Original Article

Comparison of Intra- and Post-operative Blood Loss Between Intermittent and Conventional Early Release Tourniquet Application in Total Knee Arthroplasty: A Randomized Controlled Trial

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Background: Early tourniquet release (before wound closure) in total knee arthroplasty [TKA] has been advocated to have advantages over late release (after skin closure), but the early release can significantly increase perioperative blood loss. To reduce intra-operative blood loss, a new technique called "intermittent early tourniquet release [IETR]" has been developed.

Objective: To compare intra- and post-operative blood loss between IETR and conventional early tourniquet release [CETR] techniques in primary TKA.

Materials and Methods: A prospective randomized controlled trial was conducted with 28 patients aged over 50 years who had been diagnosed with primary knee osteoarthritis and who were scheduled to undergo primary cemented TKA involving application of a pneumatic tourniquet. In all cases, after cementation of the prosthesis, the tourniquet was released. For patients randomized to the IETR group, the tourniquet was then re-inflated to the previous pressure (without re-exsanguination) one minute after the initial release. The tourniquet was again released after 2 minutes of second re-inflated. Tourniquets were not re-inflated after the initial releasein patients in the CETR group. Intra- and post-operative blood loss was measured in addition to measurement of hemoglobin and hematocrit levels 24 hours post-operatively. Estimated blood volume loss [BVL] was also calculated.

Results: Pre-operative characteristics in both groups were similar. Following the operation, there was no significant difference between the IETR and CETR groups in intra-operative blood loss (mean difference -1.0, 95% CI -51.7, 49.8), post-operative blood loss (mean difference -5.2, 95% CI -218.9, 208.5). Estimated BVL and decreases in hemoglobin and hematocrit level were not significantly smaller in the IETR group (mean difference (69.64, 95% CI -92.1, 231.3, $p = 0.384$), (0.3, 95% CI -0.1, 0.8, $p = 0.148$) and (1.5, 95% CI -0.1, 3.0, $p = 0.070$), respectively). In addition, there was no difference in either the number of blood transfusions or in the incidence of tourniquet-related complications.

Conclusion: The IETR technique helps reduce estimated post-operative BVL and decreases in hemoglobin and hematocrit levels compared to the CETR technique, although the differences are not statistically significant. Re-inflation of the tourniquet after initial deflation does, however, improve surgical field visualization, facilitating cauterization of bleeding blood vessels and results in no increase in tourniquet-related complications.

Keywords: Total knee arthroplasty, Early tourniquet release, Intra-operative blood loss

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Intra- and post-operative blood loss are considered to affect complication rates and functional recovery after primary total knee arthroplasty [TKA][1]. Conventionally, a pneumatic tourniquet is used in TKA to help reduce intraoperative blood loss and to allow better visualization of the surgical field as well as to facilitate good cementation of the prosthesis components and to reduce the duration of the surgery[2-4]. Many different tourniquet application

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strategies are used in an effort to find effective ways of reducing blood loss in primary TKA. The most commonly used strategies can be classified into three main patterns: (1) inflation of the tourniquet before incision and deflation after hardening of the cement (early release), (2) inflation before incision and deflation after skin closure (late release), and (3) inflation before prosthesis placement and deflation after hardening of the cement (at cementation)[1,5-7]. A randomized double-blind clinical trial to determine the optimal timing of pneumatic tourniquet application reported that estimated blood loss was highest when the tourniquet was inflated at cementation and that better outcomes were achieved with early tourniquet release[1]. In another randomized double-blind study, tourniquet application exclusively during cement fixation was found to result in a higher transfusion rate than the early release technique[6].

Early tourniquet release, before wound closure, has been advocated to allow secure hemostasis, especially bleeding from arterial bleeders[8], and to allow more accurate assessment of patellar tracking[9-12]. Early release has also been reported to reduce tourniquet time as well as the incidence of postoperative wound complications[13] because it reduces the duration of ischemia and low oxygen content in the soft tissue around the incision[14,15]. However, early release of the tourniquet significantly increases the surgical time due to time spent for cauterizing bleeding vessels[16,17]. A meta-analysis of randomized controlled trials comparing early and late tourniquet release in primary TKA reported significantly higher in total measured blood loss[12,13,18], calculated blood loss, post-operative blood loss[18], and post-operative transfusion rates[13]. Although late release of the tourniquet decreases perioperative blood loss significantly, it concurrently significantly increases the risk of both minor and major complications[18] as well as the rate of reoperation resulting from post-operative complications[12]. In addition, early release of the tourniquetalso results in reactive hyperemia[19, 20].

To reduce intra-operative blood loss with early tourniquet release, a new technique called "intermittent early tourniquet release" has been proposed as an alternative. This new technique involves an initial 1-minute deflation followed by a 2-minute re-inflation then a final deflation. The 2-minute re-inflation of the tourniquet may reduce hyperemia as well as bleeding from tissues. This study was designed to compare the intra- and post-operative blood loss between the intermittent early tourniquet release [IETR] and the conventional early tourniquet release [CETR] techniques in primary TKA.

Materials and Methods

This single-center, prospective randomized controlled trial was approved by the Khon Kaen University Ethics Committee for Human Research (Reference No. H 581058). Informed consent was obtained from all study participants andthe operations were performed at Srinagarind Hospital, Khon Kaen University, between June and November 2016. Patients aged over 50 years who were diagnosed with primary osteoarthritis of the knee and who were scheduled to undergo primary TKA under spinal or epidural anesthesia were assessed for eligibility. Exclusion criteria were a history of a bleeding disorder, current chronic anticoagulant therapy, a history of peripheral vascular disease or venous thromboembolism, and previous open knee surgery. Patients who developed intra-operative complications and cases where it was necessary to release the tourniquet before cementation of the prosthesis were also excluded.

Sample size calculation

According to a previous study by Christodoulou et al[16], the total intra- and post-operative blood loss associated with total knee arthroplasty in patients having tourniquet release before wound closure averages 904 ml (SD. 184). To test the hypothesis that the IETR technique can reduce total blood loss by at least 200 ml compared with the CETR technique,with a statistical significance level of Alpha = 0.05 and power set at 0.80, the calculated number of patients in each group was 14.

Patient selection and randomization

Thirty-one consecutive patients diagnosed with primary knee osteoarthritis and treated with cemented TKA were assessed for eligibility and enrolled. Three patients were subsequently excluded because of intra-operative fracture (n = 1) and having to deflate the tourniquet before cementation of the prosthesis (n = 2), leaving a total of 28 patients in the study. Patient demographic data as well as pre-operative blood volume, hemoglobin level, hematocrit level, and platelet count are shown in Table 1. A computer-generated block of 4 randomization list was created prior to recruitment. Each random number containing the assigned tourniquet release technique was kept in an opaque and sealed envelope. All enrolled patients were randomized and allocated to either the IETR group

or the CETR group.

Tourniquet application

Identical tourniquet application procedures were used with all patients. Three circumferential wraps of cast cotton padding were placed under the tourniquet to protect the skin. A tourniquet cuff with a width of 10 cm and a length of 86 cm was used. The extremity was exsanguinated using an Esmarch bandage, and the knee was flexed as much as possible prior to inflating the pneumatic tourniquet. Tourniquet pressure was set at 200 mmHg above the final systolic blood pressure measurement taken just prior to tourniquet inflation.

Surgical procedures

All surgical procedures were performed by two staff surgeons. A straight anterior midline skin incision and medial para-patellar arthrotomy was used. Intramedullary femoral and extramedullary tibial resection guides were used for all knees. The prosthesis used was a Zimmer NexGen Legacy LPS (Zimmer-Biomet, Warsaw, USA). The hole in the distal femur from intramedullary guide was plugged with bone wax. All patellae were un-resurfaced. Both femoral and tibial components were cemented. After inserting the final prosthetic components in place and waiting for the cement to cure, the randomization envelope was opened. The tourniquet was released once the cement had hardened, after which the surgeons used electrocautery to achieve hemostasis. For patients allocated to the IETR group, the tourniquet was released for one minute then was re-inflated to the previous pressure without re-exsanguination. The tourniquet was then released again at the end of the third minute, i.e., after 2 minutes of re-inflation. There was no re-inflation in patients allocated to the CETR group. Finally, a vacuum drain was placed within the knee joint in all patients before wound closure and a compression dressing was applied.

Intra- and post-operative blood loss measurement and calculation

Intra-operative blood loss was calculated from the increase in weight of the gauzes used to absorb the bleeding from after the first tourniquet deflation until wound closure. That weight was converted to volume using a whole blood specific gravity of 1.0506 g/cm^3 at 37°C[21]. Post-operative blood drainage was recorded at 6 and 24 hours, after which the drain was removed. None of the patients given thromboembolism prophylaxis medication. Hemoglobin and hematocrit levels at 24 hours after surgery were recorded. Estimated blood volume loss [BVL] was also calculated using the modified Gross formula[22] which is based on fractional changes in hematocrit levels.

Other outcomes measurement

Blood transfusion was given intra- or post-operatively when the hematocrit was 28% or lower, and the number of unit was recorded. Tourniquet-related complications were also compared.

Statistical analysis

The collected data were normally distributed according to the Shapiro-Wilk test. Analysis was performed using SPSS version 21.0 software. Outcomes are presented as mean $\pm$ SD and were compared using Student's t-test.

Results

Of the 31 patients initially enrolled in this study, 28 patients (26 females, 2 males) were included, all of whom completed the study. Patient's pre-operative characteristics in both the IETR and the CETR groups were similar (Table 1). There were no significant differences between the groups in mean age (62.43$\pm$6.63 vs. 66.86$\pm$5.31 years), BMI (27.82$\pm$5.21 vs. 27.13$\pm$3.77 kg/m^2) or radiographic grading of knee osteoarthritis. The initial blood volume (3.28$\pm$1.22 vs. 3.20$\pm$1.29 L), hemoglobin level (12.17$\pm$0.80 vs. 12.90$\pm$0.89 g/dl), hematocrit level (37.12$\pm$2.37 vs. 39.49$\pm$2.75%) and platelet count (261,929$\pm$42,769 vs. 260,357$\pm$64,606 uL) were also not significantly different.

Intra-operative blood loss, post-operative blood loss, and estimated BVL are shown in Table 2. There was no significant difference between the IETR and the CETR group in intra-operative blood loss (mean difference -1.0, 95% CI -51.7, 49.8) or post-operative blood loss (mean difference -5.2, 95% CI -218.9, 208.5). Estimated BVL was non-significantly lower in the IETR group (mean difference 69.64, 95% CI -92.1, 231.3, p = 0.384). Similarly, the decrease in hemoglobin and hematocrit levels, defined as the difference between the values at 24 hours post-operative and the pre-operative baseline values, were non-significantly lower in the IETR group (mean difference 0.3, 95% CI -0.1, 0.8, p = 0.148 and 1.5, 95% CI -0.1, 3.0, p = 0.070, respectively). There was also no significant difference in the number of blood transfusionsor the incidence of tourniquet-related complications.

Table 1. Demographic and pre-operative patient characteristics

	Group		
	IETR (n = 14)	CETR (n = 14)	*p*-value
Gender (male/female)	0/14	2/12	NS
Age (year)	62.43±6.63	66.86±5.31	0.062
Weight (kg)	68.34±13.70	65.64±12.27	0.588
Height (cm)	156±3	155±7	0.532
BMI (kg/m^2)	27.82±5.21	27.13±3.77	0.692
Side (right/left)	8/6	5/9	NS
Classification of osteoarthritis (case)			
Kellgren Lawrence III	2	2	NS
Kellgren Lawrence IV	12	12	NS
Hemoglobin (g/dl)	12.17±0.80	12.90±0.89	0.031
Hematocrit (%)	37.12±2.37	39.49±2.75	0.022
Platelet (ul)	261,929±42,769	260,357±64,606	0.940
Blood volume (L)	3.28±1.22	3.20±1.29	0.873

Values are mean ± standard deviation
BMI = body mass index; IETR= intermittent early tourniquet release; CETR = conventional early tourniquet release

Table 2. Comparison of results with IETR and CETR

	Group		*p*-value	mean difference [95% CI]
	IETR	CETR		
Intra-operative blood loss (ml)	132.0	131.0	0.969	-1.0 [-51.7,49.8]
Postoperative blood loss (ml)				
0 to 6 hours	420.4	396.4	0.762	-23.9 [-184.5,136.7]
6 to 24 hours	261.2	279.9	0.759	18.7 [-105.3,142.8]
Total (0 to 24 hours)	681.6	676.4	0.960	-5.2 [-218.9,208.5]
Decrease in hemoglobin level (g/dl)	3.0	3.4	0.148	0.3 [-0.1, 0.8]
Decrease in hematocrit level (%)	9.1	10.5	0.070	1.5 [-0.1, 3.0]
Estimated blood volume loss (ml)	1,062.86	1,132.50	0.384	69.64 [-92.10, 231.37]
Blood transfusion (units)	0.5	0.5	1.000	0 [-0.5, 0.5]
Tourniquet-related complications	0	0	1.000	NS

Values are mean ± standard deviation
IETR = intermittent early tourniquet release; CETR = conventional early tourniquet release

Discussion

The advantages and disadvantages of using a tourniquet in TKA has been a subject of discussion. Despite reports of successful TKA operations performed without a tourniquet[23,24], tourniquets are still widely employed by orthopedic surgeons during TKA and their use is considered good surgical practice[25]. The decision whether to release the tourniquet before or after wound closure remains a matter of dispute. Most of the studies in a meta-analysis found that early release of the tourniquet in primary TKA not only reduced total blood loss but also lowered the risk of both early minor and major complications early complications, both major and minor. A meta-analysis by Rama et al[12] which systematically analyzed 11 studies involving 893 primary knee arthroplasties found that early tourniquet release increased total measured and calculated blood loss significantly, but the risk of re-operation due to post-operative complications was significantly higher with late tourniquet release. Huang et al[26] also conducted a meta-analysis that included 14 high quality randomized

controlled clinical trials [RCTs]. They reported that tourniquet release before wound closure could significantly increase not only the total measured blood loss but also the calculated blood loss in TKA patients. Although tourniquet release after wound closure could reduce blood loss, the risk of complications increased. Similar results were reported by Zan et al[18] based on their meta-analysis of 8 studies (608 knees). However, a study by Tie et al[13] found no significant difference in calculated blood loss, decrease in hemoglobin level, drop in hematocrit level,or measured post-operative blood loss between early and late tourniquet release; they reported that only total measured blood loss and post-operative blood transfusion rates were significantly higher in the early tourniquet release group.

Since early tourniquet release provides a window of time for additional bleeding to occur, total blood loss would be expected to be higher than with late tourniquet release. That increased intra-operative blood loss may be the major factor in the increase in total blood loss associated with early tourniquet release. In that regard, reactive hyperemia and an increase in fibrinolytic activity have been demonstrated to occur for a few minutes following tourniquet release, leading to excessive bleeding[19,27-29]. A fibrin spray or periarticular tissue injection with a solution containing a local anesthetic and epinephrine have been used to reduce intra-operative blood loss[30,31]. The technique of re-inflation of the tourniquet after a one minute release is expected to reduce excessive bleeding from reactive hyperemia. The 2 minute re-inflation allows the normal coagulation process in small bleeding vessels, while the improved surgical field visualization allows for better cauterization of larger vessels. Although based on intra-operative observation, bleeding after re-deflation in the IETR group appeared to be reduced and there was no statistically significant difference inthe measured intra-operative blood loss between the IETR and the CETR groups (mean difference -1.0, 95% CI -51.7, 49.8). However, measurements of true blood loss using the modified Gross formula[22] to calculate perioperative blood loss did find a statistically significant reduction in the IETR group. The Gross formula, which has been used in many studies[32,33], is a linear model which calculates blood volume by using perioperative hematocrit measurements. Post-operative hematocrit level is the most important reference index as it incorporates various factors in calculating hidden blood loss[32,33]. The decrease in hematocrit level at 24 hours post-operative in the IETR group (9.1%) was less than the CETR group (10.5%), although the statistical significance of this difference cannot be proved (p = 0.070). The estimated blood volume loss of the IETR group (mean = 1,062.86 ml), calculated using the modified Gross formula, was also lower than the CETR group (mean = 1132.50 ml) (p = 0.384). The re-inflation of the tourniquet after early release is a safe alternative to the conventional early tourniquet release, with no differences in pain level or complications, either local or non-local[34]. No tourniquet-related complications were found in either group of patients in the present study.

Conclusion

The intermittent early tourniquet release technique in primary TKA helps reduce post-operative estimated blood volume loss and hemoglobin and hematocrit levels than the conventional early tourniquet release technique, although the differences are not statistically significant. Re-inflation of the tourniquet after the initial deflation improves surgical field visualization and facilitates cauterization of bleeding blood vessels but does not increase tourniquet-related complications.

What is already known on this topic?

Early tourniquet release (before wound closure) during total knee arthroplasty has been advocated to have many advantages over late tourniquet release (after wound closure) technique, but the early release of tourniquet significantly increase the total measured blood loss, calculated blood loss and post-operative blood loss.

What this study adds?

This study proposes a new technique called "intermittent early tourniquet release" and designed to compare the intra- and post-operative blood loss with the "conventional early tourniquet release" technique in primary total knee arthroplasty. The results demonstrated that the new technique helps to reduce post-operative estimated blood volume loss, the drop in hemoglobin and hematocrit level, although statistically non-significance.

Potential conflicts of interest

The authors declare no conflict of interest.

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