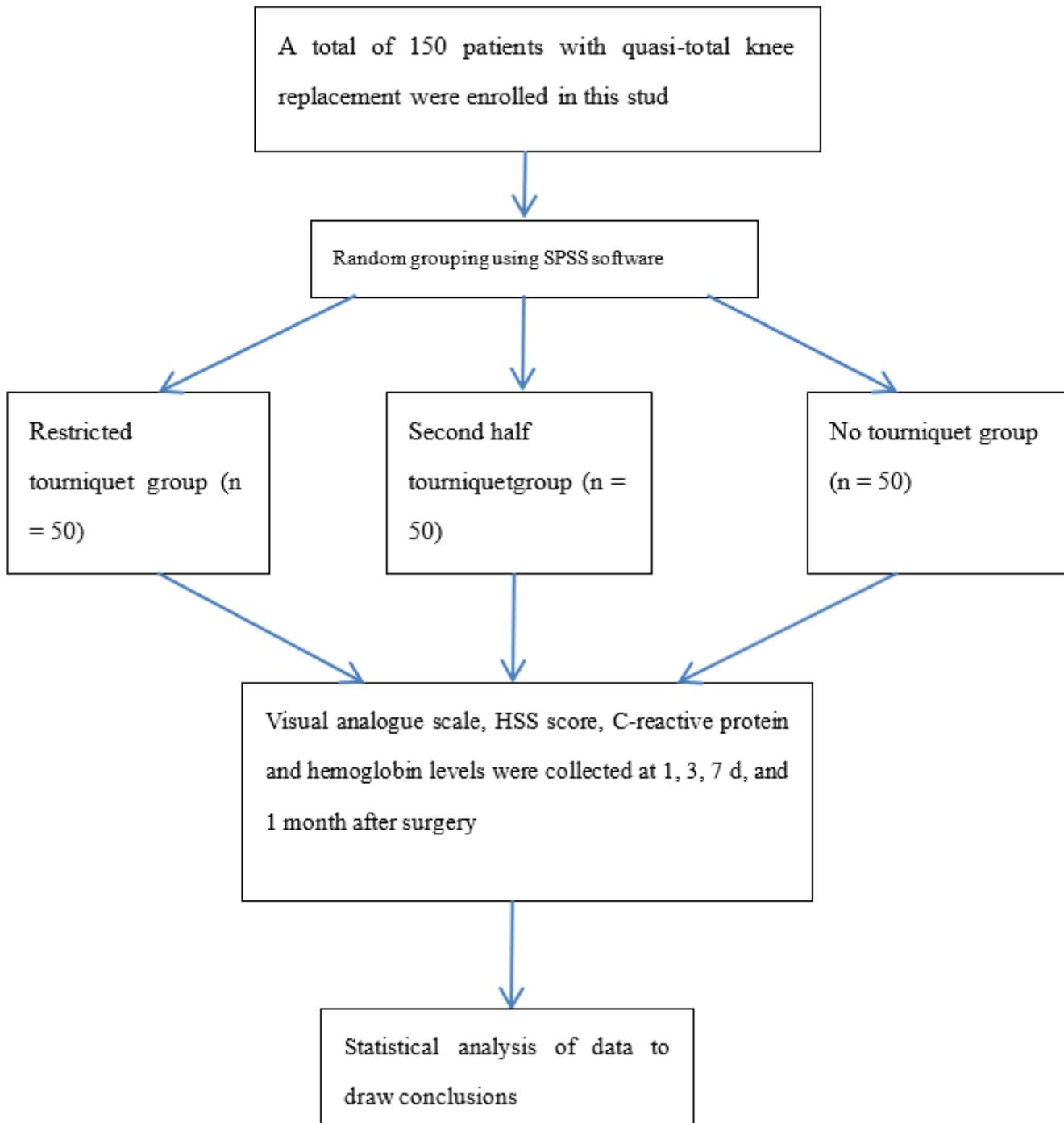


Figure 1

Experimental flow chart

## Supplementary Files

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