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KNEE ARTHROPLASTY

Three-hour interval drain clamping reduces postoperative bleeding in total knee arthroplasty: a prospective randomized controlled trial

Chaturong Pornrattanamaneewong · Rapeepat Narkbunnam · Pichet Siriwattanasakul · Keerati Chareancholvanich

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Abstract
Background Total knee arthroplasty (TKA) is a common procedure that has a risk of significant blood loss and blood transfusion, and carries a substantial risk for immunologic reactions and disease transmission. Drain clamping is a popular method that is applied to reduce blood loss after TKA. However, the clamping protocol remains controversial. Therefore, we established a new protocol, 3-h interval clamping, and compared the bleeding control efficacy of this protocol following TKA with the non-clamping technique.
Methods Between March and July 2008, we enrolled 100 patients (100 knees) who underwent uncomplicated TKA using a minimally invasive surgical technique. The patients were randomly assigned into two groups based on the draining protocol: non-clamping (group A) and 3-h interval clamping (group B). For group A, a vacuum drain was connected to a container and was run continuously during the first postoperative day, whereas the vacuum was stopped twice (for $\sim$3 h each time) for group B. Demographic characteristics and clinical data were collected, including the levels of hemoglobin and hematocrit, the total blood loss volume, the number of patients who required a blood transfusion, and any complications that developed. The perioperative data were compared between the two groups.
Results The drainage blood volume in the interval-clamping group (group B) was significantly lower than that in the non-clamping group (group A) during the first 48 h following the procedure ($p < 0.001$ and $p = 0.005$ for first and second postoperative days, respectively). The mean fall in hemoglobin levels at 12 h in the interval-clamping group (2.8 ± 0.9 g/dL) was also lower than in the non-clamping group (3.2 ± 0.8 g/dL). In the 3-h interval clamping protocol, the number of patients requiring a transfusion was 2.2 times less than the number in the non-clamping protocol, but was not significantly different (odds ratio = 2.20, $p = 0.24$), and the significant predictor of blood transfusion was the preoperative hemoglobin level (odds ratio = 7.73, $p < 0.001$). No wound infection or clinical venous thromboembolisms were detected in our study.
Conclusion The 3-h interval clamping is a newly developed protocol for reducing blood loss after TKA. The protocol lessens the decrease in postoperative hemoglobin levels. This protocol can be applied easily without increasing clinical thromboembolic events and wound complications.

Keywords Drain · Clamp · Bleeding · Knee · Arthroplasty

Introduction

Total knee arthroplasty (TKA) has become a common orthopedic procedure. Significant blood loss is observed in the early postoperative period during which time a blood transfusion may be necessary. Donor blood may lead to an immunological reaction and the transmission of viral infections (e.g., hepatitis and AIDS) [1, 2]. Therefore, various methods have been suggested to reduce blood loss following TKA, such as preoperative erythropoietin and iron supplementation, autotransfusion [3, 4], postoperative

C. Pornrattanamaneewong · R. Narkbunnam · P. Siriwattanasakul · K. Chareancholvanich (✉)
Department of Orthopedic Surgery, Faculty of Medicine, Siriraj Hospital, Mahidol University, 2 Prannok Street, Bangkoknoi district, Bangkok 10700, Thailand
e-mail: sikcr@mahidol.ac.th

blood salvage [5, 6], hypotensive anesthesia [7], tranexamic acid administration [8, 9], intra-articular epinephrine injection [10], intramedullary femoral plug [11], cryotherapy with Robert Jones bandage [12, 13] and temporary drain clamping [14, 15].

Theoretically, the use of a vacuum drain prevents hematoma formation, which is thought to decrease postoperative pain and swelling [16–18]. On the other hand, a vacuum drain placement prevents the tamponade effect, which leads to increased bleeding. It creates an entry portal for bacteria and thus increases the risk of infection [19–21]. However, the vacuum drain is still widely used in orthopedic practice [22].

Currently, there are several protocols for vacuum drain use: (1) non-clamping [11], (2) temporary clamping for a single period [14, 15] and (3) interval clamping [23], which switches back and forth between clamped and unclamped time periods. Because most of the blood loss in TKA occurs during the first postoperative day (71.1 and 84% in the first 6 and 12 h after operation, respectively) [24, 25], it seems reasonable to clamp the drain in the early postoperative period to create a tamponade effect and to control blood loss. Although various protocols for drain clamping have been reported in the literature [14, 15, 26–28], we have established a new interval clamping protocol for reducing blood loss in TKA. Therefore, the purpose of this study is to compare the efficacies of our clamping protocol and non-clamping method.

Materials and methods

From March to July 2008, 100 patients with primary osteoarthritis, who underwent unilateral TKA in our institute, were enrolled in this trial. All subjects were randomly assigned into two groups (50 subjects per group) by a blocks-of-ten randomization technique. In group A, or the non-clamping group, the drain was released following the release of the tourniquet, and in group B, or the 3-h interval clamping group, the drain was clamped for 3 h, released for 3 h, reclamped for 3 h, and then the clamp was run continuously. Patients who had history of bleeding diathesis, thromboembolic disease or previous complex knee surgery was excluded from the study. This study was approved by the Ethics Committee of Siriraj Hospital, and all the patients provided their written informed consent.

Our senior author (KC), who is experienced in TKA, performed all of the operations on patients who were under spinal anesthesia. A pneumatic tourniquet with a pressure of 350 mmHg was inflated after limb exsanguinations. A straight skin incision and a mini-medial parapatellar capsular incision were used in all knees. The patellas were not resurfaced. A Nexgen LPS-Flex fixed-bearing design (Zimmer, Warsaw, Indiana), inserted with cement, was used. An intramedullary femoral alignment rod was used in all cases, and the femoral canal was filled with a bone plug before the prosthetic implantation.

At the end of the operation, a number-10-gauge drain was placed intra-articularly and was connected to the Ultravak pressure drainage bottle (Poly Medicure Limited, India). After wound closure, a compressive Robert Jones bandage [13] and a posterior splint were applied. Envelopes were used to conceal the randomized sequence and were opened by a single investigator (CP). Following the release of tourniquet pressure, the drain in group A was immediately released and the drain in group B was kept clamped, and our protocol for unclamping and reclamping was followed. The patient was encouraged to perform a mechanical ankle pumping exercise to prevent deep vein thrombosis as soon as possible after surgery. The bandage, splint and Foley catheter were removed on the first postoperative day. On the same day, the range-of-motion exercise, an isometric/isotonic quadriceps exercise, a straight leg rising exercise and a walking exercise were initiated under the control of a physiotherapist.

The amount of drained blood was recorded at 24 and 48 h. All suction drains were removed 48 h postoperatively. The hemoglobin (Hb) and hematocrit (Hct) levels were determined preoperatively and 12 h postoperatively. The patients received a transfusion of one unit of packed red cells (PRC), if their Hb levels decreased to <10 g/dL or if the compromised clinical criteria (e.g., tachycardia, hypotension, or symptoms of anemia that were relative to the preoperative medical condition of the patient) necessitated transfusion. If Hb levels decreased to <8 g/dL, the patient received two units of PRC. Following the blood transfusions, we reevaluated Hb and Hct levels at 6 h after the end of the transfusion period, and blood replacement was considered again using the same criteria as outlined above. At 48 h after the operation, the Hb and Hct levels of all patients were recorded. Clinical deep vein thrombosis and wound complications were also examined.

Statistical analysis

The data were analyzed using the commercially available SPSS statistics software, version 13.0. Quantitative data were presented as the mean ± SD, and differences in the means between two groups were analyzed using a Student's t test. We determined differences in sex, surgical side and the number of patients requiring blood transfusions using the χ^2 test. The factors correlating with blood transfusion were analyzed using Fisher's exact test, t test and logistic regression. P values <0.05 were regarded as statistically significant.

Results

Both groups were homogenous in their demographic characteristics (Table 1). The overall blood loss was 84.7% (867 ± 384 mL) of the total amount of drained blood (1019 ± 429 mL) and occurred in the first 24 h after TKA. The mean decreasing Hb and Hct levels at 12 h were 3 g/dL and 8.8%, respectively.

The total blood loss was significantly lower ($p < 0.001$) in group B (836 ± 335 mL, range 310–2,020 mL) compared to group A (1,203 ± 438 mL, range 420–2,260 mL). The mean (± SD) volume of blood loss in the first and second 24 h was 1,019 ± 386 and 184 ± 142 mL, respectively, for the non-clamped group, and 715 ± 318 and 121 ± 57 mL, respectively, for the 3-h interval clamping group. These differences were statistically significant ($p < 0.001$ and $p = 0.005$, respectively) (Table 2).

Although there was no difference in Hb levels between the two groups at 12 h, our study revealed that the mean Hb decrease 12 h postoperatively in group B (2.8 ± 0.9 g/dL) was significantly lower ($p = 0.02$) than in group A (3.2 ± 0.8 g/dL) (Table 2). Similarly, when the percentage of decreasing Hb from preoperative Hb was calculated, group B was significantly lower than group A (22.7 ± 6.3 vs. 25.8 ± 6.1%, respectively; $p = 0.01$). There was no significant difference in the other red blood cell parameters that were measured, i.e., Hct and decreasing Hct level at 12 h (Table 2). The amount of blood transfused and the number of patients requiring a blood transfusion in the 3-h interval clamping group were lower than in the control group. However, the decrease was not significantly different between the two groups (Table 2).

To determine correlating factors with number of transfused patients, we found that preoperative Hb and Hct levels were the only two significant parameters ($p < 0.001$). From logistic regression analysis, for every 1 g/dL increase in preoperative Hb, blood transfusions decreased 7.7-fold (odds ratio = 7.73). Furthermore, in the 3-h interval clamping protocol, we found that the number of patients requiring a transfusion was 2.2 times less than the number in the non-clamping protocol, but did not show significant difference in our study (odds ratio = 2.20, $p = 0.24$).

In terms of complications, no wound infections or clinical venous thromboembolisms were detected in either group during a minimum of 6-month follow-up. Although three patients (two patients from group A and one patient from group B) developed postoperative ecchymosis around the knees, this resolved spontaneously.

Discussion

Blood loss and transfusion are important postoperative features that must be considered in TKA. Drain clamping is a simple method that reduces blood loss after TKA [14, 15, 23, 26–28]. However, a consensus has not been achieved for defining a clamping protocol, such as the optimal time and the period of clamping. The drain clamping technique can be classified into two main patterns. The first pattern is a single period of temporary clamping ranging from 1 to 24 h after surgery [10, 14, 15, 26–28]. The second is an intermittent or interval clamping pattern that switches back and forth between clamped and unclamped periods [23]. In addition, several studies [10, 14, 29, 30] have combined a drain clamping method with an intra-articular adjuvant infusion (e.g., saline or epinephrine) and have reported a successful reduction in postoperative blood loss.

Aglietti et al. [31] reported that the use of a tourniquet may increase fibrinolysis in TKA, and Kiely et al. [26] concluded that 2 h of drain clamping has no benefit in routine TKA. Thus, a longer period of drain clamping may be required. However, hematoma and wound complications must be taken into consideration for long-period clamping protocols. To balance between creating a tamponade effect and reducing wound complications, an interval clamping protocol using a 3-h interval pattern was selected for our study. This protocol has not been studied before. Our randomized controlled study was conducted to evaluate the efficacy of our protocol in controlling postoperative hemorrhage in TKA, without adjuvant infusion.

Table 1 Demographic data

Characteristics	Group A ($n = 50$) (non-clamping)	Group B ($n = 50$) (3-h interval clamping)	p value
Sex (female:male)	44:6	42:8	0.17
Side (right:left)	27:23	29:21	0.84
Age (year)[a]	69.5 ± 6.8	68.2 ± 7.6	0.36
Body mass index (kg/m^2)[a]	27.3 ± 3.9	27.9 ± 3.9	0.39
Arc of knee motion (degrees)[a]	109.9 ± 18.8	114.8 ± 21.3	0.23
Preoperative Hb level (g/dL)[a]	12.5 ± 1.2	12.4 ± 1.2	0.79
Preoperative Hct level (%)[a]	37.8 ± 3.1	37.6 ± 3.6	0.80
Operative time (min)[a]	87.3 ± 16.3	86.1 ± 14.5	0.70

Hb Hemoglobin, *Hct* Hematocrit

[a] Values are expressed as the mean ± SD

Table 2 Blood loss and transfusion requirement

Outcomes	Group 1 ($n = 50$) (Non-clamping)	Group 2 ($n = 50$) (3-h interval clamping)	p value
Volume of drained blood (mL)[a]			
In 0–24 h	1019 ± 386	715 ± 318	<0.001
In 24–48 h	184 ± 142	121 ± 57	0.005
Total drained blood	1203 ± 438	836 ± 335	<0.001
Postoperative Hb (g/dL)[a]			
At 12 h	9.3 ± 1.1	9.6 ± 1.1	0.14
Decreasing Hb at 12 h	3.2 ± 0.8	2.8 ± 0.9	0.02
At 48 h	10.2 ± 0.8	10.1 ± 1.0	0.49
Postoperative Hct (%)[a]			
At 12 h	28.7 ± 3.4	29.3 ± 3.4	0.39
Decreasing Hct at 12 h	9.1 ± 2.9	8.4 ± 3.0	0.20
At 48 h	30.9 ± 2.3	30.4 ± 2.8	0.32
Number of patients requiring blood transfusion (yes:no)	42:8	39:11	0.61
PRC transfusion (unit)[a]	1.7 ± 1.1	1.3 ± 0.9	0.10

Hb Hemoglobin, *Hct* hematocrit, *PRC* packed red blood cells

[a] Values are expressed as the mean ± SD, with the range in parentheses

Our results revealed that the 3-h interval clamping method (total clamping time was 6 h) reduces blood drainage on postoperative days 1 and 2. Because 84.7% of the total blood loss occurred on the first day, this protocol is more effective when used in the first 24 h. In addition, our study shows that patients receiving 3-h interval clamping exhibit a lower decrease in Hb levels at 12 h postoperation. The data are consistent with meta-analysis by Tai et al. [32], who concluded that clamping for no <4 h reduced the true blood loss and resulted in higher levels of postoperative hemoglobin than non-clamping. However, in 4 out of 6 randomized controlled trials [14, 15, 27, 28], from this meta-analysis that recorded the number of patients requiring a transfusion, there was no statistical significance in the number of transfusions required between clamped and non-clamped groups ($p = 0$ 0.14).

Although logistic regression analysis revealed that the number of transfused patients was not significantly different between our two groups ($p = 0.24$), the 3-h interval clamping reduced the number of patients requiring a transfusion by 2.2-fold compared to the control group (odds ratio = 2.20). Following our blood transfusion criteria, there was no difference in Hb and Hct levels, 48 h postoperatively. Moreover, no clinically thromboembolic events or wound infections were observed in our study.

Only one other randomized controlled study using intermittent clamping has been published [23]. The clamping protocol used in this study was to clamp for 5 min (or 100 mL of drainage) every 2 h for first 6 h and then again at 12 and 24 h after hybrid TKA. The results revealed that this protocol could reduce greater postoperative blood loss ($p < 0.05$) and keep the higher postoperative Hb levels ($p = 0.01$) than the continuous drain group, but there was no significant difference ($p = 0.071$) in the amount of blood that patients from each group were transfused after surgery. Comparing this study and our study, our protocol is simpler and easier to perform. Our protocol was also applied to minimally invasive TKA with cemented prosthesis. Nevertheless, our results did not show the differences from the above-mentioned study.

In conclusion, we propose a 3-h interval clamping as the new protocol for reducing blood loss after TKA. This protocol reduces the decrease in postoperative Hb levels and it can be applied easily without increasing clinical thromboembolic events and wound complications.

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