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Primary Knee

Optimized Tourniquet Use in Primary Total Knee Arthroplasty: A Comparative, Prospective, and Randomized Study



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ABSTRACT

Background: The results of recent studies investigating tourniquet (TNQ) use for knee arthroplasty are controversial. Therefore, this study aimed to compare patients undergoing total knee arthroplasty who did not have a TNQ to those in whom an optimized TNQ protocol was applied.

Methods: We prospectively evaluated 127 patients who had knee osteoarthritis who had undergone total knee arthroplasty and randomized them into two groups: “without TNQ” and “optimized TNQ” (TNQ inflation before skin incision, deflation after cementing, with pressure one hundred millimeters of mercury above the systolic blood pressure, and without articular suction drain usage). The means of surgery and TNQ duration, blood loss, number of blood transfusions, degree of pain, edema, range of motion (ROM), functional score over time, and postoperative complications were compared between the groups. Statistical significance was set at $P < .05$.

Results: No significant differences were found in terms of surgical timing, blood loss, thigh and knee pain, edema, ROM, functional scores, and complications between the “without TNQ” and “optimized TNQ” groups.

Conclusion: The use of an optimized TNQ in primary total knee arthroplasty presents similar clinical results to surgery without a TNQ and did not increase the incidence of postoperative complications. Its use allowed surgery to occur with the benefits of a clean and dry surgical field provided by TNQ without increasing procedure-related comorbidities.

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Despite the advantages of using a tourniquet (TNQ) to keep the limb free of blood flow to reduce intraoperative bleeding during total knee arthroplasty (TKA), studies have indicated that postoperative bleeding is similar to or greater than the total bleeding observed in patients operated on who do not have a TNQ [1–7]. Moreover, TNQ use may have detrimental effects on knee function in some cases, leading to more pain and complications; thus, use should be reconsidered [1,4,8,9]. On the other hand, some studies have also shown similar levels of pain and function with no differences in terms of the major complications irrespective of TNQ use [10–15].

The adverse effects related to TNQ use are related to its time and insufflation pressures. In addition, maintenance of TNQ until the end of TKA affects the assessment of hemostasis before wound closure, which, combined with the use of joint aspiration for suction drains, may result in increased postoperative bleeding [16–18].

The contradictory data in studies regarding TNQ use may be related to analytical biases [11,19–21]. Hence, we standardized the protocol of TNQ use in TKAs; in this procedure, a TNQ inflation of 100 millimeters of mercury (mmHg) above the systolic blood pressure was undertaken immediately before skin incision, with deflation being performed soon after cementation of the implants, without using a postoperative articular suction drain.

Thus, in this study, we aimed to compare the results of TKAs performed with optimized TNQ versus no TNQ use. Our primary hypothesis was that an optimized TNQ protocol in primary TKAs would result in similar or less bleeding without compromising functional recovery or increasing complications, compared to surgery without TNQ.

Materials and Methods

Patients and Surgical Procedure

A prospective randomized study was conducted at our institution between September 1st, 2019, and February 28th, 2021. The study protocol followed the recommendations of the Declaration of Helsinki and was approved by the institutional ethics board (#21118119.4.000.5273). The protocol was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (#RBR-7hcnst).

Patients aged 55 to 85 years old who had knee osteoarthritis (Kellgren and Lawrence III–IV) [22] and had undergone primary cemented TKA were enrolled in this study. Patients who had contraindications for tranexamic acid (TXA) use (such as presence of chronic heart disease, cardiac arrhythmia, deep venous thrombosis, or previous pulmonary thromboembolism), coagulopathies, regular use of oral anticoagulants, radiographic evidence of calcification of the distal superficial femoral artery, or a history of peripheral vascular disease were excluded.

Four surgeons each with more than ten years of experience in TKA performed surgeries using the same surgical technique. Randomization was performed in blocks of four brown envelopes; two each allocated to the "without TNQ" and "optimized TNQ" groups after every cycle of four surgeries. The envelopes were drawn immediately after anesthesia.

All patients underwent TKA with cemented posterior-stabilized prostheses (Legion Total Knee System, Smith and Nephew Memphis) without patellar resurfacing via the medial parapatellar approach.

TKA in the optimized TNQ group was performed under ischemia with a standard size (10 × 110 cm) pneumatic Stryker Color Dual Port cuff (Kalamazoo), inflated to a pressure 100 mmHg higher than the patient's systolic blood pressure, after exsanguination of the limb with a crepe bandage and just prior to skin incision. The TNQ was deflated as soon as the prosthesis was fixed to the bone with cement. TKA in the group without TNQ was performed without pneumatic ischemia, although the pneumatic cuff was positioned at the proximal region of the thigh without inflation.

All patients in both groups received 1 gram of TXA (Transamin, Zydus Nikkho Farmacêutica Ltd), intravenously prior to anesthetic induction, and another 750 milligrams diluted in 15 mL saline solution was applied to the surgical wound after cement drying. In the optimized TNQ group, the TNQ was deflated immediately after TXA application. After 5 minutes of TXA application, a hemostasis assessment was performed. All patients received deep venous thromboses prophylaxis with 40 milligrams of enoxaparin (Clexane, Sanofi-Aventis Farmacêutica Ltd) administered subcutaneously for 14 days starting 12 hours after the procedure.

All patients underwent the same anesthetic protocol comprising spinal, femoral, and sciatic nerve block. The postoperative protocol included simple analgesics and weak opioids for the first seven

days. The rehabilitation protocol mentioned in the institute exercise booklet was followed, and all patients were referred for physiotherapy following outpatient evaluation three weeks after surgery.

Parameters

Information on sex, age (years), weight (kilograms), height (meters), duration of surgery, and TNQ time (from the moment it was inflated until it was deflated, in minutes) was collected (if applicable).

Blood loss (mL) at 24 and 72 hours was calculated using the following formula.

Blood loss = blood volume [14] × hemoglobin (Hb) lost (24 and 72 hours)/preoperative Hb.

Hemoglobin loss at 24 and 72 hours was determined using the following formula.

Hb loss = {hospitalization Hb – postoperative Hb (24 and 72 hours)} + transfused Hb (1 gram/dL for each bag of packed red cells).

The number of patients who required allogeneic blood transfusions during hospital stay and the number of blood component units received by each patient in both groups were registered.

Pain in the knee and thigh was recorded using a visual analog scale (VAS), with scores ranging from zero (no pain) to ten (most intense pain), during the immediate preoperative period, on the first and third days, in the third week, and in the third and sixth months.

Lower limb circumference was measured 10 centimeters above and at the midpoint of the patella, 20 centimeters proximal to the medial malleolus in the preoperative period, on day 3, and in the third postoperative week using a measuring tape to infer the degree of edema according to the difference in the perimeter between the evaluations in each segment.

The active knee range of motion (ROM) was measured with the patient in the supine position, using a standard goniometer placed on the lateral side of the limb, centered on the knee joint line in the immediate preoperative period, on the first and third days, in the third week, and in the third and sixth months after surgery.

Function was evaluated using the Portuguese version of the Knee Society Score (KSS) [23] and by straight-leg-raise (SLR) as follows: in the immediate preoperative period (KSS and SLR), on the first and third postoperative days (SLR), in the third week (KSS and SLR), and in the third and sixth months of the postoperative period (KSS).

Complications were defined as any event that could alter the ordinary course of the postoperative period and required surgical intervention or acceptance of functional loss by the patient. Particular attention was paid to surgical wound complications, deep venous thromboses, as well as superficial or deep infections.

Postoperative evaluations were performed by an evaluator blinded to group allocation.

A consolidated standard of reporting trial diagram showing the recruitment, randomization, group allocation, and analyses is presented in [Figure 1](#).

Data Analyses

A sample calculation was performed to determine the sample size required to observe significant differences in bleeding between operated knees, considering a substantial difference of 50 mL between the groups, with 80% power and statistical significance of 0.05. This would have required the evaluation of 76 patients. Relative to the functional recovery/patient-reported outcome measures, power analysis (pre hoc) considering an effect size of 0.5,

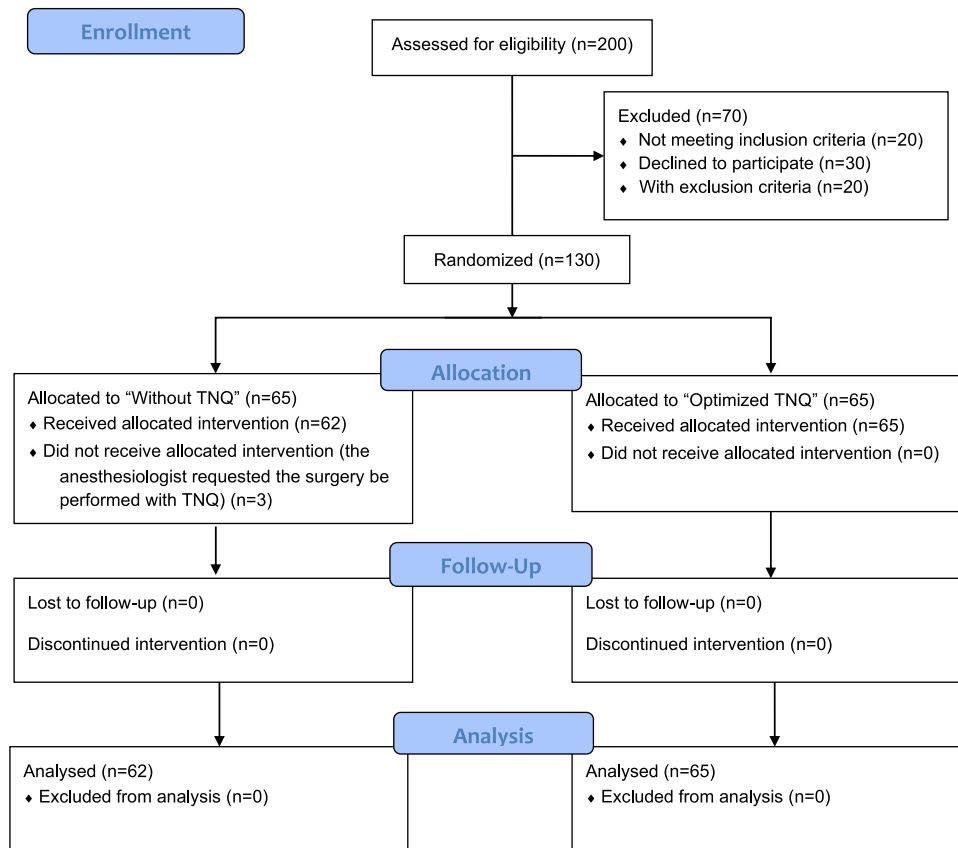


Fig. 1. CONSORT (consolidated standard of reporting trials) diagram. TKA = total knee arthroplasty; TNQ = tourniquet.

and a total sample size of 84 patients was required to detect significant differences with a statistical power >0.8 .

Numerical data were presented as the means $\pm$ standard deviations, and categorical variables were expressed as percentages. Differences in continuous variables between groups were evaluated using Student's *t*-tests or Mann–Whitney *U* tests, depending on the characteristic distribution of the data. *Chi*-square or Fisher's exact tests for percentages were applied to estimate the differences in categorical variables between the groups. Analyses were performed using GraphPad Prism (version 5) and statistical significance was considered when the *P*-value was less than 0.05.

Patient Characteristics

Patients in the treatment and control groups had similar baseline characteristics, including sex, age, weight, height, body mass index, and blood volume. The duration of surgery was shorter in the TNQ group than that in the non-TNQ group; however, this difference was not significant (See Table 1).

Results

The results for analyzed clinical variables are shown in Table 2.

We observed an increase in blood loss between 24 and 72 hours after the end of surgery in both groups ($P < .0001$) but with no difference between the groups (24 hours: $P = .59$; 72 hours: $P = .96$). The number of transfusions was lower in the optimized TNQ group than in the group without TNQ; however, this did not reach significance (0 versus 4, $P = .11$). Changes in the level of tightness, knee pain (measured by VAS), and lower limb edema were observed over time in both groups ($P < .0001$) but the difference between them was insignificant ($P > .05$). Mean ROM changed in both groups over time ($P < .0001$), with a lower ROM in the group without TNQ after three weeks of surgery ($P < .0002$); however, no difference was noted in other evaluations ($P > .05$).

The KSS functional and knee scores changed over time in both groups ($P < .0001$); however, no significant differences were observed between the groups ($P > .05$). A similar percentage of patients in both groups could perform the SLR in all assessments ($P > .05$).

Table 1
Characteristics of the Patients Included in the Study.

Characteristics	Optimized TNQ (Mean [Range])	Without TNQ (Mean [Range])	<i>P</i> Value
Mean weight in Kg	83.6 (58–116.5)	83.2 (58–131)	.87
Mean height in m	1.6 (1.39–1.89)	1.6 (1.35–1.82)	.65
Mean blood volume in L	4.5 (3.19–6.3)	4.5 (3.0–7.0)	.92
Mean surgery time in min	107 (72–220)	108 (61–170)	.57
Mean TNQ time in min	74 (45–127)	NA	NA
Mean TNQ pressure in mmHg	228 (190–300)	NA	NA

Kg, kilograms; m, meters; L, liters; min, minutes; mmHg, millimeters of mercury; NA, not applicable.

Table 2
Clinical Outcomes of Patients Undergoing Total Knee Replacement According to Group.

Analyzed Variables	Time Points	Optimized TTNQ	Without TNQ	P Value
Hb (g/dL)	Preop	12.9 ± 1.2	13.2 ± 1.5	.46
	POD 1	11.1 ± 1.5	11.1 ± 1.5	.98
	POD 3	10.2 ± 1.3	10.1 ± 1.2	.44
Blood loss (mL)	POD 1	630 ± 40	670 ± 40	.59
	POD 3	930 ± 54	930 ± 40	.96
Transfusion (Number of bags)	POD 1	0	4	.11 ^a
	POD 3	0	0	.99 ^a
VAS thigh	Preop	2.5 ± 3.1	2.6 ± 3.0	.89
	POD 1	2.3 ± 2.9	2.4 ± 1.8	.79
	POD 3	1.2 ± 2.0	1.1 ± 1.5	.70
VAS knee	3 Wk	1.2 ± 2.0	0.9 ± 1.6	.38
	Preop	8.3 ± 1.6	7.8 ± 2.0	.16
	POD 1	6.0 ± 3.0	5.9 ± 2.4	.94
	POD 3	3.0 ± 2.5	3.0 ± 2.0	.83
	3 Wk	3.5 ± 2.4	4.3 ± 2.0	.061
	3 Mo	3.0 ± 2.4	3.0 ± 1.9	.96
Thigh perimeter (cm)	6 Mo	2.2 ± 2.5	2.4 ± 2.3	.54
	Preop	48.2 ± 6.9	50.1 ± 6.9	.10
	POD 3	48.2 ± 6.9	53.6 ± 7.3	.18
Knee perimeter (cm)	3 Wk	50.3 ± 6.2	52.2 ± 6.8	.10
	Preop	43.1 ± 4.9	43.6 ± 5.5	.58
	POD 3	46.2 ± 4.7	47.0 ± 5.7	.42
Leg perimeter (cm)	3 Wk	45.7 ± 4.6	46.3 ± 5.4	.45
	Preop	36.0 ± 4.3	35.6 ± 4.8	.64
	POD 3	38.2 ± 4.4	37.8 ± 4.9	.66
ROM (degrees)	3 Wk	37.5 ± 4.3	37.0 ± 4.7	.54
	Preop	95 ± 17	95 ± 20	.89
	POD 3	56 ± 19	58 ± 1	.41
KSS Knee	3 Wk	86 ± 13	75 ± 20	.0002
	3 Mo	98 ± 14	93 ± 14	.077
	6 Mo	104 ± 4	101 ± 14	.17
	Preop	46 ± 13	47 ± 15	.55
	3 Wk	73 ± 16	71 ± 18	.62
	3 Mo	80 ± 15	82 ± 13	.48
KSS Function	6 Mo	86 ± 12	85 ± 10	.91
	Preop	39 ± 17	43 ± 19	.24
	3Wk	18 ± 19	13 ± 17	.20
	3 Mo	51 ± 16.1	52 ± 17	.61
SLR (%)	6 Mo	70 ± 23	66 ± 22	.40
	Preop	100	98.4	.48 ^a
	POD 1	43.1	43.6	.47 ^a
	POD 3	53.8	62.9	.85 ^a
	3 Wk	96.9	96.8	>.99 ^a
	3 Mo	100	100	>.99 ^a
	6 Mo	100	100	>.99 ^a

VAS, visual analog scale; cm, centimeters; ROM, range of motion; KSS, knee society score; SLR, straight-leg-raise; Preop, preoperative; POD 1, postoperative day 1; POD 3, postoperative day 3; Wk, week; Mo, month.

^a Fisher exact test.

The rate of complications was similar in both the groups. In the “without TNQ” group, 1 patient presented with deep venous thromboses, 1 had a stiff knee (manipulated under anesthesia), 1 presented with blisters, 1 had a hematoma (drained in the operating room), and 1 suffered from acute renal failure. In the “optimized TNQ” group, two patients presented with deep venous thromboses (one acute and the other subacute), 1 showed stiff knee (manipulated under anesthesia), 1 had a small area of skin necrosis (conservatively treated), and 1 presented with peroneal neuropraxia.

Discussion

Overall, this study demonstrated that the optimized TNQ protocol led to similar postoperative blood loss as surgery without TNQ, without compromising functional recovery or increasing complications, which agrees with our initial hypothesis. We did not observe any statistically significant differences in the surgical time between the optimized and without TNQ groups. This is in agreement with the results of some prior studies [3,11,14]; however, it

should be noted that other studies demonstrated a shorter operative time with a TNQ [1,2,4,14,19–21].

The average TNQ time and initiation of use varies widely among the published studies. Some applied the TNQ throughout the surgery [11,12,24], only during cementation [20], or until cementation of the implants [2]. Moreover, the insufflation pressure varied. Some studies used predetermined pressures of approximately 300 to 360 mmHg or 100 mmHg above the systolic blood pressure, while others did not control the pressure [1,4,12,14,24]. We believe that this variability in the different protocols for TNQ use explains the heterogeneity of the findings in the available literature. Indeed, 1 prior study demonstrated that TNQ optimization regarding the moment of use and insufflation pressures stimulated lower inflammatory responses to surgical trauma and lower degrees of muscle tissue injury in surgeries that used TNQ than in those who did not [24]. Pinsornsak et al [25] further concluded that lower TNQ pressures were associated with significantly less postoperative TNQ, surgical site pain, muscle damage, and wound complications. Another study confirmed that the use of suction drains, especially without revision of hemostasis after ischemia release, could

increase the rates of postoperative bleeding as bleeding is higher in the first five postoperative minutes during reperfusion [17]. Therefore, based on our results, we believe that TNQ in TKAs should be used at low pressures for a short period of time and released just before wound closure to allow visual inspection of hemostasis, without using a joint suction drain.

Our study did not identify any significant differences in blood loss or transfusion rates between the optimized TNQ and without TNQ groups, which agrees with the results of several previous studies [2,4]. However, in contrast, some studies have described lower blood loss with TNQ use [11,17,19,21,26,27], while a few have reported greater blood loss related to TNQ use [3,6,7]. The same inconsistency is observed when analyzing blood transfusion rates as some studies have shown greater [1,4], similar [3,17,27], or even lower [20] blood transfusion rates with TNQ use.

Zhao et al [6] compared TKAs without TNQ and with a TNQ that was kept inflated until the end of wound closure. They observed that the group without TNQ showed lower total blood loss, postoperative inflammatory reaction, muscle damage, VAS pain score, and better early knee function, which suggests that a TNQ should not be applied in TKAs. Huang et al [7] further observed more bleeding with TNQ use; however, in addition to using TNQ from the beginning of the surgery until the end of wound closure, patients allocated to the TNQ group were also implanted with a suction drain that was maintained for 48 hours. In another study by Liu et al, the TNQ was used at 300 mmHg over systolic blood pressure in a standard protocol, and similar results were observed [1].

In our study, no significant differences were found for pain, swelling, ROM, and function between the optimized TNQ and without TNQ groups. However, some studies have described higher levels of pain related to the use of TNQ [1,4,7,20], while others have demonstrated no differences in postoperative pain throughout the follow-up period [2,11,14,24,26]. Although a greater degree of edema and less postoperative ROM have been reported [4,20], in agreement with our results, several studies have not identified any differences in postoperative edema [1,2,17,26] or ROM [1–3,17,24,26] between the groups, except for an increased ROM in the TNQ group at 3 weeks postoperatively.

We did not identify any differences in knee and functional KSS scores between the groups, which agrees with previous studies [1,3,4,11–13,17,24,27]. The same percentage of patients in both groups was able to perform SLR in all assessments in our study. We further speculate that optimized TNQ use avoids the inhibition of active quadriceps contraction that was observed in some studies [4,20].

Our results corroborate the findings of many studies that failed to show a positive correlation between TKA complications and TNQ use [10–15,27], in opposition to 1 recently published systematic review [8], which did not perform any analysis of the TNQ protocols in the included studies, probably due to their heterogeneity.

The strength of our study is the prospective and randomized nature of the investigation, the large sample size, and the number of variables studied. In this study, we attempted to analyze all the possible advantages and disadvantages of TKA and TNQ use. We further propose an optimized protocol combined with the benefits of a blood-free surgical field provided by TNQ use at low inflation pressures for a shorter time and with minimal adverse effects.

Our study has several limitations that should be mentioned. Surgeries were performed by more than 1 surgeon, and they were not blinded to the TNQ protocol. Also, we excluded a large number of patients from the study and only followed-up the included participants for a short time. In addition, the absence of a third group with traditional use of the TNQ could be considered a limitation; however, we were unable to determine a pattern that could be adopted because of the differences in the protocols used in past studies.

Conclusion

Patients undergoing TKAs with TNQ according to the optimized protocol showed a similar blood loss with no functional impairment or complications compared to that in those undergoing surgery without TNQ. Its use allows surgery to occur with the benefits of a clean and dry surgical field provided by TNQ without increasing procedure-related comorbidities.

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