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Original Article

Influence of tourniquet on wound healing in total knee arthroplasty: a randomized and paired clinical trial

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Abstract: *Background:* The use of a tourniquet during total knee arthroplasty (TKA) remains questionable and little is known regarding its influence on wound healing. We hypothesized that TKA without tourniquet allowed for better wound healing than with tourniquet, and we sought to clarify this by means of a prospective randomized and paired investigation of patients undergoing bilateral simultaneous TKA. *Methods:* Twenty-six consecutive patients who underwent bilateral simultaneous primary TKA were randomized to undergo tourniquet placement in either the right or left knee, with the contralateral knee serving as the control (without the tourniquet). Oozing from the wound, erythema, blister formation, ecchymosis, swelling, skin necrosis, wound infection and Manchester Scar Scale (MSS) score were observed on postoperative days 2 or 3, 7, 14 and 30, in addition to MSS score measurement at year-1 of follow-up. The preoperative and postoperative range of motion (ROM) was also evaluated. The patient and the observer were blinded to the side of tourniquet placement. All patients completed follow-ups to the final evaluation at 1 year. *Results:* TKAs without tourniquet showed significantly reduced oozing from wound, erythema, blister formation and ecchymosis at postoperative day 2, as compared to the sides with tourniquet placement. Further, tourniquet placement was associated with significantly increased swelling of the knee at postoperative days 3, 7 and 14, but there was no difference on postoperative day 30. However, the MSS scores were not significantly different between the two sides of knees at 1 year after the operation. The two groups showed no significant difference in ROM. *Conclusion:* Tourniquet placement during TKA impedes wound healing in the early postoperative period, but does not affect wound healing over the long term.

Keywords: Total knee arthroplasty (TKA), tourniquet, wound healing

Introduction

Some investigators have advocated the use of a tourniquet during TKA, with the aim to reduce intraoperative blood loss and establish a bloodless surgical field, which in turn facilitates cementation of the prostheses [1-5]. However, other studies have shown that it does not improve postoperative knee motion or pain control and can potentially increase the incidence of deep vein thrombosis (DVT) and complications of wound healing [6-11]. Thus, the effects of tourniquet use on wound healing continue to be debatable, and limited data are currently available in this regard. In addition, most of the relevant studies published pertain to tourniquet use (or not) in cases of unilateral TKAs.

In the study presented herein, we sought to conduct a prospective, randomized, within-patient controlled investigation of the effects of tourniquet use in a group of patients who underwent simultaneous bilateral TKA-a surgical procedure considered to be associated with a high risk of postoperative infection. TKA is frequently associated with complications of wound healing, including oozing, erythema, blister formation, ecchymosis, swelling, poor aesthetic outcome of the incision scar, necrosis of the skin and wound infection.

The purpose of this study was to investigate whether placement of tourniquet during TKA had any influence on wound healing. We hypothesized that TKA without tourniquet would be beneficial for the wound healing and reduce postoperative complications.

Materials and methods

Study design

The study was designed as a prospective, randomized, intra-patient controlled investigation of 26 consecutive patients who underwent simultaneous bilateral primary TKA at Qilu Hos-

Table 1. Patient characteristics

Characteristics	No.
Age	65.8 years (SD±9.2 years)
Sex	
Male	8
Female	18
BMI	28.2 (SD±5.6)
Tourniquet placement group (TP)	
Right Knee	12
Left Knee	14
Non-tourniquet placement group (NTP group)	
Right Knee	14
Left Knee	12

pital of Shandong University between June 2012 and January 2015. All procedures were performed by the same surgeon, and the study was conducted by the same team at our institute. The study protocol was approved by the Ethics Committee and institutional review board of the institute. Informed consent was also obtained by all patients who participated in this study.

Patients

Among the consecutive patients diagnosed with osteoarthritis and who satisfied the indications for simultaneous bilateral TKAs, those meeting the following criteria were excluded from this study: history of coagulation disorder or medications likely to influence coagulation, diabetes, renal or liver disease, severe cardiovascular problems and lung disease, nerve disorders, cancer, or skin diseases; history of a previous surgical procedure of knee other than arthroscopy; and an apparent keloid constitution. After the exclusion of patients on the basis of these criteria, 26 patients were enrolled and all agreed to participate in the study, including 18 women and 8 men with a mean age of 65.8 years (SD±9.2 years) and mean body mass index (BMI; [weight (Kg)/height $(m)^2$] of 28.2 (SD±5.6) (**Table 1**). No patients withdrew from the study, and none were lost to follow-up. The duration of follow-up was 12 months. Procedures performed before TKA included 4 knee arthroscopies.

Surgical techniques and postoperative treatment

The right and left knees of each of the 26 patients were randomized to undergo or avoid tourniquet placement by using a random number table just before the procedure. Thus, the studied knees were classified into the tourniquet placement group (TP group; 12 right knees and 14 left knees) and non-tourniquet placement group (NTP group; 14 right knees and 12 left knees). As per the surgeon's usual practice, TKA with or without tourniquet placement was first completed on the left knee and then performed on the right side after closure of the left knee wound. All surgeries were performed under general anesthesia and by the same team of surgeons. A layer of cotton wool padding was applied over both thighs, above which the tourniquet was applied. The tourniquet size was 105 cm × 7 cm. Further, the lower limb on the side assigned to the TP group was elevated, and a rubber limb exsanguinator was inflated to a pressure of 125 mmHg above the systolic blood pressure immediately before the incision was made. Longitudinal incisions extending from a point at 4 cm proximal to the upper end of the patella to the tibial tuberosity were made at the midline with the knee at 90° flexion. The inflation of the tourniquet was maintained until the wound was closed and covered with compressive dressing. The tourniquet was maintained in place for less than 120 minutes. On the contralateral side, the systolic blood pressure was maintained with lower pressure of about 100 mmHg when the cementation was applied. The posterior stabilized knee prosthesis (Smith & Nephew, Memphis, TN, USA) was used in all patients. A peri-articular injection of ropivacaine (200 mg), adrenaline hydrochloride (0.1 mg), and morphine (5 mg) was administered just before skin closure. The wound was sutured using a stapler, and a drain was placed within the joints and connected to an auto-transfusion device (CBCII Consta Vac; Stryker Instruments, Kalamazoo, MI, USA). At the end of surgery, compression dressing was applied from the toes to the mid-thigh level. The inner layer was a lamination of cotton, and the outer layer was an elastic bandage (8 cm × 2 m) wrapped around from the toes to mid-thigh, with gradually decreasing pressure. If the patient's postoperative hemoglobin level was less than 8.0 g/L,

allogeneic blood transfusion was initiated. Intravenous tranexamic acid (15 mg/kg) was administered for control of hemostasis at the end of operation.

Intravenous morphine for patient-controlled analgesia (PCA) was started postoperatively. All the patients received rivaroxaban (10 mg, two times daily) for 2 weeks from the first day of the operation, as prophylaxis against thromboembolic complications. Ambulation and physiotherapy were started on the second postoperative day. Continuous passive motion was started on the third day, and then the patients were encouraged to walk and exercise, as much as tolerated, under the supervision of a physical therapist.

Evaluation

The outcomes studied were oozing from the wound, erythema, blister formation, ecchymosis, necrosis of the skin, wound infection, swelling, wound length and the Manchester Scar Scale (MSS) [12, 13] score. The functional assessment was also evaluated by range of motion (ROM). All assessments were performed by the same observer, who was trained for evaluation but blinded to the purpose of the study.

Operation time and wound length

The operation time for every knee was recorded from when the incision was made until it was closed. The wound length in all patients was measured with the knee in extension as far as possible on postoperative day 2, while changing the dressing after pulling out the drain.

Wound healing

Oozing from the wound: Oozing was classified as *severe* if the gauze was completely soaked or more than 10 layers of the gauze dressing were soaked with blood or serous fluid. Oozing was classified as *non-severe* if less than 10 layers of sterile absorbent gauze were stained by serous fluid or blood. All wounds were evaluated on postoperative day 2.

Erythema: Because the erythema occurred mainly around the wound, its severity was evaluated on postoperative day 2 as a measure of the area of redness along the wound margin. No redness or redness covering less than 10 cm^2 was considered mild erythema, while that covering 10 cm^2 or more was considered severe.

Blister formation: The incidence of postoperative blister formation in the wound was recorded in both the groups on postoperative day 2. If blister formation was noted on the knee of a patient, its severity was determined on the basis of its area. Cases of blisters or blister formation area of less than 5 cm^2 were considered mild, while those with area equal to or greater than 5 cm^2 were considered severe.

Skin ecchymosis: The incidence of postoperative ecchymosis of the skin around the wound was also evaluated on postoperative day 2. If ecchymosis occurred in the knee of a patient, its severity was assessed on the basis of the extent of blue discoloration around the wound. None or blue discoloration area that was less than 10 cm^2 was considered mild; it was considered severe if the area of discoloration was ≥ 10 cm^2.

Skin necrosis and wound infection: Incidences of necrosis of the skin or wound infection were also observed after the operation.

Swelling

Postoperative swelling was evaluated in terms of the change in suprapatellar girth (postoperative girth - preoperative girth, cm). The measurement was made at the superior margin of the patellar with the knee at extension as far as possible, by using a standard tape; the differences between the preoperative measurements and measurements obtained on postoperative days 3, 7, 14 and 30 were calculated.

MSS score

The MSS was used for an objective evaluation of the aesthetic appearance of the scar at the end of postoperative year 1. The MSS encompasses several factors, including color, appearance, contour, distortion and texture of the scar. All these parameters are graded on a scale of one to four points, except the last one, which is rated as one for matte and two for shiny appearance. In addition, the overall appearance of the incision scar was evaluated using a Visual Analogue Scale (VAS), with a score of 0 indicating excellent outcome and 10

Table 2. Comparison of the severity of oozing from the wound in groups with tourniquet (TP) and without tourniquet placement (NTP)

Severity	TP num. (per.)	NTP num. (per.)
Non-severe (%)	13 (50.0)	21 (80.8)
Severe (%)	13 (50.0)	5 (19.2)

Note: $\chi^2 = 4.202$, $P < 0.05$.

Table 3. Comparison of the severity of erythema in the groups with (TP) and without tourniquet placement (NTP)

Grade	TP num. (per.)	NTP num. (per.)
Mild (%)	18 (69.2)	24 (92.3)
Severe (%)	8 (30.8)	2 (7.7)

Note: $\chi^2 = 4.457$, $P < 0.05$.

indicating the worst possible outcome. The VAS score was assessed by both surgeons (objective) and patients (subjective) [14]. The VAS score was also added to the scores of the other measured variables to yield the total MSS score, which showed the best outcome at 5 and worst outcome at 28.

ROM

ROM was measured with a standard handheld goniometer, pre-operatively and on post-operative days 7, 14, 30 and 90. The center of rotation was set in line with the center of the knee, while the fixed arm was aligned with the greater trochanter and the mobile arm was aligned with the lateral malleolus. The ROM was assessed when the patient was sitting on the edge of the bed, with his/her thighs parallel and horizontal to the floor. Two trials were performed for all measurements. If the difference was less than 5°, then an average was taken. A third measurement was made if the difference was more than 5°, after which the average of the two closest measurements was taken.

Statistics

Data was recorded in Microsoft Excel spreadsheets Supplementary Table 1, and statistical analyses were carried out using the IBM SPSS Statistics for Windows, version 19.0. (IBM Corp., Armonk, NY, USA). Continuous numerical data were described by mean ± standard deviation, if the data showed normal distribution. The numerical indexes were age, BMI, operation time, wound length and MSS. Counting data were described by percentage profile, and these data included wound oozing, erythema, blister formation and skin ecchymosis. The paired *t*-test and chi-square test were used for comparisons of basic demographic characteristics and the numerical indexes. Repeated ANOVA was performed to compare differences in the suprapatellar girth between the TP group and the NTP group that were measured out to 30 days post-operation. Results were accepted if they meet the spherical symmetry requirement of repeated ANOVA; otherwise, the results of a corrected multivariate analysis method (Wilks' Lambda Test) were accepted. Subsequent pair-wise comparisons of the differences over time were then assessed by the least-significant difference (LSD) method. Significance was set at $P \leq 0.05$.

Results

Operation time and wound length

The mean operation time was 81.2 (±3.1) min and 89.7 (±4.1) min in the TP and NTP groups, respectively, showing significant intergroup difference ($P < 0.01$) in this regard. The length of the incision at extension was 14.73 (±1.56) cm and 14.65 (±1.41) cm in the TP and NTP groups, respectively, indicating no significant intergroup difference ($P = 0.65 > 0.05$).

Wound healing

Oozing from wound: There was a significant difference in the severity of oozing between the TP group and the NTP group ($\chi^2 = 4.202$, $P < 0.05$). The TP group had a greater amount and more severe oozing from the wound than the NTP group (**Table 2**).

Erythema: The severity of erythema was significantly greater in the TP group than in the NTP group ($\chi^2 = 4.457$, $P < 0.05$) (**Table 3**).

Skin blister: Severe blister formation ($\chi^2 = 4.457$, $P < 0.05$) was noted in 4 (15.4%) knees of the TP group and in none of the knees of the NTP group. Further, the TP group had significantly more severe skin blister than the NTP group (**Table 4**).

Ecchymosis: Severe ecchymosis of the skin was noted in 8 (30.8%) knees of the TP group and 3 (11.5%) knees of the NTP group. There

Table 4. Comparison of the severity of skin blister in groups with tourniquet (TP) and without tourniquet placement (NTP)

Severity	TP num. (per.)	NTP num. (per.)
Mild (%)	22 (84.6)	26 (100.0)
Severe (%)	4 (15.4)	0 (0.0)

Note: $\chi^2 = 4.333$, $P < 0.05$.

Table 5. Comparison of the severity of ecchymosis in groups with tourniquet (TP) and without tourniquet placement (NTP)

Severity	TP num. (per.)	NTP num. (per.)
Mild (%)	18 (69.2)	23 (88.5)
Severe (%)	8 (30.8)	3 (11.5)

Note: $\chi^2 = 4.710$, $P < 0.05$.

was a significant difference in the severity of erythema between the TP group and the NTP group ($\chi^2 = 4.457$, $P < 0.05$). The TP group had more severe erythema than the NTP group (**Table 5**).

Skin necrosis and wound infection: One knee in the TP group showed severe oozing, erythema, and skin blister on postoperative day 2. Necrosis of the skin occurred at the end of postoperative day 5, which progressed to deep surgical wound infection; the patient was treated with antibiotics and required revision surgery for irrigation and debridement by polyethylene liner exchange on postoperative day 21.

Mean change in suprapatellar girth (cm)

The changes in the suprapatellar girth at various time points in the follow-up period are shown in **Table 6**. Results of repeated measure ANOVA testing indicate both effects related to time and to the afflicted suprapatellar girth in the post-operation period ($P < 0.001$). The suprapatellar girth in the TP group was higher than that in the NTP group during the post-operation period, especially within a 14-day period (**Table 6**). In both groups, however, the suprapatellar girth was reduced over time in the post-operation period. Degree of swelling in the TP group declined at a faster rate than that in the NTP group, and then at a rate comparable to that of the NG group out to the day 30 post-operation. At the end of postoperative days 3, 7 and 14, there was a significant difference between the changed suprapatellar girths in the TP group and in the NTP group ($P < 0.05$). Swelling of the knees in the TP group was greater than that in the NTP group; however, this difference did not persist at the end of postoperative day 30 ($P > 0.05$) (**Table 6**).

MSS score

The mean MSS scores, as determined at 1 year after the surgery showed no significant intergroup difference between the TP and NTP groups ($P = 0.84 > 0.05$).

ROM

Repeated measure ANOVA testing indicated that there was no significant difference between the ROMs of the two groups during the pre-operation period and the post-operation period (**Table 7**). Time effect, as the most important factor, affected the ROM in both groups during the entire study period ($P < 0.001$). Group effect, interaction effect and time toward the ROM were not significantly different during the entire study period ($P > 0.05$).

Discussion

In our study, the time to complete the procedure was greater in the NTP group than the TP group, because the surgeon spent more time in efforts to stop bleeding during the operation that was performed without tourniquet. Even so, there was more severe oozing, erythema, skin blister, ecchymosis and swelling in the TP group than in the NTP group, which occurred in the early post-operative period. However, MSS score showed no significant intergroup difference at end of 1 year after the operation; therefore, it may be inferred that tourniquet use would not affect wound healing over the long term. The results were similar to those published previously [10, 15, 16].

Erythema after TKA is caused by hyperemia of the superficial capillaries following the injury to the skin caused by the operation. In fact, reactive hyperemia after tourniquet deflation causes a 10% increase in limb size [15], resulting in increased soft tissue tension around the knee, particularly at the site of the incision. Further, although the exsanguination of the limb following tourniquet inflation creates a bloodless surgical field, the edges of the wound may be rendered hypoxic during the early post-

Table 6. Comparison of the postoperative change in suprapatellar girth for groups with (TG) and without tourniquet placement (NG)

Time, day	TG, cm			NG, cm			Mauchly's test	Time effect	Group effect	Interaction
	M	SD	N	M	SD	N				
3	3.77±1.39		26	1.58±0.99		26	0.000	0.000#	0.000	0.000#
7	2.42±1.21*		26	0.65±0.94*		26				
14	1.27±1.15*		26	0.35±0.75*		26				
30	0.42±0.58*		26	0.19±0.40*		26				

Postoperative change in suprapatellar girth (cm) was calculated as: [postoperative girth - preoperative girth]. Repeated measures ANOVA were used to assess differences between two groups. #: Data did not meet the requirement of spherical symmetry, and multivariate analysis results (Wilk's Lambda test) were adopted. Subsequent pair-wise comparisons by the least-significant difference (LSD) method were to assess differences between time points. *: $P \leq 0.05$ in postoperative change over time vs. postoperative change in suprapatellar girth at day 3.

Table 7. Range of motion (ROM) in tourniquet group (TG) and non-tourniquet group (NG)

Time	TG, cm			NG, cm			Mauchly's test	Time effect	Group effect	Interaction
	M	SD	N	M	SD	N				
Pre-	100.54±8.42		26	100.96±7.33		26	0.000	0.000#	0.196	0.356#
Day 7	76.96±5.66*		26	79.69±5.68*		26				
Day 14	88.27±3.67*		26	91.38±3.81*		26				
Day 30	98.92±5.35		26	100.65±5.71		26				
Day 90	113.77±6.70*		26	113.92±6.71*		26				

Repeated measures ANOVA were used to assess differences between two groups. #: Data did not meet the requirement of spherical symmetry, and multivariate analysis results (Wilk's Lambda test) were adopted. Subsequent pair-wise comparisons by the least-significant difference (LSD) method were used to assess differences between time points. *: $P \leq 0.05$ in postoperative change over time vs. preoperative change in ROM.

operative period; this could trigger angiogenesis and migration of macrophages and fibroblasts to the wound area, which inhibits cellular response to wound healing [16, 17]. This was verified in our study, which showed a higher incidence of erythema, swelling, necrosis and wound infection in the TP group than in the NTP group. This may be attributed to the fact that in the NTP group, increased efforts for establishing hemostasis were undertaken throughout the operation, whereas in the TP group, this was not necessary; therefore, in the latter group, tourniquet release was followed by excessive perfusion of blood into the subcutaneous soft tissue around the operation field. Therefore, the severity of ecchymosis in the TP group was greater than that in the NTP group. For the same reason, oozing from the wound was more severe in the knees of the TP group than in the NTP group. Studies have shown that persistent wound oozing after joint arthroplasty increases the risk of infection [18, 19]. Wound complications may lead to deep infection, thereby necessitating revision surgery. In this study, one knee in the TP group showed signs of wound infection, which was treated by revision surgery for irrigation and debridement with polyethylene liner exchange.

A blister is a small pocket of blood, pus or clear serum or plasma fluid formed within the upper layers of the skin. The incidence of severe postoperative wound blisters in total joint surgery ranges from 5-40% [20-25]; the incidence in our study was 15.4%, which is consistent with the published rates. Blister formation is mainly the result of forceful rubbing (friction), burning, freezing or exposure to chemicals or infection. The incidence in this study was greater in the TP group than in the NTP group; this was probably because of the greater use of compression dressings for controlling bleeding in the TP group, which leads to increased friction between the dressing and skin during early rehabilitation.

This study has a few limitations. More large-scale studies are warranted to detect the effects of tourniquet use in cases of rare complications such as wound infection. The short

observation period is also one of the major limitations of this study. Another limitation of our study is the lack of complete randomization because as per the protocol followed at our hospital, TKA of the left knee was performed first; this could result in a statistical bias. Nevertheless, our findings provide some insight into the value of tourniquet use in wound healing and can serve as a basis for further investigation.

In conclusion, tourniquet use during TKA could impair wound healing in the early post-operative period. Wound healing after TKA is critical to a successful outcome, and significant wound problems are frequently encountered, resulting in the additional need for surgery of the patient and functional compromise. Therefore, in all cases of potentially complicated TKA, careful attention must be paid and tourniquet use during TKA should be avoided to enhance wound healing.

Disclosure of conflict of interest

None.

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