

Clinical Pain Research

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The effect of tourniquet use on postoperative opioid consumption after ankle fracture surgery – a retrospective cohort study

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Abstract

Objectives: A pneumatic tourniquet is often used during ankle fracture surgery to reduce bleeding and enhance the visibility of the surgical field. Tourniquet use causes both mechanical and ischemic pain. The main purpose of this study was to evaluate the effect of tourniquet time on postoperative opioid consumption after ankle fracture surgery.

Methods: We retrospectively reviewed the files of 586 adult patients with surgically treated ankle fractures during the years 2014–2016. We evaluated post hoc the effect of tourniquet time on postoperative opioid consumption during the first 24 h after surgery. The patients were divided into quartiles by the tourniquet time (4–43 min; 44–58 min; 59–82 min; and ≥83 min). Multivariable linear regression analysis was used to evaluate the results.

Results: Tourniquets were used in 486 patients. The use of a tourniquet was associated with an increase in the total postoperative opioid consumption by 5.1 mg (95 % CI 1.6–8.5; $p=0.004$) during the first 24 postoperative hours. The tourniquet time over 83 min was associated with an increase in

the mean postoperative oxycodone consumption by 5.4 mg (95 % CI 1.2 to 9.7; $p=0.012$) compared to patients with tourniquet time of 4–43 min

Conclusions: The use of a tourniquet and prolonged tourniquet time were associated with higher postoperative opioid consumption during the 24 h postoperative follow-up after surgical ankle fracture fixation.

The need for ethical approval and informed consent was waived by the Institutional Review Board of Northern Ostrobothnia Health District because of the retrospective nature of the study.

Keywords: ankle fracture; tourniquet; postoperative pain; opioid consumption

Introduction

A pneumatic tourniquet is often used in extremity surgery to reduce bleeding and to improve visualisation of the surgical field. Its use is considered safe in foot and ankle surgical procedures [1]. However, the use of a tourniquet carries a risk of increased postoperative pain and other complications, such as skin, muscle, nerves and blood vessel damage due to mechanical pressure [2–4]. A tourniquet can also cause peripheral and compression-related ischemia and cell damage [5]. A tourniquet constriction is noticed to exacerbate the painful stimulus around the site of induced secondary hyperalgesia [6]. In addition, more complications are associated with long tourniquet times than with short tourniquet times [7, 8]. Thus, the use of a tourniquet may increase postoperative pain sensation.

The effects of thigh tourniquet use on postoperative pain and opioid consumption have been debated in previous studies that used heterogeneous study designs and achieved conflicting results. Most of these studies were conducted on patients undergoing elective total knee arthroplasty [9–12], thereby raising the question of whether the results from studies performed in an elective setting can be compared with surgical procedures after traumatic injury, such as ankle

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fracture. Pain from an ankle fracture is caused by immediate mechanoc nociception due to the bone fracture, combined with pain caused by tissue swelling and inflammation. A patient with an ankle fracture experiences significant pain both pre- and postoperatively [13], whereas patients scheduled for elective surgery do not suffer from pain caused by acute tissue trauma occurring prior to surgery.

Only a few studies have evaluated the use of a tourniquet on pain sensation or opioid consumption following ankle fracture surgery [14–16], and good-quality randomised controlled trials (RCT) are lacking [17]. One RCT comparing postoperative pain in patients with open reduction and internal fixation (ORIF) of an ankle fracture operated with or without tourniquet use found that patients with a tourniquet reported significantly higher pain scores during the first 24 to 48 postoperative hours [14]. Another RCT evaluating tourniquet use in patients with ORIF of an ankle fracture noted that patients operated without a tourniquet described less postoperative pain on the fifth postoperative day and in the sixth postoperative week [15]. These two previous RCTs did not report the mean tourniquet times or opioid consumption. To our knowledge, only one previous retrospective study evaluated the effect of tourniquet insufflation time on postoperative opioid consumption during the first 24 h postoperatively in 358 patients with surgical ankle fracture fixation. An increase in opioid consumption in relation to a longer duration of tourniquet insufflation was noted [16].

The main purpose of the present study was to evaluate whether tourniquet insufflation time influences postoperative opioid consumption in patients with surgical ankle fracture fixation during the first 24 postoperative hours. Our hypothesis was that, because prolonged tourniquet insufflation time can have harmful effects, the use of a tourniquet may cause more postoperative pain, which might be accompanied by a rise in postoperative opioid consumption.

Methods

The present retrospective cohort study was a post hoc analysis of the data used in our previous study comparing postoperative opioid consumption between spinal anaesthesia (SA) and general anaesthesia (GA) in patients with surgical ankle fracture fixation [18]. The study was approved by the hospital administration. According to local policy concerning retrospective database studies, no approval was needed from the local ethics committee.

We reviewed the files of all patients who had undergone surgical ankle fracture fixation at Oulu University Hospital between January 2014 and December 2016. The data were collected from the digital medical records, surgery booking system and anaesthesia charts. We included all adult patients with an isolated surgically treated ankle fracture. The exclusion criteria were fractures of both ankles, multiple fractures and/or major trauma, other surgical procedure performed at the same time, re-operation of the ankle and patients with inadequate recording of tourniquet time.

Anaesthesia management and pain treatment

Due to the retrospective design of the study, the anaesthesia method was not pre-planned. The anaesthesia was given according to the hospital's anaesthesia guidelines for lower limb surgical procedures, which recommend GA or SA for ankle fracture patients. Fentanyl boluses were used for pain management during GA. No intrathecal or epidural analgesia or peripheral nerve blocks (PNB) were used during GA. Bupivacaine was used for SA and intrathecal fentanyl was used to enhance the analgesic effect.

In the PACU, pain was treated individually, mainly with oxycodone, acetaminophen and ketoprofen. PNBs were used only if conservative pain management was insufficient. Opioids were given (intravenously and orally) whenever needed so that the Numeric Rating Scale (NRS) score was ≤ 4 (scale 0–10) and the pain was under control. Acetaminophen was ordered for almost every patient. NSAIDs (oral ibuprofen or intravenous ketoprofen) were not ordered routinely for every patient but were given to alleviate more severe pain. In the ward, acetaminophen was given routinely around the clock if no contraindications were noted. Short-acting oxycodone was administered perorally when needed. Long-acting oxycodone was combined with the medication if the pain was moderate to severe and/or persistent in the ward. Intramuscular opioids were not administered in this patient cohort.

The doses of any opioid administered postoperatively were converted into an intravenous equivalent dose of oxycodone in milligrams. A conversion ratio of 1:2 was applied between intravenous and oral oxycodone based on the product characteristics of intravenous oxycodone [19]. Also, this ratio can be considered safer in clinical practice when compared to the observed variations in peroral bioavailability of oxycodone in previous studies [20, 21]. The amount of oral codeine in milligrams was converted into intravenous equianalgesic oxycodone in milligrams in a relation of 20:1. Intravenous fentanyl was converted into intravenous equivalent oxycodone in milligrams in a ratio of 1:75 [21, 22]. Opioid consumption during the surgical procedure, including intrathecal administration of fentanyl, was recorded, but was not included in the analysis of postoperative opioid consumption. The anaesthesia management and pain treatment have been described in detail in our previous study [18].

Primary outcome

The primary outcome was the total opioid consumption in milligrams within 24 h postoperatively in relation to tourniquet time. The duration of tourniquet insufflation in minutes was collected from the digital anaesthesia charts. A thigh tourniquet was used during surgical ankle fracture fixation. During the insufflation, a standard cuff pressure of 250 mmHg was used. The study population was divided into quartiles in relation to tourniquet time (Q1 4–43 min; Q2 44–58 min; Q3 59–82 min; Q4 ≥ 83 min).

Statistical analysis

Statistical analyses were performed using SPSS for Windows software (IBM SPSS Statistics for Windows, version 25.0; IBM Corp., Armonk, New York). Categorical data are expressed as numbers (n) and percentages (%). Continuous variables are presented as medians with 25th and 75th percentiles. Categorical data were analysed using Pearson's

chi-square and continuous variables were analysed using the non-parametric Mann–Whitney U-test.

Post hoc power analysis and sample size calculation was made with $\alpha=0.05$, mean difference of 5 mg, SD 16.4 and superiority margin of 2.5, resulting in a post hoc power of 100 % in our study, and with estimated 90 % power a sufficient sample size would be 352 patients.

Multivariable adjusted linear regression models were calculated to assess the impact of tourniquet use and the impact of tourniquet time on total opioid consumption. The constant in the linear regression modes was the mean opioid consumption for patients who had a tourniquet time within 4–43 min, an operation in SA and an unimalleolar fracture.

Multivariable adjusted logistic regression models were calculated to assess the impact of tourniquet time on the administration of post-operative NSAID and/or acetaminophen. Regression coefficients are presented as the result of the linear regression model, and odds ratios (OR's) are presented for the logistic regression model. Regression models were adjusted by the severity of trauma and anaesthesia method (SA and GA), and 95 % confidence intervals are presented with regression coefficients and ORs. Two-sided p-values <0.05 were considered as significant. DAGitty software [23] was used to identify the minimum set of variables requiring adjustment to estimate the effect of tourniquet time on opioid consumption (Figure S2, Supplementary Material).

A matched pairs dataset was created to assess opioid consumption between patients treated with and without tourniquet. The pairs were matched by operation time (± 10 min), anaesthesia method (general anaesthesia vs. spinal anaesthesia), age (± 10 years) and sex (male vs. female). A paired samples t-test was used to compare the impact of tourniquet use. The mean difference with 95 % confidence interval is presented as the result for the paired samples t-test. The p-values should be treated with caution since several comparisons were made, and p-value correction coefficient methods has not been used.

Results

A total of 586 patients were included in the analysis. Of those, 486 had a tourniquet applied during ankle fracture fixation. Of those, 141 (29 %) were operated in SA, and the same distribution between SA and GA remained regardless of fracture type or operation technique. Patients with a tourniquet were divided into four groups by the tourniquet time, and each group had nearly equal numbers of patients (Q1 4–43 min, $n=132$; Q2 44–58 min, $n=112$; Q3 59–82 min, $n=123$; Q4 >83 min, $n=119$). The median tourniquet time was 58 min (25th to 75th percentiles; 43–82). Patients who did not have a tourniquet ($n=100$) were older, had a higher ASA (American Society of Anesthesiologists) classification score and were more often operated in SA (38 vs. 29 %) compared to patients with a tourniquet. The characteristics of patients operated with and without a tourniquet are shown in Table 1.

The total opioid consumption during the first 24 post-operative hours was 25 mg (16–38.5) of equianalgesic intravenous oxycodone in the whole study population and 26 mg (17–39) in the tourniquet group vs. 20.5 mg (12.5–40) in the no-tourniquet group ($p<0.001$). The multivariable adjusted analysis suggested that tourniquet use was associated with an increase in total postoperative opioid consumption of 5.1 mg during the first 24 postoperative hours (95 % CI 1.6–8.5; $p=0.004$).

Table 1: Patient characteristics and results.

Parameters	All patients $n=586$	Tourniquet $n=486$ (82.9 %)	No tourniquet $n=100$ (17.1 %)	p-Value
Gender male	49.3 % (289)	48.1 % (234)	55.0 % (55)	0.23
Age	53 [36–64]	51 [35–52]	60 [45–74]	<0.001
BMI	27.9 [24.9–31.2]	28.0 [24.9–31.3]	27.7 [24.8–30.1]	0.49
ASA	2 [1–2]	2 [1–2]	2 [1–3]	0.012
1–2	77.4 % (452)	79.8 % (387)	65.7 % (65)	
3–4	22.6 % (132)	20.2 % (98)	34.3 % (34)	
Smoking	36.3 % (213)	38.2 % (185)	28 % (28)	0.08
Diabetes	12.8 % (75)	11.6 % (56)	19 % (19)	0.048
Fracture type		% (n)		0.023
–Unimalleolar	29.5 % (173)	31.7 % (154)	19.0 % (19)	
–Bimalleolar	27.8 % (163)	27.8 % (135)	28 % (28)	
–Luxation and/or trimalleolar	42.7 % (250)	40.5 % (197)	53.0 % (53)	
Operation technique				<0.001
–Unimalleolar fixation	46.3 % (271)	47.5 % (231)	40.0 % (40)	
–Bimalleolar and/or trimalleolar fixation	49.3 % (289)	50.8 % (247)	42.0 % (42)	
–Fibular rod only	4.4 % (26)	1.6 % (8)	18 % (18)	
Operation time in minutes	56 [38–78]	58 [39–80]	49 [33–68]	0.003
Length of PACU stays in minutes	146 [112–193]	145 [112–190]	149 [116–200]	0.41
NRS during the PACU stay	4 [2–7]	5 [2–7]	4 [2–6]	0.048
NRS ≥ 5 during the PACU stay	37.7 % (221)	39.7 % (193)	28 % (28)	0.12
Spinal anaesthesia	30.5 % (179)	29.0 % (141)	38.0 % (38)	0.095

The values are shown as medians and 25th–75th percentiles [], or percentiles (%) and number of patients (n). (BMI, body mass index; ASA, American Society of Anesthesiologists classification score; NRS, numeric rating scale; PACU, post-anaesthesia care unit).

The primary outcome is shown in Table 2. The result suggested that the increase in total postoperative opioid consumption was associated with the duration of tourniquet insufflation time. The multivariable-adjusted analysis, statistically correcting for all confounders considered (Figure S2, Supplementary Material), shows that a tourniquet time over 83 min was associated with a 5.4 mg increase in total postoperative opioid consumption (95 % CI 1.2–9.7; $p=0.012$). A similar increase in total postoperative opioid consumption was noticed when patients operated with and without a tourniquet were compared (Table 3). The mean total opioid consumption was associated with a 5.8 mg (95 % CI –1.7 to 13.2; $p=0.12$) increase in the patients operated with a tourniquet and with the surgical operation time over 68 min compared to the patients treated without a tourniquet. The characteristics of the patients with a tourniquet time over 83 min were: tourniquet time median 96 min [89–109]; ASA 1 [1–2]; age median 54 [36–64]; GA 70.6 % ($n=84$); female 55.5 % ($N=66$), diabetes 13.4 % ($n=16$); BMI 28 [25–31], smoking 37.8 % ($n=45$). An increase in the surgical procedure time was associated with the severity of trauma. The tourniquet insufflation time was comparable with the surgical procedure time (Figure 1), and the total postoperative opioid consumption was not associated with

the severity of trauma in the patients operated with a tourniquet (Table S4, Supplementary Material).

NSAIDs were given to 38 % ($n=221$) and acetaminophen to 71 % ($n=414$) of all patients during the PACU stay. Neither the use of a tourniquet nor the tourniquet time increased the rate of NSAID [OR 0.87 (95 % CI 0.49–1.56); $p=0.64$] or acetaminophen [OR 1.56 (95 % CI 0.86–2.84); $p=0.15$] administration in the PACU. The use of a tourniquet did not increase the need for postoperative PNBs (no-tourniquet 4.0 % vs. tourniquet 2.7 %), and only 13/486 patients were administered a postoperative nerve blockade.

Discussion

The findings of the present retrospective cohort study in patients with ORIF of an ankle fracture suggest that the prolonged use of a tourniquet is associated with a higher postoperative opioid consumption during the first 24 postoperative hours. To our knowledge, this is the largest cohort to be evaluated for the effect of tourniquet time on opioid consumption in patients with surgically treated ankle fracture.

In the present study, the increase in opioid consumption in relation to tourniquet insufflation time 24 h postoperative was higher compared to previous study which reported an

Table 2: The total postoperative opioid consumption associated with tourniquet insufflation time in each quartile and the effect of tourniquet time on the total postoperative opioid consumption in 24 h of follow-up compared to the first quartile (4–43 min, constant). The results are adjusted by the severity of trauma and the type of anaesthesia.

	Mean (std. deviation) [median]	Effect on opioid consumption	95 % CI	p-Value
Tourniquet time 4–43 min ($n=132$)	26.9 mg (15.1) [24.75]	0 mg/reference		
Tourniquet time 44–58 min ($n=112$)	28.9 mg (15.8) [25.25]	2.3 mg	–1.7–6.3	0.26
Tourniquet time 59–82 min ($n=123$)	30.9 mg (17.8) [28]	3.7 mg	–0.4–7.7	0.075
Tourniquet time >83 min ($n=119$)	32.1 mg (16.4) [30]	5.4 mg	1.2–9.7	0.012

Constant=19.7 mg. The constant is the mean opioid consumption for patients with tourniquet insufflation time within 4–43 min, operated in SA and who had an unimalleolar ankle fracture. Pct, percentiles. CI, confidence interval. p-value for the effect size compared to a tourniquet time of 4–43 min.

Table 3: Total opioid consumption associated with surgical procedure time and the mean difference with 95 % confidence interval between patients operated with and without tourniquet: matched pairs^a data. The opioid consumption is the total opioid consumption during the 24 h of follow-up.

Surgical procedure time in minutes	No tourniquet ($n=90$) Mean	Tourniquet ($n=90$) Mean	Mean difference (95 % CI)	p-Value
0–33 min ($n=23+23$)	28.1 mg	26.0 mg	–2.1 mg (6.9 to –11.1)	0.64
34–48 min ($n=23+23$)	23.5 mg	23.2 mg	–0.3 mg (9.4 to –10.1)	0.94
49–67 min ($n=22+22$)	20.9 mg	27.8 mg	6.9 mg (14.7 to –0.9)	0.08
>68 min ($n=22+22$)	24.7 mg	30.4 mg	5.8 mg (13.2 to –1.7)	0.12

n =number of patients. Two-sided p-value for the paired samples t-test. CI, confidence interval. ^aThe pairs were matched by operation time (± 10 min), anaesthesia method (general anaesthesia vs. spinal anaesthesia), age (± 10 years) and sex (male vs. female).

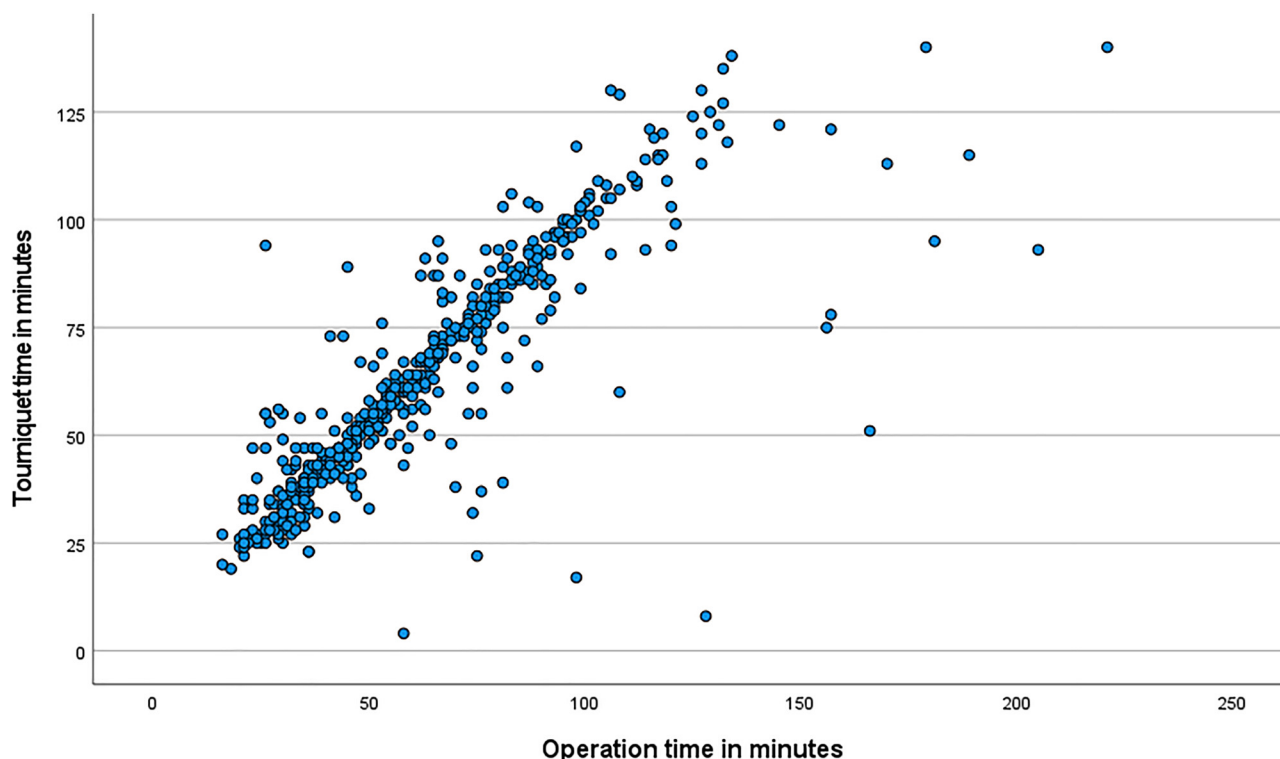


Figure 1: The tourniquet insufflation time compared to the operation time.

average rise of 0.43 mg of intravenous morphine equivalent per every 10 min of insufflated tourniquet use in postoperative opioid consumption 24 h after surgery [16]. In that study, a linear rise in opioid consumption in relation to tourniquet insufflation time was assumed; therefore, a tourniquet time over 125 min would have been needed to reach the results of the present study. However, the opioid equivalents between studies were not directly proportional, nor was the postoperative pain management. In our study, the cohort was divided into quartiles by tourniquet insufflation time, because a linear rise between tourniquet time and opioid consumption was not assumed.

An argument can be made that the results of the present study may simply reflect the pain caused by tissue damage due to the severity of the trauma and surgical procedures. This hypothesis was ultimately rejected following a comparison of the postoperative opioid consumption between the patients operated with and without tourniquet and with similar surgical procedure times. The difference in opioid consumption between the groups was associated only with the longer tourniquet insufflation time. The total opioid consumption during the first 24 h postoperatively in the patients with a tourniquet and a procedure time over 68 min was associated with an almost 20 percent rise in opioid consumption. Although the number of patients in this

comparison was too small to draw any definitive conclusions, the results support the hypothesis that the tourniquet itself and a longer tourniquet insufflation time may be associated with more postoperative pain.

The minimum clinically important difference in the visual analogue scale and NRS is often used to evaluate adequate pain relief [24]. However, no consensus is evident in the literature regarding a clinically significant difference in opioid consumption because it is influenced by a variety of factors. Some studies have shown that patients with acute postoperative pain can require approximately five mg of intravenous morphine equivalent to obtain the desired pain relief and NRS reduction [25, 26]. Also, 10 mg of intravenous morphine have been suggested as clinically meaningful difference for 24 h opioid consumption [27]. An equivalence ratio of 1:1 between intravenous oxycodone and morphine is often used in the literature but consumption of intravenous oxycodone has also noticed to be less compared to intravenous morphine with consumption ratio close to 2:3 between intravenous oxycodone and intravenous morphine [28]. In reference to these studies, a cautious interpretation can be made that a 5.4 mg increase in intravenous equianalgesic oxycodone consumption during the first 24 postoperative hours in patients with a tourniquet time over 83 min could be a clinically significant finding. Furthermore, had we

chosen an oral to intravenous oxycodone coefficient derived from the observed variations in peroral bioavailability across different studies [20, 21], such as a coefficient of 0.6 or 0.7 rather than 0.5, it would have resulted in a notable increase in the equivalent intravenous oxycodone consumption, especially in patients with the longest tourniquet times. This would reinforce our suggestion about a clinically significant finding.

A general recommendation for the longest allowable continuous tourniquet cuff insufflation time is 2–2½ h [29, 30]. Standard thigh tourniquet pressures vary, and some centres use levels of 300–350 mmHg [1, 29]. The recommended pressure for lower extremity tourniquets is less than 300 mmHg or the use of the limb occlusion pressure plus 50–100 mmHg, depending on the underlying systolic blood pressure [29–32]. The tourniquet pressures used in previous ankle studies were 250 mmHg [14] and 350 mmHg [15]. In our study, a standard cuff pressure of 250 mmHg was used. Prolonged tourniquet insufflation and higher tourniquet cuff pressures can lead to more tissue damage, overall postoperative complications, and pain [2, 3]. An increased rate of complications has been noted in patients with total knee arthroplasty and tourniquet times over 100 min, but the pain sensation and opioid consumption were not recorded [8]. A study on patients with diabetes and Charcot foot who underwent ankle and foot reconstruction surgery documented more complications with longer tourniquet times (119 ± 9 min) than with shorter tourniquet times (74 ± 56 min) [7].

Clinical impact

The advantages of a tourniquet include providing a bloodless field and better visibility for surgical area, and is thought to reduce intraoperative blood loss, and shortening the operation time. However, tourniquet use is associated with thrombotic events, hematomas, infections, nerve palsy, skin bruising and blisters, and longer hospital stays and increase in pain sensation [4]. Although our study was not designed to evaluate overall postoperative complications, the clinical impact of a prolonged tourniquet insufflation time suggests a higher postoperative opioid consumption, which can be interpreted as a surrogate for a higher postoperative pain sensation. The tourniquet may exacerbate pain sensations at the site of inflammation [6], such as the inflammation caused by ankle fracture. Moreover, prolonged tourniquet insufflation times and higher cuff pressures may cause increased pain due to tissue damage by mechanical compression and ischaemia, and prolonged tourniquet time is associated with post-tourniquet syndrome [2–5]; therefore, attention should be paid to both tourniquet cuff pressures and insufflation

times. Additionally, tourniquet insufflation and deflation may cause significant variations in cardiac output and systemic vascular resistance. After deflation, elevated blood lactate levels and oxygen consumption are associated with tourniquet-induced ischemia time [33]. These cardiovascular changes can be clinically significant for patients with related diseases and in the elderly.

Limitations and strengths

This study has some limitations. It was not a randomised prospective study, and no controlled protocols were used. Although a standard tourniquet cuff pressure is used in our hospital for ankle fracture patients, the tourniquet time was not predetermined, and the decision to use a tourniquet was left to the attending surgeon. Patients treated without tourniquet had more often SA, were older and had higher ASA score, all factors which could have confounded effect on opioid consumption and administration. NSAIDs have a clear and acknowledged analgesic and opioid sparing effect. In the present study the use of NSAIDs was heterogeneous. NSAIDs were administered to patients with more severe pain and more often to patients treated with GA. In addition, postoperative opioid consumption can be confounded by several unmeasured factors, such as pain catastrophising, anxiety and preoperative opioid consumption. The postoperative pain treatment was also not standardised and was heterogeneous, especially on the ward during the first 24 postoperative hours. However, this heterogeneity most likely influenced the cohort somewhat randomly. Pain scores were not routinely documented in the ward, which made it more difficult to evaluate the indications for on-demand opioid administration. However, postoperative opioids are prescribed and administered to patients with more severe acute pain. Therefore, opioids can be used as a surrogate for patient-reported pain assessment. A more severe type of fracture, together with the operation technique, could also have influenced postoperative pain [16], although a previous study in patients with ankle fracture indicated that the type of fracture or procedure technique did not predict more severe pain [34].

Several confounding factors could affect the association between tourniquet insufflation time and opioid consumption. For this reason, variables such as diabetes, smoking, alcohol consumption, type of fracture, pain perception, age and gender were evaluated with the DAGitty software [23] to estimate the effect of tourniquet time on opioid consumption. The type of ankle fracture and the anaesthesia method were used to adjust the regression model, as these were predicted to be factors with the greatest influence. The type

of ankle fracture was correlated with the operation technique and the duration of surgery, which in turn was related to the tourniquet time. The tourniquet time was affected by the abovementioned factors in the present study. The method of anaesthesia had been determined as the most influencing confounder for total opioid consumption in our previous study, which is why it was used to adjust the regression model [18]. SA lowers total postoperative opioid consumption significantly because of the ongoing anaesthetic effect during PACU stays, but also because of the use of intrathecal fentanyl. The effect of intrathecal fentanyl on postoperative opioid consumption was indirectly considered when the regression model was adjusted with the anaesthesia method in the present study. However, even if a multivariable model was created with adjustments for known confounders, the residual confounding by unmeasured confounders could still influence the results. The characteristics of the patients with the longest tourniquet times were comparable with the rest of the patients with tourniquet. Habitual opioid users or patients with chronic pain were included in the analysis and were not registered separately, since they were few and did not demonstrate any real difference in their postoperative opioid use compared to the other patients. This could have been a source of significant bias had there been many habitual opioid users. Approximately every tenth patient treated with tourniquet had diabetes, most of them type II diabetes mellitus. Diabetes could cause neuropathy and neuropathic pain which could have impact on post operative pain and lead to higher opioid consumption. Severe neuropathy and neuropathic pain are often considered a contraindications for tourniquet use. In the present study, neuropathy or neuropathic pain was not recognised as a confounding factor for postoperative opioid consumption.

A strength of the present study was its relatively large patient cohort with a broad scale of tourniquet insufflation times and a sufficient number of patients in each quartile for statistical analysis [35]. Also, post hoc power analysis and sample size calculation support that our cohort size was adequate.

The study population consisted of a normal clinical patient population. Also, as a retrospective study, it does not have presumptions about study outcomes, such as how much opioid should be given or how the study patients should be treated postoperatively. Therefore, the risk of observer bias is low [36]. Moreover, the cohort consisted of patients treated only with either GA or SA, and their pain was treated conservatively, mainly with opioids. PNBs were used only on a few occasions, and more frequent use could have caused significant bias when evaluating the effect of tourniquet-related postoperative pain.

Conclusions

The results of the present study suggest that the use of a tourniquet and longer tourniquet insufflation times are associated with increased postoperative opioid consumption. This finding was most pronounced in patients with tourniquet times longer than 83 min. The association between tourniquet time and opioid use may be caused by confounding factors. A randomised controlled trial is required to explore any causal relationships.

Research ethics: Procedures were followed in accordance with the ethical standards of the responsible institutional committee on human experimentation and with the Helsinki Declaration of 1975.

Informed consent: The study was approved by the hospital administration. The need for ethical approval and informed consent was waived by the Institutional Review Board of Northern Ostrobothnia Health District, because of the retrospective nature of the study.

Author contributions: All authors have contributed to the conception and design of the work, and to the interpretation and analysis of the data, and drafting or revising it. All authors have approved the final version to be published.

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Data availability: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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