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Tourniquet Use During Cementation Only During Total Knee Arthroplasty: A Randomized Trial

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Abstract

Background Total knee arthroplasty with the use of a tourniquet during the entire operation has not been shown to improve the performance of the operation and may increase the risk of complications.

Questions/purposes We asked whether the limited use of a tourniquet for cementation only would affect (1) surgical time; (2) postoperative pain and motion of the knee; (3) blood loss; or (4) complications such as risk of nerve injuries, quadriceps dysfunction, and drainage compared with use of a tourniquet throughout the procedure.

Methods Seventy-one patients (79 knees) were randomized to either use of a tourniquet from the incision through cementation of the implants and deflated for closure (operative tourniquet group) or tourniquet use only during cementation (cementation tourniquet group). The initial study population was a minimum of 30 knees in each group as suggested for randomized studies by American Society for Testing and Materials standards; termination of the study was determined by power analysis performed after 40 knees in each group showed any statistical solution to our questions would require a minimum of 260 more cases. Patients were excluded who were considered in previous randomized studies as high risk for complications, which might be attributed to the tourniquet.

Results There were no differences in terms of surgical time, pain scores, pain medicine requirements, range of motion, hemoglobin change, or total blood loss. One major complication (compartmental syndrome) occurred in a patient with tourniquet inflation until closure. No other complications were attributed to the use of a tourniquet.

Conclusions With the numbers available, our results suggest that there are no important clinical differences between patients who had a tourniquet inflated throughout the procedure compared with those who had it inflated only during cementation. Tourniquet inflation for cementation only provides the benefit of bloodless bone for fixation and may eliminate the risks associated with prolonged tourniquet use.

Level of Evidence Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Introduction

The most prevalent reasons for tourniquet use during the entire operation of TKA are a bloodless wound and dry bone surfaces for better cement penetration [9]. Several

randomized controlled trials of tourniquet versus no tourniquet use during this operation have shown no statistical difference or even less total blood loss when no tourniquet is used [1, 2, 10, 12, 14, 15, 25–29] . Moreover, there are potential complications associated with tourniquet use: nerve palsy [8, 19], delayed recovery of muscle power from microscopic changes in muscle myofibrils [21], wound complications [1, 12, 25], and venous thrombotic embolism [1, 10, 12]. Deflation of the tourniquet can cause respiratory and cardiac complications in patients with poor cardiac function [7, 18].

There is a theoretical risk associated with avoidance of the tourniquet; namely, that the bone bed may have blood or fat on its surface and that this might compromise cementation. This raises the question of whether the potential benefits of tourniquet avoidance might be married with the benefits of a dry interface for cementing if the tourniquet is used only during cementation. To our knowledge, there are no studies in the literature comparing the use of the tourniquet during cementation only with tourniquet use during the entire operation. All previous randomized studies have compared no tourniquet use at all with tourniquet use during the operation [1, 2, 10, 11, 14, 15, 24–26].

We therefore conducted a randomized study to determine whether the limited use of a tourniquet for cementation only (compared with use of a tourniquet throughout the procedure) would affect (1) surgical time; (2) postoperative pain and motion of the knee; (3) blood loss; or (4) complications such as risk of nerve injuries, quadriceps dysfunction, and drainage.

Patients and Methods

Seventy-one patients (79 knees) undergoing TKA between December 2009 and December 2010 agreed to participate in a randomized study. Study approval was given by the institutional review board and the hospital ethical committee. Demographics of age, sex, diagnosis, and body mass index did not differ (Table 1). Randomization was blinded to the nurses on the inpatient unit, physical therapists, and the patient. Eight patients had bilateral knee arthroplasty with four of these having both knees operated on at the same operation and four having staged procedures; each of these knees was randomized for tourniquet use. Thirty-five patients (39 knees) had tourniquet inflation from the incision through cementation of the implants (operative tourniquet) and 36 patients (40 knees) had tourniquet inflation only during cementation of the implants (cementation tourniquet). The tourniquet was released in all patients at the completion of cementation of the patella and the knee held in extension with compression of the patella for the subsequent 10 minutes it took for cement to complete polymerization. Exclusion criteria were diabetes, rheumatoid arthritis, calcified vessels on radiograph, history of thromboembolism, active cancer, and angular deformity in any plane beyond 10° (20° flexion contracture increases neurological complications [8, 17]). These exclusions are accepted as high risk in previous randomized studies [1, 25, 26, 28]. It is common practice to not use a tourniquet in high-risk patients [13, 20].

The randomization was performed by a research fellow (ZW) who was not involved in patient care using Microsoft Excel software (Microsoft Inc, Redmond, WA, USA). In the operating room before surgery, the research fellow informed the surgeon to which group the patient belonged. All patients remained in their randomized group. Initially, a minimum of 30 patients/knees were to be included in each group as suggested by American Society for Testing and Materials standards for randomization. Power analysis was not possible at the initiation of the study because there were no other studies in the literature using the tourniquet during cementation only; also, only one study in the literature focuses on correlation of tourniquet time to nerve injury and that retrospective study reviewed nerve injuries that occurred only after 120 minutes of tourniquet time. When the data showed no differences after 40 knees in each group, a power analysis was performed, which indicated at least 260 patients more were needed to show any difference in blood loss between the two groups and 4000 more cases needed to show any difference in nerve injury. Therefore, this study was terminated because it did show that there was equivalence between the two groups of patients, which means those operated on using the tourniquet only during cementation were as safe as those with the tourniquet during the entire procedure through cementation.

All patients received the same anesthesia: epidural (1% ropivacaine and no narcotics in the epidural); intravenous infusion of propofol; nerve blocks of the femoral nerve with an indwelling catheter; and single-injection popliteal nerve block. The epidural catheter was discontinued in the recovery room. The femoral nerve catheter was continuous until the morning after the operation with 5 mL per hour of 0.2% ropivacaine with an automatic infusion pump (ON-Q pump; MPS Medical, Braunfels, Germany).

All operations were performed by the senior surgeons (LDD, WTL, PKG). The duration of surgery from the incision until the end of closure and the duration of tourniquet inflation were recorded from the anesthesia record. The limb was exsanguinated with an Esmarch wrap (Medline, Mundelein, IL, USA) before tourniquet inflation to 250 mmHg with a standard cuff tourniquet (Stryker, Kalamazoo, MI, USA). The operative tourniquet group was inflated before the skin incision and remained so until completion of cementation of the implants; in the

Table 1. Preoperative demographics

Demographic	Operative tourniquet group (n = 39) in 35 patients	Cementation tourniquet group (n = 40) in 36 patients	p value
Male:female	13:22	14:22	
Mean age (years) (range)	66.1 ± 9.8 (47–85)	64.6 ± 9.3 (43–84)	0.429
Mean ± SD pain score on visual analog scale	6.6 ± 2.5	6.5 ± 2.3	0.935
Diagnosis	Osteoarthritis = 39	Osteoarthritis = 39, posttraumatic = 1	
Mean ± SD body mass index (kg/m^2)	29.9 ± 5.3	31.4 ± 6.4	0.29

cementation tourniquet group, inflation was only during cementing of the components. The tourniquet was released in all patients at the completion of cementation of the patella and the knee held in extension with compression of the patella for the subsequent 10 minutes it took for cement to complete polymerization. A midline skin incision and trivector medial parapatellar approach was used in all patients [6]. One patient had a vastus medialis oblique splitting incision and was dropped from the study. Hemostasis during these operations was controlled by use of the electrocautery and no hemostatic agents were used in the wound. Tranexamic acid was given at the initiation of the surgery and just before closure [29]. The knee components were all cemented including a patellar component. The implants were the Natural knee flex system (Zimmer Inc, Warsaw, IN, USA) with posterior cruciate sacrifice and an ultracongruent highly crosslinked polyethylene insert. One gram of cefazolin (Pfizer, New York, NY, USA) was given intravenously after induction of anesthesia and every 8 hours for 24 hours. Vancomycin (Baxter, Deerfield, IL, USA), dose-titrated, was used in patients allergic to penicillin or cefazolin. At closure of the knee, all patients received an injection into the capsule and muscles of 15 mg Toradol (ketorolac; Baxter), 4 mg morphine (Hospira Inc, Lake Forest, IL, USA), and 10 mL 1% ropivacaine (Naropin; APP Pharmaceuticals LLC, Schaumburg, IL, USA) diluted with 40 mL normal saline [5]. All wounds were closed over a Hemovac drain (Evacuator; Medline, Mundelein, IL, USA), which was removed the next morning.

Fifty-eight of 72 patients donated 1 unit of blood 2 to 3 weeks before their operation with the intention of infusion back into the patient during the operation or immediately postoperatively. Therefore, transfusion data in these patients are of no scientific value. Blood loss was measured intraoperatively by anesthesia from the drainage collection and blood loss estimated on lap sponges and the volume collected from Hemovac drainage. Hematologic comparison was done by daily hemoglobin measurements during the first 3 postoperative days.

Prophylaxis for venous thrombotic embolism was 600 mg aspirin per rectum in the recovery room and a dose of 325 mg orally twice a day for 28 days [4]. In those patients who could not tolerate aspirin, 25 mg Persantine (DuPont, Billerica, MA, USA) was given three times daily. TED stockings (Lifespan, Rockwood, TN, USA) and calf sequential compression devices (ALP, Santa Ana, CA, USA) were applied in the recovery room. Deep venous thrombosis assessment was performed on postoperative Day 3 by Doppler ultrasound (Acuson Sequoia 512; Siemens, Mountain View, CA, USA).

The pain management protocol avoided routine use of parenteral narcotics [5]. Parenteral narcotics were used for breakthrough pain and the amount used was compared between patients with and without a tourniquet. The routine use of oral pain medication was calculated in equal analgesic milligrams of morphine and compared. The patient's pain was self-graded, and recorded by nurses, using the visual analog score at 6-hour intervals during 24 hours and a mean for the 24 hours was established.

Quadriceps function was compared on postoperative Days 2 and 3 by the use of the grading scale of 0 to 5 (0 is absent muscle and 5 is normal to resistance) [16]. The function was graded by two physical therapists (JO, DS) who were blinded to tourniquet use. The femoral nerve block affects the quadriceps, and it was not discontinued until the first postoperative day [22]. A knee immobilizer was used for all patients during ambulation on the first postoperative day for protection against a fall. ROM was measured by extension and flexion preoperatively; postoperatively on Days 1, 2, and 3; and at 3 and 6 weeks and compared between knees with and without tourniquet use for the entire operation.

Complications were graded major or minor. Major complications were defined as those which changed the outcome of the operation, required revision of the knee replacement, or were life- or limb-threatening. Minor complications are those that required additional treatment but did not threaten the patient's well-being or ultimate outcome of the operation. Closed manipulation is

considered minor because, although it requires reoperation, it is not an open operation or a revision. Statistical analysis was done by a person not involved in patient care (ZW). Statistical analysis was done with the use of the SPSS software (SPSS, Chicago, IL, USA). The Student's t-test was used for comparing perioperative parameters of pain scores, milligrams of equianalgesic morphine pain medication, flexion of the knee, hemoglobin, intraoperative blood loss, Hemovac drain output, total blood loss, and duration of surgery.

Results

Surgical time did not differ in patients with an operative tourniquet (86 ± 22 minutes) compared with those with a cementation tourniquet (90 ± 23 minutes) ($p = 0.43$). The mean tourniquet time was 43 minutes (range, 24–62 minutes) compared with 9 minutes (range, 7–14 minutes) when used for cementation only.

The mean pain score between patients with and without tourniquet use was not statistically different at any time point (Table 2). The milligrams of equianalgesic morphine in patients with operative tourniquet use decreased from 55 ± 34 mg on postoperative Day 2 to 30 ± 18 mg on Day 3; patients with cementation tourniquet use decreased from 56 ± 35 mg to 39 ± 16.3 mg ($p = 0.061$). The mean use of pain medication was 49 ± 23 mL in the operative tourniquet group and 52 ± 24 mg in the cementation tourniquet group ($p = 0.057$). Likewise, ROM did not differ between the groups at any time point nor did quadriceps strength (Table 3).

Although intraoperative blood loss was less in operative tourniquet patients than cementation tourniquet patients ($p = 0.02$), when added to the total Hemovac drain output, the difference was not significant with the numbers available. Hemoglobin was not statistically significant preoperatively and postoperatively (Table 3). No major complications occurred in patients with a cementation tourniquet. One patient who had an operative tourniquet had a compartment syndrome after a tourniquet time of 57 minutes (body mass index = 37 kg/m^2) with diagnosis delayed 24 hours because loss of dorsiflexion was considered to be a consequence of the popliteal block. On the morning after surgery, there was excessive swelling, persistent foot drop, and pain with passive dorsiflexion. A fasciotomy with release of all compartments was done. The fasciotomy wound healed by secondary intention and the foot drop still persisted at 12 months postoperatively. A second complication in the operative tourniquet group not thought to be related to tourniquet use was a popliteal artery injury successfully repaired by thrombectomy and end-to-end saphenous vein interposition grafting. Minor complications were one patient in each group had a stiff knee of 10° to 60°, which improved to 5° to 110° and 0° to 115° after closed manipulation at 7 weeks. A third minor complication in an operative tourniquet patient was continuous drainage of the wound for 1 week, which stopped with a compression dressing. No patient in either group had venous thromboembolism diagnosed clinically.

Table 2. Pain scores on VAS in two groups

Mean ± SD pain score on VAS	Operative tourniquet (n = 39)	Cementation tourniquet (n = 40)	p value
POD 1	4.8 ± 2.1	4.7 ± 2.3	0.88
POD 2	3.6 ± 2.0	4.2 ± 2.1	0.179
POD 3	2.9 ± 1.9	3.0 ± 2.1	0.743
3 weeks	2.7 ± 2.0	3.2 ± 1.9	0.288
6 weeks	2.2 ± 2.3	2.7 ± 2.4	0.32

VAS = visual analog scale; POD = postoperative day.

Discussion

Several randomized controlled trials of tourniquet versus no tourniquet use during TKA have shown no statistical difference [1, 2, 10, 11, 14, 15, 24–26] . No study in the literature has compared use of the tourniquet just for cementation of the implants with use during the entire operation (either through cementation of the implants or through closure of the wound). We felt it was important that this method have justification in the literature and hoped that it would show some advantages, particularly in prevention of nerve injuries or vascular ischemia, which are the two most injurious complications of tourniquet use. Therefore, we asked whether the limited use of a tourniquet for cementation only would affect (1) surgical time; (2) postoperative pain and motion of the knee; (3) blood loss; or (4) complications such as risk of nerve injuries, quadriceps dysfunction, and drainage. We found no differences in operative time, blood loss, pain or motion, or the frequency of nerve injury or other complications. This study did validate the use of the tourniquet during cementation only as being at least as safe as tourniquet use during the entire operation through cementation of the implants.

This study had several limitations. First, we studied only low-risk patients. It is possible that more nerve injuries and drainage would occur with prolonged tourniquet use and if patients with calcified arteries and diabetes were included [8, 13, 20]. The second limitation was that in the operative tourniquet patients, the mean tourniquet time was 43 minutes. Complications from

Table 3. Hemodynamic and functional comparisons

Hemodynamic or functional comparison	Operative tourniquet (n = 39)	Cementation tourniquet (n = 40)	p value
Intraoperative blood loss	144 ± 53	243 ± 83	0.02
Hemovac drain output	340 ± 165	331 ± 132	0.77
Total blood loss	481 ± 174	574 ± 158	0.12
Preoperative hemoglobin	13.1 ± 1.9	13.3 ± 1.2	0.3
Postoperative day 3 hemoglobin	9.7 ± 1.2	9.7 ± 1.3	0.914
Preoperative ROM	101 ± 22 (20–140)	101 ± 16 (50–125)	0.92
Postoperative 3-week ROM	100 ± 20 (50–135)	100 ± 13 (70–130)	0.98
Postoperative quadriceps strength	4.96	4.93	NS

Values are mean ± SD with range in parentheses; blood loss is given in cc; hemoglobin is given in grams; ROM is by degrees; and quadriceps strength is graded from 0 (absent) to 5 (normal); NS = nonsignificant.

tourniquet use accumulate with increased tourniquet time [8], so if our tourniquet time had been longer, perhaps we could have observed differences. The third limitation is that we studied 79 knee operations and this study population creates the risk of a Type II statistical error. When a power analysis performed after the completion of the 79 knees showed 260 more knees to show differences in blood loss, and 4000 more knees to show differences in nerve injury with 80% power and $p < 0.05$, we could not justify the time and expense of prolonging the study. We had shown the equivalence between the two groups, which provided justification for the use of the tourniquet during cementation only.

Surgical time was the first question we studied. Actually, in this study, the important time is the tourniquet time. With our mean operative tourniquet time of 43 minutes, we did not observe complications with the tourniquet and therefore believe that this is a safe tourniquet time for those surgeons who choose to use the operative tourniquet. It would seem protective against nerve injuries because it was tourniquet times of 120 minutes or more, even with intermittent deflation, that increased the risk for nerve injury [8].

Postoperative pain and ROM likewise were not better with using the tourniquet only during cementation. No difference was observed in either pain or ROM in the two meta-analyses of TKA with either tourniquet or no tourniquet use at all [3, 24]. Perhaps this finding is explained because no difference in swelling of the knees was observed with or without tourniquet use [3, 24].

In all studies of tourniquet use, the intraoperative blood loss is always less with use of a tourniquet during the operation until at least cementation of the components [1, 2, 10, 11, 14, 15, 24–26]. We too had a mean 100 cc less blood loss with this use of the tourniquet, but do not consider this clinically significant. The hemoglobin levels of patients in both groups remained the same indicating hemodynamic stability was equivalent. The use of tranexamic acid is beneficial in reduction of blood loss [29].

The last question we studied was the occurrence of complications of nerve injury, quadriceps dysfunction, or drainage. We found no influence of tourniquet time on drainage with the tourniquet inflated 250 mmHg for the tourniquet times we used. Recently, increased drainage has been correlated to tourniquet pressure over 225 mmHg [23]. In this study quadriceps strength was the same in all patients in the hospital and at 6 weeks postoperatively, and these data were consistent with the meta-analysis studies [3, 24]. There was one major nerve injury in this study in a patient who had a tourniquet time of 57 minutes. The compartment syndrome was delayed in diagnosis because of the nerve block used for pain control. Horlocker et al. [8] showed nerve injuries occurred with an odds ratio of 2.8 for each 30 minutes beyond 120 minutes of tourniquet time. Because our tourniquet time was a mean 43 minutes, it was unlikely we could observe a preponderance of nerve injuries.

TKA can be successfully performed with tourniquet use during the operation if the tourniquet time is not long and the tourniquet pressure is not high [8, 23]. Two meta-analysis reports of randomized studies of tourniquet use versus no tourniquet at all showed differences in total blood loss but no other differences with or without the tourniquet [3, 24], and a separate study showed tourniquet pressures of 225 mmHg reduced drainage [23]. The importance of our study is the evidence that using a tourniquet for cementation only of the implants provides the benefit of bloodless bone for fixation while not compromising the intraoperative time or perioperative morbidity and recovery. Although TKA can be performed safely with correct tourniquet time and pressure, based on our results, we prefer to limit the use of a tourniquet to the cementation portion of the procedure.

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