

Original research

Comparing Sequential vs Simultaneous Tourniquet Inflation in Bilateral Total Knee Arthroplasty

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ABSTRACT

Background: There is little evidence on outcomes of tourniquet use during bilateral total knee arthroplasty (BTKA). Tourniquet use in BTKA affects postoperative outcomes and efficiency inside the operating room. This study evaluates the safety and efficacy of simultaneous tourniquet inflation in BTKA.

Materials and Methods: A retrospective review was performed on BTKA patients between March 2013 and May 2018. A total of 285 patients were divided into 2 cohorts. Patients in the simultaneous cohort had concomitant elevation of both tourniquets, but the sequential cohort did not. Perioperative variables were collected, and postoperative complications were tracked for a minimum of 90 days. Patients followed a uniform postoperative protocol. Complications were grouped by category to increase statistical power and compared using a noninferiority test. "Clinically noninferior" was defined as a margin $\leq 5\%$. **Results:** The simultaneous cohort had significantly ($P < .05$) higher American Society of Anesthesiologists class and smokers. Tourniquet time, delta hemoglobin, and surgical time were significantly lower. For the complication categories of "Any Thrombotic Event", "Respiratory", and "Soft Tissue/Wound", the difference in occurrence rates was no more than 2.8%, 2.8%, and 5.2% between cohorts, respectively. The "Cardiovascular (non-MI)" group was no more than 9.3% different, that is, authors are 95% confident that 3 of 4 complication categories meet the clinically noninferior threshold.

Conclusion: The study demonstrates the noninferiority of simultaneous as compared to sequential tourniquet inflation in BTKA. Patients with cardiac history may need sequential inflation or staged TKA. The information presented in the study assists surgeons in safely and efficiently performing BTKA.

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Introduction

Total knee arthroplasty (TKA) continues to be one of the most common surgeries performed in the United States of America (USA) with a projected demand of 3.48 million procedures by 2030 [1]. This projection includes a concomitant increase for bilateral total knee arthroplasty (BTKA), with bilateral procedures accounting for approximately 6% of TKA cases performed annually in the USA [2–4].

Performing BTKA is highly risky. Meehan et al. [3] identified an increased risk of adverse cardiovascular outcome within 30 days

postoperatively. Springer and Odum also noted similar findings. In their study population, the overall complication rate for unilateral TKA or BTKA was low, but the odds of in-hospital complications, including mortality, were higher in the BTKA group [5].

However, in the properly selected patient, benefits of BTKA include decreased cumulative hospital stays, a single anesthetic event, and decreased overall rehabilitation time [6]. Cost-utility analysis on the National Inpatient Sample found BTKA to be cost-effective with better outcomes, calculating a \$28,800 savings in the estimated mean cost for the average patient [7]. An area for further investigation in performing BTKA safely and efficiently is the manner in which tourniquets are used and managed.

Tourniquet use in TKA is common and has been demonstrated to decrease intraoperative blood loss and allow for increased surgical field visualization [8,9]. When compared to TKA where no

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tourniquet is used, current literature has shown functional and pain outcomes to be similar [8,10]. Dennis et al. [11] echoed these findings in a randomized prospective trial, adding that there is an early (<3 months) quadriceps strength advantage in tourniquet-less TKA with unknown clinical significance. There is evidence both for and against the position that tourniquet use improves implant fixation to bone. Pftizner et al. [12] and Touzopoulos et al. [13] both showed a significant increase in tibial cement thickness using a tourniquet. The clinical significance of this, however, is unknown. Jawhar et al. [14] did not find a significant difference in bone cement penetration between tourniquet and tourniquet-less TKA. In summary, adequate evidence exists for surgeons to make an informed decision on tourniquet use in the unilateral TKA setting. However, this still leaves a gap in evidence for use and management of tourniquets in BTKA.

Considering the paucity of information regarding this subject in the current body of orthopedic literature, the authors wish to examine 2 different methods for managing tourniquets in BTKA. We hope to demonstrate noninferiority of having both tourniquets elevated simultaneously during a portion of the procedure, as compared to sequential elevation. The study will provide further evidence for surgeons to rely upon when deciding how to safely, but efficiently, manage both tourniquets during BTKA.

Material and Methods

After obtaining institutional review board approval, a retrospective analysis was conducted to identify all BTKAs performed by the senior author and an additional 4 arthroplasty fellowship-trained surgeons between March 2013 and May 2018. Surgeries were performed at 2 academic tertiary referral centers which perform high volumes of arthroplasty. Patient variables including demographics, perioperative details, tourniquet parameters, and postoperative complications including local, minor systemic, and major systemic complications were recorded for all patients. A minimum of 90-day postoperative follow-up was obtained. Individuals with pathology other than primary osteoarthritis were excluded. Patients undergoing revision surgery were excluded. Patients meeting these inclusion criteria, but with simultaneous tourniquet elevation of 5 minutes or less, were also excluded. The senior author used Zimmer Persona total knee components, the second surgeon used Biomet Vanguard, the third surgeon used Zimmer NexGen, and the fourth and fifth surgeon used Smith and Nephew Legion total knee components. Postoperatively, all patients were placed on 28 days of 81-mg aspirin daily for deep venous thrombosis prophylaxis unless medically indicated for stronger therapy. All patients were allowed to fully weight-bear after surgery and began working with physical therapy on the first postoperative day. Postoperative care before discharge was provided by adult reconstruction fellows, orthopedic residents, and dedicated orthopedic physician's assistants.

The surgical team consisted of an arthroplasty fellowship-trained attending surgeon, an arthroplasty fellow, and 2 physician assistants or a physician assistant and a junior resident. All BTKA surgeries were performed either "simultaneously" or "sequentially" under a single anesthetic session, predominantly spinal. Both knees were sterilely prepped and draped at the same time. Operating on either the right or left knee first was left to the patient's discretion. A standard midline incision and medial parapatellar approach was performed in all surgeries. Whether the attending or fellow began the procedure on either side or performed various parts of the procedure on either side was left up to the attending's discretion. The trainee involvement was that of a typical academic training center setting with residents and fellows participating in many

aspects of patient care, both surgical and clinical. Trainees were under direct supervision of the attending physician at all times.

Tourniquet use for the "simultaneous" cases was as follows, an Esmarch bandage was used to exsanguinate the first extremity to be operated on. The knee was then flexed, and the tourniquet was elevated to 250 mmHg. The tourniquet was deflated only once the incision was fully closed and dressings were applied. Tourniquet application and inflation was also performed independently in the contralateral and subsequent knee. Meaning, as soon as the implants in the first knee were cemented into place and the patient remained stable, the procedure for the second knee was begun in the aforementioned manner. The initial portions of the procedure on the subsequent knee were performed while the first knee was irrigated, closed, and dressings applied. During this time, both tourniquets are inflated. After application of dressings on the first knee, the first tourniquet is deflated. Everyone in the surgical team then assisted in finishing the second knee with only one tourniquet inflated. Once the second knee was closed and dressings applied, the remaining tourniquet was deflated. In these cases, there was a period of time in which both tourniquets were inflated at once.

Tourniquet use for the "sequential" cases differed in that the first knee was performed from start to finish (incision fully closed and dressings applied) without concurrent operating on the second knee. The second tourniquet was not inflated until the first knee was closed, dressings on, and tourniquet deflated. In these cases, there was no period of time when both tourniquets were inflated at once. [Figure 1](#) shows a simple visual representation of each protocol.

The preference of the surgeons in this study was to perform BTKA using the "simultaneous" protocol. At one of the 2 academic centers in this study, institutional policies dictated that no BTKA could be performed with concomitant elevation of tourniquets and no BTKA could be performed in patient's older than 75 years and with a body mass index (BMI) higher than 40. With the exception of patients older than 75 years and with a BMI higher than 40, patient's chose which institution to have surgery at based on personal preference and proximity to their residence. Selection for each cohort occurred in this manner. There was no patient selection bias on behalf of the surgeon as a result of this.

Postoperative complications were recorded and grouped into 4 categories. The "Any Thrombotic Event" group included any occurrence of deep vein thrombosis or pulmonary embolism. The "Cardiovascular (non-MI)" group included transfusions, episodes of hypotension or hypertension, and episodes of cardiac arrhythmias such as atrial fibrillation or supraventricular tachycardia and any new cardiac diagnosis found postoperatively, such as congestive heart failure. "Respiratory" group included pulmonary edema, pleural effusion, and pulmonary compromise. Pulmonary compromise was defined as any oxygen desaturation, pneumothorax, or pneumonia. The "Soft Tissue/Wound" group included occurrence of hematoma or seroma, delayed wound healing, nonhealing wound, wound dehiscence, peripheral vascular injury, cellulitis, and acute postoperative infection.

The simultaneous and sequential cohorts were compared to one another in each of the 4 grouped variable categories using a noninferiority test. Complications were grouped by category to increase statistical power, and 2-sided 95% confidence interval (CI) for the difference in event rates was constructed. "Clinically non-inferior" was defined heuristically as an occurrence margin $\leq 5\%$. No adjustment for multiplicity was done. Patient and perioperative variables such as estimated blood loss, operative time, and so on were analyzed using Chi-Square, *T*-Tests, or Mann-Whitney *U* tests. All statistics were calculated using SAS 9.4 (SAS Institute, Cary, NC).

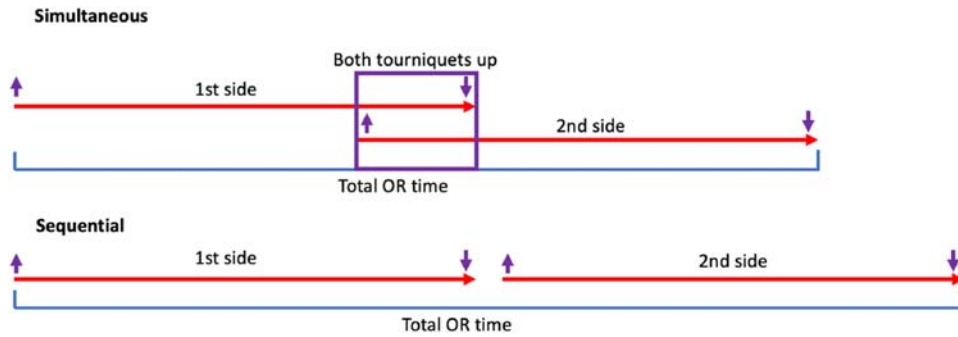


Figure 1. Timeline representation for tourniquet management in each cohort.

Results

A total of 285 patients were included in the study. There were 106 in the sequential cohort and 179 in the simultaneous cohort. There were a majority of females in each cohort: 73 females and 33 males in the sequential cohort, and 111 and 68, respectively, in the simultaneous cohort ($P = .242$). A total of 17 patients who originally met the inclusion criteria for the simultaneous cohort were excluded because of having 5 minutes or less of simultaneous tourniquet elevation. In the study period, the senior author performed 187 procedures, the second surgeon performed 56, the third surgeon performed 2, the fourth surgeon performed 25, and the fifth surgeon performed 15 procedures. Of the 285 patients in the study, 260 were performed under spinal anesthetic, 15 were performed under general anesthetic, and 8 were performed with both spinal and general. There were 2 patients without accessible documentation of anesthesia type.

The simultaneous cohort was larger by 73 patients. The mean age was 63.5 years and 65.3 years for the sequential and simultaneous cohorts, respectively, and this difference was not significant ($P = .080$). The BMI was 0.8 points higher in the simultaneous cohort and not significant ($P = .242$). There were 116 American Society of Anesthesiologists (ASA) III patients in the simultaneous cohort as compared to 31 in the sequential cohort, and this difference was significant ($P \leq .001$). There were also significantly more patients with current or previous smoking status in the simultaneous group, 81 patients as compared to 35 patients ($P = .041$). There was a greater number of patients with cardiac history in the simultaneous cohort, 32 as compared to 16 patients, but this was

not significant ($P = .544$). There were 29 patients with diabetes in the simultaneous cohort, and 14 patients with diabetes in the sequential cohort; this was not significant ($P = .495$; Table 1).

The mean tourniquet time in the simultaneous cohort was 135.8 minutes, as compared to 153.8 minutes for the sequential cohort ($P < .001$). The mean change in hemoglobin from preoperative to postoperative time period in the simultaneous cohort was 2.8 g/dL, while the mean change in the sequential cohort was 3.2 g/dL ($P = .004$). Total surgical time was improved in the simultaneous cohort at a mean of 158.4 minutes as compared to 141.5 minutes in the sequential cohort ($P < .001$). While hemoglobin change was significant, there was no significant difference in postoperative transfusion incidence in between cohorts. Length of stay was not significantly different between cohorts (Table 2).

In the “Any Thrombotic Event” category, statistical analysis revealed there to be a difference of no worse than 2.8% between cohorts with 95% confidence. There were 5 occurrences in each cohort. In the “Respiratory” category, statistical analysis revealed there to be a difference of no worse than 2.8% between cohorts with 95% confidence. There were 6 occurrences in each cohort. In the “Soft tissue/Wound” category, statistical analysis revealed there to be a difference of no worse than 5.2% between cohorts with 95% confidence. There were 2 occurrences in the sequential cohort and 7 occurrences in the simultaneous cohort. In the “Cardiovascular (non-MI)” category, noninferiority analysis revealed there to be a difference of no worse than 9.3% between cohorts with 95% confidence. There were 2 occurrences in the sequential cohort, and 14 occurrences in the simultaneous cohort. Atrial fibrillation was identified postoperatively in 10 patients from the simultaneous

Table 1
Baseline cohort characteristics.

Variable	Staged tourniquet (N = 106)		Simultaneous tourniquet (N = 179)		P value
	Mean or count (SD or %)				
Age at surgery (y)	63.5 (7.6)		65.3 (8.7)		.080 ^a
Gender	73 (68.9%) Female 33 (31.1%) Male		111 (62.0%) Female 68 (38.0%) Male		.242 ^b
BMI (Kg/M ²)	31.4 (5.0)		32.2 (5.6)		.242 ^a
ASA score	I	2 (1.9%)	I	1 (0.6%)	<.001 ^b
	II	72 (68.6%)	II	61 (34.1%)	
	III	31 (29.5%)	III	116 (64.8%)	
	IV	0 (0.0%)	IV	1 (0.6%)	
Smoking status	Never	71 (67.0%)	Never	97 (54.5%)	.041 ^b
	Ex-smoker	33 (31.1%)	Ex-smoker	68 (38.2%)	
	Smoker	2 (1.9%)	Smoker	13 (7.3%)	
Cardiac history (positive)	16 (15.1%)		32 (17.9%)		.544 ^b
Diabetes (positive)	14 (13.2%)		29 (16.2%)		.495 ^b
Time since surgery (y)	4.0 (1.7)		4.0 (1.8)		.980 ^b

ASA, American Society of Anesthesiologists; BMI, body mass index; SD, standard deviation.

^a Independent Student's *T*-Test or Mann-Whitney *U* Test.

^b χ^2 Test.

Table 2
Surgical outcomes according to cohorts.

Outcomes	Staged tourniquet	Simultaneous tourniquet	P value
	Mean or count (SD or %)		
Tourniquet time (mins)	153.8 (32.9)	135.8 (24.9)	<.001 ^a
Packed red blood cell transfusion	14 (13.2%)	16 (8.9%)	.256 ^b
ΔHemoglobin (g/dL)	3.2 (1.2)	2.8 (1.0)	.004 ^a
Surgical time (mins)	158.4 (37.7)	141.5 (25.6)	<.001 ^a
Length of stay (d)	4.0 (1.9)	4.0 (2.2)	.812 ^a

^a Independent Student's *T*-Test or Mann-Whitney *U* Test.

^b χ^2 Test.

cohort. Of these patients, 8 had previous cardiac history such as atrial fibrillation, septal defects, or murmur. New-onset atrial fibrillation occurred in 2 patients from this cohort. The remaining 4 patients had postoperative hypertension in 3 instances and a nonsustained ventricular tachycardia in one instance. No cardiac complications identified postoperatively required invasive procedural intervention. There were no occurrences of myocardial infarction in either cohort (Table 3).

Figure 2 shows a graph of the 179 patients in the simultaneous cohort, demonstrating the frequency of amount of time (in minutes) both tourniquets were simultaneous elevated. The mean duration of simultaneous elevation was 44.36 minutes with a range of 6–125 minutes.

Discussion

The most important findings of this study are the demonstration of shorter operating room (OR) time and total time under tourniquet, as well as decreased postoperative hemoglobin drop with the simultaneous cohort. With respect to complications, the simultaneous cohort was found to be noninferior in most variable categories in the initial 90-day postoperative window. While outside of the 5% margin, the “Cardiovascular (non-MI)” group findings correlate with previous literature findings of patients undergoing BTKA regardless of tourniquet protocol [3,5]. The study was able to demonstrate what was described previously, despite the simultaneous cohort having a larger percentage of patients with more systemic illness.

As referenced in Table 1, the ASA class was higher in the simultaneous cohort with more than double the percentage of ASA class III patients (29.5% vs 66.3%). There were also significantly more smokers in the simultaneous cohort. Simultaneous tourniquets were associated with significantly shorter OR times (141.5 vs 158.4 minutes), overall time under tourniquet (135.8 vs 153.8 minutes), and a lower drop in hemoglobin (2.8 vs 3.2 g/dL). It was also able to demonstrate a difference of 5% or less, between the simultaneous and sequential cohorts, for 3 out of 4 postoperative complication variable groups. The last variable group, “Cardiovascular non-MI,” showed a greater occurrence at 9.3% in the simultaneous cohort than the 5% clinically noninferior margin.

It is important to note that the patients in the simultaneous cohort received care at an institution that is not only a high-volume arthroplasty center but also a high-volume cardiac surgery center. As part of their routine postoperative management, all patients are rhythm monitored on the floor. There is no increased postoperative monitoring at the center where the sequential cases were performed unless called for by the anesthesia care team because of intraoperative rhythm abnormalities or significant cardiac history. Thus, these non-MI cardiac events are likely identified at a higher rate in the simultaneous group, and as stated previously, none required invasive procedural intervention. Most events, 9 out of 14, were in patients with a previous cardiac history.

In performing power analyses for the patient numbers in this study and their ability to provide meaningful conclusions in an equivalence test for a specific singular variable, such as deep vein thrombosis, the authors found the study to be underpowered. The decision was made to group similar variables into larger categories and perform a noninferiority test. Given our chosen 5% clinically noninferior margin, the sample size was large enough to produce precise CIs containing the 5% margin, in most adverse event categories. Two categories (“Any Thrombotic Event” and “Respiratory”) showed a less than 3% difference between the 2 cohorts. One category showed a near 5% difference (“Soft Tissue/Wound”). The “Cardiovascular (non-MI)” category, however, showed a slight increase in difference between the 2 cohorts at 9.3%.

The noninferiority test is used to determine, with a 95% CI, the difference in occurrence between the 2 cohorts. This is different than an equivalence trial, in that the desired outcome is not that one method is no different than another but rather one method is not unacceptably worse than the other. If the lower bound of the CI does not extend past the margin, in either direction from zero, then the treatment method is considered noninferior [15]. In interpreting these data, one needs to decide for themselves if an equal or less than 5% difference in complication occurrence is worth the advantages discussed in the following parts. The percentage difference listed in the results represents an “at-worst” frequency of occurrence, not an average occurrence. The less than or equal to 5% margin was chosen as an acceptable difference based on consensus among the authors. Often times in noninferiority analysis, the margin is set by an expert panel opinion, or by statistical method.

Table 3
Noninferiority assessment of adverse events and complications.

Adverse events/complications	Staged tourniquet	Simultaneous tourniquet	Δ = (staged - simultaneous)	
	N (%)		P value ^a	Δ (95% Confidence intervals)
Any thrombotic event	5 (4.7%)	5 (2.6%)	.51	1.9% (−2.8%, 6.6%)
Cardiovascular non-myocardial infarction	2 (1.9%)	14 (7.1%)	.09	−4.8% (−9.3%, −0.3%)
Respiratory noninfectious	6 (5.7%)	6 (3.1%)	.37	2.3% (−2.8%, 7.4%)
Soft tissue/wound	2 (1.9%)	7 (3.6%)	.71	−1.5% (−5.2%, 2.2%)

^a Fisher's Exact test.

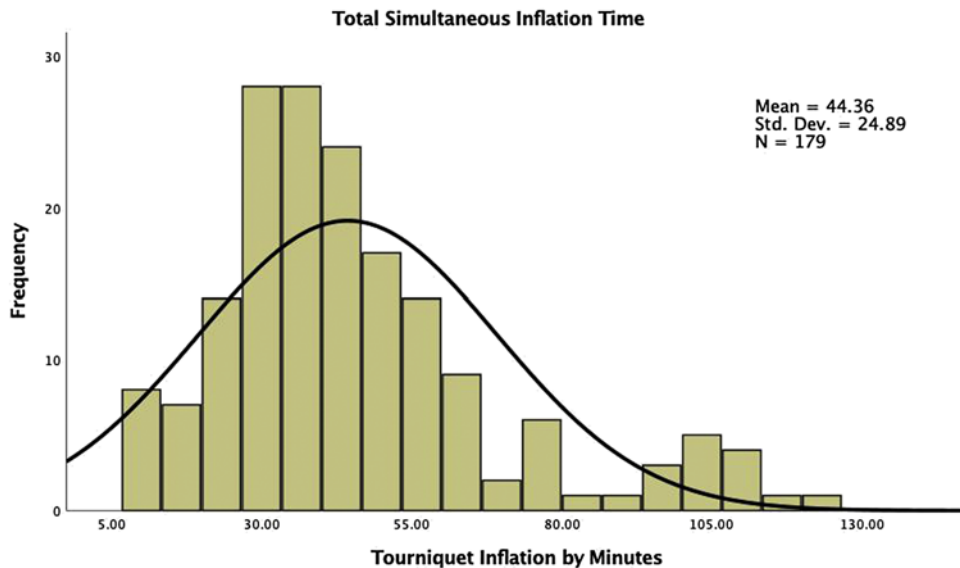


Figure 2. Graph representation of the distribution of total time (minutes) of simultaneous tourniquet elevation.

Over the last decade, orthopedics, specifically adult reconstruction, has been experiencing a transition into a system of compensation that places more emphasis on value and outcomes. As this model is likely to become more prevalent, it behooves surgeons to be critical of outcomes when trying to increase efficiency. The benefits from an efficiency standpoint are synergized not only when performing both TKA under the same spinal anesthetic but also when beginning the second knee tourniquet time while the first one is still elevated. In this manner, there is only one surgical episode, one recovery period, less time in the OR, and less time under anesthetic. All these represent increased cost savings and increased efficiency.

Tourniquet inflation, even on just one extremity at a time, is not without risk. In addition to an increased pain response, there are cardiovascular, respiratory, hematologic, and metabolic changes caused by tourniquet inflation [16]. Cardiovascular effects include an increase in circulating blood volume and systemic vascular resistance. As tourniquet time increases, as do heart rate and blood pressure. Those patients with a history of heart disease are not generally considered candidates for bilateral TKA; the data set presented in our study further supports that decision [17].

With this in mind, surgeons who wish to proceed with simultaneous tourniquet inflation may wish to avoid this technique or BTKA all together in those with a cardiac history. Or, if wishing to proceed with bilateral TKA, they may wish to do so in a sequential manner. If performing bilateral TKA in a simultaneous inflation manner, surgeons can confer with their anesthesia teams to be vigilant for non-MI cardiovascular abnormalities in the perioperative period.

Study limitations include a retrospective cohort design. The patient numbers did not allow for adequately powered independent statistical analysis for each postoperative variable. A 5% clinically noninferior margin was chosen as the watershed mark for this study, but further examination would be needed to demonstrate its clinical importance. In addition, the simultaneous cohort included patients who had both tourniquets elevated for as little as 6 minutes but also as great as 40 minutes. Those patients with 5 minutes of simultaneous elevation or less were excluded. The authors desired to avoid having patients with very little overlapped tourniquet times being able to positively skew the results in favor of the simultaneous cohort. In addition, the simultaneous cohort was analyzed as one because of power concerns. With increased patient numbers in future studies, time of simultaneous tourniquet

inflation could be investigated as a continuous variable in its relation to frequency of postoperative complication occurrence.

With these limitations in mind, this article is the first that we are aware of that critically examines the outcomes associated with simultaneous and sequential tourniquet elevation in BTKA. As previously noted, with a large predicted increase in BTKA volumes over the coming decade, this is an important area of research.

Additional areas for further study include characterization of physiologic response using tourniquets on both lower extremities simultaneously. The information presented here could lend itself to a cost analysis of saved operating room time vs any increased incidence and cost in cardiovascular complications. As mentioned previously, an investigation into the clinical significance of a 5% noninferior margin could be pursued. Complications and outcomes could be tracked with longer follow-up than the 90-day postoperative period examined in this study.

Conclusions

This study presents a multisurgeon and multicenter experience of BTKA using 2 different tourniquet protocols. Our noninferiority analysis shows a 5% or less difference in grouped postoperative complications, with the exception of the “Cardiovascular (non-MI)” group, which is increased at 9.3%. With similar postoperative outcomes, simultaneous tourniquet use with an experienced team can lead to more efficient surgery, meaning decreased operating room time, decreased blood loss, decreased time under anesthesia, and an increase in number of cases able to be performed per unit of time. Special attention should be paid to those patients with a cardiovascular history in the perioperative period.

Conflict of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

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