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Original Article

Comparison of Spinal Anesthesia and Ultrasound-Guided Combined Sciatic-Femoral Block on Perioperative Anesthesia and Postoperative Analgesic Effect in Lower Limb Surgery: A Randomized Controlled Clinical Trial

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Keywords: Anesthesia; femoral nerve; nerve block; pain; postoperative; sciatic nerve; spinal.

ABSTRACT

Objective: The aim of this study was to compare the clinical efficacy and safety of an ultrasound-guided combined sciatic-femoral nerve block (SFNB) with spinal anesthesia (SA) in lower limb surgical procedures in terms of clinical properties, postoperative analgesia, and adverse outcomes.

Methods: This prospective, randomized study comprised 60 patients aged 18–65 years with an American Society of Anesthesiologists physical status of I-III scheduled for a lower limb surgical procedure. The patients were randomly divided into 2 groups to receive either SA (n=30) or an ultrasound-guided combined SFNB (n=30). The duration of the intervention, time to achieve surgical anesthesia, analgesia duration, intraoperative hemodynamic parameters, patient satisfaction, quality of the postoperative analgesia, and adverse outcomes were recorded and analyzed.

Results: The duration of the intervention, time to onset of sensorial and motor block, time to start of surgery, motor block reversal time, and time to first postoperative analgesic were significantly longer in the SFNB group ($p<0.001$). Significantly fewer patients required rescue analgesia in the first postoperative 24 hours compared with the SA group ($p<0.001$). The intraoperative hemodynamic parameters and adverse outcomes were similar in both groups.

Conclusion: SFNB is a safe and efficient alternative regional anesthesia technique to SA in lower limb surgical interventions, and particularly for high-risk cases where SA is contraindicated. The prolonged duration of postoperative analgesia and reduced need for postoperative analgesic drug consumption were superior to SA in terms of postoperative pain management.

INTRODUCTION

Regional anesthesia techniques have become increasingly popular for lower limb surgical interventions. Regional anesthesia methods can provide optimal anesthesia care, including prolonged postoperative analgesia and good patient satisfaction, which can reduce postoperative resource use and speed hospital discharge.[1] Spinal anesthesia (SA) is a widely used operative anesthesia technique for lower limb surgery. The choice of method depends on the preference of the patient, the ability of the anesthesiologists, the expected duration of the operation, and hospital practices.[2]

In recent years, with the increasing the use of ultrasound (US) in clinical practice, many peripheral nerve blocks have been associated with benefits, including fewer insertion attempts, a smaller local anesthetic dosage, improved block quality, and rapid onset of nerve blockade.[3]

Although some articles in the literature have stated that a femoral nerve block (FNB) provided sufficient analgesia in lower limb surgical procedures, some studies have also

reported that an FNB alone was inadequate for operative anesthesia.[4,5] Due to sciatic nerve innervation of posterior regions of the knee, the combination of a sciatic nerve block with FNB has been recommended.[6]

A combined sciatic-femoral nerve block (SFNB) is sometimes considered a less preferable option for lower limb surgery than SA because it requires more time and local anesthetics, and can have a paresthesia effect.[7,8]

The objective of this study was to compare US-guided SFNB with SA used for lower limb surgery in terms of hemodynamic parameters, quality of nerve block, time to readiness for the surgical intervention, perioperative adverse reactions, and the duration of postoperative analgesia.

MATERIALS AND METHODS

This prospective randomized controlled clinical trial was conducted after receiving approval from the University of Health Sciences Kartal Dr. Lutfi Kırdar Training and Research Hospital Clinical Research Ethics Committee (no: 2018/514/121/3). Written, informed consent was obtained from all the participants, and the study was conducted according to the Good Clinical Practice guidelines and the principles of the Declaration of Helsinki.

A total of 60 patients aged 18–65 years with an American Society of Anesthesiology (ASA) physical status of I-III who were scheduled to undergo elective unilateral knee and lower limb surgery were enrolled. Patients with a body mass index of >35 kg/m^2; known allergy or drug intolerance; pre-existing chronic pain complaints; any contraindication for regional anesthesia; bleeding disorder; history of drug abuse; localized infection; history of neurological disease; significant respiratory, cardiac, renal or liver failure; vertebral deformity; peripheral neuropathy; and cases of bilateral surgery, pregnancy, emergency, or patient refusal were excluded from the study.

According to institution protocol, an anesthesiologist conducted the preoperative assessment for ASA risk stratification by evaluating the laboratory findings, chest X-ray, and electrocardiogram (ECG) results. In the event the patient had significant systemic co-morbidities, consultations were arranged to evaluate and treat pre-existing systemic disorders.

In the operating room, routine intraoperative monitoring included ECG as well as peripheral oxygen saturation (SpO_2) and non-invasive blood pressure monitoring. A 5-7 mL/kg intravenous saline infusion was initiated before the anesthetic procedure. The patients were randomly allocated to 2 groups of SA or combined SFNB using a computer-generated randomization table. One senior anesthesiologist performed all of the interventions studied.

Spinal anesthesia technique

SA was performed using a midline approach in the lateral position according to the operative site. SA was performed at the L2-3 or L4-5 interspace with a 25-gauge Quincke spinal needle. After the free flow of cerebrospinal fluid drainage was confirmed, 12.5 mg 0.5% hyperbaric bupivacaine was injected through the spinal needle with the aperture of the needle facing in the cephalic direction. The patient was turned to the supine position after testing the paresthesia on the dependent side. Sensorial block at the T12 level assessed using the pinprick test was considered an adequate sensorial block. The motor block degree was evaluated according to the Bromage scale and recorded as nil (0), partial (1), almost complete (2), or complete (3).

Combined sciatic-femoral nerve block technique

The patients in this group were positioned in the lateral decubitus position with the operative side upward. The US device (Sonoline Adara; Siemens AG, Munich, Germany) was placed opposite the anesthesiologist so that the operator's line of sight, needle, and the screen were in a straight line. A peripheral nerve stimulator (Plexygon 7501.31; Vygon SA, Ecouen, France) was used to confirm the nerve location in order to account for possible anatomical diversity.

For the sciatic nerve block, the patient was positioned with the side to be blocked uppermost. The knee of the affected leg was flexed at a 90° angle with the posterior superior iliac spine, greater trochanter, and knee in a straight line. The popliteal fossa was visualized to identify the tibial and popliteal nerves with the aid of a curvilinear, low-frequency US probe. The sciatic nerve connection above the popliteal crease was visualized with the probe. The best visibility was usually provided in the mid-thigh region. The needle was inserted at the junction midpoint of the line between greater trochanter and the posterior superior iliac spine and the line drawn between the major trochanter and the sacral hiatus. A 100-mm block needle (Stimuplex; B. Braun Melsungen AG, Melsungen, Germany) was connected to the peripheral nerve stimulator and advanced with US guidance until a plantar flexion or dorsiflexion contraction was assessed at a current of 0.3 mA. Following confirmation of negative blood aspiration, a 10-mL 2% lidocaine+10-mL 0.5% bupivacaine mixture was injected and the image of the spread of local anesthetic was assessed on the US screen.

For a femoral block, the patient was turned to the supine position and the femoral artery was palpated behind the inguinal ligament. A linear high-frequency US probe was placed perpendicular to the path of the femoral nerve. Femoral artery pulsation was confirmed with slight movements of the probe. Just below the fascia iliaca and femoral artery, the femoral nerve was visualized in the wedge-shaped space. The block needle was inserted to the US probe with an in-plane approach. The proximity of the needle tip was indicated by quadriceps contractions and patellar movement in response to a current of 0.2–0.5 mA. After the confirmation of clear suction, the mixture of 10 mL 0.5% bupivacain+5 mL 2% lidocaine+5 mL 0.9% sodium chloride was administered. The spread of drug was visualized on the US screen.

During the operative procedure, all patients received 4 L/minute oxygen via face mask and were sedated with 1–2 mg midazolam. Incremental doses were administered when necessary. Increased intravenous hydration and 5 mg ephedrine hydrochloride was prepared for use in a hypotension episode, defined as a decrease of mean arterial pressure of >25% of basal value. For a hypertensive episode, 50 µg glyceryl trinitrate for a 10-minute infusion was prepared, and a continuous infusion dose of 50 µg/kg/min glyceryl trinitrate was readied for unresponsive cases. A 10 mg intravenous dose of metoclopramide was available for intolerable nausea and vomiting. Inadequate anesthesia (complaint of pain during the surgical procedure) was considered threatening and a bolus dose of 1 µg/kg fentanyl was provided and repeated at the same dosage if the complaint persisted. If the discomfort continued after 2 bolus doses of fentanyl, it was considered an intervention failure and general anesthesia was induced.

Data collection

The primary outcome measure of this study was the duration of analgesia (the time between the injection of local anesthetic to the first need for rescue analgesia). The duration of intervention (time between the skin preparation to completion of the intervention), the time to achieve surgical anesthesia (the time between the completion of the anesthesia procedure to determination of adequate sensorial and motor block on the operated side), intraoperative hemodynamic parameters, patient satisfaction with pain control [rated by the patients as poor (0–4), moderate (5–8) and perfect (9–10)], and the quality of postoperative analgesia [evaluated using a visual analogue scale (VAS), which was assessed by a nurse blinded to the study and patients scored pain intensity on a numeric scale from 0 (no pain) to 10 (insufferable pain)] were secondary outcomes. Also, the quality of surgical anesthesia was assessed by the surgeon with a score between 1 (very bad) and 10 (excellent).

Demographic characteristics of age; gender; height; weight; patient ASA physical status; non-invasive systolic (SAP), diastolic (DAP), and MAP measurements in 5-minute intervals throughout surgery; SpO_2; heart rate (HR); and duration of operation were recorded and analyzed. The surgical satisfaction [scored by the surgeon as poor (0–4), acceptable (4–7), or satisfactory (≥8)] and adverse reactions (nausea, vomiting, etc.) in both groups were also recorded by a blinded nurse as secondary outcome measures.

Statistical analysis

The sample size was estimated using the duration of analgesia assessment in the 2 groups as the primary outcome measure. Using a 2-tailed test, a power calculation with a probability level of 0.05 and a power of 0.8 with a confidence interval of 95% yielded a sample size of 18 patients in each group. PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL, USA) was used to perform all of the statistical analyses. Data were expressed as mean±SD, and number (percentage). Student's t-test was used to determine the significance of normally distributed parametric values. Categorical variables were tested using Pearson's chi-squared and Fisher's exact test. A p value of <0.05 was accepted as statistically significant.

RESULTS

All of the patients enrolled completed the study. The primary surgical interventions were medial or lateral malleolus fracture repair, wound debridement, hallux valgus surgery, and mass biopsy. There were no significant differences between the groups in terms of patient characteristics (Table 1).

The duration of operation (p=0.910) and the surgeon satisfaction (p=0.173) were similar between groups. The duration of intervention and the time to achieve surgical anesthesia were significantly less in the SA group (p<0.001) (Table 2).

The intensity of pain at the 1st, 6th, 12th, and 24th hour was significantly lower in the SFBN group of patients (p<0.001). The need for analgesic drugs was also significantly less in the SFBN group of patients (p<0.001). The patients' satisfaction was similar in both groups at the 24th hour (p=0.595) (Table 3). More nausea was recorded in the SA group of patients, but without a significant difference (Table 3). The intraoperative SAP, DAP, MAP, HR, and SpO_2 data recorded in 5-minute intervals throughout surgery were comparable (p>0.05).

DISCUSSION

Our findings indicated that a US-guided SFNB block procedure resulted in a significantly prolonged duration of intervention, onset time of sensorial and motor block, and time to readiness for surgery. However, it provided a longer time

Table 1. Patient characteristics

Variables	SA (n=30)	SFNB (n=30)	p value
Age (years), Mean±SD	46.5±18.7	48.0±11.7	0.705
Gender, n (%)			
Male	19 (63.3)	19 (63.3)	1.000
Female	11 (36.7)	11 (36.7)	
Height (cm), Mean±SD	167.9±8.5	168.8±8.6	0.401
Weight (kg), Mean±SD	73.8±13.4	73.2±9.0	0.831
ASA status, n (%)			
I	8 (26.7)	4 (13.3)	0.552
II	15 (50.0)	20 (66.7)	
III	7 (23.8)	6 (20.0)	
Pre-existing systemic disease, n (%)	22 (73.3)	26 (86.7)	0.333

ASA: American Society of Anesthesiology; SA: Spinal anesthesia; SFBN: Sciatic-femoral nerve block; SD: Standard deviation.

Table 2. Intraoperative data

Variables (min)	SA (n=30)	SFBN (n=30)	p value
	Mean±SD	Mean±SD	
Duration of intervention	3.2±0.7	11.5±1.6	<0.001*
Time to onset of sensorial block	4.9±0.8	13.1±2.6	<0.001*
Time to onset of motor block	9.5±1.2	32.1±4.0	<0.001*
Time to start of surgery	7.3±0.5	24.3±4.3	<0.001*
Duration of surgery	48.4±22.3	47.6±24.1	0.910
Surgeon satisfaction	9.5±0.8	9.2±0.8	0.173

*Statistically highly significant. SA: Spinal anesthesia; SFBN: Sciatic-femoral nerve block; SD: Standard deviation.

Table 3. Postoperative outcomes

Variables	SA (n=30)	SFBN (n=30)	p value
Patient satisfaction	9.3±0.5	9.4±0.6	0.595
VAS			
1 hour	1.51	1.03	<0.001*
6 hours	4.93	1.78	
12 hours	5.62	2.07	
24 hours	2.75	2.10	
Motor block reversal time (hours)	3.6±0.4	5.1±1.4	<0.001*
Time to first analgesic requirement (min)	195.55±25.36	412.22±62.21	<0.001*
Patients requiring rescue analgesia in postoperative 24 hours	27 (90.00)	14 (46.66)	<0.001*
Presence of adverse reaction (nausea, vomiting)	5 (16.66)	1 (3.33)	0.194

*Statistically highly significant. SA: Spinal anesthesia; SFBN: Sciatic-femoral nerve block; VAS: Visual analogue scale.

to first need for analgesia and decreased demand for rescue analgesia during the first postoperative 24 hours. SFBN may be a good alternative in patients with a contraindication for SA during lower limb surgical procedures.

In previous research, it has been noted that blocking more than 1 nerve in different patient positions resulted in prolongation of preparation time for surgery.[8–11] Applying peripheral nerve blocks preoperatively outside the operating room is usually preferred and reduces the waiting time in the operating room.[12] Our hospital is a very busy teaching hospital and operating rooms are busy. As a clinical principle, we usually perform peripheral nerve blocks outside the operating room in an area designed for this type of intervention. The time to achieve surgical anesthesia in SFBN group did not affect operating room turnover.

It has been reported that the use of US during the application of a peripheral nerve block significantly decreased the time to achieve surgical anesthesia.[3,9] However, the duration of intervention (3.2±0.7 min vs. 11.5±1.6 min; p<0.001) and the time to readiness for surgery (7.3±0.5 min vs. 24.3±4.3 min; p<0.001) was significantly longer in the SFBN group in our study. SFNB is a relatively new intervention in our daily practice; this difference may be a result of limited clinical experience.

Adequate pain management is essential after orthopedic procedures, and regional techniques are usually superior to general anesthesia. There are many comparative studies about the postoperative analgesic effects of different regional anesthesia techniques in the literature. Some authors have suggested that multimodal analgesia maintained sufficient postoperative analgesia in minimally invasive knee surgery, regardless of the anesthesia choice.[8,13,14] In our opinion, these considerations merit attention due to decreased requirements for postoperative nursing care and additional medications, as well as the cost implications. In our study, the time until there was a need for a postoperative analgesic drug was significantly longer in the SFBN group (412.22±62.21 min) compared with the SA group of patients (195.55±25.36 min), which resulted in less rescue analgesia in the SFBN group of patients (p<0.001).

SA was selected as a control group in this study because of the broad preference as a regional anesthesia technique in lower limb surgery in our center. The clinical setting was similar for both groups, and neither technique demonstrated superiority in terms of the success rate.

The prolonged motor block with SFBN was a disadvantage in the postoperative period, which may be important for ambulatory cases. However, previous reports have indicated that long-acting blocks were not contraindicated for outpatient surgery with no adverse reactions observed after discharge.[9,15] The patients in our study were not ambulatory, so this factor was not evaluated in this study.

Intraoperative hemodynamic stability during a regional block is a critical point and the superiority of one technique to another continues to be a subject of discussion. Cappelleri et al.[16] found no significant difference in hemodynamic characteristics of cases of unilateral SA and combined SFNB during knee arthroscopy. The work of Spasiano et al.[7] supported this result; they noted only heart rate changes in an SFNB group at early intervals. However, some authors have suggested that SFNB provided more hemodynamic stability during the intraoperative period compared with SA.[17] Our results indicated that the difference in hemodynamic variables throughout the surgical procedure was insignificant and that both techniques yielded similar clinical characteristics. In addition, the incidence of nausea and vomiting was comparable in this study. This research included a limited number of patients and therefore, additional powered studies may produce different results and should further compare adverse outcomes of these 2 techniques.

Limitations

US-guided SFNB is a new clinical technique for those participated in this research. This study was designed to compare this approach to the SA method widely used in lower limb surgical procedures. The study was not blinded for the researchers; VAS, patient satisfaction, and adverse reactions were assessed by a nurse blinded to the study. There may be risk of bias in subjective measures. High-risk patients were excluded from this study, so clinical properties of SFNB in these patients may differ. These points may be the subject of other research.

CONCLUSION

US-guided combined SFNB is a safe and effective alternative to SA for lower limb surgical procedures in patients for whom SA is risky or difficult. The prolonged postoperative analgesia and low rescue analgesia requirement resulted in high patient satisfaction and comfort. This suggests that SFNB may be superior to SA in the appropriate circumstances.

Ethics Committee Approval

Approved by the University of Health Sciences Kartal Dr. Lutfi Kırdar Training and Research Hospital Clinical Research Ethics Committee (no: 2018/514/121/3).

Informed Consent

Prospective study.

Peer-review

Internally peer-reviewed.

Authorship Contributions

Concept: Y.K., B.C., F.D.G.; Design: Y.K., F.D.G.; Supervision: B.C., K.T.S.; Fundings: Y.K., B.C., B.Y.; Materials: Y.K., B.Y.; Data: Y.K., B.Y.; F.D.G.; Analysis: Y.K., B.C.; Literature search: Y.K., B.C. Writing: Y.K., B.C.; Critical revision: B.C., K.T.S.

Conflict of Interest

None declared.

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Alt Ekstremite Cerrahisinde Spinal Anestezi ve Ultrason Eşliğinde Yapılan Kombine Siyatik-Femoral Sinir Bloğunun Peroperatif Anestezi ve Postoperatif Analjezi Üzerine Etkilerinin Karşılaştırılması: Randomize Kontrollü Bir Klinik Çalışma

Amaç: Bu çalışmada alt ekstremite cerrahisinde ultrasonografi eşliğinde yapılan kombine siyatik-femoral sinir bloğu ile spinal anestezinin klinik özellikler, postoperatif analjezi ve yan etkiler açısından karşılaştırılması amaçlanmıştır.

Gereç ve Yöntem: İleriye yönelik randomize olan bu çalışma yaşları 18–65 arasında değişen ve ASA fizik durumu I-III arasında alt ekstremite cerrahisi geçirecek 60 hastayı kapsamaktadır. Hastalar rastlantısal olarak iki gruba ayrılarak bir gruba spinal anestezi (n=30) diğerine ultrason eşliğinde kombine siyatik-femoral sinir bloğu (n=30) uygulandı. İşlem süresi, cerrahi anestezi derinliğinin sağlanmasına kadar geçen süre, analjezi süresi, intraoperatif hemodinamik parametreler, hasta memnuniyeti, postoperatif analjezi kalitesi ve istenmeyen sonuçlar kaydedildi.

Bulgular: İşlem süresi, duyusal ve motor blok başlama süresi, cerrahiye başlama süresi, motor blok geri dönüş zamanı ve ilk analjezik ihtiyacına kadar geçen süre siyatik-femoral blok uygulanan grupta anlamlı olarak uzundu ($p<0.001$). Postoperatif 24 saat içerisinde kurtarıcı analjezik ihtiyacı olan hasta sayısı anlamlı olarak düşük bulundu ($p<0.001$). İntraoperatif hemodinamik parametreler ve olumsuz sonuçlar açısından her iki grubun sonuçları benzer güvenlikte idi.

Sonuç: Siyatik-femoral sinir bloğu, alt ekstremite cerrahisinde özellikle spinal anestezinin riskli olacağı hasta grubunda güvenli ve etkin bir bölgesel anestezi alternatifidir. Postoperatif ağrı yönetiminde, uzamış postoperatif analjezi etkisi ve analjezik tüketimini azaltması açısından spinal anesteziye klinik üstünlük sağlamaktadır.

Anahtar Sözcükler: Femoral sinir bloğu; postoperatif ağrı; siyatik sinir bloğu; spinal anestezi.