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Tourniquet versus no tourniquet on knee-extension strength early after fast-track total knee arthroplasty; a randomized controlled trial

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TKA= total knee arthroplasty, CNS= central nervous system, ASA = American Society of Anesthesiologists, PACU= post anaesthesia care unit, LOS = length of hospital stay

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Short title: tourniquet vs. no tourniquet for knee arthroplasty

Authors' contributions

A.H. did preoperative evaluation, enrolled patients, administered anaesthesia, participated in the design of the study and performed statistical analyses and wrote the manuscript. T.B., H.K. and S.T.-L. coordinated and designed the study and contributed in writing the manuscript. AH and STL have reviewed the data and data analysis and attest to the integrity of the original data reported in this manuscript.

Declaration of interest

None declared

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Trial registry number: NCT01808859. The study was approved by the Research Ethics Committee at Lund University (no 2012/11) and was carried out at Hässleholm Hospital, Sweden.

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Abstract

Background. Thigh tourniquet is commonly used in total knee arthroplasty (TKA) but may contribute to pain and muscle damage. Consequently, the reduction in knee-extension strength after TKA may be caused by quadriceps muscle ischaemia underneath the cuff.

Aim. To examine if not using a thigh tourniquet during surgery was more effective than using a thigh tourniquet in preserving knee-extension strength 48 hours after fast-track TKA.

Methods. A total of 64 patients undergoing TKA were randomized (1:1) to the use of tourniquet (T-group) or no tourniquet (NT-group). In the T-group the tourniquet cuff pressure was based on the patient's systolic pressure and a margin of 100 mm Hg. It was inflated immediately before surgery and deflated as soon as surgery ended. The primary outcome was the change in knee-extension strength from pre-surgery to 48 hours after surgery (primary end point). Secondary outcomes were pain, nausea, length of hospital stay (LOS) and periarticular swelling.

Results. Knee-extension strength 48 hours after surgery was substantially reduced by about 90% in both groups, with no statistically significant difference between groups (mean difference 1.5 N/kg, 95% CI 1.3-1.6). Among the secondary outcomes, the T-group had less bleeding during surgery (56 vs 182 mL, $P < 0.01$) compared with the NT-group. There was no difference in postoperative haemoglobin levels, pain, nausea, LOS or periarticular swelling between the groups.

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Conclusion. Not using a thigh tourniquet during surgery was not superior in preserving knee-extension strength at the primary endpoint 48 hours after fast-track TKA, compared to using a tourniquet.

Keywords: tourniquet, total knee arthroplasty, complication, quadriceps muscle function

Throughout the world TKA is often performed using a thigh tourniquet (1). The cuff produces a distal bloodless field improving visualization which allows the surgeon to work with greater technical precision (2). It also facilitates cement setting and decrease blood loss and operating time (3, 4). A bloodless field time of 120 min has been considered to be safe (5) and a lower cuff pressure is probably beneficial to the patient (6, 7). However, the use of tourniquet may be associated with skin burns, injury of calcified vessels, soft tissue and muscle damage and occasionally cardio-pulmonary or thromboembolic complications (8). Systemic effects are usually seen after inflation or deflation but local effects may come as a result from direct pressure or ischaemia (9). It has been suggested that the injury is greater in the tissues directly underneath the cuff than in ischemic distal tissues (10). Muscle ischaemia, oedema and vascular congestion may lead to the post-tourniquet syndrome (9), characterised by weakness, stiffness, oedema, dysesthesia and pain in the extremity (11), which may contribute to the substantial loss of knee-extension shortly following TKA.

In the early postoperative phase, an average loss of knee-extension strength of about 80% has been reported at hospital discharge (12, 13), even when undergoing surgery in an enhanced or fast-track surgery setting (14). The strength loss is likely caused primarily by a change in afferent discharge from

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the operated knee joint, which affects the CNS, and ultimately reduces the efferent activation of the quadriceps muscle (15). In this way, less knee-extension force can be produced early after surgery, whereby functional recovery may be delayed (16) and functional performance reduced (17).

With respect to the use of tourniquet and quadriceps muscle function early after TKA, it has been suggested that the no-use of tourniquet improves performance of a straight leg raise 1 and 3 days after TKA (18) but the impact on quadriceps muscle activation derived knee-extension strength early after TKA is unknown.

The aim of this study was to examine if not using a thigh tourniquet during surgery was more effective than using a thigh tourniquet of 100 mm Hg above systolic blood pressure in preserving knee-extension strength 48 hours after fast-track TKA.

Methods

The study was approved by the Research Ethics Committee at Lund University (no. 2012/11) and carried out at Hässleholm Hospital, Sweden. It was registered with ClinicalTrial.gov under the US National Library of Medicine (reg. no. NCT01808859). Written informed consent was obtained from all patients.

Study design

The design of the study was superiority, consecutive and randomized with blinding of the data-assessor. Patients with osteoarthritis scheduled for a primary TKA at the Dept Orthopaedic Surgery, Hässleholm Hospital, Sweden, were eligible for participation during the period from August 2013 to May 2014. Inclusion criteria were ASA physical status I-III, able to understand the given information, age > 45 yr and < 85 yr and having signed the informed consent.

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Exclusion criteria were previous major knee surgery to the same knee, preoperative inability to flex the knee > 90°, rheumatoid arthritis and allergy to any of the drugs used in the study.

Randomization

An employee not involved in the study prepared non-transparent, sealed envelopes containing a slip of paper with a computer generated description of whether the patient should receive a thigh tourniquet (T-group) or no tourniquet (NT-group).

Blinding

Subjects and personnel involved in the study were blinded to treatment group until 1-2 hrs before surgery. After that, both patients and all personnel in the operating theatre were aware of if tourniquet was being used or not. Once the patients reached the PACU, staff involved in the study were blinded as to treatment group.

Surgery

TKA was performed using a ventral incision with a parapatellar medial entrance to the joint. The patella was everted. A cemented single radius cruciate retaining total knee was used [Triathlon™ Knee System (Stryker, Mahwah, New Jersey, USA)]. Appropriate guide instruments were used according to the surgical-technique manual supplied with the knee system.

Anaesthesia and perioperative care

As premedication all patients received oral celecoxib 400 mg and acetaminophen 1 g, and thereafter 12-hourly (celecoxib 200 mg) and 6-hourly (acetaminophen 1g). No subjects received an indwelling urinary catheter and no drains were used. A low-volume fluid regimen was used with 2000 mL of

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Ringer's solution during the first 24 h. All subjects were given 1 g of tranexamic acid i.v. Oxycodone 5 mg i.v. was used as postoperatively rescue pain medication. No femoral nerve blocks were used.

All patients were anaesthetized using intrathecal administration of hyperbaric bupivacaine 0.5%, 3 mL. An infusion of propofol 10 mg mL^{-1} was given to induce light sedation during surgery. All patients breathed spontaneously with supplemental oxygen 2 litre min^{-1}.

All subjects received infiltration of local anaesthetic in the perisurgical area consisting of 150 mL of ropivacaine (0.2%) with epinephrine (10 μg mL^{-1}) (i.e. 148.5 mL ropivacaine 2 mg mL^{-1} + 1.5 mL epinephrine 1 mg mL^{-1}). This mixture was injected using a systematic technique to ensure uniform delivery of local anaesthetic to all tissues incised, handled or instrumented during the surgery. The first 50 mL were injected into the posterior joint capsule and both collateral ligaments after the bone cuts were done. After insertion of the prosthesis, 50 mL were injected along the borders of and into the capsule and cut quadriceps tendon, infra-patellar ligament, possible remnants of the fat pad, cruciate ligaments and soft tissues surrounding the joint. Finally, 50 mL were infiltrated into the subcutaneous tissues before wound closure (19).

Based on the circumference of the thigh, a 61 or 86 cm cuff (VBM Medizin Tecknik, Germany) was chosen. The pressure in the cuff was 100 mm Hg above the patient's systolic blood pressure and was maintained using a Tourniquet 2500 (VMB Medizin Tecknik, Germany). Immediately prior to surgery, the orthopedic surgeon elevated the leg for one minute and then inflated the cuff. After the end of surgery, the bandage was applied and the cuff was deflated.

Outcomes:

Baseline characteristics included demographics variables, age, weight, height, gender and ASA physical status.

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Primary outcome

The primary efficacy outcome was the loss of knee-extension strength from pre-surgery to 48 hours after surgery in the operated leg. Knee-extension strength was measured isometrically at 60 degrees knee flexion using an isokinetic dynamometer (Biodex), and expressed as Newtons per kilo body mass (20). One data assessor, who was blinded to allocation, performed all measurements. The highest value of 5 maximal contractions was used as the data point. Positioning of the patient was as follows: The patients sat in the dynamometer chair with the hips flexed to 110 degrees, the knees flexed to 60 degrees, their hands rested on the thighs (palms up). One strap was used to fixate the involved leg, and two straps were used to fixate the upper body. The center of the dynamometer strain gauge was placed 4-5 cm above the center of the lateral malleolus. The rotational axis of the dynamometer was visually aligned with the rotational flexion/extension axis of the involved knee joint, and the dynamometer lever arm was visually aligned with the center of the lower leg. Maximal voluntary contractions of 5 seconds duration each were performed during strong standardized verbal encouragement. Contractions were separated by 120 second pauses. Measurements were performed on both the operated and non- operated knee in all patients.

Secondary outcomes

Pain, swelling, nausea, LOS and intraoperative bleeding.

Statistical analyses

For the primary analysis, power and sample size estimations were calculated to detect a between-group difference in the change in knee-extension of 40% (40% less strength loss without the use of tourniquet). The magnitude of this between-group difference is larger than that considered the minimal clinically important difference, as the average knee-extension strength loss at discharge is 83% (12)

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and because the study was considered exploratory. In the case of promising results without the use of a tourniquet in the present study, we considered it necessary to verify this in at least one (phase-3.like) confirmatory trial (21).

For the estimations, a mean (1 SD) strength loss of 0.8 (0.39) Nm/kg at the primary endpoint (12), a type I error rate of 5% and a type II error rate of 20% (80% power), were used. For a 2-sample t-test of a normal mean difference with a 2-sided significance level of 0.05, assuming a common standard deviation, 29 patients were required per group. To allow for a 10% potential dropout, 64 patients were included. The primary analysis followed the intention-to-treat principle, using the last observation carried forward-approach for missing data.

Height, weight and age were normally distributed. Hence, data are reported as mean ±SD. To investigate between-group difference in knee extension strength at the primary endpoint, Mann-Whitneys test was used. Likewise for the remaining secondary variables and analyses apart from length of hospital stay where Chi-Square test was used.

Deviations from the trial registration

In the registration of the trial it is stated that the primary outcome will be expressed as Nm/kg body mass. Erroneously, the distance from the knee flexion/extension axis to the point of force application was not measured in all patients. As the study design used a comparison of within-subject changes in knee-extension strength, we considered it feasible to not creating a body size independent muscle strength measure. Hence, we chose to report all data for the primary outcome as N/kg body mass to use the complete data set and to adhere to the pre-specified and registered sample size.

Results

Study flow and patient characteristics

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During the inclusion period, a total of 66 patients were assessed for eligibility, and 64 were included in the trial. The groups had similar clinical characteristics at baseline (Table 1). Figure 1 depicts the flow of patients through the trial. Thirty-two patients were allocated to receive TKA with tourniquet and 32 were allocated to receive TKA without TKA. During the study, no patients were lost to follow-up at the primary endpoint, but knee-extension strength at follow-up in the non-operated leg was missing in five patients due to technical mishaps in three cases, human error in one and finally organizational cause in one .

Primary outcome

Knee-extension strength was reduced by about 90% from 1.6 N/kg at baseline to 1.1 N/kg after surgery (Table 2). However, for the primary endpoint, 48 hours after surgery, there was no statistical significant between-group difference in the knee-extension strength loss (T-group vs NT-group: mean difference 1.5 N/kg [95% CI, 1.3 to 1.6], Table 2).

Secondary outcomes

There were no differences in pain, nausea, LOS or periarticular swelling between the groups. Approximately 50% of the patients met the discharge criteria from the ward during the first postoperative day without statistically significant differences between the groups (Table 3).

Adverse events

There were no adverse events during the study.

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Discussion

The primary finding of the present study was that not using a thigh tourniquet during surgery was not superior to using a thigh tourniquet during surgery in preserving knee-extension strength 48 hours after a fast-track TKA.

Explanation of results

The primary finding was contradictory to that hypothesized prior to the study. We hypothesized that not using a tourniquet would preserve knee-extension strength to a greater extent than using one. We based this on several previous findings. First, knee swelling has been reported to relate to the loss of knee-extension strength at hospital discharge after TKA (12) and some patients present with increased knee swelling following the use of tourniquet (3). Quadriceps muscle afferents – that may change their discharge due to compression damage using the tourniquet – have been implicated to be involved in quadriceps muscle inhibition in knee osteoarthritis (15). Finally, quadriceps muscle force production was substantially reduced in rabbits following tourniquet compression of the quadriceps muscle (22). Based on this, we thought that tourniquet use would to add to the effect of the surgical trauma on changing afferent signalling to the CNS, whereby efferent activation of the quadriceps muscle would be further reduced. Reduced efferent activation of the quadriceps muscle – known as central activation deficits or arthrogenic muscle inhibition – (15, 23) is well known shortly following TKA (13, 24). The neural mechanisms are not fully understood, but it has been attributed, at least in part,

to altered afferent feedback from the operated knee joint due to swelling, inflammation, pain, and damage to joint afferent (15, 23)

From the analyses of the secondary outcomes, the degree of postoperative knee pain and periarticular swelling was not different between groups. So, the indicators of the surgical trauma, which is likely the major contributor to the loss of knee-extension strength, were comparable between groups. Apparently any additional change in afferent signalling from the knee or quadriceps muscle induced by the use of tourniquet did not constitute enough stimulus to change the course of knee-extension strength loss. This was also indicated by the very similar reduction in knee-extension strength in both groups to values of 0.14 and 0.15 N/kg (about 90 %) at the primary end point in the NT-group and T-group, respectively. Hence, the mechanisms underlying the substantial loss of knee-extension strength shortly following a TKA in an enhanced surgery program do not seem to implicate the use of tourniquet (please see study limitations).

Shorter tourniquet time has been shown to improve the postoperative range of knee motion (25). In this study the time of bloodless field was relatively short compared to previously published data (26, 27). Tourniquet-related nerve injuries could be caused by high cuff pressure (26). However, a cuff pressure of 240 mm Hg for up to 80 min appears to be safe in this respect (26). In the present study the mean time that the tourniquet cuff was inflated was 47 min and, hence, pressure- related nerve injuries seems less likely to be the cause of the loss of muscular function. Many other effects of tourniquet are clinically relevant and a recent meta-analysis showed that TKA without a tourniquet was superior to TKA with a tourniquet in thromboembolic events, infection, blister, hematoma, wound oozing and nerve palsy (28). Furthermore, a recent study showed that TKA without tourniquet resulted in faster recovery and improved range of motion (29)

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Postoperative pain control was achieved by a multimodal technique using acetaminophen, celecoxib and oxycodone together with local infiltration analgesia in the perisurgical tissues. No peripheral nerve blocks such as femoral block were used, eliminating this as an explanation for the pronounced reduction in knee-extension strength.

Clinical implications

The use of a tourniquet should depend on other factors than an expected effect on knee-extension strength.

Limitations

A few precautions should be taken when interpreting the present results. Firstly, not using a tourniquet was thought to be superior to using one in preserving knee-extension strength, and the study powered to detect a between-group difference of at least 40%, 48 hours after surgery. Hence, the present results do not rule out that a superior effect of not using a tourniquet of less than 40% exists 48 hour s after surgery or at a later time point. However, the present data do not suggest this to be the case.

Conclusion

Not using a thigh tourniquet during surgery was not more effective in preserving knee-extension strength at the primary endpoint 48 hours after fast-track TKA compared to using a tourniquet.

References

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Table 1

Demographics and surgical data		
	NT-group *n*=32	T-group *n*=32
Weight (kg)	84 ± 14	83 ± 14
Height (cm)	172 ± 10	174 ± 8
Male/Female	18/14	77/15
Age (yrs)	66 ± 8	68 ± 8
ASA physical status		
I	11	9
II	19	16
III	2	7
Duration of surgery (min)	39 ± 8	43 ± 10
Intra-operative bleeding (ml)	182 (89-243)	56 (25-118)
Duration of bloodless field (min)		47 ± 8

Weight, height age, duration of surgery and bloodless field presented as mean ± SD. Intra-operative bleeding presented as median (IQR). Gender and ASA status presented as numbers. No significant differences between the groups were found except for less bleeding in the T-group compared with the NT-group ($P < 0.01$, Mann-Whitney test)

Table 2

Knee-extension strength (N/kg)				
	Operated knee			Non operated knee
	NT-group	T-group	*P*	
	n=32	*n*=32		*n*=64
Pre-op	1.54 (1.02-2.3)	1.69 (1.17-2.2)		1.76 (1.15-2.48)
48 hrs post-op	0.14(0.08-0.29)	0.15 (0.08-0.29)		1.59 (1.14-2.18)
Loss	1.4 (0.9-1.9)	1.54 (1.0-2.0)	n.s.	

Median (IQR) knee-extension strength (Mann-Whitney).

Table 3

Discharge from the ward	according to critera		
	NT-group *n*=32	T-group *n*=32	*P*
Day 1, 08.00 hrs	1	3	n.s.
Day 1, 14.00 hrs	14	15	n.s.
Day 2, 08.00 hrs	29	27	n.s.
Day 2, 14.00 hrs	32	31	n.s.

Cumulative number of patients meeting the discharge criteria from the ward at different post operative times (Chi-Square test, NT-group vs. T-group). Day 1 is the first day following the day of surgery.