No benefit of using pneumatic tourniquet in reducing blood loss after total knee replacement: a randomized controlled trial

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Background
The use of a pneumatic tourniquet in Total knee Arthroplasty (TKA) has always been a controversial issue with several reports of significant blood loss following TKA without tourniquet use that can sometimes require transfusion.
Purpose
To examine whether tourniquet use during TKA has reduced total measured blood loss, altered postoperative hemoglobin concentration and operative time, improved postoperative limb swelling, or decreased the postoperative pain and complication rate.
Methods
It is a single-center randomized controlled trial in which 90 patients, who underwent primary TKA and met the inclusion criteria, were enrolled with 45 patients were operated on with the use of pneumatic tourniquet and 45 patients without the use of tourniquet in a random allocation. Afterward, patients were assessed for total perioperative measured blood loss, operative time, postoperative limb swelling, postoperative pain, and complication.
Results
No statistically significant difference was found between the two groups regarding total perioperative measured blood loss (P=0.107), the need for blood transfusion (P=1), and the 6M walking test (P=0.324). However, there was a significant difference between patients with and without a tourniquet in terms of operating time with lower operative time with using tourniquet (P=0.007), hospital stay with shorter hospital stay in patients without tourniquet (P=0.023), postoperative knee pain visual analog scale with lower perception of pain in patients without tourniquet (P=<0.001), and modifications in limb circumference after 48 h with significantly less limb swelling in patients without tourniquet (P=<0.001).
Conclusion
The use of a tourniquet was associated with higher postoperative loss of blood, postoperative knee pain, lower limb swelling, and consequently a prolonged hospital stay, but it took a shorter operative time and was associated with lower intraoperative loss of blood. However, the total measured perioperative blood loss was the same without the need for blood transfusion in any group. Not using a tourniquet seems to be associated with a better functional outcome, less perception of pain and less swollen limb.

Keywords:
pneumatic tourniquet, postoperative knee pain, total knee arthroplasty

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Introduction

Total knee Arthroplasty (TKA) is one of the most successful procedures for knee osteoarthritis in the last decades with substantial reports about the risk of blood loss. To reduce this rusk, the use of pneumatic tourniquet has been introduced to be used by many surgeons [1–3].

While some research has demonstrated that a tourniquet can decrease overall blood loss during TKA [4,5], other studies found no benefits of its use in decreasing blood loss [6–9].

Consequently, the effect of tourniquet use on overall blood loss is still controversial. While using cemented TKA, it is thought that a tourniquet can reduce intraoperative loss of blood& provide a bloodless surgical field and a better cementing technique. On the other hand, the tourniquet's relaxation causes reactive blood flow to peak just 5 min later [10].

Skin injuries (such as blisters, abrasions, fractures, and pressure necrosis), nerve injuries, post-tourniquet syndrome, deep venous thrombosis, postoperative pain, wound healing abnormalities, early infection, and postoperative discomfort are some of the complications that can arise from using a tourniquet [11].

This study aims at examining the effects of using a pneumatic tourniquet in primary TKA on total measured loss of blood, operation time, rate of complications, limb swelling, hemoglobin level reduction, and postoperative pain.

Patients and methods

This study is a prospective, randomized controlled trial that was conducted after IRB approval (IRB. No. 17101527) and after written informed consent from all patients were taken In this study ninety patients who underwent primary TKA for end-stage knee osteoarthritis were included, and divided into two groups. Group A, which includes 45 patients who underwent the surgery under pneumatic tourniquets the second group included the other 45 patients who underwent the surgery without using tourniquet.

Patients with inflammatory arthritis, patients undergoing revision TKA, patients with abnormal coagulation and bleeding profiles, patients with hemorrhagic disease and patients with renal and hepatic disease were excluded from this study.

Sample size calculation: Based on data from prior studies, the sample size was determined using G*power 3.1.9.2. According to Wanderley *et al.*, for total knee replacement, the 48 h average blood loss is 838.38+/–283.4. To detect a 20% decrease in the amount of blood loss with an error of 0.5 and an 80% power of the study and a 1: 1 allocation ratio, we need to include 40 patients in each group; another five patients will be added to each group to compensate for dropouts, so the total sample size will be 90 patients [12].

Surgical Technique: spinal anesthesia was employed in all cases. One of four experienced knee surgeons conducted each procedure using the medial parapatellar approach. All patients had a suction drain after the operation which was continued for a full 48 h period. The patients in the tourniquet group had their tourniquets deflated after complete wound closure. They had been inflated to a pressure of 100 mm of mercury higher than their systolic blood pressure. Hemostasis was achieved by wrapping the limb with a compression crepe bandage just before deflation of the tourniquet and continued for 6 h postoperatively. The drain was opened for drainage after 30 min of tourniquet deflation to prevent a gush of blood after the sudden drop of the tourniquet. Both the tourniquet and nontourniquet groups received 1 g of tranexamic acid intravenously 10 min before surgery. All patients took a 75 mg intramuscular injection of diclofenac sodium twice daily postoperatively for 2 days. Weight-bearing was allowed on the same day of the surgery at night. A hemoglobin level below eight g/dl or the presence of symptoms of anemia are the requirements for receiving a blood transfusion. Twelve hours following surgery, all patients had thromboprophylaxis after injecting forty international units of low molecular weight heparin subcutaneously. This was done regardless of whether a tourniquet was used or not. Then patients were shifted to aspirin 150 mg daily for one month and stopped any other thromboprophylaxis unless indicated for other comorbidities. All patients start walking on the same operating day.

Research outcome measures: Primary (main): postoperative blood loss during a TKA procedure, measured in milliliters, both with and without the use of a tourniquet. And secondary (subsidiary): Pain following TKA as measured on a visual analog scale (VAS) with and without a tourniquet, total surgical time (measured in minutes) with and without a tourniquet, and postoperative change in hemoglobin level (in gm/dl) with and without a tourniquet.

Statistical analysis

A computer program called IBM-SPSS version 23 (IBM, Armank, New York, USA) was used to collect and analyze the data being collected. The mean (SD), the minimum, and the maximum were how quantitative amounts were expressed, respectively. Variables of a qualitative nature that are expressed in numerical and percentage form. The Kolmogorov–Smirnov test of normality was utilized in order to investigate the normality of the data. The value of P was established at 0.05. The χ^2 test, the student t-test, and the Mann–Whitney test were the ones that were used.

Results

The age ranged from 55 to 71 years, with a mean of 58.876.464 years. 18 (20%) cases of the patients were males, while 72 (80%) were females. BMI ranged between 22.40 and 33.10 kg/m^2 with a mean value of 26.65±2.902 kg/m^2. Among the studied sample, 33 (36.7%) patients had hypertension, and six (6.7%) had diabetes mellitus.

Operative time in patients without a tourniquet ranged between 60 and 90 min with a mean value of

73.57±9.645 min, while in patients with a tourniquet, it ranged between 60 and 80 min with a mean value of 68.75±6.564 min. There was a statistically significant difference between patients with or without a tourniquet regarding the operative time, which was shorter with the tourniquet (*P*=0.007). Hospital Stay in patients without a tourniquet ranged between −2 and 3 days with a mean value of 2.71±0.457 days, while in patients with a tourniquet it ranged between −2 and 4 days with a mean value of 2.94±0.433 days. Patients with and without tourniquets differ statistically significantly Tables 1–4. (*P*=0.023).

Table 1 Distribution of the studied sample according to demographic data

	Number (Percentage)
Age (years)	
Range	55–71
Mean±standard deviation	58.87±6.464
Sex	
Male	18 (20.0)
Female	72 (80.0)
BMI (Kg/m^2)	
Range	22.40–33.10
Mean±S.D.	26.65±2.902
Medical Comorbidity	
HTN	33 (36.7)
DM	6 (6.7)

DM, diabetes mellitus; HTN, hypertension; S.D, standard deviation.

Between patients with and without tourniquets, a statistically significant difference was found, with tourniquet-using patients experiencing reduced intraoperative blood loss and tourniquet-using patients experiencing higher postoperative blood loss (*P*<0.001). Regarding the total amount of blood lost during surgery, there was no statistically significant difference between patients who used a tourniquet and those who did not. (*P*=0.107). Blood loss per kg in patients without a tourniquet ranged between 8.5 and 11.4 ml^3/kg, while in patients with a tourniquet, it ranged between 8.5 and 15.3 ml^3/kg. There were statistically significant differences between patients with or without a tourniquet (*P*=0.048). The need for blood transfusion in patients without a tourniquet shows that only three (7.1%) patients needed a blood transfusion in the postoperative period in the form of 500 ml^3 of packed RBCS in the nontourniquet group, compared with four (8.3%) patients in the tourniquet

Table 2 Comparison between total knee arthroplasty with and without a pneumatic tourniquet about the patient's operation time and hospital stay

	Pneumatic Tourniquet		U	*P* value
	Without	With		
Operation time (min)				
Range	60–90	60–80	679.50	0.007*
Mean±S.D.	73.57±9.645	68.75±6.564		
Hospital Stay (days)				
Range	2–3	2–4	801.00	0.023*
Mean±S.D.	2.71±0.457	2.94±0.433		

S.D, standard deviation; U, Mann–Whitney test.

Table 3 Comparison between total knee arthroplasty with and without a pneumatic tourniquet with regard to the patient's blood loss

Blood loss	Pneumatic Tourniquet		U	*P* value
	Without *N* (%)	With *N* (%)		
Intraoperative (ml)				
Range	200–500	50–150	0.00	<0.001*
Mean±S.D.	322.86±86.003	94.37±28.577		
Postoperative (ml)				
Range	400–650	500–1000	247.50	<0.001*
Mean±SD	514.29±75.131	693.75±133.538		
P value	<0.001*	<0.001*		
Perioperative (ml)				
Range	600–1050	580–1100	810.00	0.107
Mean±SD	837.14±135.813	791.25±150.865		
Blood loss per kg (ml/kg)				
Range	8.5–11.4	8.5–15.3	765.00	0.048*
Mean±SD	10.06±0.778	10.08±1.604		
Need for blood transfusion				
No	39 (92.9)	44 (91.7)	–	1.000
Yes (500 ml^3)	3 (7.1)	4 (8.3)		

S.D, standard deviation; *U*, Mann–Whitney test.

Table 4 Comparison between total knee arthroplasty with and without a pneumatic tourniquet with regard to the patient's postoperative knee pain visual analog scale

Postoperative knee pain (VAS) (/10)	Pneumatic Tourniquet		U	*P* value
	Without	With		
Range	3–5	3–6	508.50	<0.001*
Mean±SD	3.71±0.805	4.56±0.873		

S.D, Standard Deviation; *U*, Mann–Whitney test; VAS, visual analog scale.

group. In terms of the need for a blood transfusion, there was no statistically significant difference between the two groups, as indicated by the numerical value *P*=1.000.

Regarding postoperative pain those who received a tourniquet showed a statistically significant difference, where patients without a tourniquet experienced less postoperative knee pain (VAS) than patients in whom the tourniquet was used (*P*<0.001).

Limb circumference changes after 48 h in patients without a tourniquet ranged between 2 and 5% with a mean value of 4.36±0.983 more than preoperative measurements, while in patients with a tourniquet, they ranged between 5 and 10% with a mean value of 7.81±1.525. When comparing patients with or without tourniquets, there were highly statistically significant differences, with a *P* value of less than 0.001. Table 5: Comparison between TKA with and without a pneumatic tourniquet with regard to the patient's limb circumference change after 48 h.

The 6M walking test in patients without a tourniquet ranged between 250 and 400m with a mean value of 322.14±37.711 m while in patients with a tourniquet, it ranged between 250 and 380 m with a mean value of 313.75±40.404m. When comparing patients who had or did not get a tourniquet, no statistically significant difference was found (*P*=0.324). Table 6: Comparison between TKA with and without a pneumatic tourniquet with regard to the patient's 6M walking.

Discussion

The most significant finding of this study was that the use of a pneumatic tourniquet during TKA resulted in a significant reduction in the operative time, but it was associated with a significantly longer hospital stay compared with the group without a tourniquet. Moreover, patients with a tourniquet had significantly less intraoperative bleeding and higher postoperative blood loss than those without a tourniquet. There was no difference between both groups as regards the overall perioperative blood loss, hemoglobin level, hematocrit value, or the need for blood transfusion.

Table 5 Comparison between total knee arthroplasty with and without a pneumatic tourniquet with regard to the Limb circumference change

Limb circumference changes after 48 h (cm)	Pneumatic Tourniquet		*P* value
	Without	With	
Range	2–5	5–10	<0.001*
Mean±SD	4.36±0.983	7.81±1.525	

S.D, Standard Deviation.

Table 6 Comparison between total knee arthroplasty with and without a pneumatic tourniquet with regard to the 6M walking test

6M walking test (m)	Pneumatic Tourniquet		U	*P* value
	Without	With		
Range	250–400	250–380	891.00	0.324
Mean±SD	322.14±37.711	313.75±40.404		

S.D, Standard Deviation; *U*, Mann–Whitney test.

In agreement with the current study Lai *et al.* evaluated the impacts of tourniquet use in TKA. The study enrolled 14 patients in each group, and both groups were well matched with regard to baseline data. The study revealed that the tourniquet group had significantly shorter surgical times and a longer hospital stay compared with the nontourniquet group [13].

Additionally, a meta-analysis conducted by Zhang and colleagues comprised 13 randomized controlled trials involving 689 patients and 689 knees. The results showed that TKA with a tourniquet reduced operation time in comparison to TKA without a tourniquet (*P* < . 0.01) [14].

He *et al.*'s meta-analysis, which drew from eight randomized controlled trials including 484 patients, did not find a statistically significant difference in operating time between the groups that used and did not use tourniquets [15].

Regarding pre- and postoperative hemoglobin levels, the current study showed that the hemoglobin level significantly decreased postoperatively in both groups. There were no statistically significant differences between patients with or without a tourniquet. Also, regarding pre- and postoperative hematocrit levels, the current study showed that the hematocrit level was significantly decreased postoperatively in both groups. Both the tourniquet- and nontourniquet-wearing patients showed no statistically significant difference.

This agrees with the findings of Alzahrani *et al.*, who studied 276 patients to determine the effect of a tourniquet on total loss of blood after TKA; the study

found that there was a statistically significant decrease in hemoglobin level in both groups. Regarding pre- and postoperative hemoglobin levels, there were no statistically significant changes between patients with and without tourniquets [16].

On the other hand, a meta-analysis by Magan *et al.* showed that the hemoglobin drop (0.33, 95% CI =0.12–0.54, *P* =0.002) was higher in the tourniquet group than in the nontourniquet group [17].

There were no statistically significant differences between the groups when it came to perioperative loss of blood and the need for transfusion of blood. However, the tourniquet group did have significantly lower intraoperative blood loss and significantly higher postoperative loss of blood and blood loss/kg.

Arshad *et al.* reported that the mean blood loss of patients who had TKA under a tourniquet was 307.33±36.03 ml, while in patients without a tourniquet, it was 425.67±21.04 ml. Statistically, the difference between the two groups is significant ($P<0.05$) [18].

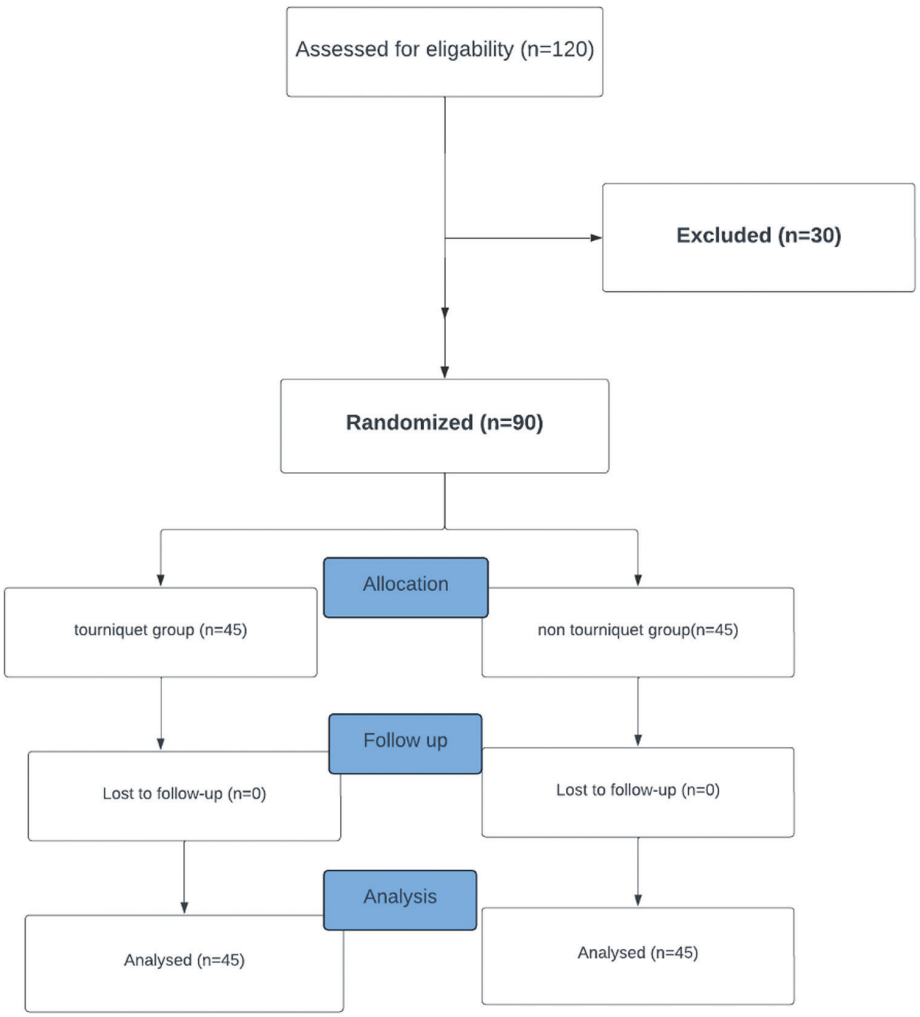
The current study also agreed with Alzahrani *et al.*, who revealed that there was no significant difference between the studied groups as regard the need for blood transfusion [16].

The use of a pneumatic tourniquet was linked to a considerably higher score for postoperative knee discomfort when comparing TKA procedures with and without one.

The current study's findings are in line with those of Kumar *et al.*, who found that tourniquet use was linked to noticeably higher postoperative VAS pain scores on the first, second, and third postoperative days. However, at the 2nd and 6-weeks postoperative, no statistically significant difference was seen [11].

Regarding limb circumference changes after 48 h, the current study showed that the use of a tourniquet leads

Figure 1



Flow diagram of the study.

to a higher limb circumference compared with not using a tourniquet.

In agreement with our results, Lai *et al.* showed that the nontourniquet group showed less thigh swelling on postoperative days 2 and 3 (P<0.05) [13].

The present study showed that not using a tourniquet in TKA results in a better functional outcome assessed by 6M walking but without statistical significance.

After 6 months of follow-up, patients who had TKA without a tourniquet completed the stair climb 14.6 s faster than those who had a tourniquet (17.4 s) placed [19]. A 5.5 s improvement on the stair climb test is considered a minimally clinically meaningful difference, which was once again not met [20].

Strengths and limitations

One strength of this study was that it used the same operating rooms and doctors. A single-center study with a brief follow-up time and a small sample size were the limitations of the current investigation. It is necessary to conduct additional comparison studies with a larger sample size and a longer follow-up period to validate our findings and determine the elements that contribute to poor outcomes.

Conclusion

In conclusion, the current study showed that the use of a tourniquet was associated with higher postoperative blood loss, postoperative knee pain, lower limb swelling, and consequently a prolonged hospital stay, but it took a shorter operative time and was associated with lower intraoperative blood loss. Not using a tourniquet seems to be associated with a better functional outcome, but without statistical significance, Fig. 1.

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Nil.

Conflicts of interest

There are no conflicts of interest.

List of abbreviations

OA, Osteoarthritis
SD, Standard Deviation
TKA, Total Knee Arthroplasty
U, Mann–Whitney test
VAS, visual analog scale

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