The limited use of a tourniquet during total knee arthroplasty: A randomized controlled trial

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Abstract

Background: Total knee arthroplasty (TKA) is commonly performed using a tourniquet. However, some studies have reported that several complications were associated with the use of a tourniquet in TKA. In this study we investigate whether the limited use of a tourniquet in TKA would reduce complications and facilitate postoperative recovery.

Methods: Sixty patients were randomly divided into two groups (30 cases/group): group A using the tourniquet throughout the surgical procedure, and group B using the tourniquet starting from the cementation to the completion of the procedure. Operation time, total measured blood loss, and incidence of complications were all recorded.

Results: There was no significant difference in operation time, total measured blood loss, and hemoglobin concentration between the two groups. Incidence of postoperative complications in group B was significantly decreased in comparison to that in group A. The limb circumference at 10 cm above the superior patellar pole or below the inferior patellar pole and the pain score in group B were significantly decreased compared with that in group A at any time point. Range of motion in group B was significantly increased at three and 5 days postoperatively in comparison to that in group A.

Conclusions: The limited use of a tourniquet in TKA provides the benefit of decreased limb swelling and knee joint pain while not compromising the operation time or blood loss and recovery.

Level of evidence: Level I (Therapeutic).

Trial registration number: NCT02102581.

1. Introduction

Tourniquets are widely used in total knee arthroplasty (TKA) [1,2]. TKA has been reported to be be associate with significant blood loss. Although the tourniquet is widely used by orthopedic surgeons, its role is controversial [3]. Several studies have shown that using a tourniquet in TKA could reduce the total blood loss [1,4], while results from others indicated the opposite [5–9]. Therefore the relationship between the use of a tourniquet and the total blood loss of patients undergoing TKA is still unclear.

In addition, some potential complications associated with tourniquet use have been reported in the literature, which include nerve palsy [10], vascular injuries [11], rhabdomyolysis [12], subcutaneous thigh fat necrosis [13], delayed recovery of muscle strength from microscopic changes in muscle myofibrils [14], wound complications [1,4,15], and venous thrombotic embolism [4,15,16].

Completely eliminating the use of a tourniquet during TKA may bring risk. The bone bed may have blood or fat on its surface and this might compromise cementation. This raises the question of whether the potential benefits of tourniquet avoidance might be married with the benefits of a dry interface for cementing if the tourniquet is used from cementation. To our knowledge, previous randomized studies mainly focused on the comparison between no tourniquet use at all and tourniquet use during the operation [1,3,4,6,16]. At the time the current study was conducted, there are no published studies in the literature that compared the limited use of a tourniquet starting from the cementation to the completion of the procedure with tourniquet use during the entire operation procedure.

The aims of our study were to determine whether the limited use of a tourniquet (compared with the use of a tourniquet throughout the procedure) would affect (1) operation time, tourniquet time, total measured blood loss, and complications; (2) hemoglobin concentration; (3) limb swelling and postoperative pain, or (4) knee flexion range of motion. We hypothesize that limited tourniquet application would reduce the complications associated with tourniquet use but still prevent blood loss and aid the recovery after TKA.

2. Patients and methods

2.1. Patients

The study was approved by the Ethics Committee of Peking Union Medical College Hospital, China, and written informed consent was...
obtained from all subjects. Between August 2011 and December 2011, 60 patients who underwent routine TKA were included in this randomized study (Fig. 1). Patients were classified according to the American Society of Anesthesiologists (ASA) physical status classification system. Patients eligible for the study included those who underwent initial unilateral TKA for osteoarthritis or rheumatoid arthritis. Patients with diabetes, hemorrhagic disease, peripheral neurovascular disease, malignant tumors, history of vascular thrombosis, history of infection in the lower limb, or Hb < 100 g/L were excluded from the study. Patients taking anti-platelet agents due to cardiovascular disease were also excluded. The patients were randomly divided into two groups using a successive random number table, with odd numbered patients (group A) receiving a full time tourniquet, and even numbered patients (group B) receiving non-full time tourniquet. Randomization was blinded to the nurses on the inpatient unit, physical therapists, and the patients. The randomization was performed by a research fellow (TX) who was not involved in patient care. In group A, tourniquet was applied during the whole operation if the procedure lasted less than 90 min. In cases where the operation lasted longer than 90 min, the tourniquet was released after implantation of the patellar implant. In group B, the tourniquet was applied from cementation to the completion of the procedure and was released after implantation of the patellar implant. Each group contained 30 cases and the characteristics of patients in both groups are summarized in Table 1.

### 2.2. Surgical procedures

Standard techniques were used in all of the cases. In group A, 19 patients received general anesthesia and 11 received spinal anesthesia, while in group B, 17 patients received general anesthesia and 13 received spinal anesthesia. Each procedure was performed by a group of four experienced staff surgeons. Intramedullary instrumentation of the tibia was used in all patients. After opening up the femoral canal using a 9.5 mm drill, the valgus alignment was sided to touch the distal femur at least one side. Then, the distal femur was resected. After the assembly was placed in neutral rotation, the floating spike was impacted into the distal femur and secured on to the distal block with pins. The sizing guide was positioned flush with the lateral ridge of the anterior cortex and the size determined from the

### Table 1

<table>
<thead>
<tr>
<th>Groups</th>
<th>Sex (n)</th>
<th>Age (years)</th>
<th>ABP (mm Hg)</th>
<th>ROM (°)</th>
<th>FC (°)</th>
<th>ICH (mm Hg)</th>
<th>FTA (°)</th>
<th>BMI (kg/m²)</th>
<th>ASA classification (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>7/23</td>
<td>65.37 ± 7.11</td>
<td>95.26 ± 8.33</td>
<td>106.47 ± 19.29</td>
<td>8 (5, 12)</td>
<td>90.26 ± 8.34</td>
<td>172.2 ± 3.96</td>
<td>27.24 ± 2.69</td>
<td>1398</td>
</tr>
<tr>
<td>Group B</td>
<td>9/21</td>
<td>63.27 ± 7.39</td>
<td>94.84 ± 3.43</td>
<td>107.77 ± 12.56</td>
<td>7 (5, 10)</td>
<td>89.77 ± 2.85</td>
<td>171.2 ± 4.21</td>
<td>26.26 ± 1.52</td>
<td>1211 7</td>
</tr>
</tbody>
</table>

ABP = Arterial blood pressure; ROM = Knee flexion range of motion and was given in degrees; FC = Flexion contracture and was expressed as median and range; ICH = Intra-operative controlled hypotension; FTA = Femoro-tibial angle and was given in degrees; BMI = Body mass index; ASA = American Society of Anesthesiologists.

**Fig. 1.** The CONSORT flowchart of subject screening and enrollment.
graduations on the shaft of the stylus. If the indicated size is in-between sizes, the lower hex screw was rotated to raise the anterior surface to the next smaller size. Once appropriate size is determined, the upper hex screw was rotated to lock-in the position. Then, the drill was used to mark the location holes for the AP cutting block. Finally, AP cutting block with appropriate size was placed on the distal femur and thereafter anterior, posterior and chamfer distal femur was cut. The hole for femoral intramedullary guide was sealed with autogenous cancellous bone segment. Femoral alignment was guided by an intramedullary rod. All the same methods were used in all patients in this study. The implant used was the type of posterior cruciate ligament-substituting total knee prosthetic components (Genesis II, Smith & Nephew Inc., Memphis, TN, USA).

All of the procedures were completed by the same group of surgeons and were performed through a mini medial parapatellar approach. If the duration exceeded 90 min, the tourniquet was released intraoperatively and haemostasis was completed. The operation time listed in Table 2 refers to the period from the beginning of anesthesia until the completion of the wound closure. Tourniquet was applied just before skin incision and was let down after patellar resurfacing.

The tourniquet pressure was based on the patient’s arterial systolic pressure + 100 mm Hg (1 mm Hg = 0.133 kPa). The wound was closed and dressed using standard wound dressings and compression before the loosening of the tourniquet. A diathermy was used to coagulate any intra-operative bleeding points.

2.3. Postoperative management

A uniform perioperative regimen was used in all of the cases. Antibiotic treatment with second-generation cephalosporin was infused intravenously. Cefuroxime 1.5 g was given intravenously at induction of anesthesia, and another single dose of 1.5 g was given postoperatively. Erythromycin was used in patients allergic to cefuroxime. Every patient was evaluated to decide whether blood transfusion was needed according to the result of the hemoglobin level measured at the first, third, seventh and fourteen days post-operatively. Thus, the patients’ hematocrit levels were well matched. All patients received a patient-controlled analgesia (PCA) pump after surgery for 24 h. Morphine (1 mg/mL) was given intravenously with increases of 2 mL and a lockout interval of 10 min. They had 200 mg oral celecoxib every 12 h from the first to fourteen postoperative days. No extra dose of painkillers was given. Conventional low molecular weight heparin and a foot pump were used postoperatively for two weeks to prevent deep vein thrombosis (DVT). Patients didn’t undergo continuous passive motion (CPM) on knee joint after TKA. All patients were discharged 15 days after the operation.

2.4. Outcome assessment

Research indexes included operation time, tourniquet time, intraoperative blood loss (IBL), postoperative visible blood loss from the hemovac drains, total measured blood loss, transfusion volume, hemoglobin (Hb) level, limb circumference change, knee pain score, range of active knee flexion and complications.

2.4.1. Intraoperative blood loss

Intraoperative blood loss was calculated as the volume of the liquid in the suction bottle plus the increase in gauze weight minus the volume of irrigation fluid used during surgery. The suction bottle and the gauze were collected after the operation and the measurements were performed by technicians who were uninformd of the ongoing study.

2.4.2. Postoperative visible blood loss

Postoperative visible blood loss was principally recorded as the volume of visible drainage fluid collected in the hemovac drain. The hemovac drain was inserted subcutaneously. The measurements were carried out by nurses as a routine recording for all patients who went through surgery at the moment the study was conducted. The hemovac drain was removed 48 h after operation.

2.4.3. Total measured blood loss

Total measured blood loss was calculated as the volume of the intraoperative blood loss plus the volume of postoperative visible blood loss from the hemovac drains divided by patient weight and was expressed as mL/kg.

2.4.4. Hemoglobin level

Hemoglobin level was measured pre-operatively and at the 1st, 3rd, 7th and 14th days post-operatively. Patients with Hb < 80 g/L or those who have exhibited symptoms of acute anemia received blood transfusion therapy. The amount of blood transfused was recorded.

2.4.5. Limb circumference change

Limb circumference change was measured and the increased rate compared with the preoperative result was calculated. These measurements were performed at 10 cm above the superior patellar pole and 10 cm below the inferior patellar pole on the 3rd, 5th, 7th, and 14th postoperative days. Nurses who carried out this measurement as well as the following measurements (knee joint pain, range of motion and post operational complications) were not informed of the ongoing study.

2.4.6. Knee joint pain

Knee joint pain was measured on a visual analog scale (VAS) (range, 0–10) pre-operatively and on the 3rd, 5th, 7th and 14th postoperative days [17]. A higher score on the VAS equates to a higher level of pain.

2.4.7. Knee flexion range of motion

The arc of knee flexion was measured preoperatively and at 3 days, 5 days, 7 days, and 14 days postoperatively.

2.4.8. Complications

All complications were recorded. Any clinical suspicion of venous thrombosis was promptly investigated by Doppler ultrasound.

2.5. Statistical analysis

Statistical analysis was done by a person not involved in patient care. SAS software version 9.2 (SAS Institute Inc., Cary, North Carolina) was used for data analysis. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the relation between

Table 2

<table>
<thead>
<tr>
<th>groups</th>
<th>Operation time (min)</th>
<th>Tourniquet time (min)</th>
<th>Total measured blood loss (ml/kg)</th>
<th>Incidence of complications (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>120.81 ± 8.12</td>
<td>75.03 ± 13.99</td>
<td>11.70 (5.60; 16.05)</td>
<td>20</td>
</tr>
<tr>
<td>Group B</td>
<td>111.25 ± 20.04</td>
<td>23.20 ± 5.30</td>
<td>10.40 (5.98; 15.43)</td>
<td>0</td>
</tr>
<tr>
<td>Statistic</td>
<td>t = 1.416</td>
<td>t = 18.98</td>
<td>Z = −0.104</td>
<td>χ² = 4.63</td>
</tr>
<tr>
<td>P values</td>
<td>0.167</td>
<td>&lt;0.001</td>
<td>0.917</td>
<td>0.031</td>
</tr>
</tbody>
</table>

Operation time and tourniquet time are expressed as mean ± standard deviation; total measured blood loss is expressed as median and range.
Table 3
Hemoglobin concentration change in two groups.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Preoperative (g/L)</th>
<th>POD 1 (g/L)</th>
<th>POD 3 (g/L)</th>
<th>POD 7 (g/L)</th>
<th>POD 14 (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>124.10 ± 6.40</td>
<td>34.00 (26.00; 40.00)</td>
<td>55.00 (41.00; 59.00)</td>
<td>36.00 (31.00; 40.00)</td>
<td>28.00 (24.00; 31.00)</td>
</tr>
<tr>
<td>Group B</td>
<td>125.13 ± 9.12</td>
<td>30.00 (27.00; 36.00)</td>
<td>52.00 (41.00; 58.00)</td>
<td>38.50 (29.00; 46.00)</td>
<td>29.50 (22.00; 35.00)</td>
</tr>
<tr>
<td>Statistic</td>
<td>t = 0.508</td>
<td>Z = 1.533</td>
<td>Z = 0.620</td>
<td>Z = 0.570</td>
<td>Z = 0.644</td>
</tr>
<tr>
<td>P values</td>
<td>0.613</td>
<td>0.125</td>
<td>0.530</td>
<td>0.569</td>
<td>0.519</td>
</tr>
</tbody>
</table>

Preoperative values are expressed as mean ± standard deviation; POD values are expressed as median and range; POD values = preoperative hemoglobin concentration–postoperative day hemoglobin concentration; Hb = hemoglobin; POD = postoperative day.

Table 4
Limb circumference change at 10 cm above the superior patellar pole in two groups.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Preoperative (cm)</th>
<th>POD 3 (cm)</th>
<th>POD 5 (cm)</th>
<th>POD 7 (cm)</th>
<th>POD 14 (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>45.47 ± 4.28</td>
<td>2.50</td>
<td>2.50</td>
<td>1.50</td>
<td>1.00</td>
</tr>
<tr>
<td>Group B</td>
<td>45.29 ± 3.95</td>
<td>1.00</td>
<td>1.00</td>
<td>0.50</td>
<td>0.00</td>
</tr>
<tr>
<td>Statistic</td>
<td>t = 0.169</td>
<td>Z = 6.378</td>
<td>Z = 5.617</td>
<td>Z = 4.461</td>
<td>Z = 6.023</td>
</tr>
<tr>
<td>P values</td>
<td>0.866</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Preoperative values are expressed as mean ± standard deviation; POD values are expressed as median and range; POD values = postoperative day circumference–preoperative circumference; POD = postoperative day.

3. Results

3.1. Patients

Patients characteristics are presented in Table 1. There were no significant differences with respect to gender, age, and arterial blood pressure before the operation, knee flexion range of motion, flexion contracture, controlled hypotenion during operation, femorotibial angle, body mass index, and the results of ASA classification.

3.2. Surgical procedure

As shown in Table 2, tourniquet time was significantly greater in group A than that in group B (P < 0.05) and no significant differences were observed in operation time. There were only four patients who had operation time over 90 min and had the tourniquet released intraoperatively.

3.3. Outcome assessment

Of the several outcomes we have assessed, postoperative VAS pain score was considered primary outcomes. A power analysis was performed to define the number of patients in each group. Therefore a mean difference of 1.0 with a standard deviation of 1.0 was assumed. This was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical significance. With the proposed sample size of 22 pairs of cases, the study would have power of 90%, which means that the probability of detecting mean differences of 1.0 is 90%. Given the possible loss of follow-up, 30 cases are enrolled in each group.

3.4. Discussion

TKA can be successfully performed with tourniquet use during the operation if the tourniquet time is not long [10,18]. Two meta-analysis reports of randomized studies of tourniquet use versus no tourniquet at all showed differences in total blood loss but no other differences with or without the tourniquet [3,19]. Several other randomized controlled trials of tourniquet versus no tourniquet use during TKA have shown no statistical difference [1,3,6,16,20]. To our knowledge, no study in the literature has compared the use of a tourniquet starting from the cementation to the completion of the operation with use during the entire operation. We believe that limited tourniquet use was important in that this method has been indicated as effective in the literature and therefore it can be advantageous, particularly in prevention of nerve injuries or vascular ischemia, which are the two most injurious complications of tourniquet use. Therefore, we investigated whether the limited use of a tourniquet would affect (1) operation time, tourniquet time, total measured blood loss, and complications; (2) hemoglobin concentration; (3) limb swelling and postoperative pain, or (4) knee flexion range of motion.

The reduced tourniquet application time had no significant effect on operation time, blood loss, transfusion volume, postoperative motion or the rate of complication. However, decreased tourniquet time did reduce the postoperative limb swelling and alleviated the postoperative pain around the knee. This study did confirm that the limited use of tourniquet is feasible in TKA.
the tourniquet starting from the installation of the prosthesis to the completion of the operation was at least safe as tourniquet use during the entire operation.

Increased tourniquet time may increase the risk of nerve injury or other complications [10,21]. In the current study, we have reduced the mean tourniquet application time by 23.2 min, less than a third of the regular application time (75.03 min) and observed no complications. Therefore we believe that in total knee arthroplasty (TKA) tourniquet use should be limited or eliminated to prevent development of complications.

Blood loss following TKA due to extensive soft tissue release and bone cuts may result in significant anemia and prolonged postoperative recovery [20,22]. Sehat et al. [23] reported that the total blood loss included the visible blood loss and the hidden blood loss. In our study, perioperative blood loss was assessed by total measured (visible) blood loss and the change of hemoglobin concentration. Since the change of hemoglobin level can represent the total blood loss [24], we did not calculate the hidden blood loss in this study. We found no difference in the total measured blood loss and the hemoglobin concentration between the two groups which indicates that limiting the use of the tourniquet does not have a significant effect on blood loss during TKA.

Typical complication results from the use of a tourniquet may include cardiopulmonary dysfunction, vascular injury, DVT and impaired wound healing, in addition to masking the actual amount of blood lost and delaying the functional recovery of patients. Therefore, clinical importance of applying a tourniquet during TKA surgery is questionable [2,4,25,26]. In the study, we found that six patients (20%) in group A developed symptomatic deep vein thrombosis in the calf in the immediate postoperative period and none (0%) in group B. Statistical analysis showed that the incidence of postoperative complications in group B is significantly lower than in group A, which indicates that prolonging tourniquet time may be the cause of higher occurrence of thrombosis. An explanation for our findings is that during TKA the use of a tourniquet may promote the local release of neutrophil elastase from neutrophils together with reactive-oxygen derivatives, which can contribute to the development of venous thrombosis, pulmonary thromboembolism and tissue injury [27].

Lower limb swelling occurs in most patients undergoing TKA. After TKA, blood accumulates in the joint cavity and penetrates into the surrounding soft tissue, increasing the circumference of the thigh. Thus, the soft tissue around the joint has a higher tension, which causes local pain to pressure. One to two days later, pitting edema appears in the middle-to-lower sections of the calf, causing the skin to become thinner and lighter, but less elastic [28–30]. In this study, post-TKA limb swelling occurred on the 3rd, 5th, 7th, and 14th postoperative days in the thigh and calf. Limb circumference change at 10 cm above or below the knee at any time point in group B was significantly lower than in group A which suggests that the limited use of a tourniquet could alleviate thigh swelling. Therefore, taking early preventative measures could benefit a patient’s rehabilitation. Nonetheless, we cannot exclude the other factors as a cause of postoperative limb swelling. Previous studies have shown that post-TKA limb swelling is related to damage to blood and lymph vessels, their increased permeability, extravasation into tissue, and the release of inflammatory factors [30]. The pathophysiologic basis of post-TKA limb swelling will be the subject of future studies.

A recent systematic review has shown that between 19% and 31% of patients had an unfavorable pain outcome after TKA [31]. Bourne et al. [32] showed that the strongest risk factor for patient dissatisfaction was a failure to meet patient expectations. Post-operative pain is thought to play a major role in patient satisfaction [33,34]. In the present study, we found that knee pain showed a lower VAS score on the 3rd, 5th, 7th, and 14th postoperative days in comparison to the score obtained preoperatively. Additionally, we also found that pain score in patients in group B was significantly and consistently lower than that in group A during the two weeks after TKA, which may indicate that the limited use of the tourniquet could alleviate the postoperative pain.

In this study, active knee flexion in the early postoperative period in group B was better than that in group A at 3rd and 5th days post operatively, but not on the 7th and 14th days after operation, which may suggest that the limited use of a tourniquet can benefit the knee flexion range of motion in the early postoperative period by reducing limb swelling and alleviating the postoperative pain. However, during the second week, as the patients recover, swelling and pain decreased in both groups thus eliminating the difference in knee flexion. In addition, we also found no significant difference between the preoperative and postoperative range of the knee flexion in the two groups which was consistent with the opinion that tourniquet use versus no tourniquet at all shows no difference in the range of the knee motion [3,19].

We are very aware that our study had several limitations. First, the surgeons involved in the study were not completely blind. Second, in the operative tourniquet patients, the mean tourniquet time was 75 min. Complications from tourniquet use accumulate with increased tourniquet time [10], so longer tourniquet application time may review more complication. Third, the patients who reported suspected venous thrombosis in our study were diagnosed by color Doppler ultrasound only which is not always accurate. Also, measurement for postoperative blood loss did not include wound drainage and hidden blood loss was not measured. Instead, Hb level was included to compensate for the lack of those measurements and provide better estimation for total blood loss.
5. Conclusions

Our study showed important evidence that the limited use of a tourniquet in TKA provides the benefit of the decreased limb swelling and the knee joint pain while not compromising the operation time or blood loss and recovery. Therefore we recommend limiting use of a tourniquet starting from the installation of the prosthesis or eliminating the use of tourniquet in TKA.

Conflict of interest statement

None of the authors have any financial or personal relationship with other people or organizations that could inappropriately influence the work.

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