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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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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 h 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 h after surgery (primary end point). Secondary outcomes were pain, nausea, length of hospital stay (LOS) and periarticular swelling.
Results: Knee-extension strength 48 h 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.
Conclusion: Not using a thigh tourniquet during surgery was not superior in preserving knee-extension strength at the primary endpoint 48 h after fast-track TKA, compared to using a tourniquet.

1. Introduction

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 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

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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 h after fast-track TKA.

2. 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.

2.1. 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 of Orthopedic 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. 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.

2.2. 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).

2.3. Blinding

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

2.4. 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.

2.5. 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 1 g). No subjects received an indwelling urinary catheter and no drains were used. A low-volume fluid regimen was used with 2000 mL of 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 L 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 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 was injected into the posterior joint capsule and both collateral ligaments after the bone cuts were done. After insertion of the prosthesis, 50 mL was 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 was 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 orthopaedic surgeon elevated the leg for 1 min and then inflated the cuff. After the end of surgery, the bandage was applied and the cuff was deflated.

2.6. Outcomes

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

2.7. Primary outcome

The primary efficacy outcome was the loss of knee-extension strength from pre-surgery to 48 h after surgery in the operated leg. Knee-extension strength was measured isometrically at 60° 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 five 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°, the knees flexed to 60°, 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 centre of the dynamometer strain gauge was placed 4–5 cm above the centre 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 centre of the lower leg. Maximal voluntary contractions of 5 s duration each were performed during strong standardized verbal encouragement. Contractions were separated by 120 s pauses. Measurements were performed on both the operated and non-operated knee in all patients.

2.8. Secondary outcomes

Secondary outcomes are pain, swelling, nausea, LOS and intraoperative bleeding.

2.9. 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