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Comparison Between Ultrasound-Guided Sciatic-Femoral Nerve Block and Unilateral Spinal Anaesthesia for Patients Undergoing Total Knee Arthroplasty; A Prospective Randomized Controlled Trial

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ABSTRACT

Background: Selective unilateral spinal anaesthesia has many benefits, like early ambulation and more hemodynamic stability. Sciatic-femoral nerve block provides early recovery of the motor, urinary and GIT function, besides prolonged postoperative analgesia. Aim: is to compare an ultrasound-guided combined sciatic–femoral nerve block (USFB) and unilateral spinal anaesthesia (USA) in cases undergoing total knee arthroplasty (TKA).

Methods: The study is a randomized, controlled, single-blind prospective study. Ninety patients were included and divided into two equal groups. USFB group received a 30 ml mixture consisting of 7.5 ml of 2.0% lidocaine, 15 ml of 0.25% bupivacaine and 7.5 ml of saline (15 ml for the femoral and 15 ml for the sciatic nerve block). USA Group received 2.2 ml (12 mg) of 0.5% levobupivacaine.

Results: visual analogue scale (VAS) recordings were significantly lower among the USFB group, compared to the USA group at 4, 8, 12 and 16 hours postoperatively. The duration of the first request of analgesia was significantly longer in the USFB group in comparison to the USA group (347.2 vs 182.63 minutes; $P<0.001$), respectively. The USA group showed shorter onset and faster sensory and motor block recovery, compared to the USFB group. No significant difference was reported between the two groups regarding the hemodynamic parameters either intra- or post-operatively. No serious complications were noticed in both groups.

Conclusion: Both USA and USFB resulted in comparable adequate intraoperative anaesthesia with stable hemodynamics and minimal side effects. USFB was superior to the USA regarding postoperative analgesia.

Keywords: *Unilateral Spinal Anaesthesia, Femoral Nerve Block, Sciatic Nerve Block, Total Knee Arthroplasty*

INTRODUCTION

Subarachnoid anaesthesia and peripheral nerve blocks provide adequate anaesthesia and post-operative analgesia with high patient satisfaction. Regional anaesthesia is a minimally invasive procedure that requires fewer resources. Furthermore, it reduces the risk of gastric aspiration, which is one of the most serious complications of general anaesthesia. Consequently, regional anaesthesia is used as an alternative technique to general anaesthesia.[1] The benefits of USA over traditional spinal anaesthesia include stronger blockade during surgery with a lower dose of bupivacaine, improved haemodynamic stability, and a shorter hospital stay. The disadvantage is that the patients have be in the lateral position. Indeed, patients may have comorbidities that preclude general anaesthesia or traditional spinal anaesthesia. Consequently, an alternative anaesthetic technique, such as femoral/sciatic nerve block, is required.[2] Ultrasound guided femoral/sciatic nerve block (USFB) has several advantages over the blind technique, including the ability to improve the onset and the quality of sensory block. In addition, the nerve block is applied more precisely with ultrasound guidance, making patients less vulnerable to local anaesthetic toxicity. [3]

PATIENTS AND METHODS

Ethical Approval

After obtaining the approval of the Al-Azhar University Ethical Committee and written informed consent, 90 patients of both sexes were admitted for total knee arthroplasty surgery.

Study Design and Sampling

This study is a randomized, controlled, single-blind prospective study, conducted on 90 patients eligible for total knee arthroplasty. The sample size was calculated using Epi-Info software. Setting a 95% confidence limit, and 80% power, the ratio between intervention and control groups is 1:1, and the expected effect size in the USFB group is double times better than the USA group, 45 patients per each group were included. Patients were randomized using a computerized random number generator into two equal groups; group (USFB= 45 patients) received a 30 ml mixture consisting of 7.5ml of 2.0% lidocaine, 15ml of 0.25% bupivacaine and 7.5ml of saline (15ml for the femoral and 15ml for the sciatic nerve block) and group (USA= 45 patients) received 2.2 ml (12 mg) of 0.5% levobupivacaine. This study was done in Alazhar University Hospitals, between June 2021- May 2022.

Eligibility criteria

We included patients of both sexes, ages 30 to 65, ASA I-II, and BMI 17-32%, who were candidates for total knee arthroplasty. Exclusion criteria included patient refusal, uncooperative, unconscious patients, head trauma, local anaesthetics allergy, local infection, coagulopathies, and impaired platelet function. Patients with previous femoral artery grafts or injuries and those with hemodynamic instability were also excluded.

Procedure

Before the intervention, all patients in this study were subjected to clinical, laboratory, and imaging evaluations. The clinical evaluation included a full history, vital data, and ASA physical status. All patients received basic monitoring (pulse oximetry, noninvasive blood pressure (NIBP), and electrocardiogram (ECG). All patients were sedated 5 minutes before the start with 1mg midazolam and 50µg fentanyl was administered intravenously. In addition, 500mL Ringer's lactate IV was administered as a preload.

USA Group: USA was performed with the patient in the lateral position, laying on the side of the scheduled surgery with their knees securely dragged up to their chest. Following thorough aseptic procedure, the iliac crest was palpated, and the thumb was stretched to meet the midline, feeling the gap between L3-4 or L4-5, before receiving lidocaine 2% 1.5-2.5ml as local anaesthetic. At the L3,4 or L4,5 level, a 22-gauge spinal needle (Atraucan®, B. Braun Melsungen, Melsungen, Germany) was inserted. After confirming proper spinal needle insertion with free flow of Cerebrospinal Fluid (CSF), 2.2 ml (12mg) of 0.5% hyperbaric bupivacaine (Sunnypivacaine, Sunny Pharmaceutical®, Cairo, Egypt) was progressively administered over one minute without aspiration, and the spinal needle was then removed.

USFB: The Labat technique was the first to be

used for sciatic nerve block.[4] The patient was placed in the sim's position. The patient is positioned in lateral decubitus with the operating side up and the leg flexed at the knee. If the patient cannot flex the leg, it should be stretched at the hip as far as feasible without causing discomfort to the patient. An imaginary line was drawn lateral to the greater trochanter (GT) and medially to the ischial tuberosity (IT). Then, a low frequency (2-4.5 MHZ) curved ultrasonic probe (Sonosite M-Turbo, Bothell, USA) was attached to the line connecting the greater trochanter with the ischial tuberosity. The sciatic nerve is frequently hyperechoic and lip-shaped. It is typically detected within a region bounded by a hyperechoic margin generated by surrounding muscles, immediately deep to the gluteus maximus muscle. To access the subgluteal site, a 22-gauge needle (Stimuplex; B-Braun, Boulogne-Billancourt, France) was inserted out-of-plane. For the sciatic nerve block, a 30 ml combination of 7.5 ml of 2.0% lidocaine, 15 ml of 0.25% bupivacaine, and 7.5ml of saline was prepared, and 15 ml of the mixture was injected.

The femoral nerve block is performed in the supine posture. The inguinal ligament was represented by a line drawn between the anterior superior iliac spine (ASIS) and the pubic tubercle. After skin preparation with povidone-iodine and local anaesthetic injection, a 6-13 mHz linear probe was positioned below the inguinal crease parallel to the inguinal ligament. The needle was inserted from lateral to medial using an in-plane method. Then, 15 cc of the anaesthetic combination was injected around the nerve, causing the fascia iliaca to separate.

Outcome Assessment

Data were collected by a well-trained medical staff, blinded to the study participants and groups allocation. The time points for outcome assessment were at baseline, 2, 4, 8, 12, 16 and 24 hours postoperatively.

Demographic data (age, gender, BMI and ASA classification), and duration of surgery were obtained by the study assessors. The hemodynamic variables (heart rate and mean blood pressure) were assessed intraoperatively every 10min at 4, 8, 12, 16, and 24 hours postoperatively. Pain intensity was assessed using a visual analogue scale (VAS), a 0-10 scale, in which zero indicates no pain and 10 indicates severe pain. Successful pain relief is defined as ≥50% reduction of the pain intensity at the postoperative time points, compared to the preoperative recordings.

The onset of sensory block (the time from the end of the injection till loss of response to painful stimuli), the onset of motor block (the time from the end of injection till the loss of motor power to Grade 3 of modified Bromage scale), duration of sensory block (the time from the onset of sensory block till the time of the first requirement of analgesia by using Visual Analogue Pain Scale, when VAS ≥ 4, duration of motor block (the time from the onset of motor block till the return of motor power to grade 0 by using the modified Bromage scale) were documented. The time to the first request of rescue analgesia (morphine) and the total amount of doses of rescue analgesia was recorded. Morphine 2mg IV was administered if VAS ≥ 4, and then VAS was reassessed after 30 minutes. Cases with VAS ≥ 4 after three successive doses of morphine rescue analgesia are considered failed. The primary outcome is the time first to request rescue analgesia, and the secondary outcomes are the visual analogue scale, the total amount of morphine consumption and side effects.

Statistical Analysis

The statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA) was applied for data analysis. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to examine the data for normality. Non-normally distributed variables (non-parametric data) were presented as median and range, whereas normally distributed variables were presented as mean and standard deviation. Numbers and percentages were used to describe qualitative variables. To assess proportions between qualitative variables, the Chi-square $(x)^2$ test was utilized. In non-parametric data, the Mann-Whitney U test was utilized for two-group comparisons.

RESULTS

Patient Demographics

This study included 90 patients, eligible for total knee arthroplasty, equally randomized into two groups. **Figure 1.** illustrates the flow of the study process. Group (USFB) received a 30 ml mixture consisting of 7.5ml of 2.0% lidocaine, 15ml of 0.25% bupivacaine and 7.5ml of saline (15ml for the femoral and 15ml for the sciatic nerve block) and group (USA) received 2.2 ml (12 mg) of 0.5% levobupivacaine. **Table 1** represented the demographic characteristics, and showed no significant difference between the two groups, regarding age, ASA physical status and duration of surgery.

Assessment of hemodynamic stability

Preoperative heart rate recordings were comparable between the two study groups with no statistically significant difference. Similarly, no significant difference was reported between the two groups regarding the hemodynamic parameters either intra- or post-operatively (**Table 2).**

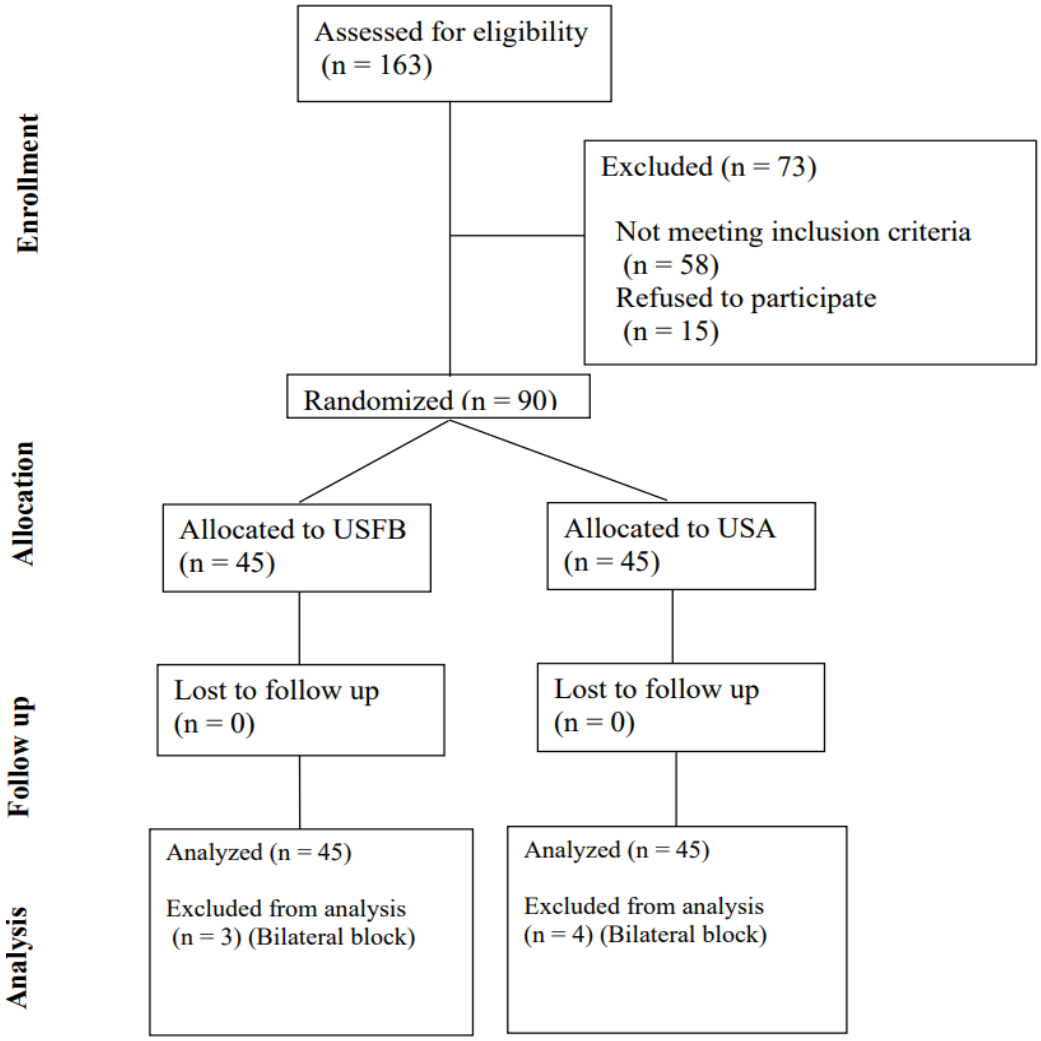

FIGURE 1: CONSORT flow diagram.

TABLE 1: Comparison between both groups according to the baseline and demographic characteristics.

Demographic data	Group USFB (n=45)	Group USA (n=45)	P-value
Age (years)	55.17±7.73	58.41±9.12	0.161
Sex (Male/Female)	17/28	19/26	0.538
BMI (kg/m^2)	28.3±3.67	29.8±2.16	0.679
ASA physical status n (%)			
ASA I/ASA II	22/23	19/26	0.278
Duration of surgery	104.3±9.19	107.8±10.76	0.318

Abbreviations; (BMI, Body Mass Index; ASA, American Society of Anesthesiology)

TABLE 2: Comparison between the two study groups regarding the hemodynamic variables.

Hemodynamic parameters		Group USFB (n=45)	Group USA (n=45)	P-value
HR				
	Preoperative	82.22±11.42	83.87±11.65	0.113
	Intraoperative	68.33±7.05	69.70±7.19	0.138
	Postoperative	66.33±6.00	67.66±6.12	0.155
MBP				
	Preoperative	102.56±14.75	101.02±14.53	0.119
	Intraoperative	90.44±14.23	89.09±14.02	0.100
	Postoperative	87.33±9.31	86.02±9.17	0.132
SBP				
	Preoperative	140.00±17.32	137.90±17.06	0.117
	Intraoperative	123.89±15.96	123.89±15.96	0.109
	Postoperative	122.00±10.71	122.00±10.71	0.101
DBP				
	Preoperative	83.18±13.81	84.44±14.02	0.129
	Intraoperative	73.33±14.03	74.44±14.24	0.108
	Postoperative	70.56±9.50	69.50±9.36	0.105

Abbreviations; (HR, heart rate); (MBP, mean blood pressure); (SBP, systolic blood pressure); (DBP, diastolic blood pressure).

Assessment of the analgesic efficacy and requirements

No significant difference was reported between the two study groups regarding the preoperative VAS score. In addition, group USA showed significantly higher VAS recordings at the subsequent time points, during the first 24 hours, compared to the USFB group (Table 3). In addition, the prevalence of patients who required opioid analgesia was significantly higher in the USA group, compared to the USFB group (29 vs. 7, p <0.001) respectively. The cumulative morphine consumption in the USA group was 63.1 mg, whilst it was 19.3 mg in the USFB group (p <0.001). Moreover, the duration of the first request of analgesia was more extended in the USFB group, rather than the USA group (347.2 vs. 182.63 minutes, p <0.001), respectively (Table 4).

TABLE 3: Comparison between the two groups regarding the postoperative VAS score.

Time	Group USFB (n=45)	Group USA (n=45)	P value
At 2 h	2.43±0.76	3.26±0.73	0.151
At 4 h	3.15±0.84	4.21±0.86	<0.001*
At 8 h	3.64±1.34	3.97±1.21	<0.001*
At 12 h	3.07±1.08	3.95±1.22	<0.001*
At 16 h	2.53±0.99	3.84±0.88	0.021*
At 24 h	2.47±1.08	2.88±0.87	0.002*

Abbreviations; (VAS, Visual Analogue Scale)

TABLE 4: Analgesic efficacy and requirements in the two study groups.

Parameter	Group USFB (n=45)	Group USA (n=45)	P value
Analgesia request n (%)	7 (15.6)	29 (64.4)	<0.001*
Cumulative morphine consumption	19.3±4.58	63.1 ±15.62	<0.001*
Duration to first request of analgesia	347.2±43.09	182.63± 37.08	<0.001*

Indeed, group USA showed shorter onset of sensory and motor block, compared to USFB group (5.3 vs. 16.2 and 7.23 vs. 22.36; p <0.001) respectively. On the other hand, the time to regression of sensory and motor block were more prolonged in the USFB group, with a significant comparison with USA group **(Table 5).** No significant side effects were observed in the two study groups.

TABLE 5: Analgesic efficacy and requirements in the two study groups.

Parameter	Group USFB (n=45)	Group USA (n=45)	P value
The onset of sensory block	16.2±3.65	5.3± 2.6	<0.001*
The onset of motor block	22.36±3.56	7.23± 2.7	<0.001*
Time to regression of sensory block	234.33±9.52	127.71± 9.39	<0.001*
Time to regression of motor block	255.33±7.69	143.66± 19.26	<0.001*

DISCUSSION

ULSA is a potential alternative to the classic and commonly used the technique of central neuraxial blocks since it significantly limits the anaesthetized region, lowering the likelihood of adverse events and problems. In individuals with moderate to severe heart failure, spinal anaesthetic is less favoured or even contraindicated.[5] Concurrent disorders that impair circulatory and pulmonary function, as well as spinal stability, may exist in the patient. The uncompensated hemodynamic response to SA-induced physiologic alterations caused by significantly reduced heart function.[6] These variables even preclude the use of general anaesthesia, and a femoral/sciatic nerve block may be a feasible alternative. In this trial, the mean procedure duration in Group USA was less than in Group USFB. The posture of the patient during and soon following spinal anaesthesia affects drug distribution throughout the spine. It is feasible to produce a unilateral block if the anaesthetic medication solution is hypo or hyperbaric in relation to the cerebrospinal fluid. Furthermore, the distance between the left and right nerve roots in the lumbar and thoracic areas is roughly 10-15cm, allowing for unilateral spinal anaesthesia.[7] Indeed, four patients from the USA group and three from the USFB group were excluded due to bilateral spinal anaesthesia. In concordance with this study, Tekye and Alipour administered 1.5ml of 0.5% hyperbaric bupivacaine and held the patient in the lateral posture for 20 minutes, resulting in ULSA in 94.45% of instances.[8] The anaesthetic agent spread to the other side in two occasions, resulting in bilateral spinal anaesthesia.

Hemodynamic parameters

When HR and MAP were compared between the two study groups, the current study revealed that they were insignificant. There was hemodynamic stability since no patients had hypotension or bradycardia. This might be explained by the preload and the confinement of the block to one side in Group USA, whereas there was no sympathetic or autonomic block in Group USFB. Tummala V, in conjunction with this study, evaluated high-risk geriatric patients for hip joint surgery.[9] A unilateral spinal approach has been developed in an attempt to lessen the incidence and severity of hypotension by using a low dosage intrathecal local anaesthetic. This approach did not delay the onset of block, but it did provide an adequate level of sensory block.

The ULSA proved especially helpful in reducing hemodynamic side effects in high-risk elderly individuals. When compared to spinal anaesthesia in geriatric patients undergoing major hip joint operations, the results showed that unilateral spinal approach was successful and safe, maintained stable hemodynamics, and provided extending analgesia with low dosage intrathecal local anaesthetic. In accordance with this study, Chohan et al., used unilateral spinal anaesthesia prior to lower-limb surgery in elderly patients with ASA III or IV. They found no substantial hemodynamic alterations. They utilised 0.5% hyperbaric bupivacaine (1.1-1.8mL).[10] Similarly, Akkaya et al., compared ultrasound guided femoral and sciatic nerve block to spinal anaesthetic for total knee arthroplasty and discovered peripheral nerve block to be a concise, safe, and effective approach.[11] Patients who are not candidates for safe spinal or general anaesthesia due to cardiovascular instability can have lower limb surgery performed safely with a combination of femoral and sciatic nerve block. Tantry et al. did research in anticoagulated patients with severe valvular disease who had combined femoral and sciatic nerve block without consequences. [12] *The onset of sensory and motor block* This study revealed that the onset of sensory and motor block was significantly shorter in Group USA as compared to Group USFB, in terms of sensory and motor block duration. There was a significant difference between the two groups in the current study. Group USA experienced quick recovery from sensory and motor block. Fanelli et al., evaluated unilateral and standard bilateral bupivacaine spinal blocks in outpatients having knee arthroscopy, which is consistent with this study. They employed 8mg of hyperbaric bupivacaine 0.5% in 50 patients in lateral decubitus posture after spinal injection who were kept in the lateral position for 15 minutes in the unilateral group.[13] Valanne et al., examined the impact of 4mg and 6mg hyperbaric bupivacaine for ULSA in 106 ambulatory adult patients having knee arthroscopy and discovered that both dosages induced effective and appropriate sensory and motor block. The lesser dosage, on the other hand, was associated with quick recovery of motor function.[14] In concordance with our findings, V. Chakravarthy et al., reported similar motor block regression time.[15]

Analgesic efficacy and requirements

In terms of VAS and total amount of morphine (mg) consumption, Group USA had a significant increase in the amount of morphine rescue analgesia required to keep VAS below 4. Furthermore, VAS showed significant increase Group USA than in Group USFB. According to Casati et al., who compared sciatic and femoral block to unilateral spinal anaesthesia, larger dosages of post-operative analgesia were necessary in unilateral spinal anaesthesia.[16] Supportingly, Cohen JM, et al., investigated the effect of adding a preoperative sciatic nerve block to a femoral nerve block on adult patients undergoing Anterior Cruciate Ligament Reconstruction and discovered that adding a preoperative sciatic nerve block (20-30mL ropivacaine 0.5% or bupivacaine 0.375%) to a femoral nerve block (20-30mL ropivacaine 0.5% or bupivacaine 0.375%) results in decreasing the postoperative VAS and need for rescue analgesics.[17]

Side effects

This study found no significant side effects in either of the two study groups. Tantry et al. supported this finding by demonstrating that USA and USFB were safe and effective procedures with no adverse events observed after discharge.[12] Furthermore, Kim JH et al., compared femoral/sciatic nerve block to lateral femoral cutaneous nerve block and unilateral spinal anaesthesia for total knee replacement arthroplasty. They came to the conclusion that there was no difference in the frequency of complications.[18]

On the contrary, Imbelloni LE, et al., investigated the USA in patients undergoing major orthopaedic surgery of the lower limbs. They reported that the incidence of post-dural puncture headaches was 1.7%. This may be attributable to the intrathecal administration of 0.2mg morphine to 3.5-4ml of bupivacaine 0.5%.[7]

CONCLUSION

Both USA and USFB resulted in comparable adequate intraoperative anaesthesia with stable hemodynamics and minimal side effects. USFB was superior to the USA in postoperative

analgesia, evidenced by a long time first to rescue analgesia, lower VAS score and a smaller amount of rescue analgesia.

Declaration of Interest

The authors reported there are no conflicts of interest to declare.

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