

A Tourniquet Versus Non-Tourniquet Method in Total Knee Arthroplasty: A Single Center Study in Aden

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Abstract

Introduction: Tourniquet use in surgery of lower limb was a standard method in orthopaedic, mainly in total knee replacement arthroplasty (TKA), and the avoidance of a tourniquet still a matter of concern and debate among orthopaedic surgeons. This study was conducted to compare the results of using tourniquet versus non-tourniquet method during total knee replacement operation done in a private hospital in Aden Governorate.

Methods: A prospective comparative study included 49 patients underwent TKA in a private hospital in Aden during 2018-2020. They were randomized 1:1 to the use of tourniquet (group I, n=23) or non-tourniquet (group II, n=26). In group I, the tourniquet cuff pressure was inflated based on the patients' systolic pressure and a margin of 100 mm Hg (generally the pressure was ≤ 225 mmHg). The cuff was inflated immediately before surgery and deflated as soon as surgery ended. The primary outcome was the blood requirements after surgery. Secondary outcomes were pain, quadriceps extension strength and range of motion.

Results: The median age was 57 years in group I and 60 years in group II. The female to male ratio was 2.3:1 in group I and 1.8:1 in group II. Bleeding during operation was statistically significantly higher among group II (mean: 575 ± 91.9 ml); compared with 276 ± 83.7 ml in group I. Post-operatively, bleeding was statistically significantly higher among group I (767 ± 101.8 ml); compared to 198 ± 107.2 ml in group II. Post-operatively, three patients from group I needed transfusion of 1 unit packed red blood cells and no patient from group II needed blood transfusion. Pain was mild in all group II patients and in 60.9% of group I patients with significant statistical difference ($p < 0.05$). The quadriceps extension strength (QES) was not significantly affected in 88.5% of group II, while 73.9% of group I showed mild to moderate weakness. The range of motion was significantly full range in 88.5% of group II patients while mild limitation was observed among 69.6% of group I patients.

Conclusion: This study concluded that in spite of the higher intra-operative blood loss, performing TKA without tourniquet is superior to the use of tourniquet in terms of post-operative outcome.

Keywords: Tourniquet, TKA, Bleeding, Pain, QES, Range of motion.

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استخدام العاصبة مقابل عدم استخدامها كطريقة في تقويم مفصل الركبة الكلي: دراسة في مركز طبي واحد في عدن

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ملخص الدراسة

المقدمة: كان استخدام العاصبة في جراحة الأطراف السفلية طريقة قياسية في جراحة العظام، وخاصة في تقويم مفاصل الركبة بالكامل، ولا يزال تجنب العاصبة أمرًا مثيرًا للقلق والنقاش بين جراحي العظام. أجريت هذه الدراسة لمقارنة نتائج استخدام العاصبة مقابل عدم استخدامها خلال عمليات تقويم مفصل الركبة الكلي التي أجريت في مستشفى خاص بمحافظة عدن.

المنهجية: دراسة مستقبلية مقارنة شملت 49 مريضاً خضعوا لتقويم مفاصل الركبة بالكامل في مستشفى خاص في محافظة عدن، خلال 2018-2020. تم اختيارهم بشكل عشوائي بنسبة 1:1 لاستخدام العاصبة (المجموعة الأولى، العدد = 23) أو عدم استخدامها (المجموعة الثانية، العدد = 26). في المجموعة الأولى، تم عمل ضغط الكفة العاصبة بناءً على الضغط الانقباضي للمريض وهامش 100 مم زئبق (كان الضغط عمومًا ≥ 225 مم زئبق). تم نفخ الكفة مباشرة قبل الجراحة وتفرغها بمجرد انتهاء الجراحة. كانت النتيجة الأولية هي الاحتياج للدم بعد الجراحة. وكانت النتائج الثانوية هي الألم، وقوة تمديد العضلة الرباعية ومدى الحركة.

النتائج: كان متوسط العمر 57 عامًا في المجموعة الأولى و60 عامًا في المجموعة الثانية. كانت نسبة الإناث إلى الذكور 2.3:1 في المجموعة الأولى و1.8:1 في المجموعة الثانية. كان النزيف أثناء العملية أكثر من الناحية الإحصائية بين المجموعة الثانية (المتوسط: 91.9 ± 575 مل)؛ مقارنة مع 83.7 ± 276 مل في المجموعة الأولى. بعد الجراحة، كان النزيف أكثر بشكل ملحوظ إحصائيًا بين المجموعة الأولى (101.8 ± 767 مل)؛ مقارنة بـ 107.2 ± 198 مل في المجموعة الثانية. احتاج ثلاثة مرضى من المجموعة الأولى إلى نقل وحدة دم واحدة ولم يكن أي مريض من المجموعة الثانية بحاجة لنقل الدم. كان الألم خفيفًا في جميع مرضى المجموعة الثانية وفي 60.9% من مرضى المجموعة الأولى مع وجود فرق إحصائي كبير. لم تتأثر قوة تمديد العضلة الرباعية بشكل معنوي في 88.5% من المجموعة الثانية، بينما أظهر 73.9% من المجموعة الأولى ضعفًا خفيفًا إلى متوسط. كان نطاق الحركة كاملاً بشكل ملحوظ في 88.5% من مرضى المجموعة الثانية بينما لوحظ وجود حدود طفيفة بين 69.6% من مرضى المجموعة الأولى.

الاستنتاج: خلصت هذه الدراسة إلى أنه على الرغم من زيادة فقدان الدم أثناء الجراحة، فإن إجراء تقويم مفاصل الركبة بالكامل بدون عاصبة يتفوق على استخدام العاصبة من حيث نتائج ما بعد الجراحة.

الكلمات المفتاحية: العاصبة، تقويم مفاصل الركبة بالكامل، النزيف، الألم، قوة تمديد العضلة الرباعية، مدى الحركة.

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Introduction

Knee joints are the largest joints in human body, essential to perform most daily activities. Knee arthroplastic surgery was first performed in 1968. After which a dramatic improvement in surgical materials and techniques occurred facilitating its effectiveness. Total knee arthroplasty (TKA) is considered as the treatment of choice to patients with end stage knee diseases. It can improve the lower limb function and relieve pain. Overall, it affects positively the quality of life of operated patients in a noticeable way [1,2].

Since the start of knee arthroplasty, tourniquets were used to decrease operative blood loss, to provide clear bloodless operating field, and to obtain drier bone surfaces for the best interdigitation of cement [3].

Nowadays, the procedure of TKA is still a matter of debate. Multiple clinical trials and systemic reviews were conducted during the last few years with variable conclusions regarding the use of tourniquet versus the operation without tourniquet. Some trials support the use of tourniquet such as the prospective double-blinded, randomized controlled trial (RCT) of Goel *et al* [4], who observed that tourniquet use during TKA significantly decreases blood loss and does not adversely affect early postoperative outcomes. They concluded that tourniquet use during routine TKA is safe and effective, and concerns about deleterious effects on function and pain may not be justified.

On the other side, some clinical studies support the operation without tourniquet, such as the study of Ajnin and Fernandes in 2020 [5], who reported that TKA done without tourniquet was associated with shorter length of stay, lesser pain and swelling, in addition to improved range of motion in the early post-operative period.

Other trials did not find difference between both procedures, such as that of Alexandersson *et al* [6], who observed no clear benefit for either procedure, as the more pain exhibited by the non-tourniquet group was only evident for a short period and the improved mobility in this group was not at a clinically relevant level.

Recently, some schools instituted the use of tranexamic acid during TKA operation without tourniquet as multiple intravenous injections [7], or intra-articular injections [8].

A thorough search in the literature did not show any study conducted in Yemen regarding TKA. Up to the knowledge of the author, this study is considered the first study in Yemen that compares TKA with the use of tourniquet and without the use of tourniquet. Thus, this study aimed to compare the use of tourniquet with non-tourniquet method during total knee replacement operation done in a private hospital in Aden Governorate.

Methods

Study design and setting

This is a prospective comparative study included 49 patients underwent TKA for end stage knee diseases in a private hospital in Aden, during 2018-2020.

Patients and procedures

Patients were randomized 1:1 to the use of tourniquet (group I) or non-tourniquet (group II) method during surgery. All patients were operated by the same team of senior orthopedic consultant and assistant surgeons using a standardized technique and prosthesis. Operation involves replacement of all surfaces of the knee, by excising both diseased and normal femoral condyles, the tibial plateau, and often the patella, and removing or releasing some of the ligaments. Then the artificial implant was cemented in position. In group I, the tourniquet cuff pressure was inflated based on the patients' systolic pressure and a margin of 100 mm Hg (generally the pressure was ≤ 225 mmHg) [9]. The cuff was inflated immediately before surgery and deflated as soon as surgery ended.

The primary outcome was the blood requirements after surgery. Secondary outcomes were pain (measured by the visual analogue pain score), quadriceps extension strength (measured isometrically at 60° knee flexion) and range of motion (active flexion and active extension of the knee were measured with a standard plastic goniometer with a scale marked in 1° increments and 30-cm arms with the patient lying supine on a gurney). Post-operatively, patients were followed till discharged well with postoperative pain management and rehabilitation program.

Statistical analysis

Data collected were analyzed by the SPSS program version 24. Quantitative data were tested for normality using Kolmogorov-Smirnov test, which revealed parametric distribution except for age of patients. Operative parameters

were presented as mean values with standard deviation and tested by the student t-test. Age of patients was non-parametric variable and presented as median value with range and tested by the Mann-Whitney test. Qualitative variables were tested by the Chi-square and Fisher exact tests as appropriate. p -value of ≤ 0.05 was considered as statistically significant.

Ethical considerations

This study was approved by the hospital authority. All operated patients signed a written consent for surgery and anesthesia. At that time, they were informed about the aim of this study and verbal consents were obtained. Patients who agreed were fully informed about the main objective of the study and the way of handling of the obtainable information.

Results

In this study, 49 patients submitted to total knee replacement. They were separated into 2 groups; group I with the use of tourniquet method ($n=23$) and group II without the use of tourniquet method ($n=26$). The median age was 57 years in group I and 60 years in group II. The female to male ratio was 2.3:1 in group I and 1.8:1 in group II. There was no significant difference between sex and age group distribution between the groups. Even the side of operation, left or right knee, was not significantly differing between both groups as seen in Table 1.

In group I, the tourniquet was applied with a pressure of ≤ 225 mmHg for a time ranged from 70 to 100 minutes and a mean of 85.0 ± 10.0 minutes.

Table 1: Sex and Age Distribution of Patients Subjected to Tourniquet Versus Non-Tourniquet Methods

Variables	Group I Tourniquet (n=23)		Group II Non-tourniquet (n=26)		Total (n=49)		p
	No.	%	No.	%	No.	%	
Sex							
Male	7	30.4	9	34.6	16	32.7	0.498
Female	16	69.6	17	65.4	33	67.3	
Age (years)							
< 50	3	13.0	6	23.1	9	18.4	0.053
50 – 59	10	43.5	3	11.5	13	26.5	
60 – 69	3	13.0	9	34.6	12	24.5	
≥ 70	7	30.4	8	30.8	15	30.6	
Median age(Range)	57 (36 – 80)		60 (25 – 85)		60 (25 – 85)		0.667 [#]
Side of operation							
Left knee	15	65.2	14	53.8	29	59.2	0.303
Right knee	8	34.8	12	46.2	20	40.8	

conducted by Mann-Whitney Test, while others by Chi-square test.

The operation time ranged from 90 minutes to 125 minutes without significant difference between the mean time for tourniquet versus non-tourniquet methods (105.6 vs. 106.7) minutes respectively. The mean pre-operative hemoglobin concentration was not different between both groups (12.1 g/dl for group I vs. 12.3 g/dl for group II). However, the mean post-operative hemoglobin concentration

was statistically significantly lower in group I when compared to group II (11.1 g/dl vs. 11.8 g/dl) respectively. Mean bleeding during operation was significantly higher among group II (575ml±91.9); compared with 276±83.7 ml in group I. Post-operatively, bleeding was significantly higher among group I (767±101.8ml); compared to 198±107.2 ml in group II; (Table 2).

Table 2: Mean Operative Parameters in Patients Subjected to Tourniquet Versus Non-Tourniquet Methods

Parameters	Group I Tourniquet(n=23)	Group II Non-tourniquet(n=26)	p
	Mean ± SD (Min. – Max.)	Mean ± SD (Min. – Max.)	
Operative time (minutes)	105.6 ± 10.1 (90 – 120)	106.7 ± 10.1 (90 -125)	0.699
Pre-operative hemoglobin concentration (g/dl)	12.1 ± 1.1 (11.0 - 14.0)	12.3 ± 1.2 (11.0 - 14.0)	0.426
Intra-operative bleeding (ml)	276 ± 83.7 (200 – 450)	575 ± 91.9 (450 – 750)	0.001*
Post-operative bleeding (ml)	767 ± 101.8 (600 – 900)	198 ± 107.2 (50 – 450)	0.001*
Post-operative hemoglobin concentration (g/dl)	11.1 ± 1.3 (9.0 - 13.0)	11.8 ± 1.2 (10.0 - 14.0)	0.050*

* Statistically significant

All patients received pre-operative transfusion of 1 unit packed red blood cells (PRBCs), while post-operatively, three patients from group I needed transfusion of 1 unit PRBCs and no patient from group II needed blood transfusion. Post-operatively, pain was mild and expected in all group II patients and in 60.9% of group I patients with significant statistical difference ($p=0.001$). The quadriceps extension strength was not

significantly affected in 88.5% of group II, while 73.9% of group I showed mild to moderate weakness. The range of motion was significantly full range in 88.5% of group II patients while mild limitation was observed among 69.6% of group I patients as shown in Table 3. No post-operative complications were reported in both groups until discharge from hospital.

Table 3: Post-Operative Parameters in Patients Subjected to Tourniquet Versus Non-Tourniquet Methods

Parameters	Group I [Tourniquet] (n=23)		Group II [Non-tourniquet] (n=26)		Total (n=49)		<i>p</i>
	No.	%	No.	%	No.	%	
Post-operative pain							
Mild (expected)	14	60.9	26	100.0	40	81.6	0.001*
Moderate	9	39.1	0	0.0	9	18.4	
Post-operative quadriceps extension strength[#]							
Mild weakness	9	39.1	3	11.5	12	24.5	0.001*
Moderate weakness	8	34.8	0	0.0	8	16.3	
Not affected	6	26.1	23	88.5	29	59.2	
Post-operative range of motion [ROM]							
Full ROM	7	30.4	23	88.5	30	61.2	0.001*
Mild limitation ROM	16	69.6	3	11.5	19	38.8	

* Statistically significant *p*-values were calculated by Fisher Exact test.

[#]Calculated as affected [mild plus moderate]

versus not affected.

Discussion

Tourniquet use in surgery of lower limb was a standard method in orthopaedic, mainly in total knee replacement arthroplasty, and the avoidance of a tourniquet still a matter of concern and debate among orthopaedic surgeons [10].

More females were operated compared to males. However, in both groups; the female to male ratio did not show significant statistical difference. Even, the age and the side of operation did not show significant statistical difference between both groups. Similar to our study, Ejaz *et al* [11], included 70 patients with total knee replacement randomized equally into a tourniquet group and a non-tourniquet group without significant difference between their age.

The duration of tourniquet uses and cuff pressure play very important roles in tourniquet-related adverse effects. In this study, among group I, the tourniquet was applied with a pressure of ≤ 225 mmHg for a time ranged from 70 to 100 minutes and a mean of 85.0 ± 10.0 minutes. Olivecrona *et al* [9] compared the technique of limb-occlusion-pressure measurement (LOP) to systolic-blood-pressure measurement as a guide for deciding the cuff pressure. The study concluded that patients with a cuff pressure of ≤ 225 mm Hg had a better outcome and lower rate of wound complications.

There are various studies supported the TKA operation without the use of tourniquet [11-15]. On the other side, various studies reported no significant difference between using and not

using a tourniquet in TKA [4-16]. Some studies support the use of tourniquet during TKA [17-18]. The findings of the current study support the non-tourniquet method in TKA. In this study, it was observed that the mean pre-operative hemoglobin concentration was not differing between both groups. However, the mean post-operative hemoglobin concentration was statistically significantly lower in tourniquet group. The tourniquet has been used in total knee arthroplasty aiming to decrease operative blood loss; however, questions exist regarding efficacy and safety.

In their study, Xu *et al* [12] analyzed data from 6325 patients who underwent primary unilateral TKA and reported that following TKA, the transfusion rate was 14.52% in the tourniquet group, and 6.47% in the no-tourniquet group. After adjusting for the different related variables, tourniquet use was significantly correlated with a higher transfusion rate (risk ratio = 1.888, 95% CI: 1.449–2.461, $p < 0.001$).

Schnettler *et al* [13], in a retrospective cohort study of 132 patients concluded that the use of a limited tourniquet protocol during TKA resulted in a paradoxical increase in blood loss. They recommended surgeons to consider omitting routine tourniquet use in total knee arthroplasty. In the current study, the non-tourniquet group showed significantly higher bleeding during operation, no postoperative transfusions requirement, less post-operative pain, and increased range of motion. Similarly, Ejaz *et al* [11], in their study reported that intraoperative blood loss was greater when not using a tourniquet, but no

postoperative transfusions were required. Patients in the non-tourniquet group showed a better early knee ROM from surgery to week 8. Postoperative pain and analgesic consumption were less when a tourniquet was not used [11]. This is coinciding with the report of Liu *et al* [14], in their recent systematic review and meta-analysis that included 25 RCTs comparing both methods. They concluded that intra-operative blood loss and range of motion were significantly increased while post-operative pain was decreased in the non-tourniquet group ($p=0.0001$).

This study observed that quadriceps extension strength was significantly not affected in higher percentage of non-tourniquet group, while higher percentage of tourniquet group showed affected quadriceps extension strength. Liu *et al* [15], reported similar findings in their prospective randomized single-blinded trial undertaken to examine the effect of the tourniquet on post-operative pain, swelling, blood loss, quadriceps function and outcome following TKA. They reported that Quadriceps function, measured by surface EMG, was compromised for the first six months' post-surgery by tourniquet use. They believed that it is safe and beneficial for their patients to routinely perform TKA without a tourniquet.

McCarthy *et al* [16], in a meta-analysis done in 2019, revealed no difference in terms of postoperative pain or range of motion between tourniquet and no-tourniquet groups. Likewise, Goel *et al* [4], in a prospective, double-blinded RCT found no difference in functional outcome measures and pain, but the

tourniquet group had significantly reduced blood loss compared with the no-tourniquet group.

In another meta-analysis [17], Jiang *et al* demonstrated that tourniquet use was associated with significantly decreased intra-operative blood loss, transfusion rates, and operation time but slow joint functional recovery, an increased prevalence of deep vein thrombosis, and other minor wound complications. On the other hand, Harsten *et al* [18], in a RCT reported that not using a thigh tourniquet during TKA was found not superior in preserving knee-extension strength at the primary endpoint 48 hours after fast track TKA, compared to using a tourniquet.

Conclusion

This study concluded that in spite of the higher intra-operative blood loss, performing TKA without tourniquet is superior to the use of tourniquet in terms of post-operative outcome. It is recommended to perform a national wide clinical trial study that includes large sample size with long term duration for follow-up to compare the short term as well as the long term outcomes after TKA with and without tourniquet.

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