

Faster recovery without the use of a tourniquet in total knee arthroplasty

A randomized study of 70 patients

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Background and purpose — Tourniquet application is still a common practice in total knee arthroplasty (TKA) surgery despite being associated with several adverse effects. We evaluated the effects of tourniquet use on functional and clinical outcome and on knee range of motion (ROM).

Patients and methods — 70 patients who underwent TKA were randomized into a tourniquet group (n = 35) and a non-tourniquet group (n = 35). All operations were performed by the same surgeon and follow-up was for 1 year. Primary outcomes were functional and clinical outcomes, as evaluated by KOOS and knee ROM. Secondary outcomes were intraoperative blood loss, surgical time and visibility, postoperative pain, analgesic consumption, and transfusion requirements.

Results — Patients in the non-tourniquet group showed a better outcome in all KOOS subscores and better early knee ROM from surgery to week 8. No difference was detected at the 6- and 12-month follow-ups. Postoperative pain and analgesic consumption were less when a tourniquet was not used. Surgical time and visibility were similar between groups. Intraoperative blood loss was greater when not using a tourniquet, but no postoperative transfusions were required.

Interpretation — This study shows that TKA without the use of a tourniquet results in faster recovery in terms of better functional outcome and improved knee ROM. Furthermore, reduced pain and analgesic use were registered and no intraoperative difficulties were encountered.

Tourniquets are frequently applied in total knee arthroplasty (TKA) to ensure less intraoperative bleeding and create a bloodless surgical field, thereby potentially reducing surgical time, improving the quality of cementation, and ensuring

long-term implant fixation (Bannister and Miles 1988, Rama et al. 2007, Smith and Hing 2010, Tsarouhas et al. 2012).

There are, however disadvantages when using a tourniquet, including thigh pain, nerve palsy, ischemia, soft tissue damage, thromboembolic complications, poor wound healing, and patella maltracking (Komatsu et al. 2003, Smith and Hing 2010, Tai et al. 2011). Furthermore, recovery may be delayed due to reduced muscle strength, reduced knee ROM, and increased pain (Saunders et al. 1979). Other studies have shown increased pain and impaired ROM up to 1 year after surgery in which a tourniquet is used (Abdel-Salam and Eyres 1995, Ledin et al. 2012).

Several randomized controlled trials and meta-analyses dealing with adverse effects of tourniquet use have been published, but disagreement still remains as to whether TKA surgery should be performed with or without the use of a tourniquet (Smith and Hing 2010, Tai et al. 2011, Alcelik et al. 2012).

We examined the effects of tourniquet use on functional and clinical outcome and on knee ROM. Furthermore, intraoperative blood loss, surgical time, surgical visibility and difficulties, postoperative pain, analgesic consumption, and transfusion requirements were registered. We hypothesized that the absence of a tourniquet during TKA would improve functional outcomes and increase knee ROM, reduce postoperative pain levels, and reduce analgesic consumption.

Patients and methods

This prospective randomized clinical trial was conducted at Aalborg University Hospital, Aalborg, Denmark. 70 primary TKAs were included in the study; they were performed between January 2011 and January 2012.

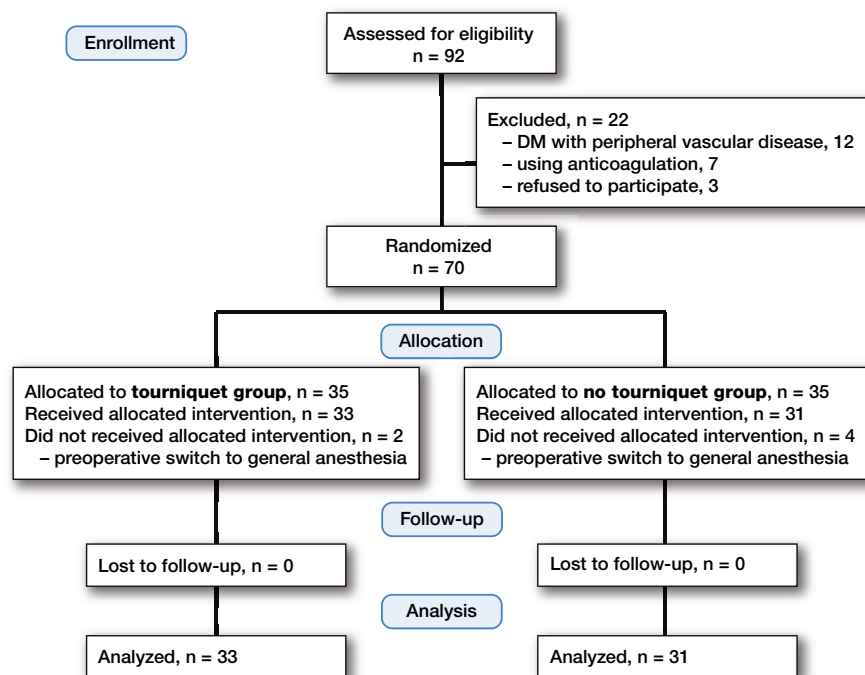


Figure 1. Flow diagram of the participants.

Demographics

| | Total sample (n = 64) | Tourniquet (n = 33) | Non-tourniquet (n = 31) |
|----------------|--------------------------|------------------------|----------------------------|
| Sex M/F | 35/29 | 18/15 | 17/14 |
| ASA I/II | 38/26 | 21/10 | 17/16 |
| Age, mean (SD) | 68 (8.0) | 68 (8.4) | 68 (7.8) |
| BMI, mean (SD) | 25 (2.3) | 25 (2.0) | 25 (2.5) |

Approval from the local Ethics Committee was obtained (approval no. N-20090045) and the study was registered at ClinicalTrials.gov (NCT01309035). All patients gave their written consent and they were enrolled in the study in accordance with the Consolidated Standards of Reporting Trials (CONSORT) and the Helsinki Declaration (Figure 1).

This study was part of a larger randomized controlled trial where 2 other main study questions were investigated: the effects of tourniquets on implant fixation and on ischemic conditions. The clinical outcomes of tourniquet use are presented in this publication.

Patients

Patients aged 50–85 were included if elective unilateral TKA was planned because of gonarthrosis stage 3–5 according to Ahlbäck (1968). None of the patients had other severe disease and were classified as American Society of Anesthesiologists ASA 1–2. Patients with BMI \geq 35 were not eligible for inclusion. Other exclusion criteria included rheumatoid arthritis,

peripheral vascular disease, diabetes, previous knee surgery, and use of anticoagulation medicine.

Patients were block-randomized using sealed envelopes. The envelope was opened when the surgeon was present, in the operating theater before surgery. The patients were unaware of the group to which they were allocated. 33 patients had surgery using a tourniquet (the Tq group) and 31 patients had surgery without the use of a tourniquet (the non-Tq group). Of the 70 patients enrolled in the trial, 64 (35 males and 29 females) completed the study (Figure 1). All patients were comparable regarding demographics (Table).

Surgical technique

All procedures were standardized with regard to preoperative tranexamic acid, spinal anesthesia, postoperative pain treatment, and rehabilitation regimen.

Before surgery, tranexamic acid (1 g) was administered orally, and cefuroxime (1.5 g) was administered intravenously immediately before skin incision. In addition, tranexamic acid (0.5 g) was given 3 h after surgery and cefuroxime (750 mg) was given 6 and 12 h postoperatively. Thrombosis prophylaxis was achieved with use of rivaroxaban (10 mg/day) throughout the hospital stay.

Both groups had an appropriate-sized thigh tourniquet applied, but it was only inflated in the Tq group. In non-Tq group, it was placed on the thigh but not inflated, thereby serving as a safety device in case of uncontrollable bleeding. In the Tq group, limb exsanguination was done by elevation for 2 min and the cuff was inflated to 250 mmHg. The standard procedure in our clinic is TKA surgery using a tourniquet.

All knee implants were the NexGen CR-Flex Fixed Bearing Knee (Zimmer, Warsaw, IN) with use of Biomet Refobacin Bone Cement R (Biomet, Warsaw, IN). In all cases, the patella was resurfaced. All surgery was performed by the same surgeon. A midline skin incision and medial parapatellar arthrotomy were applied. An intramedullary guide system was used for the femur and external guides for the tibia. Distal femur holes were plugged with autogenous bone grafts. Cement was applied on the tibia plateau surface, beneath the tibial tray and along the stem. Anchorage holes were drilled into the tibia plateau to increase the contact area between bone and cement. High-pressure pulse lavage was performed to remove blood and provide better cement interdigitation.

Modern cementing technique was used that involved meticulous pulse lavage of debridement before cement application. A 2-stage cementation procedure was performed. The tibia and patella were implanted first, and then another package of cement was used to fixate the femoral component. This was

done to ensure that there was enough time to obtain a careful cementation with proper pressurization. After cementation, further pulse lavage debridement was performed to eliminate cement debris from the wound (Niki et al. 2007). Immediately after wound closure, dressings were applied, and the cuff was deflated in the Tq group and removed. The mean operation time was 70 (68–72) min for Tq group and 71 (70–73) min for non-Tq group.

Postoperative rehabilitation and pain management followed a standard protocol including full weight bearing, paracetamol, and morphine analogs. Mobilization was allowed on the same evening as the day of operation. Patients received daily functional training under the supervision of physiotherapists until the day of discharge (2 days after surgery).

Primary outcome

To evaluate functional and clinical outcomes, KOOS was used (Roos et al. 1998). In this validated knee-specific questionnaire, the outcome is expressed as the change in average score from baseline to 12 months for each subscale. Knee ROM was measured by extension and flexion with a goniometer 2 weeks preoperatively as a baseline, postoperatively on day 2, and during follow-up (8 weeks, 6 months, and 12 months) (Figure 3).

At discharge, 90% of the patients had obtained full extension; at 6-month follow-up, all the patients had full extension. Mean preoperative knee ROM was similar in the 2 groups: 108 degrees (95% CI: 105–111) in the non-Tq group and 107 degrees (95% CI: 104–111) in the Tq group.

Secondary outcomes

Pain was assessed using a VAS score (0 = no pain, 10 = worst pain) with no distinction between thigh pain and knee pain. Pain was registered at rest, just before surgery and postoperatively after 2, 4, 6, 8, and 10 h on the day of surgery (day 0). On the following days, pain was evaluated during rest and after walking 20 m. The mean of all consecutive VAS scores during the first 3 days was used for analysis. Analgesic consumption was expressed as a mean morphine equivalent during hospitalization, and the consumption was standardized using 10 mg of morphine as reference analgesic dose. Surgical data were recorded regarding blood loss estimation, which was measured by summing fluid volume in suction bottles and the weight of operation swabs. The transfusion policy of the hospital was followed regarding transfusion needs, and patients were transfused postoperatively if their hemoglobin level was 4.5 mmol/L or lower. Surgical time and surgical visibility during the operation were registered by the same surgeon.

Statistics

Sample size was based in part on the KOOS score (Roos et

KOOS absolute scores

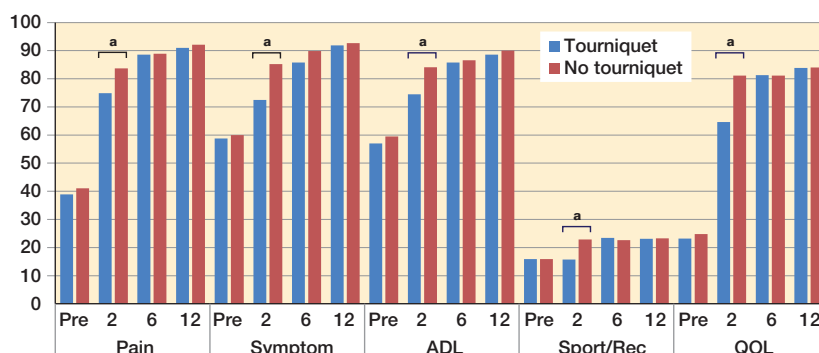


Figure 2. Mean values for KOOS subscales at baseline and through follow-up as an outcome profile for the tourniquet group vs. the non-tourniquet group. KOOS subscales: pain, symptoms, activity in daily living (ADL), sport and recreation (Sport/Rec), and quality of life (QOL). Early improvement was detected in all KOOS subscales at 8 weeks in the non-tourniquet group. Statistical significance is shown with the symbol ^a.

al. 1998) and in part on earlier studies with knee ROM and surgery with and without a tourniquet (Wakankar et al. 1999, Ledin et al. 2012). A minimum change of 10 points was considered clinically significant. A power calculation was determined to 80%, the confidence intervals were set to 95%, and any p-value less than 0.05 was considered significant. Data such as KOOS, VAS pain, and other continuous variables that were normally distributed were analyzed with Student's t-test (unpaired). Mann-Whitney U-test was used for continuous variables that were not normally distributed. The chi-squared test was used to analyze categorical variables. Data are presented as mean (SD) with 95% confidence intervals (CIs). Statistical analyses were performed with STATA 11.0.

Results

Patients were similar regarding age, weight, sex, preoperative KOOS score, and radiographic osteoarthritis grade (Table).

Primary outcomes

KOOS. Both groups improved in all KOOS subscales, from baseline until 8 weeks, with more improvement in the non-Tq group ($p < 0.001$) (Figure 2).

ROM. Postoperatively, there was better knee ROM in the non-Tq group (48 (SD 9.5, CI: 44–51) degrees vs. 36 (SD 7.9, CI: 33–39) degrees; $p < 0.001$). This difference was still detectable at 8 weeks, where the non-Tq group had better knee ROM (100 (SD 7.2, CI: 97–102) degrees vs. 93 (SD 8.2, CI: 90–96) degrees; $p = 0.002$). At 6 months, ROM was similar in the non-Tq group and the Tq group: 108 (SD 8.5) degrees vs. 107 (SD 11) degrees.

This was also registered at the 1-year evaluation, where no difference was found between the 2 groups: (113 (SD 8, CI: 111–116) degrees vs. 113 (SD 8, CI: 110–116) degrees; $p = 0.845$) (Figure 3).

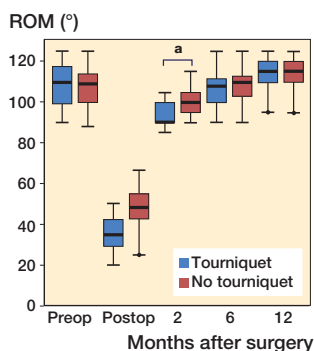


Figure 3. Range of motion. Better knee ROM was seen postoperatively and at the 8 week follow-up when a tourniquet had not been used. Statistical significance is shown with the symbol ^a.

Secondary outcomes

Pain. The mean VAS score on the day of discharge was lower in the non-Tq group (4.6 (SD 1.4, CI: 4.1–5.1) vs. 5.5 (SD 1.6, CI: 5–6.1); $p < 0.02$). VAS was similar in the 2 groups on postoperative day 0 and again at the 8-week follow-up. Patients in the tourniquet group had greater analgesic consumption and greater discomfort from the thigh until 2–3 weeks after discharge. In the Tq group, higher equi-analgesic morphine use was registered during hospitalization: 38 (SD 9.8, CI: 35–41) mg vs. 31 (SD 6.1, CI: 29–33) mg.

Intraoperative bleeding was greater when a tourniquet was not used: 280 (SD 52) mL vs. 140 (SD 32.7) mL in the Tq group. None of the patients required transfusion during hospitalization.

Surgical time was similar in the Tq group (mean 70 (SD 5.3) min) to that in the non-Tq group (mean 71 (SD 4.5) min). Surgical visibility was similar in the 2 groups. Visibility was graded on a scale from 1 to 5 (1 = no problems, 5 = extreme problems). Obtaining a dry and well-exposed tibia surface for cementing was no challenge, especially after high pulse lavage and swab packing.

Adverse events. Deep vein thrombosis was suspected in 3 patients and confirmed by ultrasonography: 1 patient in the non-Tq group and 2 patients in the Tq group.

At week 8, 2 patients in the Tq group had flexion < 90 degrees that required forced manipulation in general anesthesia.

During hospitalization and the postoperative period, there was no excessive oozing of blood or wound complications in either group.

Discussion

We found better function and less pain at the initial rehabilitation stage in the patients in whom a tourniquet was not used. Recovery of ROM was achieved faster in the non-Tq group than in the Tq group, which was also found by Wakankar et al. (1999) and Chang et al. (2012). We also found better subjective

knee performance in the non-Tq group until 6 months, with decreasing clinical differences between the groups with time. These findings are in accordance with Ledin et al. (2012), who found that pain was increased during the first 4 postoperative days and knee ROM was still reduced at 2 years when a tourniquet had been used. Vandebussche et al. (2002) and Li et al. (2009) also found early improvement in knee flexion and initial postoperative pain was reduced. Tai et al. (2012) found reduced postoperative pain when a tourniquet was not used, but no difference in knee flexion.

The ischemic effects and changes in the limb due to a tourniquet are poorly described. Ostman et al. (2004) described the ischemic changes in skeletal muscle when a tourniquet is used during arthroscopic ligament reconstruction, where surgical trauma is not as severe as in TKA. Tsarouhas et al. (2012) investigated tourniquet-induced soft tissue damage during arthroscopic meniscectomy, measured by serum creatine phosphokinase in patients aged ≤ 40 years. They found that tourniquet use for less than 30 min was safe, with no systemic response detectable. In our study, the Tq group had more pain and also a higher requirement for analgesics, which may have been due to the local ischemic conditions caused by the tourniquet and longer surgical time than in arthroscopic procedures.

We found similar surgical time and visibility in the 2 groups. Control of intraoperative bleeding was not an obstacle. Pre- and postoperative tranexamic acid was given, and during initial surgery the knee was flexed so that further hemostasis was achieved. Surgical time is an objective measure of difficulties caused by impaired visibility; thus, it appears that not using a tourniquet had no effect on surgical visibility. We recognize that our grading of surgical visibility was subjective, although the same surgeon performed all the operations. Similar conclusions have been expressed elsewhere, where the surgical field was not impaired by tourniquet absence (Abdel-Salam and Eyres 1995, Vandebussche et al. 2002).

Smith and Hing (2010) and Zhang et al. (2010) found that intraoperative bleeding is reduced with tourniquet application, but that tourniquet use had no benefits regarding postoperative bleeding, total blood loss, or transfusion rates. We found less intraoperative bleeding with tourniquet use; this did not have any clinical relevance, however—not a single patient required transfusion. Tetro and Rudan (2001) suggested that using a tourniquet was not effective in reducing overall blood loss volume, a conclusion also reached in meta-analyses by Smith and Hing (2010) and Tai et al. (2011).

A major concern when using a tourniquet is the risk of nerve damage secondary to ischemia and increased tourniquet time and pressure (Pedowitz 1991, Klenerman 1995, Olivecrona et al. 2013). EMG changes have been studied, and thigh weakness and pain may be affected by the mechanical compression caused by a tourniquet (Saunders et al. 1979, Worland et al. 1997, Tai et al. 2012).

The main reason for still using tourniquets in cemented TKA surgery has been concern regarding not obtaining an

adequate bone-cement interdigitation because of active bleeding, thereby impairing fixation and causing inferior long-term implant survival (Juliussen et al. 1994, Alcelik et al. 2012).

In 2 randomized controlled trials, implant fixation was investigated using radiostereometric analysis to assess the effect of a tourniquet on fixation during cemented TKA. Both studies showed that a tourniquet did not improve fixation of the implant (Ledin et al. 2012, Molt et al. 2014). We performed high pulse lavage; swabs were used to obtain clean dry-cut bone surfaces for proper cementing, and the absence of a tourniquet caused no problems. This has been established in several studies, where no technical difficulties or difficulties in achieving a dry bone surface have occurred (Abdel-Salam and Eyres 1995, Tetro et al. 2001).

We registered one case of early tibial component loosening in the Tq group. The patient initially had no symptoms and mobilized well, but the loosening was detected at week 8 on plain radiographs. The implant failure had occurred due to impaired subchondral tibial bone quality caused by a cyst, which had not been recognized before or during surgery. After revision, the new implant was well fixated 1 year later.

In conclusion, this randomized study has shown that TKA surgery without a tourniquet results in better functional outcomes and improved knee ROM in the early period of rehabilitation.

AE: study design, data collection, statistics, analysis, and writing. PTN, SR, and TJ: study design, analysis, and writing. ACL: data collection, analysis, and writing. MBL: study design and writing. AK: data collection and writing. Critical revision of the manuscript was performed by all authors. They all read and approved the final manuscript.

No competing interests declared.

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