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Original Contribution

Femoral vs sciatic nerve block to provide analgesia after medial open wedge high tibial osteotomy in the setting of multimodal analgesia: A randomized, controlled, single-blinded trial

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HIGHLIGHTS

- Medial open wedge high tibial osteotomy (MOW HTO) is associated with moderate to severe postoperative pain.
- There is a paucity of data on the optimal peripheral nerve block for postoperative analgesia with minimal impact on motor function.
- A femoral nerve block provides superior analgesia to a sciatic nerve block after MPOW HTO under general anesthesia in the setting of multmimodal analgesia.
- There was no significant difference in quality of life and functional outcomes at 6 months postoperatively between groups.

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ABSTRACT

Study objective: Medial open wedge high tibial osteotomy (MOW HTO) is associated with moderate to severe postoperative pain. The proximal part of the tibia is innervated by branches from the femoral nerve anteriorly and the sciatic nerve posteriorly. There is a paucity of information regarding the optimal peripheral nerve block for postoperative analgesia with minimal impact on motor function. This study tested the hypothesis that a femoral nerve block provides superior analgesia to a sciatic nerve block after MOW HTO in the setting of multimodal analgesia.
Design: Randomized controlled single-blind trial.
Setting: Operating room, postoperative recovery area and ward, up to 6 postoperative months.
Patients: Fifty patients undergoing MOW HTO.
Interventions: Interventions were femoral or sciatic nerve block under ultrasound guidance. For each intervention, a total of 100 mg of ropivacaine was injected. Postoperative pain treatment followed a pre-defined protocol with intravenous patient-controlled analgesia of morphine, paracetamol, and ibuprofen.
Measurements: The primary outcome was intravenous morphine consumption at 24 h postoperatively. Secondary outcomes included rest and dynamic pain scores (on a numeric rating scale out of 10) at 2, 24 and 48 h post-operatively. Functional outcomes included the Short Form-12, Knee injury and Osteoarthritis Outcome Score, and International Knee Documentation Committee (IKDC) scores measured at 6 months postoperatively.
Main results: Mean [95% confidence interval] i.v. morphine consumption at 24 postoperative hours were 24 mg [15 mg,33 mg] in the femoral nerve block group and 24 mg [16 mg,32 mg] in the sciatic nerve block group (p = 0.98). There were no significant differences in the secondary outcomes between groups.
Conclusions: This trial failed to demonstrate that a femoral nerve block provides superior analgesia to a sciatic nerve block after MOW HTO under general anesthesia in the setting of multimodal analgesia. There was no significant difference in quality of life and functional outcomes at 6 months postoperatively between groups.
Trial registry number: Clinicaltrials.com – NCT05728294; Kofam.ch – SNCTP000003048 | BASEC2018-01774

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1. Introduction

Medial open wedge high tibial osteotomy (MOW HTO) is associated with moderate to severe postoperative pain. Regional anesthesia provides optimal analgesia after a wide range of orthopedic surgery [1–4]. Very few trials have prospectively explored the analgesic benefit of nerve blocks for this surgery, and those that have been performed were limited by statistical methodology issues that resulted in erroneous conclusions [5,6].

The proximal part of the tibia is innervated by branches from the femoral and the sciatic nerves [7]. More specifically, the femoral nerve, via the anterior and medial genicular nerves, innervates the anteromedial aspect of the knee joint and the proximal tibia, while the sciatic nerve supplies the anterolateral and posterior parts of the knee joint and proximal tibia [7].

There is a paucity of information regarding the optimal peripheral nerve block for postoperative analgesia with minimal impact on motor function because previous trials only investigated the analgesic benefit of blocking the femoral component, without distinguishing between whether the pain location was anterior or posterior [5,6]. Given that the sciatic nerve is also a major source of the innervation of the proximal tibia, it is important to understand whether or not blocking the sciatic nerve would result in superior analgesia.

This randomized controlled single-blind trial tested the hypothesis that a femoral nerve block provides superior analgesia to a sciatic nerve block after MOW HTO in the setting of multimodal analgesia. We also included functional outcomes to determine whether a potential analgesic benefit would improve quality of life and function.

2. Materials and methods

2.1. Recruitment and randomization

The University Hospital of Lausanne Ethics Committee approved this trial (Commission d'Ethique Romande, protocol number 2018–01774) and the protocol was prospectively registered in French at the Swiss portal kofam.ch (SNCTP000003048 | BASEC2018–01774) and retrospectively registered at clinicaltrials.gov (NCT05728294). In reporting this investigation, we followed the CONSORT guidelines [8]. All patients 18 years or older who were scheduled to undergo elective MOW HTO for medial knee osteoarthritis with varus deformity were eligible to participate. Exclusion criteria were existing femoral or sciatic nerve deficit, pre-existing peripheral neuropathy, chronic pain diagnosis, pregnancy, or identified contraindications to peripheral nerve block (e.g., local anesthetic allergy, coagulopathy, or infection at the block site). After appropriate written and informed consent, subjects were randomly allocated on the day of surgery to either a femoral or sciatic nerve block under ultrasound guidance. This process was undertaken using a computer-generated randomization table in blocks of 10. Group assignments were concealed within a sealed opaque envelope.

2.2. Regional procedures

Before induction, an experienced staff regional anesthesiologist, or a directly supervised regional anesthesia fellow, performed the femoral or sciatic nerve block under ultrasound (US) guidance. The patients were in the supine position, and ECG, pulse oximetry and blood pressure monitors were applied. Peripheral intravenous (i.v.) access was established, and midazolam 1–4 mg i.v. was administered for anxiolysis as needed.

For the femoral nerve block, the groin site was sterilized with a solution of chlorhexidine 2% in isopropyl alcohol 70%. Under sterile conditions, a high-frequency linear array transducer was placed parallel to the inguinal crease and adjusted as necessary to visualize the femoral nerve in short axis. A 22-gauge 50-mm insulated facet tip needle (SonoLong NanoLine cannula; Pajunk® GmbH, Geisingen, Germany) was inserted in-plane with the US beam. The needle tip was advanced under direct US guidance until deep to the fascia iliaca and superficial to the anterior surface of the femoral nerve in the anterior-posterior plane, and at the midpoint of the femoral nerve in the medial-lateral plane. Once the needle tip was satisfactorily positioned, 20 mL of ropivacaine 0.5% was injected in slow 5 mL increments, with intermittent aspiration to prevent intravascular injection.

For the sciatic nerve block, patients were in a semi-prone position with the lower extremity (hip and knee) flexed to 90° and bolstered by a pillow between the legs ("Sims" position). A curvilinear, low frequency probe was placed in a transverse position on the lateral side of the buttocks, halfway between the greater trochanter and the ischial tuberosity. The sciatic nerve was identified in the fascia between the gluteus maximus and quadratus femoris muscles, slightly closer to the ischial tuberosity than to the greater trochanter. A 22-gauge 100-mm insulated facet tip needle (SonoLong NanoLine cannula; Pajunk® GmbH, Geisingen, Germany) was inserted in-plane with the US beam until the needle tip was adjacent to the sciatic nerve. Twenty mL of ropivacaine 0.5% was injected in slow 5 mL increments, with intermittent aspiration to prevent intravascular injection.

The research assistant collecting the data, the surgeon, and the statistician were all blinded to group allocation.

2.3. Intraoperative procedure

All patients received a standard general anesthetic including routine application of physiologic monitors. Anesthesia was induced with sufentanil 0.1 $\mu g.kg^{-1}$ i.v. and propofol 2–4 $mg.kg^{-1}$ i.v. Endotracheal intubation was then performed after a dose of rocuronium 0.6 $mg.kg^{-1}$ i.v. Anesthesia was maintained by application of 1.6%–2.4% inhaled sevoflurane in a 40:60 mixture of oxygen and air. Positive pressure ventilation was applied, with ventilation parameters set to maintain end-tidal carbon dioxide at 35–40 mmHg. Sufentanil 2.5–5.0 μg i.v. was given to treat increases in blood pressure or heart rate to >15% above preinduction values. Our routine local practice includes the administration of magnesium sulphate and all patients received 50 $mg.kg^{-1}$ i.v [9]. in addition to dexamethasone 0.15 $mg.kg^{-1}$ i.v [10]. at the beginning of surgery. Ketorolac 30 mg, paracetamol 1 g, and ondansetron 4 mg were provided i.v. as components of multimodal analgesia and antiemetic medications at the end of the procedure. All surgeries were performed with a tourniquet by one consultant surgeon under tourniquet control (pressure at 280 mmHg). The patient was supine and the involved lower limb was prepped and draped in a standard fashion. The surgical procedure followed a description published in 2014 [11]. Briefly, a diagnostic arthroscopy was performed, and partial meniscectomy was considered if there were unstable meniscal tears. This was followed by a medial high tibial osteotomy, with an 8 cm vertical incision made between the anterior tibial tubercle and the posteromedial border of the tibia. An open wedge was created through the osteotomy and the correction was fixed with a plate. After filling the gap with cancellous bone allograft, a drain was inserted. The subcutaneous tissue and skin were closed with absorbable sutures. Prior to extubation, muscle relaxation was antagonized with neostigmine 50 $\mu g.kg^{-1}$ and glycopyrrolate 5–10 $\mu g.kg^{-1}$.

2.4. Postoperative procedure

After surgery, patients were brought to phase I recovery. Patients were provided with i.v. patient-controlled analgesia (PCA) of morphine with boluses of 2 mg available every 10 min and were instructed on the use of the PCA device. All patients received our institutional standard multimodal analgesic regimen of acetaminophen 1 g every 6 h, and ibuprofen 400 mg every 8 h. Antiemetic medications on the ward included ondansetron 4 mg i.v. and metoclopramide 10 mg i.v. as needed. On the morning of postoperative day 2, the i.v. PCA was discontinued.

2.5. Outcomes

The primary outcome was i.v. morphine consumption at 24 postoperative hours. Secondary outcomes were i.v. morphine consumption at 2 and 48 postoperative hours, rest pain score (on a numeric rating scale [NRS] from 0 to 10) at 2, 24, and 48 postoperative hours, dynamic pain score (NRS, 0–10) at 24 and 48 postoperative hours, rates of postoperative nausea & vomiting and pruritus at 2, 24 and 48 postoperative hours, satisfaction score (NRS, 0–10), and length of hospital stay. At 3 and 6 months postoperatively, patients were contacted by telephone to assess any wound infection, wound healing delay or neuropathic pain. At 6 months postoperatively, functional outcomes were assessed using the 12-item Short Form Survey (SF-12), Knee injury and Osteoarthritis Outcome Score (KOOS), and International Knee Documentation Committee (IKDC) score.

2.6. Statistical analysis

Based on our retrospective data, the mean cumulative consumption of i.v. morphine at 24 postoperative hours in patients who received a femoral nerve block was 16.4 mg (standard deviation 11.1 mg). Assuming that patients with a femoral nerve block would have i.v. morphine consumption that was 40% lower than that in patients receiving a sciatic nerve block, mean consumption would be 27.3 mg after sciatic nerve block. Based on this between-group difference in i.v. morphine consumption, an alpha error of 0.05 and a power of 80%, it was calculated that 34 patients would be required to detect a difference (17 per group). The plan was to recruit 50 patients to allow for a 40% drop-out rate.

Data were analyzed on an intention-to-treat basis. Categorical variables are presented as frequencies, and ordinal, continuous variables as mean with 95% confidence interval or median and interquartile range (IQR) as appropriate. Continuous parametric and non-parametric data were compared using the Student *t*-test and the Mann–Whitney–Wilcoxon test, respectively. Categorical and dichotomous data were compared using the Fisher's exact test or Pearson test as appropriate. Statistical analysis was performed using the Stata software (Stata version 16.1, StataCorp, College Station, TX, USA).

3. Results

Fifty patients were recruited and 46 completed the protocol to measurement of the primary outcome and were included in the intention-to-treat analysis. Fig. 1 describes the flow of patients during the trial and Table 1 presents patient characteristics at baseline.

Mean [95% confidence interval] i.v. morphine consumption at 24 postoperative hours were 24 mg [15 mg, 33 mg] in the femoral nerve block group and 24 mg [16 mg, 32 mg] in the sciatic nerve block group ($p = 0.98$). There were no significant differences in the secondary outcomes between groups (Table 2). At 3 months postoperatively, 11/17

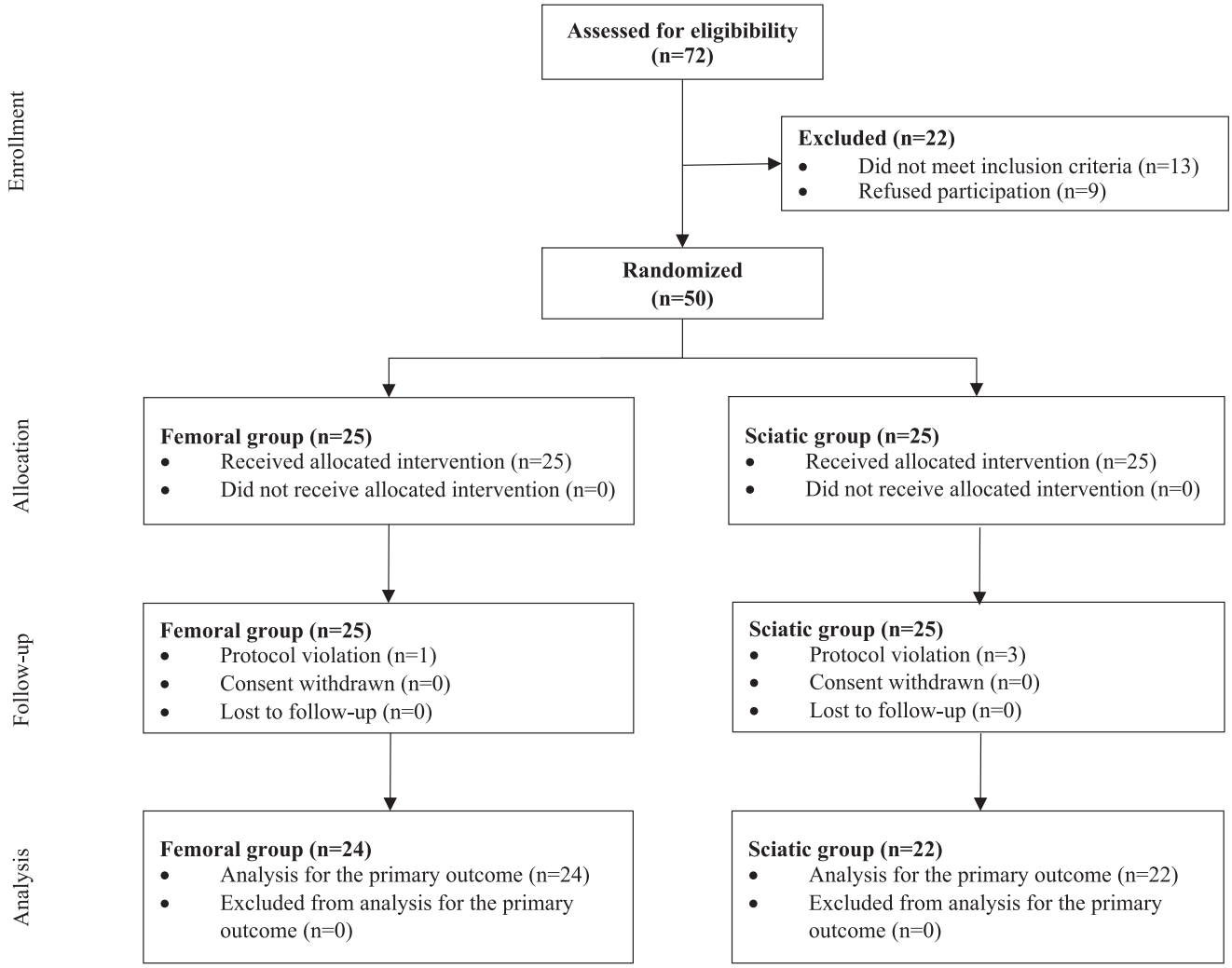

Fig. 1. Flow of patients through trial. FNB, femoral nerve block; SNB, sciatic nerve block.

and 10/18 patients in the femoral and sciatic nerve block groups reported chronic pain, with an overall median (IQR) pain score of 4 (3, 5) ($p = 0.59$); at 6 months, chronic pain was present in 12/17 and 9/15 patients, respectively, in the two groups, with an overall median (IQR) pain score of 2 (2, 3.5) ($p = 0.90$). There were no significant differences in the functional outcomes at 6 postoperative months between groups (Table 3). None of the patients with available data experienced wound infection or wound healing delay (14 patients missing).

4. Discussion

This randomized controlled single-blind trial of 46 patients failed to demonstrate that a femoral nerve block provides superior analgesia to a sciatic nerve block after MOW HTO under general anesthesia in the setting of multimodal analgesia. There was no significant difference in quality of life and functional outcomes at 6 months postoperatively between groups. A type II error cannot be excluded due to the limited number of included patients. However, a post-hoc analysis based on data from our study using mean morphine consumption at 24 postoperative hours of 23.8 mg and 23.9 mg and a standard deviation of 22.1 mg showed that 766,695 patients would be needed to reject the null hypothesis, with alpha and beta values of 0.05 and 0.2, respectively. This highlights the potential futility of performing another trial on the same topic, and shows the absence of superiority of one type of block over the other. However, these results should now be confirmed in a proper equivalence study.

Very few articles have explored the advantages of regional anesthesia for MOW HTO [5,6]. Ren and colleagues prospectively investigated the analgesic benefit of an ultrasound-guided femoral nerve block in 41 patients undergoing the same type of surgery under spinal anesthesia compared with a control group [5]. The authors concluded that the block reduced the rest pain score at 12 postoperative hours from 4.7 to 3.5 (on a visual analogue scale out of 10), but there was no between-group difference in rest pain at other time points or opioid consumption [5]. In another prospective trial, Sim and colleagues included 35 patients that were allocated to either a control group or an US-guided adductor canal block performed before the induction of general anesthesia [6]. There was a statistically significant reduction in rest pain scores at 12 postoperative hours in the block versus control group, but the between-group difference was probably not clinically meaningful because mean pain scores were 6.0 and 5.5 in the control and adductor canal block groups, respectively [6]. Of note, patients who had a peripheral nerve block in both studies reported rest pain scores at 24 postoperative hours of 3.8 [5] and 4.5 [6], while values in our patients at the same time point were 1.5 to 2.0. The lower scores in our study may reflect the wide multimodal analgesia regimen that we prescribed both intraoperatively and postoperatively, which included intraoperative i.v. administration of magnesium, dexamethasone, ketorolac, and acetaminophen followed by oral acetaminophen and ibuprofen postoperatively [12].

Table 1
Patient characteristics and clinical data at baseline. Data are presented as mean (95% confidence interval) or number of participants, as appropriate. ASA, American Society of Anesthesiologists.

	Femoral nerve block group ($n = 24$)	Sciatic nerve block group ($n = 22$)	p-value
Sex (male / female)	19 / 5	16 / 6	0.73
Age (years)	47 (42, 52)	45 (40, 50)	0.54
Height (cm)	174 (170, 178)	176 (170, 181)	0.65
Weight (kg)	81 (74, 88)	92 (86, 98)	0.02
Body mass index ($kg.m^{-2}$)	27 (25, 28)	30 (28, 32)	0.006
ASA (I / II / III)	9 / 14 / 1	2 / 20 / 0	0.03
Duration of surgery (minutes)	168 (142, 193)	192 (169, 215)	0.15

Table 2
Secondary outcomes. Data are presented as mean (95% confidence interval) or number of participants, as appropriate. i.v., intravenous; NRS, numeric rating scale; PONV, postoperative nausea and vomiting.

	Femoral nerve block group	Sciatic nerve block group	p-value
2 postoperative hours			
i.v. morphine consumption (mg)	8 (5, 11)	7 (5, 9)	0.64
Rest pain score (NRS, 0–10)	2.7 (2.0, 3.4)	3.6 (2.7, 4.4)	0.11
Presence of PONV (Yes / No)	0 / 24	2 / 22	0.22
Presence of pruritus (Yes / No)	0 / 24	0 / 22	N/A
24 postoperative hours			
Rest pain score (NRS, 0–10)	2.4 (1.4, 3.3)	2.0 (1.1, 2.9)	0.56
Dynamic pain score (NRS, 0–10)	3.8 (2.7, 5.0)	4.0 (2.9, 5.1)	0.83
Presence of PONV (Yes / No)	3 / 21	3 / 19	1.00
Presence of pruritus (Yes / No)	2 / 22	0 / 20	0.49
48 postoperative hours			
i.v. morphine consumption (mg)	41 (18, 63)	51 (36, 66)	0.44
Rest pain score (NRS, 0–10)	2.4 (1.8, 3.1)	2.7 (1.5, 3.9)	0.65
Dynamic pain score (NRS, 0–10)	4.0 (3.1, 4.8)	5.0 (3.8, 6.2)	0.14
Presence of PONV (Yes / No)	3 / 21	1 / 19	0.61
Presence of pruritus (Yes / No)	2 / 21	1 / 19	1.00
Satisfaction score (NRS, 0–10)	7.2 (6.2, 8.2)	7.9 (7.3, 8.5)	0.23
Length of hospital stay (days)	3.5 (2.9, 4.0)	3.5 (3.0, 4.0)	0.91

Of note, 60% and 66% of our patients reported persistent postoperative pain at 3 and 6 months, respectively, despite the regional blocks and the prescription of a multimodal analgesic regimen. These rates are surprisingly high when compared with other procedures known to be associated with persistent pain several months after surgery. For example, the rate of persistent postoperative pain at 3 months after breast cancer surgery was reported to be 30% [13]. Furthermore, Fletcher and colleagues reported a persistent pain rate of 13% at 6 postoperative months in a cohort of 1044 patients undergoing all types of surgeries [14]. Differences in the rate of postoperative pain between our study and other published could be due to several factors. First, the main indication for this surgery was a chronic pain state secondary to

Table 3
Functional outcomes at six months postoperatively. Data are presented as mean (95% confidence interval).

	Femoral nerve block group	Sciatic nerve block group	p-value
12-item Short Form Survey (SF-12)			
Physical score	41 (37, 44)	41 (36, 45)	0.90
Mental score	43 (39, 47)	43 (38, 47)	0.87
Knee injury and Osteoarthritis Outcome Score (KOOS)			
Symptoms	64 (55, 73)	56 (44, 67)	0.26
Pain	58 (47, 68)	63 (53, 73)	0.43
Function, daily living	63 (53, 74)	68 (57, 79)	0.58
Function, sports and recreational activities	31 (17, 45)	21 (9, 33)	0.29
Quality of life	34 (23, 46)	37 (27, 47)	0.73
International Knee Documentation Committee (IKDC) score	47 (40, 55)	47 (40, 54)	0.91

arthritis of the intern compartment of the knee that might persist for up to 8 months after surgery. Secondly, the material used for the osteosynthesis might cause pain and many patients undergo a procedure to remove this material at 12 months. Finally, in our study, the presence of pain at 3 and 6 months after surgery was only investigated by a single question during a telephone interview rather than in a systematic way using a structured questionnaire, and therefore the rate of postoperative pain might have been overestimated. That said, a systematic review and meta-analysis reported that regional anesthesia may reduce the risk of developing persistent postoperative pain [15]. It remains uncertain whether the combination of femoral and sciatic nerve blocks, which provides optimal analgesia of the knee, would reduce persistent postoperative pain at 3 and 6 months with an improvement in the functional outcome in the intermediate postoperative period. We suggest that this represents an area where additional studies are needed to better understand the overall impact of this combination on the occurrence of persistence pain, and its effect on the acute postoperative period and joint mobility. It would be expected that the combination of blocks would impact on motor function and some readers might be interested in motor-sparing alternatives. However, after that type of surgery, patients are not allowed to load the leg with >10% of body weight for 6 weeks postoperatively, which hinders any attempt to prevent weakness induced by regional anesthesia.

Several limitations deserve to be mentioned, such as the choice of our primary outcome. Cumulative consumption of i.v. morphine might not be considered to be a patient-oriented outcome by some physicians. However, we are convinced that this is an important outcome because any reduction in opioid consumption is associated with reduced postoperative nausea and vomiting, among other side-effects, contributing to better postoperative patient comfort, and even function. Another limitation is that although the research assistant, surgeon and the statistician were all blinded to group allocation, the fact that patients were not blinded to treatment group could have led to performance and detection biases, especially regarding subjective endpoints such as pain. Moreover, there were some statistical significant between-group differences in baseline characteristics (weight, BMI and ASA class), but we do not think that this impacts the validity of our results. Finally, we did not gather data on the specific location of the pain in the operated knee (anterior or posterior), which would have provided additional insight into the effectiveness of the two different types of nerve block investigated.

In conclusion, this trial failed to demonstrate that a femoral nerve block provides superior analgesia to a sciatic nerve block after MOW HTO under general anesthesia in the setting of multimodal analgesia. There was no significant difference in quality of life and functional outcomes at 6 months postoperatively between groups.

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Author statement

Corey Kull: this authors analyzed the data and prepared the primary manuscript.

Robin Martin: this author recruited the patients and completed the primary manuscript.

Jean-Benoit Rossel: this author performed the statistical analysis.

Alexandre Nguyen: this author collected the data.

Eric Albrecht: this author designed the study, interpreted the data and completed the primary manuscript.

Declaration of Competing Interest

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