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Journal

HSS Journal ®, 10(3)

ISSN

1556-3316

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Publication Date

2014-10-01

DOI

10.1007/s11420-014-9392-x

Peer reviewed

Postoperative Analgesia with Saphenous Block Appears Equivalent to Femoral Nerve Block in ACL Reconstruction

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Received: 3 January 2014/Accepted: 1 April 2014/Published online: 7 June 2014
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Abstract *Background:* Adequate pain control following anterior cruciate ligament reconstruction (ACL) often requires regional nerve block. The femoral nerve block (FNB) has been traditionally employed. Ultrasound application to regional nerve blocks allows for the use of alternatives such as the saphenous nerve block following ACL reconstruction. *Questions/Purposes:* This study evaluated postoperative analgesia provided by the subsartorial saphenous nerve block (SSNB) compared to that provided by the traditional FNB for patients undergoing ACL reconstruction with patellar tendon (bone–tendon–bone (BTB)) autografts. *Methods:* A randomized, blinded, controlled clinical trial was conducted using 80 ASA I–III patients, ages 16–65, undergoing ACL reconstruction with BTB. The individuals assessing all outcome measures were blinded to the treatment group. Postoperatively, all patients received cryotherapy and parenteral hydromorphone to achieve numeric

rating scale pain scores less than 4. At discharge, patients were given prescriptions for oral opioid analgesics and a scheduled NSAID. Patients were instructed to complete pain diaries and record oral opioid utilization. Patients were contacted on postoperative days (POD) 1 and 2 to ascertain the level of patient satisfaction with the analgesic regimen. *Results:* No differences between the two groups were found. Patient demographics and postoperative pain scores at rest were not different. In addition, there was no difference in opioid use, as measured in daily oral morphine equivalents between groups. A small but statistically significant report of higher patient satisfaction with the FNB was found on POD 1 but not on POD 2. *Conclusion:* These data support our hypothesis that the SSNB provides similar and adequate postoperative analgesia when compared to the FNB, following arthroscopic ACL reconstruction with patellar tendon autograft.

Level of Evidence: Therapeutic Study Level I.

Electronic supplementary material The online version of this article (doi:10.1007/s11420-014-9392-x) contains supplementary material, which is available to authorized users.

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Keywords postoperative analgesia · ACL reconstruction · saphenous nerve block · femoral nerve block · pain

Introduction

Anterior cruciate ligament (ACL) reconstruction using patellar tendon autograft is the most painful type of ACL reconstruction [2, 8, 10]. Although cadaver allografts and hamstring autografts may have acceptable levels of pain control postoperatively with traditional multimodal analgesic regimens, patients undergoing reconstruction with patellar tendon autografts fare better with the administration of femoral nerve blocks. These patients report lower visual analog scale (VAS) pain scores for 24 h postoperatively, as well as an opioid-sparing effect [2, 8, 10]. The development of ultrasound now allows us to perform the saphenous nerve block in the anteromedial thigh with very high success rates. The infrapatellar nerve, which innervates the peripatellar plexus of the knee [12] and includes the site where the

patellar tendon is harvested, branches off from the saphenous nerve. Thus, anesthetizing the saphenous nerve and providing sensory nerve blockade to this area alone may allow effective supplementary postoperative analgesia. Given the multiple innervations of the knee, complete pain relief would not be expected from either the femoral nerve block (FNB) or the saphenous nerve block [13].

The primary aim of this randomized, blinded, controlled clinical trial was to compare the effectiveness of the FNB with the subsartorial saphenous nerve block (SSNB) for postoperative analgesia using the numerical rating scale (NRS) pain score. We hypothesized that pain scores would be similar. Furthermore, our secondary aims were postoperative narcotic consumption, whether there would be any difference between groups with respect to patient satisfaction using a modification of the OR-SDS scale [1], and the perceived duration of each block.

Patients and Methods

The study was approved by the Institutional Review Board for Hospital for Special Surgery, where the study was performed (IRB #29133; see <http://www.hss.edu/clinical-trials-directory.asp> for the HSS IRB clinical trials registry). All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients included in the study. Randomizer™, an Excel-compatible randomizing program, was used to assign treatments using two treatment arms and a target enrollment number of 80 patients. Non-study personnel prepared opaque sealed treatment envelopes. On the day of surgery, a co-investigator anesthesiologist approached the patient preoperatively. Once written informed consent had been obtained (patients under 18 signed an assent form and consent was also obtained from their legal guardian), the investigator opened the sealed treatment envelope, which randomized the patient to the control group (FNB, treatment I) or to the treatment group (SSNB, treatment II).

Eligible patients were all ASA Class I–III patients, ages 16 to 65, undergoing ambulatory surgery for ACL reconstruction with a patellar tendon autograft. Exclusion criteria were obesity (defined as body mass index greater than 35), allergy to study medications, NRS pain scores greater than 3 with frequent opioid use prior to surgery (defined as daily for more than 3 weeks), lower extremity neurological dysfunction, or diabetes.

Research assistants obtained basic demographic data from the patients by interviewing them after informed consent was obtained and prior to the operation. The patient and the research assistants were blinded to the treatment groups. A notice was also placed in the study patients' charts requesting non-study-affiliated hospital staff not to inform the patients of their group status.

In the operating room, patients were sedated with midazolam in order to achieve anxiolysis and mild sedation. The nerve block was performed prior to placement of the spinal

for the surgical procedure. Spinal anesthetics are routine at our institution for all ACL reconstructive cases. In comparison to general anesthesia, they have been shown to provide better hemodynamic stability and improved postoperative analgesia [16].

The saphenous nerve block was performed under ultrasound guidance using a 6–13-MHz linear probe L25x by Sonosite®. The probe was placed to obtain a short axis view of the femoral artery at the mid-femoral level. The saphenous nerve adjacent to the femoral artery was identified. The femoral artery was followed distally to the point at which it deviates posteriorly into the popliteal fossa [17]. At this point, the saphenous nerve was identified as it continued in its original course just underneath the sartorius muscle. At a distance of no more than 7 cm proximal to the medial condyle [11], a short axis view of the sartorius and vastus medialis muscles was obtained with the saphenous nerve identified between the two muscles [13] (Fig. 1a, b). A 22-gauge 2-in. Stimuplex® needle connected to a nerve stimulator that was turned off was advanced in the plane of the ultrasound beam anteroposteriorly. The needle tip was positioned between the sartorius and vastus medialis muscles in the proximity of the saphenous nerve. The nerve stimulator was then turned on and set to deliver a current of 0.5 mA at a frequency of 2 Hz and pulse duration of 0.1 ms. The presence of a quadriceps muscle twitch, if elicited, was recorded, and the needle was repositioned until the muscle twitch disappeared. Local anesthetic dose (10 ml bupivacaine 0.5% with epinephrine 1:200,000) was then injected, with intermittent aspirations every 5 ml.

The femoral nerve block was performed with a 22-gauge 2-in. Stimuplex® needle that was connected to a nerve stimulator set to deliver a current of 1–1.2 mA, frequency of 2 Hz, and pulse duration of 0.1 ms. Under ultrasound guidance, the block needle was inserted in plane with the ultrasound probe (C11/5–8 MHz or L25 Sonosite®). The needle tip was positioned below the fascia iliaca, in the same tissue plane as the femoral nerve. The nerve stimulator was used to confirm the identity of the femoral nerve, keeping the current at less than 1 mA. After the final needle position was achieved, the operator could reposition the needle tip to ensure adequate spread of the local anesthetic injectate in the desired location. Local anesthetic (30 ml of 0.25% bupivacaine with epinephrine 1:200,000) was injected with intermittent aspiration every 5 ml.

After nerve block administration, a spinal anesthetic of 60 mg (4 ml) of 1.5% mepivacaine was administered using a 27-gauge Whitacre needle. Propofol infusion was titrated at the anesthesiologist's discretion. All patients received ondansetron (4 mg), dexamethasone (4 mg), and famotidine (20 mg) for postoperative nausea/vomiting prophylaxis. Ketorolac (30 mg) was administered intravenously at the end of the case. Surgeon, tourniquet use, tourniquet time, and surgical duration were also documented.

Postoperatively, patients received cryotherapy and supplemental parenteral hydromorphone and oral narcotic analgesics as needed until NRS pain scores of less than 4 were achieved. At discharge, patients were given prescriptions for an oral opioid to be taken as needed and a nonsteroidal anti-

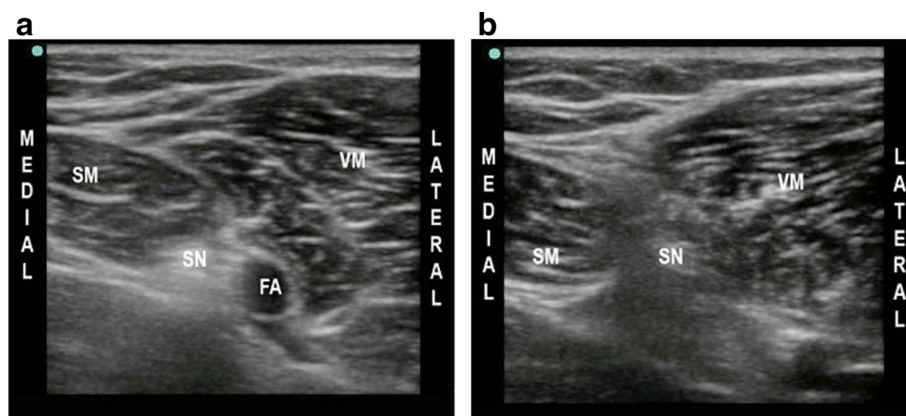


Fig. 1. **a** An ultrasound view of the subsartorial saphenous nerve block. At the mid-femoral level, the probe was placed transversely. *SM* sartorius muscle; *SN* saphenous nerve; *FA* femoral artery; *VM* vastus medialis. **b** This image was recorded 7 cm proximal to the medial condyle. The probe was placed transversely. *SM* sartorius muscle; *SN* saphenous nerve; *VM* vastus medialis.

inflammatory drug (NSAID), which was to be taken on a regular schedule.

The primary outcome was the number of hours that patients reported NRS pain scores of less than 5. NRS pain scores of 5 and above reflect moderate to severe pain. NRS pain scores were recorded by blinded research assistants starting 2.5 h after administration of the spinal anesthetic and at 30-min intervals until discharge, when full sensation to the lower extremities had returned and the patient was able to void and ambulate with crutches and the operative leg in a Bledsoe brace. Prior to discharge, the research assistants instructed each patient in the use of the pain diary (see Supplementary Fig. 1 for an example of the pain diary). The pain diary allowed patients to record three types of pain scores: NRS-rest, NRS-activity (transitioning from rest to ambulation) and NRS-sleep (upon awakening in the morning). NRS-rest and NRS-activity were to be recorded every 4 h while awake through postoperative day (POD) 2.

To calculate the total patient narcotic consumption for the first of our secondary outcomes, analgesic dosages were obtained via hospital records and by pain diary review, where patients recorded the number of pain pills consumed. Using published equianalgesic opioid calculations (see Supplementary Fig. 2 for the conversion factors used) [9], a morphine equivalent total for each patient was then used for analysis.

To determine the patient's level of satisfaction with the analgesic regimen, questions taken from the Apfelbaum [1] postoperative recovery survey were included in the telephone interview on PODs 1 and 2 (see Supplementary Fig. 3).

To determine the duration of the analgesia the saphenous nerve block would provide (14–18 h of postoperative analgesia expected), patients were educated both at the time of consent and before discharge from the post-anesthesia care unit (PACU) regarding signs that might be expected as the nerve block resolved. These signs included an increase in pain intensity or an experience of a full return of sensation in the operative leg. Patients were asked to keep track of when they perceived that the anesthesia wore off and to write down the time. They were then contacted on POD 1 at

18 h after the administration of anesthesia to ascertain if and when the perceived nerve block resolution occurred.

For the sample size calculation and definition of statistical equivalence, we hypothesized that the number of hours with NRS pain scores less than 5 in patients receiving SSNB would be at least 80% of the number of hours with NRS pain scores less than 5 in patients receiving FNB. Using published data for the duration of the analgesic effect of FNB (23.2 ± 7 h) [13], and assuming the standard deviations would be the same for SSNB, we calculated that 38 subjects were needed per group to test the given hypotheses with 80% power. Assuming a 5% dropout rate, target enrollment was set for 80 patients.

Continuous data were summarized by mean (standard deviation [SD]) and categorical data were summarized by frequency/percentage. For one measure per patient, we used *t* test (for continuous variables) or Fisher's exact test (for categorical variables). NRS pain scores at rest were used to test the primary outcome and were treated as repeated-measures data. These were analyzed using the generalized estimating equation (GEE) [7]. GEE accounts for the correlation of data within patient population, and the first-order autoregressive model (i.e., AR(1)) was employed for correlation structure. For standard error, empirical estimates were used. We assumed two-sided hypotheses/tests for all statistical estimations and inferences. We had one primary outcome/hypothesis and three secondary outcomes. *P* values were unadjusted for multiple testing. All analyses were done using SAS software (version 9.2, Cary, NC).

Results

The first patient was enrolled on February 11, 2010, and data collection continued through January 12, 2011. Ninety-three patients were enrolled in the study (Fig. 2: CONSORT flow diagram). Thirteen of these patients were excluded (11 patients dropped out before data collection was complete, two patients were initially enrolled but later found to meet exclusion criteria: one having diabetes mellitus, and the second

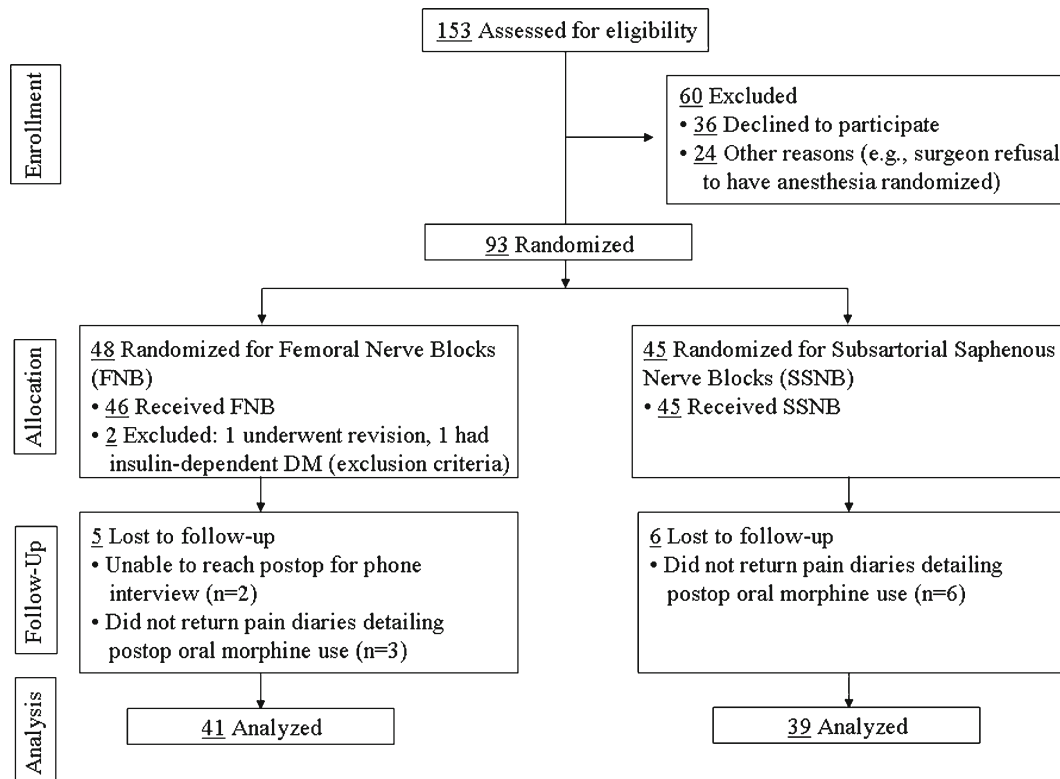


Fig. 2. The consort flow diagram

undergoing a revision surgery). Data from 80 patients were used for analysis. There were no significant differences in baseline characteristics between the two groups (Table 1).

The number of hours that patients reported postoperative NRS pain scores less than 5 was not different between the FNB and SSNB groups ($p=0.789$). Combining all measurements available, estimated from GEE, the observed treatment effect was -0.08 (FNB vs. SSNB). Postoperative NRS pain scores with activity were also collected (Fig. 3 and Table 2). However, because most patients were not very

active in the first 48 h, only the NRS-rest scores were used in the analysis. NRS-rest scores in the PACU (recovery room) were not significantly different between the FNB (2.09 ± 1.56) and SSNB (2.69 ± 1.47) groups. In addition, preoperative pain scores preoperatively were not significantly different between the two groups.

There were no significant differences between the FNB and SSNB groups with respect to narcotic consumption on POD 1 ($p=0.422$) and POD 2 ($p=0.949$). Figure 4 depicts the narcotic consumption in the form of oral morphine equivalents. Narcotic consumption in the recovery room was also not significantly different between the two groups.

Patient satisfaction scores were higher in the FNB group than the SSNB group on POD 1 ($p=0.048$), and no differences in patient satisfaction score were observed on POD 2 ($p=0.52$). As shown in Table 3, the mean satisfaction score (on a 1–7 scale) on POD 1 for the FNB group is 1.73 ± 1.04 , and the SSNB group has a mean score of 2.36 ± 1.64 . On POD 2, both groups had similar satisfaction scores: 2.07 ± 1.06 for the FNB group and 2.28 ± 1.59 for the SSNB group. Equivalent numbers of patients reported side effects in both groups (Table 3).

Accurate data regarding block resolution time could not be acquired, and whether the SSNB provided longer block duration could not be determined. Some patients believed the anesthesia wore off while they slept but could not give a definite time. Other patients, taking prescribed analgesics on a regular basis, said that they did not notice any increase in pain, making it difficult to approximate block duration.

Table 1 Basic demographic data

	Femoral nerve block group	Saphenous nerve block group
<i>N</i>	41	39
Age (years)	28 ± 11	28 ± 8
Height (cm)	175 ± 9	174 ± 11
Weight (kg)	79 ± 14	79 ± 18
BMI	26 ± 4	26 ± 5
Female/male (<i>N</i>)	14/27	11/28
ASA Class: 1, 2 (<i>N</i>)	35, 6	35, 4
Ability to flex quadriceps (<i>N</i>)	41	39
Use of opioids preoperatively (<i>N</i>)	1	1
Preoperative NRS at rest	0.63 ± 1.15	0.87 ± 1.38

Values are represented as mean±standard deviation, unless otherwise stated

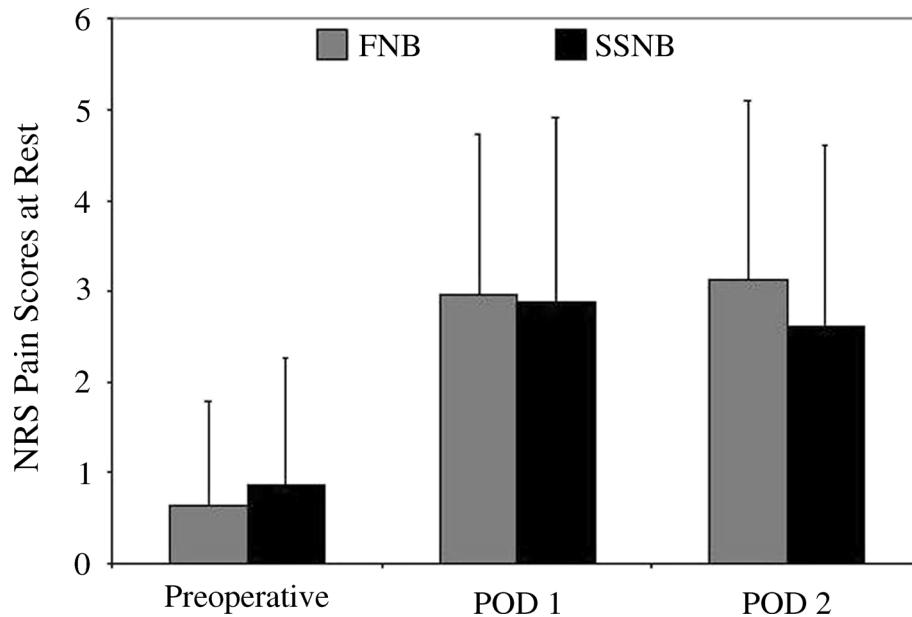


Fig. 3. Numerical rating scale (NRS) pain scores at rest over the first 48 h following surgery. Note that block type made no significant difference ($p=0.789$).

Discussion

This study compared the outcomes of patients receiving either a FNB or a SSNB for postoperative analgesia following ACL reconstruction using patellar tendon autografts. The specific aims of the study were (1) to assess postoperative NRS pain scores, (2) to evaluate narcotic consumption, (3) to analyze patient satisfaction scores, which were reported by the patients based on their satisfaction with postoperative analgesia, and (4) to determine whether the perceived duration of the SSNB would be greater than that of the FNB.

There are several limitations to this study. First, we did not include a “no-block” control for the study since peripheral nerve blocks with ACL reconstruction using patellar tendon autografts are the standard of care at our institution. This also seemed to be in line with findings of previous studies [6, 10, 13, 15] that have established the superior

analgesic benefit of the femoral nerve block, and even femoral nerve catheters [5], for this particular surgical procedure. Secondly, we did not assess the onset or presence of the sensory block postoperatively. Instead, the surrogate measure of analgesia was used. Finally, because this study focused only on postoperative analgesia, we are unable to provide an in-depth assessment of quadriceps function and whether or not block type would have an impact on rehabilitation. A possible advantage for choosing the subsartorial saphenous nerve block would be to avoid quadriceps motor blockade. On the one hand, femoral nerve blockade is associated with postoperative falls [18] and can cause prolonged quadriceps weakness [3]. On the other hand, quadriceps weakness following ACL rupture has been shown to be more a result of the initial injury [4, 14] than the anesthetic nerve block. Assessing quadriceps function over longer periods of time (e.g., 6 months, 9 months, etc.) is a worthy topic for future investigation.

Table 2 Primary outcome analysis

	Femoral nerve block group		Saphenous nerve block group		p value
	Per measurement, % (N of cases/N of total)	Per patient, mean (SD)	Per measurement, % (N of cases/N of total)	Per patient	
NRS pain score at rest <5	83% (414/499)	10 (3.4)	82% (377/460)	9.7 (3.0)	0.94 ^a 0.39 ^b
NRS pain score with activity <5	70% (91/130)	3.0 (2.7)	65% (83/128)	2.7 (2.0)	0.72 ^a 0.79 ^b

SD standard deviation

^a p values were computed from GEE that analyzed all available measurements together, i.e., multiple observations per patient

^b p values were computed from Wilcoxon test that analyzed the number of hours per patient, i.e., one observation per patient

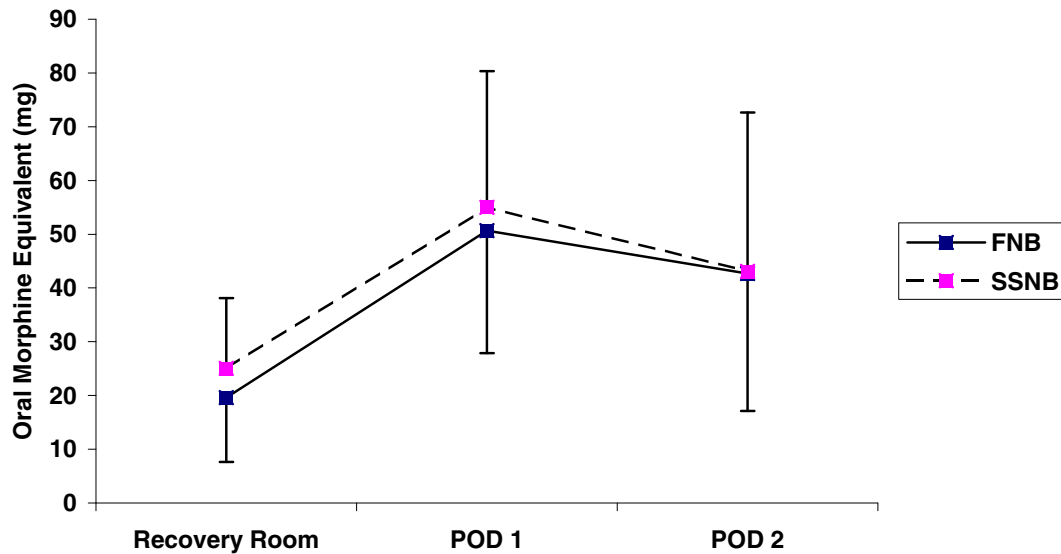


Fig. 4. Daily oral morphine equivalents over the first 48 h following surgery. Block type made no significant difference in oral morphine consumption ($p=0.055$ for oral morphine consumption in the recovery room; $p=0.422$ and 0.949 for PODs 1 and 2, respectively).

There was no significant difference in NRS pain scores between groups, either in the recovery room or on POD 1 or 2. Our results consistently show pain scores ~3 out of 10, which are similar to those reported in studies investigating the postoperative benefits of FNBs. Less pain has been reported by patients receiving single-shot FNBs compared to those receiving no block [6]. Additionally, lower VAS pain scores were obtained when patients receiving the FNB of 20 ml 1% ropivacaine were compared to patients receiving intra-articular injections of 20 ml 1% ropivacaine [10].

In addition, narcotic consumption was not significantly different between the FNB and SSNB groups. It was slightly increased after discharge from the hospital in both groups, but this was not statistically significant. Previous studies have demonstrated that patients receiving FNBs consume less morphine (4.7 ± 2.0 vs. 13.7 ± 4.5 mg) than patients receiving intra-articular injections of local anesthetics [10]. Also, patients

undergoing general anesthesia for ACL reconstruction and who received the FNB did not consume as much morphine (27 ± 24 vs. 49 ± 28 mg) compared to patients receiving a placebo block [15]. However, in our study, we were unable to assess the exact benefits of the SSNB and FNB on narcotic consumption due to the lack of a no-block control.

Patient satisfaction scores on POD 1 showed a small, but statistically significant, preference for the FNB, which was no longer present by the second postoperative day. Despite this preference, rates of adverse effects, such as nausea, vomiting, dry mouth, and headaches, were the same in each group (see Table 3). This suggests that the small statistical significance for the FNB carries little clinical impact. Regional blocks in ACL reconstruction have been shown by others to provide more postoperative analgesia in general [6, 10, 15], although the incidence of side effects and recovery milestones are similar in the presence or absence of the block.

Table 3 Patient satisfaction and side effect profile

	Femoral nerve block group (FNB)		Saphenous nerve block group (SSNB)		<i>p</i> value*	
	POD 1	POD 2	POD 1	POD 2	POD 1	POD 2
Satisfaction score (scale 1–7; see below)*	1.73±1.04	2.07±1.06	2.36±1.64	2.28±1.59	0.048	0.52
Number reporting nausea	15	13	16	10	0.82	0.52
Number reporting vomiting	2	2	1	0	0.49	1.00
Used anti-emetics	9	8	9	9	1.00	0.79
Number reporting drowsiness	27	26	26	24	1.00	1.00
Number reporting itching	10	13	13	14	0.34	0.81
Number reporting dry mouth	16	13	13	15	0.72	0.64
Number reporting headaches	5	4	6	5	0.87	0.73

Satisfaction scored on a scale of 1–7: 1 = very satisfied, 2 = somewhat satisfied, 3 = slightly satisfied, 4 = neither satisfied or dissatisfied, 5 = slightly dissatisfied, 6 = somewhat dissatisfied, 7 = very dissatisfied
 POD postoperative day

Unfortunately, we were unable to acquire accurate data on the duration of the block. This highlights another limitation that can occur when data collection depends on the patients' commitments to recording their pain scores, pill count, and subjective impressions in a diary. This being the nature of ambulatory surgery, however, highlights the need for further study. More definitive assessments of SSNB characteristics, onset, offset, and duration would be best obtained in the hospital setting, where more objective data collection using a research team could be utilized.

The strengths of the study include the randomized trial design, the comprehensive data collection, and the consistency of the data results with respect to pain scores, narcotic consumption, and incidence of side effects. Collectively, these data support our hypothesis that the SSNB provides similar and adequate postoperative analgesia when compared to the FNB, following arthroscopic ACL reconstruction with patellar tendon autograft.

Disclosures

Conflict of Interest: Mary F. Chisholm, MD, Heejung Bang, PhD, Daniel B. Maalouf, MD, MPH, Dorothy Marcello, BA, Marco A. Lotano, MD, Robert G. Marx, MD, MSc, FRCSC, Gregory A. Liguori, MD, Victor M. Zayas, MD, Michael A. Gordon, MD and Jason Jacobs and Jacques T. YaDeau, MD, PhD have declared that they have no conflict of interest.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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