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The effects of tourniquet use in total knee arthroplasty: a randomized, controlled trial

Kai Wang[1] · Songjia Ni[1] · Zhichang Li[1] · Qunjie Zhong[1] · Rujun Li[1] · Hu Li[1] · Yan Ke[1] · Jianhao Lin[1]

Abstract

Purpose   Tourniquets are still widely used in total knee arthroplasty (TKA), although they may be associated with several adverse effects. An observer-blinded, randomized, controlled trial was performed to evaluate the effects of tourniquet use in TKA.

Methods   Fifty participants who underwent staged bilateral TKA were recruited for this study. The first-side TKA was randomly allocated to either long-duration tourniquet use or short-duration tourniquet use followed by a 3-month washout period and crossover to the other tourniquet strategy for the opposite-side TKA. Blood loss was monitored perioperatively. The operating time, allogeneic blood transfusion rate, thigh pain, knee pain, limb swelling, clinical outcome as measured by the Likert-type Western Ontario and McMaster University (WOMAC) score, straight leg raising and knee active range of motion (ROM) were also recorded.

Results   The long-duration tourniquet group exhibited reduced total blood loss [−99.1 ml, 95 % confidence interval (CI) −168.1 to −30.1, $P = 0.0411$] and intraoperative blood loss (−225.2 ml, 95 % CI −369.5 to −80.9, $P = 0.0071$) compared with the short-duration tourniquet group. However, there were greater postoperative blood loss (69.6 ml, 95 % CI 21.1 to 118.2, $P = 0.0282$) and hidden blood loss (52.8 ml, 95 % CI 10.5 to 95.1, $P = 0.0332$) in the long-duration tourniquet group. The short-duration tourniquet group showed better outcomes for thigh and knee pain, limb swelling, WOMAC score at 6-week follow-up, straight leg raising and knee ROM. Similar allogeneic blood transfusion rates were observed for both groups.

Conclusion   Total and intraoperative blood losses were reduced with the long-duration tourniquet use, whereas the short-duration tourniquet use would reduce postoperative and hidden blood losses without increasing the allogeneic blood transfusion rate. In addition, short-duration tourniquet use would result in faster recovery and less pain during the early rehabilitation period following TKA.

Level of evidence   I.

Keywords   Tourniquet · Total knee arthroplasty · Blood loss · Clinical outcome

Introduction

Tourniquets are widely used during total knee arthroplasty (TKA) to provide better visualization and to facilitate the cementing technique and other surgical procedures [26]. Moreover, the use of tourniquets may reduce the operating time [9], which may then decrease the incidence of infection [3].

However, tourniquets may also be associated with several disadvantages, including thigh pain, limb swelling, nerve palsy, muscle injury, postoperative stiffness and deep vein thrombosis (DVT) [3, 4, 9, 18, 19, 22, 28]. Additionally, whereas various studies have demonstrated that tourniquets effectively reduce blood loss [7, 29], others have demonstrated that tourniquets increase blood loss [1, 17, 28].

Several randomized controlled trials (RCTs) and meta-analyses comparing the effects of tourniquet use have been published [2, 3, 14, 22, 26, 28, 31]; however, no medical consensus

✉ Jianhao Lin
   linjianhao@pkuph.edu.cn

[1]   Arthritis Clinic and Research Center, Peking University People's Hospital, Peking University, Xizhimen South Street No. 11, Beijing, China

regarding tourniquet use has been reached. Heterogeneous data were reported for various trials. Furthermore, most of these studies were not based on a crossover design. Therefore, we conducted an observer-blinded, randomized, controlled, crossover trial in which all the patients received staged bilateral TKA employing two different durations of tourniquet use with a 3-month washout period between the interventions, allowing each patient to serve as his or her own control to minimize confounding variables between the groups. In this study, the effect of tourniquet use on blood loss reduction and its impact on functional and clinical outcomes were evaluated.

The hypothesis was that applying long-duration tourniquet use would reduce the intraoperative blood loss but might increase the postoperative blood loss and the hidden blood loss, while applying short-duration tourniquet use would result in faster recovery and less pain during the early postoperative rehabilitative period.

Materials and methods

Before this study began, approval was obtained from the Ethics Committee of Peking University People's Hospital, Beijing, China [Approval Number: (2013) IRB-Clinical-No. 17], and the study was registered at ClinicalTrials.gov (NCT02429713). Participants were recruited consecutively between January 2013 and June 2014 during a period of approximately 1.5 years. All patients provided written consent and were enrolled in the study in accordance with the Consolidated Standards of Reporting Trials (CONSORT) and the Helsinki Declaration.

Fifty patients who were scheduled for staged bilateral TKA were recruited. The inclusion criteria were being 50 years or older and being classified as American Society of Anesthesiologists (ASA) class 1 or 2. The exclusion criteria included coagulopathy, uncontrolled hypertension, peripheral vascular disease, previous knee surgery and body mass index (BMI) >35.

For each patient, the first-side TKA was randomly allocated to either long-duration tourniquet use (tourniquet inflated just before the incision and deflated after the hardening of the cement) or short-duration tourniquet use (tourniquet inflated just before the cement application and deflated after its hardening) followed by a 3-month washout period and crossover to the other tourniquet strategy for the opposite-side TKA operation (see Fig. 1).

The randomization sequence was generated by an independent statistician via a computer-generated random-number table. The randomization numbers were contained in sealed, opaque envelopes and were retained by office staff who were not involved in outcome measurements. The observers collecting the data after surgery were uninvolved in the experimental operations and were unaware of the intervention assignments.

Each patient received the same protocol of intraoperative tranexamic acid injection, spinal anaesthesia, postoperative pain treatment and rehabilitation. Both groups had an appropriately sized thigh tourniquet applied. The tourniquet was inflated with the patient's leg fully extended to a pressure that equaled the systolic blood pressure plus 100 mmHg for both groups.

All the operations were performed by the same surgeon using the same type of cemented prosthesis (NexGen, Complete Knee Solution, Zimmer, Warsaw, IN, USA). A medial parapatellar approach was used in all the arthroplasties. An intramedullary guide was used for both the femoral and tibial cuts. Anchorage holes were drilled into the tibial plateau to increase the contact area between bone and cement. High-pressure pulsatile lavage was used to remove blood and to provide better cement interdigitation. For both groups, blood collected during the operation was re-infused. A non-suction wound drainage system was used in both groups and removed 48 h after surgery. After the joint capsule was closed, tranexamic acid (1 g) was injected into the capsule to control bleeding.

Oral rivaroxaban (10 mg per day) was administered 12 h after surgery and was continued for 2 weeks after the operation as thrombosis prophylaxis. Absent patient contraindications, an oral non-steroidal anti-inflammatory drug (celecoxib, 200 mg twice a day) was routinely prescribed for pain control. Fluid replacement was standardized in both groups. The criteria for blood transfusion included haemoglobin (Hb) < 8 g/dl or Hb < 9 g/dl along with symptoms of anaemia, such as tachycardia, dyspnoea, hypotension and angina pectoris. Postoperative rehabilitation began on the second postoperative day and followed a standard protocol including muscle power training, passive and active range-of-motion training, and walking. This protocol was begun on postoperative day 2.

Outcome measurements

The primary outcome was perioperative blood loss. We tested the level of Hb and haematocrit (Hct) preoperatively and on days 1, 2, and 5, postoperatively. The decreases in Hb and Hct were defined as the difference between the lowest values and the preoperative baseline values. The blood volume of each patient was calculated according to a formula published by Nadler and colleagues which takes into account patient weight, height and sex [21]. Thus, multiplying the blood volume by the change in Hct yields the calculated total blood loss [23]. In addition, the volumes of intraoperative blood loss, postoperative blood loss, blood transfusion and hidden blood loss were also recorded. The increased weight of the gauze pads plus the volume in the aspirator bottle excluding the rinse represented the intraoperative blood loss. The postoperative blood loss was calculated by measuring the drainage volume and by weighing the dressings. Hidden blood loss was calculated according to a formula published by Gross [8], which is calculated by subtracting the intraoperative and

Fig. 1 CONSORT diagram for the present trial. *LDTG* long-duration tourniquet group, *SDTG* short-duration tourniquet group
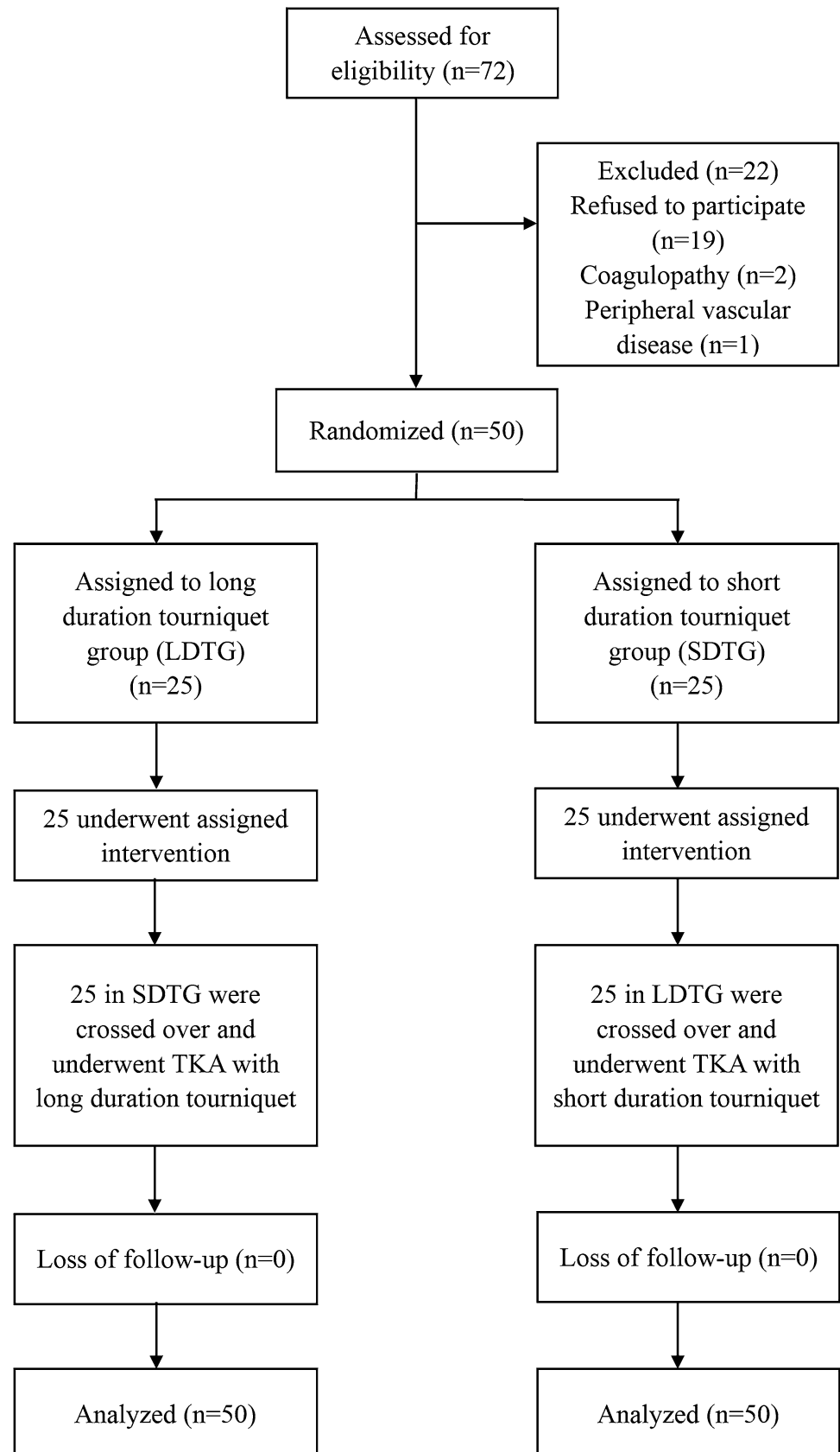
postoperative blood losses from the calculated total blood loss and then adding the volume of blood re-infused or transfused.

Postoperative visual analog scale (VAS) scores were obtained for thigh and knee pain. Patients were asked to rate the pain in their thigh and knee on a scale of 0–10, with 0 representing no pain and 10 representing the worst pain imaginable. Thigh circumference (10 cm proximal to the superior border of the patella), knee circumference (midpoint of the patella) and calf circumference (20 cm proximal to the medial malleolus) were recorded to assess the degree of limb swelling. The degree of limb swelling was presented as a percentage compared with the preoperative measure. To ensure the reliability of our results, we used an oil pen that slowly fades over time to preoperatively demarcate the patients' skin sites where we measured the circumference; this demarcation served as a reference for the sites postoperatively. Notably, this measurement should be performed when there is no tension over the skin. That is, when the observer releases the elastic tape, the two ends of the tape should not be retracted by limb tissue at the measured site. Clinical outcome assessments included the Likert-type Western Ontario and McMaster University (WOMAC) pain scale (ranging from 0 to 20, with lower scores indicative of better outcome), physical function (ranging from 0 to 68) and knee stiffness (ranging from 0 to 8) subscales at the 6-week follow-up visit. The WOMAC translation into Chinese has been validated in Chinese patients [30]. Knee active range of motion (ROM) was measured in the supine position using a long-arm goniometer. The time needed to achieve straight leg raise was also recorded. Special attention was paid to whether symptomatic pulmonary embolism (PE) or DVT occurred. Occult DVT was detected by a regular bilateral lower extremity deep venous color Doppler ultrasound examination.

Statistical analysis

Continuous variables are reported as the mean and the standard deviation (SD), and categorical variables are reported as proportions. Comparisons between groups were determined using an independent t test if the data were normally distributed; otherwise, a Mann–Whitney U test was used. The Chi square test was used to analyse categorical variables. The effects of long-duration tourniquet use and short-duration tourniquet use were compared using a paired t test if the data were normally distributed; otherwise, the Wilcoxon signed-rank test was used. Parameters that were measured in the same group but at different times were analysed with the repeated-measures general linear model. Two-sided P values of <0.05 indicated statistical significance.

Based on our previous study, the SD of blood loss was assumed to be 110 ml. It was estimated that we would need to enroll 38 patients to detect a reduction in the blood loss of 50 ml with the long-duration tourniquet use as compared with the short-duration tourniquet use, with statistical power (1 minus the β value) of 80 %, allowing for a type I (α) error of 0.05. Allowing for a loss to follow-up of 20 %, 48 patients were required to undergo randomization.

Results

Fifty participants were enrolled in this trial. Twenty-five of these participants were assigned to the long-duration tourniquet group for their first operation, whereas the other 25 participants were first assigned to the short-duration tourniquet group (Fig. 1). No participants were lost to follow-up.

At baseline, no significant differences in demographic data were noted between the two groups. The operating time was reduced in the long-duration tourniquet group (Table 1).

The mean total blood loss was reduced in the long-duration tourniquet group compared with the short-duration group, and the difference was significant [−99.1 ml, 95 % confidence interval (CI) −168.1 to −30.1, $P = 0.0411$]. Similarly, intraoperative blood loss was also reduced in the long-duration tourniquet group (−225.2 ml, 95 % CI −369.5 to

Table 1 Baseline characteristics of the study participants and operating time

	Long-duration tourniquet used first	Short-duration tourniquet used first	P value
Number of patients	25	25	–
Age (years)	72.3 ± 7.1	72.5 ± 6.8	NS
Female sex (nos./%)	20 (80.0 %)	21 (84.0 %)	NS
Body mass index (kg/m^2)	28.8 ± 6.2	29.1 ± 6.6	NS
Diagnosis (OA/RA)	22/3	23/2	NS
Preoperative haemoglobin (g/dl)	12.8 ± 1.1	13.1 ± 1.2	NS
Preoperative haematocrit (%)	38.5 ± 2.5	38.8 ± 3.8	NS
Tourniquet duration (min)	54.8 ± 6.7	10.9 ± 1.8	<0.0001
Operating time (min)	84.7 ± 12.4	93.8 ± 22.7	0.0449

The values are presented as the mean and SD; body mass index (BMI) equals weight in kilograms divided by the square of the height in metres

NS the difference between the groups is not significant

Table 2 Perioperative blood loss and allogeneic blood transfusion

	Long-duration tourniquet group	Short-duration tourniquet group	Difference (95 % CI)	*P* value
Total blood loss (ml)	735.5 ± 125.3	834.6 ± 168.5	−99.1 (−168.1 to −30.1)	0.0411
Intraoperative blood loss (ml)	166.3 ± 62.0	391.5 ± 72.1	−225.2 (−369.5 to −80.9)	0.0071
Postoperative blood loss (ml)	208.4 ± 68.5	138.8 ± 42.7	69.6 (21.1 to 118.2)	0.0282
Hidden blood loss (ml)	411.4 ± 118.2	358.6 ± 123.4	52.8 (10.5 to 95.1)	0.0332
Allogeneic blood transfusion (nos./%)	2 (8.0 %)	3 (12.0 %)	–	NS

The values are presented as the mean and SD

CI confidence interva, *NS* the difference between the groups is not significant

−80.9, $P = 0.0071$]. However, the long-duration tourniquet group exhibited greater postoperative blood loss (69.6 ml, 95 % CI 21.1 to 118.2, $P = 0.0282$) and hidden blood loss (52.8 ml, 95 % CI 10.5 to 95.1, $P = 0.0332$) compared with the short-duration tourniquet group (Table 2). Three patients in the short-duration tourniquet group and two patients in the long-duration tourniquet group received allogeneic blood transfusions. These patients were transfused due to low Hb levels (Hb < 8 g/dl). The number of allogeneic blood transfusions in each group was similar (Table 2).

The short-duration tourniquet group exhibited reduced thigh and knee pain (assessed by VAS scores) on days 1 and 2 as well as 1 week postoperatively compared with the long-duration tourniquet group (Fig. 2a, b). The short-duration tourniquet group also exhibited reduced thigh and knee circumferences compared with the long-duration tourniquet group (Fig. 2c, d). No significant difference between the groups was noted with respect to calf circumference (Fig. 2e).

There was more significant improvement in WOMAC scores in the short-duration tourniquet group at the 6-week follow-up (Table 3). The short-duration tourniquet group also exhibited better outcomes in terms of the active knee ROM postoperatively and the time interval required for patients to achieve straight leg raise (Table 3).

As investigated by ultrasound on postoperative day 7, no patients in either group exhibited DVT. However, two patients in the long-duration tourniquet group exhibited intramuscular vein thrombosis without obvious symptoms. No excessive oozing of blood or wound complications were noted in either group postoperatively.

Discussion

The most important finding of the present study was that although reduced total and intraoperative blood loss were observed with long-duration tourniquet use, the short-duration tourniquet use would reduce the postoperative and hidden blood loss and not increase the incidence of allogeneic

blood transfusion. In addition, short-duration tourniquet use would result in faster recovery and less pain during the early rehabilitation period following TKA.

The debate continues as to whether tourniquet use can reduce blood loss. Various studies [2, 7, 14, 25, 29] claim that the tourniquet effectively reduces blood loss; however, results from other studies show no reduction in blood loss. Numerous studies [1, 12, 31] reported no significant difference in the amount of blood loss with or without tourniquet use. Moreover, various studies demonstrate even greater blood loss [17, 28] when using a tourniquet. Despite adequate blinding and randomization, patients in the two intervention groups may differ at baseline with regard to key characteristics such as total blood volume, muscle strength and coagulation function. However, since this was a crossover trial, these differences should have had minimal effects on the results.

It was demonstrated in our study that the mean total blood loss and intraoperative blood loss were significantly higher in the short-duration tourniquet group, which were consistent with some previous studies [2, 7, 14, 25, 29]. Furthermore, as Sehat et al. reported [24], hidden or unmeasured blood loss could often be substantial during TKA, which we therefore considered. Our study demonstrated that postoperative blood loss and hidden blood loss were increased in the long-duration tourniquet group. There are multiple reasons why blood loss may be greater in the long-duration tourniquet group. First, the ischaemic conditions caused by the use of a tourniquet could induce sustained local reactive hyperaemia that lasts several hours after tourniquet deflation. This hyperaemia would subsequently promote more haemorrhage into the traumatized tissue and bleeding from the incision site during the postoperative period. Second, bleeding into the local tissues was promoted by the increased fibrinolytic activity associated with tourniquet-induced ischaemia [1]. Third, according to our own experiences, this latter condition is convenient for surgical haemostasis because the bleeding structure is clearly observed without a tourniquet. Conversely, bleeding

Fig. 2 **a**, **b** Depict thigh pain and knee pain on postoperative day 1, day 2, 1 week (1 W), 2 weeks (2 W) and 6 weeks (6 W). Pain was assessed using VAS scores. VAS scores were lower in the short-duration tourniquet group. **c–e** Depict thigh swelling, knee swelling and calf swelling, respectively, on postoperative day 1, day 2, 1 weeks, 2 weeks and 6 weeks. Limb swelling was assessed by measuring the rate of limb circumference increase. *Vertical bars* represent SD. The *asterisks* indicate values that were significantly different between the two groups ($P < 0.05$)
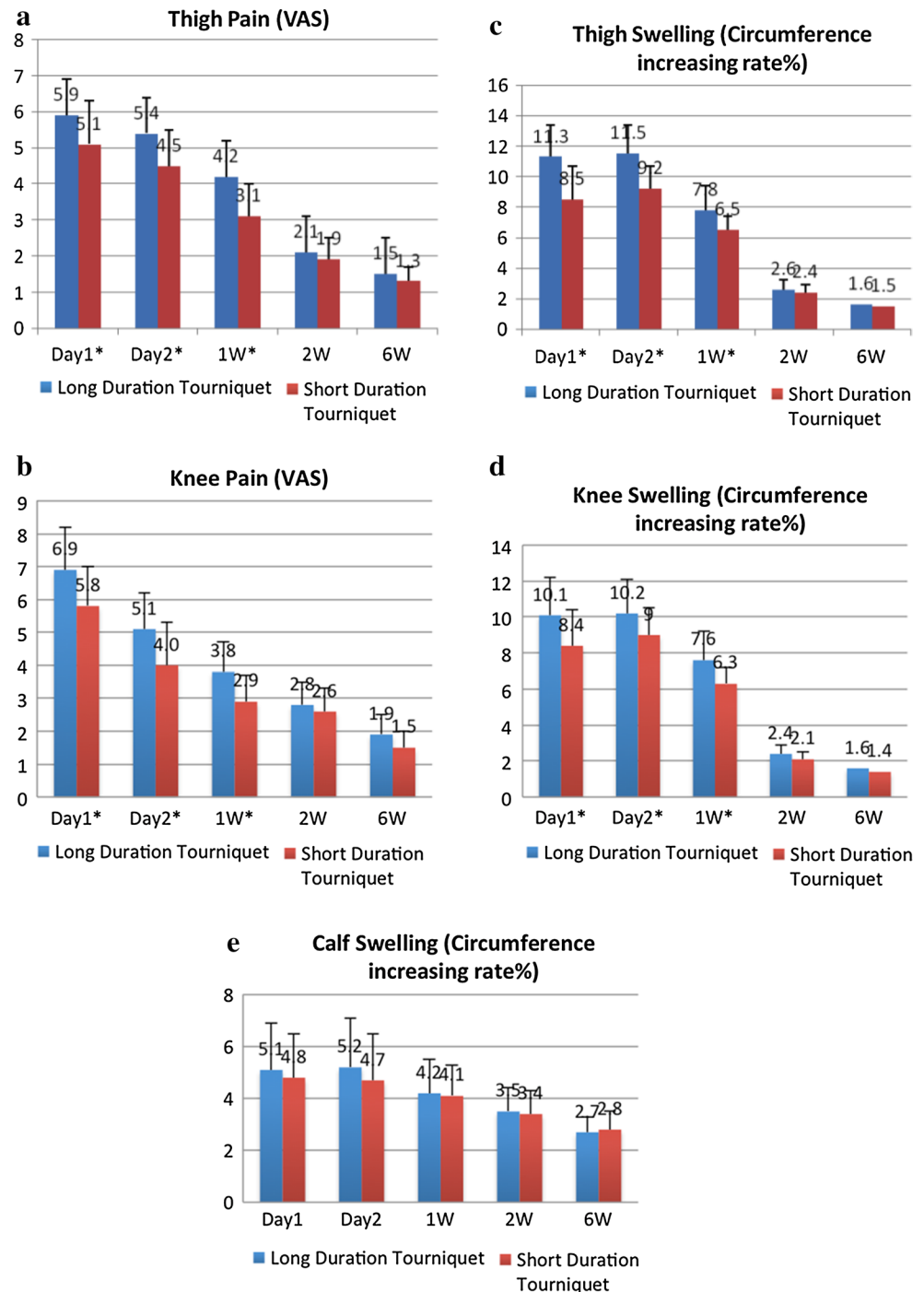
vessels might be missed when the tourniquet is inflated during TKA surgery.

In our trial, the short-duration tourniquet group was associated with better clinical outcomes, less pain and less limb swelling during the early stage of rehabilitation. Similar results were reported by Zhang et al. [31] and Ejaz et al. [6]. A possible explanation for improved outcomes among patients in the short-duration tourniquet group is that the direct compression of the tourniquet on tissue and

reperfusion injury may increase pain, which would influence patients' postoperative rehabilitation [15]. In the long-duration tourniquet group, the postoperative blood loss was increased. This lost blood may escape into the soft tissue, potentially resulting in limb swelling. Additional swelling may hinder patients' early postoperative rehabilitation exercises. Increased swelling also increases the soft tissue tension, thus decreasing oxygen tension [16]. Furthermore, as Dennis et al. [5] reported, patients who underwent TKA

Table 3 Clinical outcomes between the long-duration tourniquet group and the short-duration tourniquet group

	Long-duration tourniquet group	Short-duration tourniquet group	Difference (95 % CI)	P value
WOMAC pain scale				
Baseline (range 0–20)[a]	9.6 ± 1.8	9.4 ± 1.7	0.2 (−0.1 to 0.5)	NS
CFB at 6 weeks[b]	−4.6 ± 1.1	−5.9 ± 0.8	1.3 (0.8 to 1.8)	0.0326
WOMAC knee stiffness scale				
Baseline (range 0–8)[a]	3.3 ± 1.2	2.9 ± 0.9	0.4 (0.2 to 1.0)	NS
CFB at 6 weeks[b]	−1.3 ± 0.7	−2.1 ± 0.6	0.8 (0.4 to 1.2)	0.0256
WOMAC physical function scale				
Baseline (range 0–68)[a]	51.6 ± 9.1	53.8 ± 9.8	−1.9 (−4.2 to 0.4)	NS
CFB at 6 weeks[b]	−15.9 ± 2.2	−22.3 ± 3.6	6.4 (4.7 to 8.1)	0.0358
Knee active range of motion (ROM)				
1 Day	31° ± 10°	40° ± 9°	−9° (−16° to −2°)	0.0212
2 Days	38° ± 11°	49° ± 12°	−11° (−18° to −4°)	0.0258
1 Week	57° ± 9°	66° ± 10°	−9° (−13° to −5°)	0.0479
2 Weeks	85° ± 8°	89° ± 7°	−4° (−10° to 2°)	NS
6 Weeks	110° ± 6°	113° ± 7°	−3° (−9° to 3°)	NS
Straight leg raise (days)	2.7 ± 1.2	1.8 ± 1.1	0.9 (0.5 to 1.3)	0.0412

The values are provided as the mean and SD

CI confidence interva, *WOMAC* Western Ontario McMasters University Osteoarthritis Index, *CFB* change from baseline, calculated by subtracting the baseline WOMAC score from that at the 6-week follow-up, *NS* the difference between the groups is not significant

[a] Lower scores indicate better outcomes

[b] A negative change from baseline is an improvement

using a tourniquet had diminished quadriceps strength during the first 3 months after TKA. Loss of lower quadriceps strength may result in reduced recovery of the active ROM of the knee and instability when walking and climbing stairs.

Thromboembolism is one of the most serious postoperative complications following TKA. For the long-duration tourniquet group, thromboembolism potentially increases the risk of DVT due to stasis of venous blood in the lower limb and possible damage to blood vessels [2]. However, in our study, DVT was not detected in either of the two groups. Chemical prophylaxis with rivaroxaban and early physiotherapy may be of great benefit. Two meta-analyses also found no difference in DVT or PE occurrence with the use of the tourniquet application during TKA surgery [2, 26]. Moreover, various additional tourniquet-related complications have been reported in the literature, including nerve palsy [10], vascular injuries [2], rhabdomyolysis [25] and subcutaneous fat necrosis [27]. Some studies have also reported changes in intraoperative patellofemoral tracking caused by tourniquet use [11, 13, 20]. None of these complications occurred during our trial.

The operating time mainly depends on the surgical technique used by the surgeons. The application of a tourniquet during TKA is thought to effectively provide a relative bloodless field, which saves time in surgery [31]. In our trial, the operating time of the long-duration tourniquet group decreased by approximately 9 min, which had little influence on our clinical practice. Furthermore, Ejaz et al. [6] reported that the visibility of the surgical field was not impaired when a tourniquet was not used. Similarly, we found that control of intraoperative bleeding was not an obstacle with short-duration tourniquet use.

There were some limitations with our study. First, testing was continued for only 6 weeks postoperatively. However, the focus of this report was to investigate the effects of a tourniquet on early TKA recovery. Second, we studied relatively low-risk patients (ASA class 1 or 2). Complications such as nerve palsy, vascular injuries and DVT could occur with prolonged tourniquet use if high-risk patients such as older patients or those with calcified arteries were included. Third, deep venous color Doppler ultrasound is an operator-dependent examination that relies on operator experience and technique. A future trial with more precise diagnostic testing to detect thrombosis, such as echoscope or venography, is needed to reach a more definitive conclusion.

According to our study, the postoperative and hidden blood losses were reduced with the short-duration tourniquet use (tourniquet inflated just before the cement application and deflated after its hardening) in TKA. Furthermore, faster recovery, less limb swelling and less pain during the early rehabilitation period were observed with the short-duration tourniquet use.

Conclusion

Total and intraoperative blood losses were reduced with the long-duration tourniquet use. However, short-duration tourniquet use was associated with lower postoperative blood loss, hidden blood loss and would lead to faster recovery and less pain during the early rehabilitation period following TKA.

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