

Tourniquet time affects postoperative complications after knee arthroplasty

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Abstract

Purpose Pneumatic tourniquets are frequently used in knee arthroplasty surgery. However, there is a lack of evidence to define safe tourniquet time in lower limb surgery. The primary aim of this study was to investigate whether tourniquet time influences the risk of postoperative complications after primary and secondary knee arthroplasty.

Methods This study was a prospective register study. Since we wanted dispersion in tourniquet time, we included a consecutive series of 577 primary knee arthroplasties, 46 revision knee arthroplasties, and 18 patellar supplementing knee arthroplasties from a clinical audit database over a period of five years. The following postoperative complications were recorded: superficial wound infections, deep wound infections, deep vein thrombosis, pulmonary embolism, nerve injuries, compartment syndrome, cuff pressure injuries, and bandage injuries.

Results Tourniquet time over 100 minutes was associated with an increased risk of complications after knee arthroplasty surgery (OR 2.2, CI 1.5–3.1). This increase in risk remained after adjusting for cuff pressure, sex, age, American Society of Anesthesiologists (ASA) classification, smoking, diabetes, and surgery indication (OR 2.4, CI 1.6–3.6).

Conclusions Tourniquet time over 100 minutes increases the risk of complications after knee arthroplasty surgery and special attention is advocated to reduce the tourniquet time.

Introduction

The use of a pneumatic tourniquet may be helpful during knee arthroplasty surgery [1]. However, a number of disadvantages have been reported and their use is not without risk as complications may still occur [2–4]. The reported injuries are often pressure-related, but they can also be caused by excessive tourniquet time [5].

There is a lack of evidence to define a safe tourniquet time in lower limb surgery [6]. Recommendations suggest a time limit of two hours for healthy patients [5, 7, 8], but elderly, trauma patients and those with peripheral vascular disease are probably more susceptible [7]. Most studies of tourniquet time are of the experimental animal type [9–11], and few clinical human studies use tourniquet times of more than two hours. In a retrospective study, Horlocker et al. (2006) found that tourniquet times over 120 minutes were associated with an increased risk of nerve injury in total knee arthroplasties (TKA). Other studies have shown an increased rate of re-operations, a higher incidence of nerve injuries, inferior knee mobility, and more surgical wound complications when longer tourniquet times have been used [12–15]. In a review evaluating tourniquet use, Fitzgibbons et al. (2012) concluded that the existing assumption of a two-hour safe time limit is mainly based on animal studies, and because the reported complications are mostly minor and of a short-term nature are therefore questionable.

Since earlier investigations have different endpoints and few are human prospective studies, there is still a lack of evidence for clear clinical guidance regarding a safe tourniquet time.

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The primary aim of this study was to investigate whether tourniquet time influences the risk of postoperative complications after a knee arthroplasty. The secondary aim was to investigate whether factors such as age, sex, the American Society of Anesthesiologists (ASA) classification, diabetes, smoking, or tourniquet cuff pressure affect the risk of postoperative complications.

Patients and methods

This study was a prospective register study conducted at the Department of Orthopedics at Södersjukhuset in Stockholm, Sweden. All patients who have undergone surgery at the department since 1996 have been registered prospectively in a clinical audit database where all complications within six weeks after surgery have been recorded and validated. This audit was part of a routine quality control and a follow-up rate of 99.3 % was achieved.

Since we wanted dispersion in tourniquet time, a consecutive series of 577 primary knee arthroplasties (465 total knee arthroplasties and 112 unicompartmental knee arthroplasties), 46 revision knee arthroplasties, and 18 patellar supplementing knee arthroplasties was identified in the registry during the period 1999–2003 and included in the study.

In 16 patients undergoing revision knee arthroplasty, the tourniquet cuff was deflated and then re-inflated because of a prolonged surgery time. The mean reperfusion interval was 29 minutes, (standard deviation [SD] 12) and the second tourniquet time ranged from 15 to 76 minutes. The longest total bloodless field period was 193 minutes. These minutes from the re-inflated period are not included in the statistical analysis.

The postoperative complications recorded for this study were: superficial wound infections (treated with antibiotics), deep wound infections (requiring surgical intervention), deep vein thrombosis (verified by ultrasonography or phlebography), pulmonary embolism (verified by computed tomography), nerve injuries (verified by clinical examination or electromyography (EMG), compartment syndrome (verified by clinical examination and fasciotomy), cuff pressure injury (documented on the medical chart), and bandage injury (blisters or other surgical skin related complications) (Table 3). These complications were chosen because they have been described earlier as possibly being associated with the use of a bloodless field [2, 5, 8, 12]. All surgical procedures were performed according to local protocols. Patients received prophylactic intravenous antibiotics at induction and two further doses postoperatively. Low molecular weight heparin (LMWH) was used for thromboprophylaxis. The limb underneath the tourniquet cuff was protected by cast padding, a two-layer elastic stockinette or, in some patients, no protection at all, since this was our routine over some years. A standard 140-mm-wide contour thigh tourniquet cuff or a 100-mm-

wide cylindrical tourniquet cuff has been used. The tourniquet cuff pressure was decided by the surgeon, often based on the patient's systolic blood pressure plus a margin.

Statistical analysis

Statistical analyses were performed using SPSS statistics 20 (IBM Corp, Armonk, New York, USA) and R version 2.15.1 (R Foundation for Statistical Computing, Vienna, Austria). For all analyses, the level of significance was set to 0.05, and all *p* values are two-sided. Baseline data are presented as 100 minutes or less vs. over 100 minutes and tested with a Fisher's exact test for categorical variables and student's *t* test for continuous variables (Table 1). Associations between tourniquet time and complication were investigated with univariable and multivariable logistic regression analyses and the results are presented as odds ratios (ORs) and with 95 % confidence intervals (CIs). The receiver Operator Curve (ROC) analyses showed that a cut-off of 106 minutes would be appropriated for tourniquet time, but since it is clinically more suitable, we have used the categories 100 minutes or less vs. more than 100 minutes. We have also analysed tourniquet time categorised as 120 minutes or less vs. over 120 minutes since that is the general recommendation in the literature [5, 7, 8], and also as a continuous variable (Table 2). Variables included in the multivariable model besides tourniquet time were sex, age, ASA classification, surgery indication, diabetes, smoking, and cuff pressure. These factors have been described earlier in complications related to the use of pneumatic tourniquets or wound complications in general [2, 5, 7, 12, 16–18].

The Hosmer-Lemeshow goodness-of-fit test was used to examine the multivariable model, with $P=0.525$ indicating an acceptable fit. Outliers were investigated using Cook's distance and no extreme outliers were detected. The Variance Inflation Factors (VIF) was relatively low, less than 3 for all variables, indicating that no multicollinearity was present. Linearity for the continuous variables was investigated using smoothed partial residual plots and by modelling the variables with restricted cubic splines and plotting the functional form. Tourniquet time and cuff pressure were deemed to have a linear association with complications, but age was not, and was therefore categorized as 70 years or less vs. over 70 years, based on visual inspection of the plots.

Interactions between tourniquet time and all variables from the multivariable model were tested, and they are presented in a Forest plot (Fig. 1). Cuff pressure was dichotomised for presentational purposes in the Forest plot. Modelling interactions make it possible to interpret the results for subgroups of the population, but with the additional benefit of formally testing for differences in effect of tourniquet time on complications between the different levels of the respective variables.

Table 1 Demographic baseline data for all patients included ($n=641$)

	All patients	≤ 100 min ($n=373$)	> 100 min ($n=268$)	p value
Sex ^a				0.110
Female	420 (65)	254 (68)	166 (62)	
Male	221 (34)	119 (32)	102 (38)	
Age, years ^b	70 (10)	70 (11)	70 (10)	0.767
ASA ^c				0.729
1	95 (15)	58 (16)	37 (14)	
2	297 (46)	170 (46)	127 (47)	
3	150 (23)	84 (23)	66 (25)	
Diabetes				0.418
Yes	89 (14)	48 (13)	41(15)	
Smokers				0.904
Yes	80 (12)	46 (12)	34 (13)	
Surgery indication				< 0.001
Primary	577 (90)	346 (93)	231(86)	
Revision	46 (7)	9 (2)	37 (14)	
Patellar- supplementing	18 (3)	18 (5)	0	
Cuff pressure, mmHg ^b	259 (20)	261 (20)	256 (20)	0.001
Tourniquet time, min ^b	97 (22)	82 (12)	119 (12)	< 0.001

ASA American Society of Anesthesiologists
p values have been tested with Fisher's exact test and student's *t* test

^aThe values are given as the number of patients with the percentage in parentheses

^bThe values are given as the mean and standard deviation

^c99 patients with missing ASA recording

Two sensitivity analyses were performed. One without the ASA classification, since ASA recording was missing on 99 patients, and one for tourniquet time, excluding the 16 patients with a re-inflated tourniquet cuff.

The study was conducted according to the Helsinki Declaration and was approved by the Ethics Committee of the Karolinska Institute (2009/1152-31/2).

Results

In our eligibility assessment, we identified 641 patients who had all undergone knee arthroplasty surgery. Tourniquet

Table 2 Odds ratio for tourniquet time in relation to a complication after total knee arthroplasty (TKA)

Model	Tourniquet time, min	OR	95 % CI	p value
Crude model	$> 100^b$	2.2	1.5–3.1	< 0.001
Adjusted model ^a	$> 100^b$	2.4	1.6–3.6	< 0.001
Adjusted model ^a	$> 120^c$	1.9	1.1–3.2	0.014
Adjusted model ^a	Continuous ^d	1.2	1.1–1.4	< 0.001

^a Adjusted for sex, age, ASA classification, smokers, diabetes, surgery indication, and cuff pressure

^b Reference ≤ 100 min

^c reference ≤ 120 min

^d the variable was analyzed as continuous but is presented as per 10 min

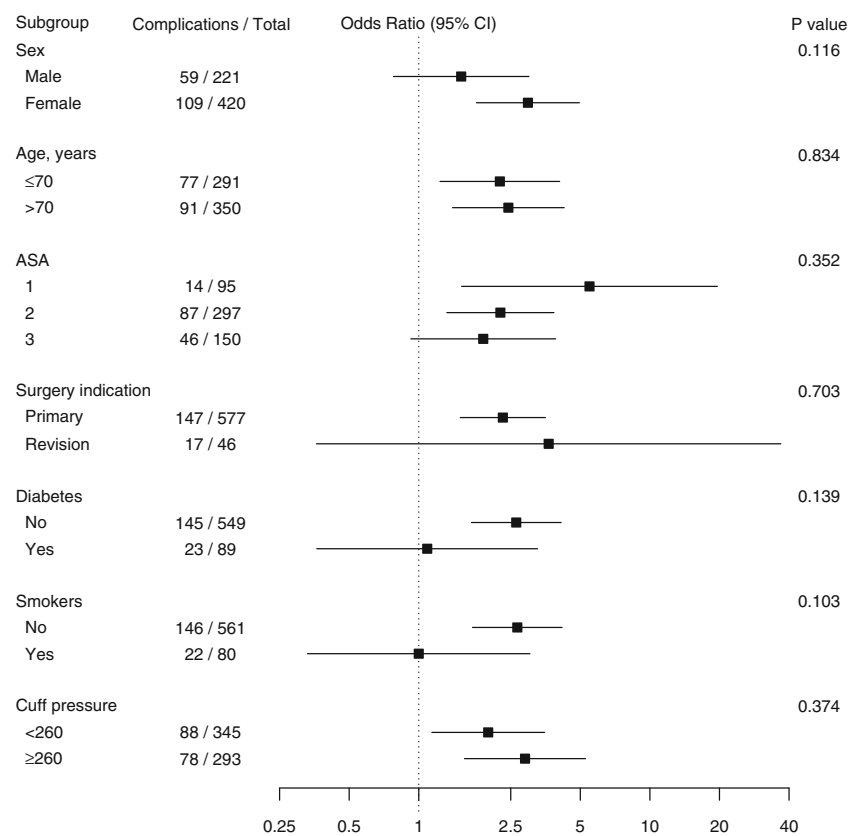
time ranged from 39 minutes to 156 minutes. Baseline data for all patients and by ≤ 100 min and > 100 min tourniquet times are presented in Table 1. As shown in the Table, the indication for surgery, mean cuff pressure, and of course the mean tourniquet time are not equally distributed.

We found an association between tourniquet time and an increased risk of a complication after knee arthroplasty surgery in a bloodless field. When tourniquet time exceeded 100 minutes, a crude model analysis showed an increased risk for a complication compared with a tourniquet time 100 minutes or less (OR 2.2, CI 1.5–3.1). This result remained after adjusting for cuff pressure (continuous), sex, age (70 years and under vs. over 70 years), ASA classification (1–3), smoking (yes/no), diabetes (yes/no), surgery indication (primary, revision, patella supplementing) (OR 2.4, CI 1.6–3.6) (Table 2). When tourniquet time was analysed as a continuous variable, the odds for having a complication increased by 20 % for every ten minutes of longer tourniquet time (OR 1.2, CI 1.1–1.4). Since the recommended time limit at our department is 120 minutes, we also analysed the tourniquet time variable as 120 minutes or less vs. over 120 minutes. These results also showed increased odds for suffering a complication (OR 1.9, CI 1.1–3.2) (Table 2).

In sensitivity analyses without the ASA classification or without patients with a re-inflated tourniquet cuff, the association between tourniquet time of over 100 min and complications remained (without ASA OR 2.3, CI 1.6–3.3 and without re-inflated OR 2.4, CI 1.6–3.7).

Interactions between tourniquet time and the other variables included in the multivariable model are shown in Fig. 1, where the number of complications in each subgroup

Fig. 1 Multivariable odds ratio (OR) for suffering a complication by subgroups and p values are for interactions between tourniquet time ≤ 100 min vs. > 100 min and sex, age, ASA, surgery indication, diabetes, smokers, and cuff pressure. Numbers of complications by subgroups



is also presented (Fig. 1). We found no statistically significant interaction between a tourniquet time of over 100 minutes and the other variables in our adjusted model. Even patients classified as ASA 2 and ASA 3 or as diabetics or smokers tourniquet time showed no association with complications (Fig. 1). However, among women, the impact of tourniquet time for suffering a complication was higher (OR 3.0, CI 1.8–5.0) compared to men (OR 1.6, CI 0.8–3.0), although this difference was not statistically significant. Thirty -nine percent of the women who

had a tourniquet time of over 100 minutes had a complication compared to 29 % of the men.

Age, sex, surgery indication, diabetes, smoking, and cuff pressure showed no statistically significant association for suffering a complication in either the crude model or the different adjusted models. However, patients classified as ASA 2 and ASA 3 did show an association for suffering a complication compared to ASA 1 (ASA 2, OR 2.5, CI 1.3–4.7, $p=0.006$ and ASA 3, OR 2.9, CI 1.4–5.9, $p=0.003$).

Table 3 Incidence of complications for all patients, and also when the bloodless field time was shorter or longer than 100 min ($n=641$)

	Complications ^b	$\leq 100^b$ ($n=373$)	$> 100^b$ ($n=268$)
Complication ^a			
Yes	168 (26)	74 (20)	94 (35)
Wound complication	99 (15)	41(11)	58 (22)
Superficial wound infection	92 (14)	37 (10)	55 (21)
Deep wound infection	6 (1)	4 (1)	2 (1)
Bleeding	1 (0.2)	0	1(0.4)
Cuff pressure injury	49 (8)	17 (5)	32 (12)
Bandage injury	21 (3)	10 (2)	11 (4)
Peripheral nerve injury	4 (0.6)	2 (0.5)	2 (1)
Compartment syndrome	2 (0.3)	1 (0.3)	1 (0.4)
DVT	22 (3)	11 (3)	11 (4)
PE	1 (0.2)	1 (0.3)	0

^aSome patients have more than one complication and are therefore presented in multiple cells

^bThe values are given as the number of patients with the percentage in parentheses

DVT Deep vein thrombosis, PE Pulmonary embolism

In total, 168 (26 %) patients had a complication recorded. Ninety-four (35 %) of these patients had had a bloodless field time longer than 100 minutes (Table 3). The mean bloodless field time for the patients who had a recorded complication was 104 minutes compared to 95 minutes for those who had no complication. Three of the 16 patients with a re-inflated tourniquet cuff had a complication (two wound complications and one DVT) (data not shown).

Discussion

This study shows a statistically significant association between tourniquet time and complications after knee arthroplasty surgery.

Our findings are in accordance with earlier published studies, i.e. a longer tourniquet time increases the risk of complications [12–14]. In a meta-analysis, comparing early tourniquet release with releasing the tourniquet after wound closure, Rama et al. (2007) reported a significantly increased rate of re-operations, due to postoperative complications when the tourniquet was left inflated until wound closure was completed. Tourniquet time had a mean of 80 minutes compared to 69 minutes in the early release group ($p=0.002$). Jacob et al. (2011) demonstrated a correlation between tourniquet time and nerve injury after a TKA (OR 1.28, 95 % CI 1.09–1.50, $p=0.003$). Chang et al. (2012) found that at six-week follow-up after a TKA, patients with a mean tourniquet time of 53 (SD 8.7) minutes, compared to those with 75.5 (SD 9.9) minutes, had better active knee flexion and subjective knee performance. Butt et al. (2011) found an association between cessation of oozing wounds and the duration of the bloodless field ($p=0.03$).

It is generally recommended that the use of tourniquet should be limited to two hours due to the risk complications. Fitzgibbons et al. (2012) concluded, however, that these complications are mostly minor and of a short-term nature and that there are no contraindications to longer tourniquet time when necessary. In our study, we found that every additional ten minutes of tourniquet time was associated with an increased risk for complications. In our experience, every complication may interfere with the postoperative functional recovery and could lead to unnecessary discomfort for the patient. We therefore believe that it is important that the tourniquet time is minimised for an optimal outcome. Individual patient comorbidities might also be worthy of consideration, since patients classified as ASA 2 or ASA 3 also had statistically significant higher odds for suffering a complication compared to patients with ASA 1 (OR 2.5, 2.9). This finding that a patient with comorbidities will have an increased risk for complications connected with knee surgery also seems logical. In this study, it appears that women might be less tolerant to tourniquet time than men. Women had almost doubled the

odds for a complication (OR 3) compared to men (OR 1.6) after a tourniquet time of over 100 minutes. A difference between the sexes in terms of tolerating tourniquet time has never been demonstrated before. However, this difference was not statistically significant. Still, this is maybe something that needs further research.

When discussing disadvantages of pneumatic tourniquets, not only the tourniquet time, but also the cuff pressure, has to be considered. However, cuff pressure showed no association with complications in this study. The mean tourniquet cuff pressure was 259 mmHg. This is a rather low mean cuff pressure compared to other published studies, where pressures of 300–350 mmHg have been reported [5, 19–21]. The relatively low cuff pressures used by our surgeons might have had an influence on the results in this study with no impact of cuff pressure in the multivariable model. However, we have seen earlier that even lower cuff pressures of 225 mmHg or less result in fewer wound complications [22]. In this study, only a few patients have had a cuff pressure of less than 225 mmHg.

The strength of this study is the consecutive cohort of quite a substantial number of knee arthroplasty surgery patients. The patients were prospectively followed and all complications were verified with a follow-up rate of 99.3 %. One weakness of the study might be the relatively old material; however, the surgical methods, length of surgery, tourniquet time, cuff pressure, and patient comorbidities have not generally changed, and therefore the results should still be valid. Another limitation is the inclusion of both primary and secondary interventions in order to achieve tourniquet time dispersion among the patients. Obviously, a revision surgical procedure should carry a higher risk of complications than primary surgery. However, categorisation as primary, revision, and patellar supplementing procedures in this study showed no statistically significant association with complications.

Conclusions

The results of this study indicate that tourniquet time has an impact on the complication rate after knee arthroplasty.

Conflict of interest The authors declare that they have no conflict of interest.

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