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" Ultra-Sound Guided Fascia Iliaca Compartmental Block Versus Spinal Anesthesia in Femoral Thrombectomy Surgery: A Randomized Controlled Trial"

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ABSTRACT:

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Background: Anesthetic management for lower limb revascularization can involve several techniques, including regional nerve blocks, neuraxial approaches, and general anesthesia. The fascia iliaca compartment block (FICB) is a single-injection method known to effectively produce a thorough nerve blockade of the femoral nerve and the lateral femoral cutaneous nerve (LFCN) also it can also achieve a partial blockade of the genitofemoral and ilioinguinal nerves.

Objective: This research aimed to compare the outcomes of spinal anesthesia versus ultrasound-guided fascia iliaca block for femoral thrombectomy procedures.

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Methods: A total of 84 patients undergoing femoral thrombectomy were enrolled in this randomized controlled trial. The trial's participants were divided into two groups of 42 patients each. Anesthetic management differed between the groups: An injection of 2.5 mL of 0.5% hyperbaric bupivacaine was administered to the spinal anesthesia

cohort, whereas 40 mL of 0.25% bupivacaine was administered to the FICB group under ultrasound guidance. The investigation assessed various factors, including the success rate, onset, duration of sensory and motor blockade, Visual Analog Scale (VAS) scores, analgesic duration, intraoperative hemodynamics, and complications.

Results: Success rate in the spinal group had a 100% success rate, the FICB group also achieved a high success rate of 80.9%, with a statistically significant difference between the two groups (p=0.005). The postoperative VAS ratings at 6 and 12 hours were markedly reduced in the FICB group. The sensory block duration and time to initial analgesic request were significantly extended in the FICB group, which also demonstrated a reduced requirement for supplemental analgesia compared to the spinal group.

Conclusion: Ultrasound-guided FICB provides a safe and effective alternative to spinal anesthesia in femoral thrombectomy, offering superior hemodynamic stability, prolonged analgesia, and reduced postoperative analgesic demand.

Keywords: Fascia iliaca compartment block, spinal anesthesia, femoral thrombectomy, ultrasound guidance, postoperative analgesi

Introduction

Patients who have lower limb revascularization surgery for peripheral artery disease (PAD) have a significant risk of perioperative morbidity and mortality, frequently resulting in extended hospitalizations. The utilization of neuraxial or regional anaesthesia in substitute of general anaesthesia may constitute a strategy for enhancing outcomes and minimizing resource consumption in these individuals [1]. The adoption of regional nerve block has surged significantly among both surgeons and patients in recent years [2]. The FICB, which targets the lumbar plexus, was first documented in 1989 and was first applied to children's patients before being expanded to adults [3]. It effectively blocks the femoral nerve, LFCN, and a small number of neighboring nerves, including the genitofemoral and ilioinguinal [4]. So, it can accustomed anesthesia to the anterior part of the thigh. The conventional method of determining the appropriate plane through 'loss-of-resistance' has been substantially outperformed using ultrasound for the FICB. Nevertheless, it still requires a significant amount of local anesthetic [5].

The use of FICB avoids the systemic side effects linked to traditional analgesics, including opioid-related nausea, vomiting, urinary retention, and itching, as well as the gastrointestinal and neurological adverse effects of NSAIDs [6].

Many LA additives, including opioid medications, clonidine, and neostigmine, are used to extend the blockage, decrease the need for catheter placement, amount of local anesthetic requested, and improve postoperative analgesia [7].

The purpose of this study was to compare the effectiveness of spinal anesthesia (SA) and ultrasound-guided unilateral FICB in patients undergoing femoral thrombectomy. The primary outcome was blocking success, defined as loss of pin-prick sensation in target dermatomes within 30 minutes after injection, whereas secondary outcomes encompassed hemodynamic stability and block characteristics, postoperative pain scores, and 24-hour rescue analgesic requirements.

METHODS:

The study was carried out at Mansoura Emergency Hospital between April 2017 and May 2021 as a randomized controlled trial. Under code number MS/17.10.109, The research was authorized by the Institutional Review Board (IRB) at Mansoura University's Faculty of Medicine

Inclusion criteria: Patients scheduled for femoral thrombectomy included both genders, aged 40 to 65 years, and with an American Society of Anaesthesiologists (ASA) physical status of II or III. Patients granted informed written consent for the procedure's acceptance.

Exclusion criteria: we excluded patients with ASA status Grade IV, patient refused to participate, patients with contraindication to neuraxial anesthesia as (systemic infection or history of allergy to anesthetic drugs), coagulopathy and a documented infection at the site of injection served as a formal contraindication for participation in the study.

Randomization: Random assignment of each patient to one of the two groups was performed using the closed-envelope technique; spinal anesthesia included 42 patients who had spinal anesthesia by 2.5 mL of 0.5% hyperbaric bupivacaine (12.5 mg) and fascia iliaca compartment block (FICB) ultrasound guided group included 42 with total volume of 40 mL of 0.25% isobaric bupivacaine (100 mg).

Patient Preparation

A thorough medical history, clinical examination, baseline laboratory tests (complete blood count, coagulation profile, blood glucose measurement, liver and renal function tests), electrocardiography (ECG), and echocardiography (ECHO) were performed on all patients prior to surgery. Before the procedure, patients were instructed and acquainted with the visual analogue scale (VAS), , where "0" denotes complete absence of pain and "10" denotes the highest possible level of agony. Upon entering the operation room, an 18-gauge intravenous catheter was placed, and 500 mL of lactate Ringer's solution was infused as preload followed by fluid maintenance at rate of 2 ml/kg/h.

Intra-operative Technique

Patient monitoring for oxygen saturation, arterial pressure, and heart rate began in the operating room. Using a hemi-spinal approach, with the patient in a lateral decubitus position, spinal anesthesia was induced by injecting a 2.5 mL solution of 0.5% hyperbaric bupivacaine via a 25-gauge spinal needle at the L3-L4 interspace. The patient was kept in the same position for 15 minutes before being placed supine to assess motor and sensory block with the modified Bromage scale and pinprick test.

The scale was characterized as follows: Grade 0 signifies the absence of motor block (complete mobility of the hips, knees, and ankles); Grade 1 denotes the inability to elevate extended legs while preserving knee and foot movement; Grade 2 indicates the incapacity to elevate extended legs or move knees while maintaining foot movement; and Grade 3 reflects a total lack of lower limb movement. The length of the motor block was measured from the start of the full block to grade 3 recuperations [8].

Patients were positioned supine with the table flattened to facilitate inguinal access. After skin preparation, an ultrasound machine (Korean Siemens ACUSON X300) with a 13–16 MHz linear transducer was used to identify the femoral artery, vein, and nerve below the inguinal ligament, as well as the Sartorius muscle, fascia lata, and fascia iliaca. A 22-gauge needle was inserted at a 45° angle from the lateral aspect using ultrasound guidance. After negative aspiration, the needle was pushed directly under the fascia iliaca, evidenced by the distinctive “pop” and ultrasonographic visualization of dispersion.

After the administration of a 1 mL test dosage, 40 mL of 0.25% isobaric bupivacaine was administered in 10-mL increments through repeated aspiration. The medial and lateral dispersion of the anesthetic beneath the fascia iliaca indicated good block placement. An assessment of sensory blockade was conducted over a thirty-minute period by systematically applying a pinprick stimulus every five minutes to the regions supplied by the femoral, obturator, and lateral femoral cutaneous nerves.

The outcomes were evaluated as follows: 0 indicated normal sensitivity, 1 represented loss of pinprick sensation, and 2 signified losses of tactile sensibility. Block duration was defined as the interval required to restore normal feeling, while block onset was defined as the time taken to complete a grade 2 block. Knee extension deficit was utilized to assess motor block. Fentanyl (0.5 µg/kg) was intravenously delivered to those without enough analgesia.

Postoperative Assessment

Immediately following surgery, patients were transferred to the recovery room unit. Postoperative pain was managed with 15 mg/kg of paracetamol administered every 8 hours throughout the first day. Visual Analog Scale (VAS) scores were used to assess pain at specific time points: 1, 6, 12, 18, and 24-hours post-surgery. Administer rescue analgesia consisting of 50 µg of fentanyl if the VAS score is > 4. If the VAS score remains > 4 after 30 minutes, inject 25 µg of fentanyl. The total number of patients requiring analgesia, the total amount of fentanyl delivered were documented and hypotension was defined as MAP decrease >20% from baseline or MAP <65 mmHg and treated with IV ephedrine 5–10 mg; bradycardia was HR <50 bpm treated with IV atropine 0.5 mg.

Sample size

A pilot trial with 15 patients per group found a 60% success rate for FICB (40ml) , with an alpha error of 0.05 and 80% research power (beta error of 0.2). Using G*Power software version 3.0.10, it is established that 38 patients per group are necessary to improve the success rate between the two groups. Considering a 10% dropout rate, we need 42 patients in each group to discern the minimal clinical effect between the groups.

Statistical Analysis

Statistical analysis was performed using SPSS software for Windows (Standard version 21). The normality of the data was initially assessed using the one-sample Kolmogorov-Smirnov test. The qualitative data were presented as numerical values and percentages. Categorical variable relationships were evaluated with a Chi-square test. Continuous data was reported as mean ± SD for normally distributed variables, with group comparisons made via the student's t-test. A two-tailed P-value of less than 0.05 indicated statistical significance.

RESULTS

This study assessed 96 patients for eligibility; 7 did not satisfy the requirements, and 5 declined to participate. The remaining eligible patients were randomized into two equal cohorts, each comprising 42 individuals. All participants were statistically evaluated and monitored throughout the study (Figure 1). The two groups were comparable at baseline in terms of demographic characteristics, showing no statistically significant differences (Table 1)

During intraoperative intervals (5, 10, 20, 30, 45, and 60 minutes), the spinal group experienced a more pronounced decrease in both heart rate and MAP when compared to the FICB group (Figures 2 and 3).

Postoperative pain scores, as shown in Table 2, were not significantly different between the spinal and FICB groups at the end of surgery and one hour later. Conversely, the FICB group exhibited a significant decrease in VAS score relative to the spinal group (P=0.026, p=0.001) at 6 and 12 hours post-surgery.

According to the data presented in (Table 3), the sensory block developed in a significantly shorter time for patients in the spinal group. (1.7±0.65) compared to FICB group (12.5±10.15). The spinal group experienced motor block much earlier (5.02±5.00) than the FICB group (17.2±9.20). The FICB group experienced a considerably longer sensory block (10.59±4.07) than the spinal group (4.66±0.87). The FICB group experienced a significantly longer motor block duration (7.57 ± 2.69 hours) compared to the spinal group (3.35 ± 1.37 hours).

The interval to the initial analgesic request in the FICB group (10.40±0.85) was prolonged relative to the Spinal group (8.09±0.98). A statistically significant reduction in total postoperative rescue fentanyl consumption was observed in the FICB group

over the first 24 hours compared to the Spinal group (Table 4). Patients in the FICB group requested supplemental analgesia significantly less often than those in the Spinal group (p=0.026). In spinal group, the amount used of ephedrine and atropine was significantly high compared with FICB group.

Success rate in the spinal group had a 100% success rate, the FICB group also achieved a high success rate of 80.9%, with a statistically significant difference between the two groups (p=0.005). The 19.1% failure rate in the FICB group suggests that a small number of patients might still require conversion into a different anesthetic method (Table 4).

Regarding Postoperative complications, table [5] shows that 15 patients (38.1%) complained from postoperative hypotension in spinal group while in FICB group zero patients. Four patients (9.5%) complained from nausea in the spinal group compared with FICB group one patient (2%). One patient (2 %) complained about vomiting in spinal group while in FICB group zero patients. Fifteen patients (38.1%) complained from bradycardia in the spinal group compared with FICB group zero patients. Seven patients (16%) complained from shivering in spinal group while in FICB group three patients (7.1%).

Table [1]: Demographic data in the studied groups

variable	Fascia iliaca group (n=42)	Hemi-Spinal group (n=42)	p value
Age (years) **			
Mean ± SD	52.85±3.15	53.83±2.64	0.128
Min-Max	48.00-59.00	50.00-60.00	
BMI**			0.228
Mean ± SD	27.88±3.57	27.02±2.84	
Surgical duration**	110.85±4.39	109.35±4.32	0.119
Sex***			
Male	31 (73.8%)	33 (78.6%)	0.608
Female	11 (26.2%)	9 (21.4%)	
ASA***			
II	8 (19.0%)	5 (11.9%)	0.365
III	34 (81.0%)	37 (88.1%)	

** *t denotes Student's t-test,* *** *χ^2 denotes Chi-square test. Continuous data are reported as mean ± standard deviation, while categorical data are reported as percentages. Statistical significance was defined as P < 0.05.*

Table [2]: Postoperative Pain Scores (Visual Analogue Scale) Over Time

Time	Fascia iliaca group (n=42)	Hemi-Spinal group (n=42)	p value
early postoperative	1(1-2)	1(1-2)	0.113
1 h	2(1-2)	1(1-2)	0.133
6 h	2(1-3)	4(3-5)	0.026*
12 h	3(2-3)	5(4-6)	0.001*
18 h	4(3-5)	4(3-5)	0.146
24 h	4(3-5)	4(3-5)	0.134

Data are in median (IQR), Statistical significance was defined as P < 0.05.*

Table [3]: Motor and sensory block duration (hour) in the studied groups

	Fascia iliaca group (n=42)	**Hemi-Spinal group (n=42)**	**p value**
Onset sensory block	12.5±10.15(min)	1.76±0.65(min)	0.001*
Onset motor block	17.2±9.20(min)	5.02±5.00(min)	0.013*
Duration sensory block	10.59±4.07(hour)	4.66±0.87(hour)	≤0.001*
Duration motor block	7.57±2.69(hour)	3.35±1.37(hour)	≤0.001*

Data expresses mean and standard deviation, Statistical significance was defined as P < 0.05.

Table [4]: number of patients needed analgesia, the time of first request of analgesia (hour), total amount rescue analgesia in 24(h), amount of ephedrine and atropine (mg) given in the studied groups and success rate of the block.

Items	**Fascia iliaca group (n=42)**	**Hemi-Spinal group (n=42)**	**Statistical Test**	**p value**
No of patients need analgesia	5 (11.9%)	10 (23.8%)	Chi-square (chi2)	0.026*
Time to First request of analgesia (hour)	10.40±0.85	8.09±0.98	Independent Samples t-test	≤0.001*
Amount of rescue analgesia in 24 h (Fentanyl) (μg)	50.2±10.6	100 ±11.9	Independent Samples t-test	0.023*
No of patients need ephedrine	0 (0%)	15 (35.7%)	Fisher's Exact Test (FET)	≤0.001*
Amount of ephedrine (mg)	-	20.0±0.0	Mann-Whitney U Test	-
Amount of atropine (mg)	-	0.3±0.0	Mann-Whitney U Test	-
Success rate (%) Succeeded Failed	34 (80.9%) 8 (19.1%)	42 (100%) 0 (0%)	Fisher's Exact Test (FET)	0.005*

Data are expressed as mean ± standard deviation and number percentage, FET: Fischer exact test, *Statistical Mann-Whitney U Test, significance was defined as P < 0.05.*

Table [5]: complications in the groups studied

Variable	Fascia iliaca group (n=42)	Spinal group (n=42)	p value	χ2 value
Hypotension	-	15 (35.7%)	0.01*	6.64
Nausea	1 (2.4 %)	4 (9.5%)	0.010*	6.64
Vomiting	-	1 (2%)	0.123	2.38
Bradycardia	-	15 (35.7%)	0.008*	7.06
Shivering	3(7.1%)	7 (16%)	0.002*	9.57

Data are expressed as **number (percentage)**., *χ^2 denotes Chi-square test. * Statistical significance was defined as P < 0.05.*

Figure (1): CONSORT (Consolidated Standards of Reporting Trials) 2010 flow diagram of the consecutive steps of the study**.**

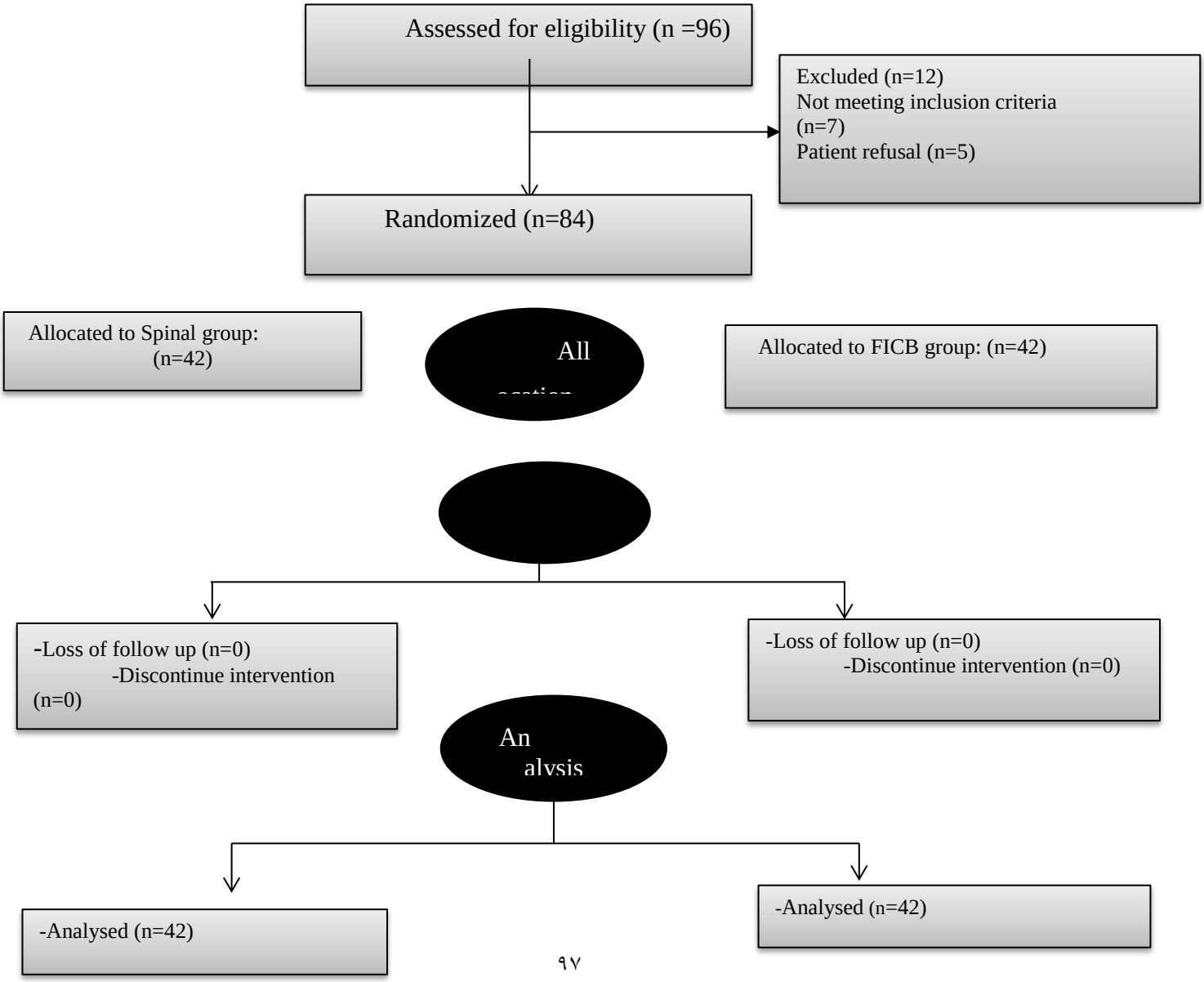


Figure 2: The graph shows the Heart rate (HR) for two different patient groups over a period:

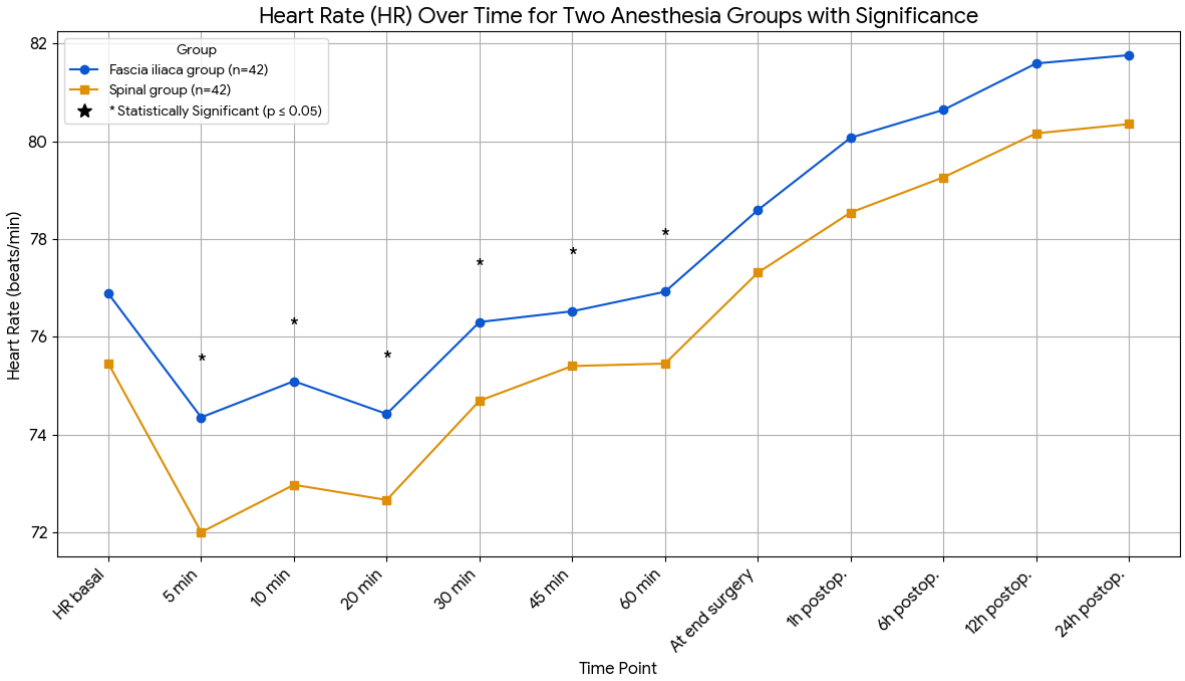
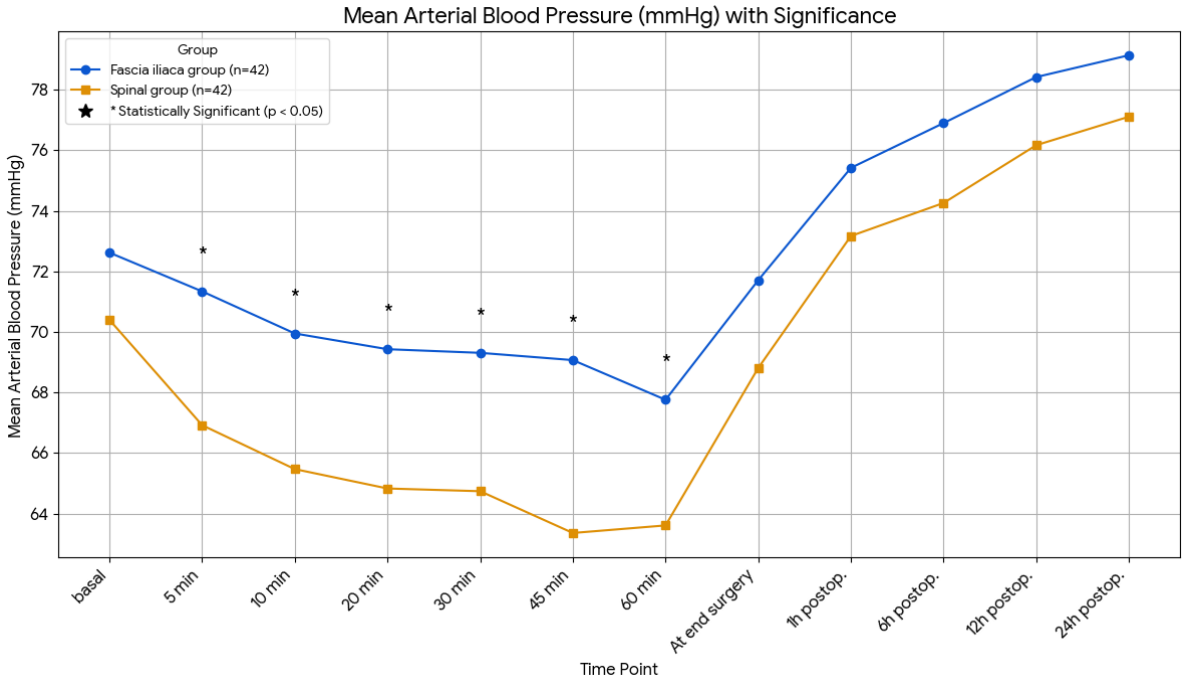


Figure 3: The graph shows the mean arterial blood pressure for two different patient groups over a period:



DISCUSSION

Critical limb ischemia (CLI) affects patients with peripheral artery disease. Thrombolytics, angioplasty, CABG, or amputation may treat severe peripheral ischemia. Age-related tissue perfusion difficulties and limited physiological reserve make post-spinal fast hemodynamic instability harmful in many CLI cases [9]. This study was to investigate the anesthetic effectiveness, safety, and hemodynamic stability of FICB and spinal anesthesia, respectively, in patients having femoral thrombectomy.

The present study compared spinal anesthesia (control group) with the FICB group concerning the time to the initial request for analgesia, heart rate, mean arterial pressure, postoperative pain scores, total dosage of postoperative systemic analgesics, and any post operative adverse effects during the first 24 hours. The combined factors guaranteed the protocol's safety and enhanced the outcomes by mitigating the influence of extraneous variables.

This study indicated that the success rate using ultrasound-guided FICB as the sole anesthetic method, compared to spinal anesthesia (which had a one hundred percent success rate), was 81 percent for thrombo-embolectomy of unilateral CLI, without necessitating conversion to general anesthesia. The ultrasound-guided technique improves the success rate by enabling precise nerve location, ensuring appropriate local anesthetic injections surrounding the nerve, and minimizing the risk of problems related to the block. In alignment with our current study, **Haines *et al.*** documented that ultrasound guidance facilitated the confirmation of avoidance of vascular structures, enabled visualization of accurate local anesthetic placement, and resulted in a significant success rate of the block (95 percent) while enhancing both sensory and motor blockade [10].

On the other hand, the successfulness ratio of FIB as the main anesthetic approach was one hundred percent with no transformation to GA in **Ruzbarsky *et al*.** research [11]. This study utilized 20 ml of 0.5 percent ropivacaine, 2 percent lidocaine, and 0.005 mg/ml adrenaline in FIB for hip fracture surgery. No switch to general anesthesia occurred. Nonetheless, there were no intraoperative complications or fatalities within 30 days. This shift may be attributed to the small sample size, and the administration of midazolam at 1–2 mg and fentanyl up to 50 µg as sedative.

This study revealed that the FICB group exhibited superior hemodynamic stability throughout the intraoperative and postoperative periods. Furthermore, a significant reduction in mean blood pressure was documented in the spinal group relative to the FICB group during the intraoperative phase, attributed to vasodilation of blood vessels, which leads to hypotension and diminished venous return, subsequently decreasing cardiac output and exacerbating hypotension.

Our investigation identified little hemodynamic changes in the FICB group, consistent with the findings of Parate et al. FICB induces negligible hemodynamic alterations, promotes vasodilation, and provides significant postoperative analgesia, particularly in geriatric cardiac patients [12].

In the present study, the FICB group reported significantly lower postoperative Visual Analog Scale (VAS) scores at both 6 and 12 hours, as well as in the total quantity of rescue analgesia administered within the first 24 hours (fentanyl). **Arrola *et al***. and **Krych *et al.*** observed that FIB (0.45% Ropivacaine at 0.3ml/kg with maximum dose 30 ml) controlled postoperative pain, narcotic usage, and patient satisfaction after total hip replacement surgery, supporting the current study [13, 14].

Also, in agreement with our current study, **Yang *et al.*** confirmed the effectiveness of FICB for pain relief during the early postoperative period and the reduction of opioid consumption after lower limb surgery [15].

contrast to our study, Shariat et al. reported on 32 cases receiving FIB (30ml of 0.5 percent ropivacaine) post-arthroplasty, finding no significant difference in postoperative pain scores or narcotic consumption within the first 24 hours. Ropivacaine's enhanced sensory-motor dissociation results in a less pronounced motor blockade and facilitates quicker patient mobilization [16]**.**

In our study, the effective volume to induce successful blockage in FIB (80.9 percent) was 30 ml of bupivacaine 0.25 percent, While our study used 40 mL, Helayel et al. demonstrated that a slightly smaller volume of 37.3 mL for bupivacaine and 36.6 mL for ropivacaine could successfully block 99% of cases [17].

As regards post-operative nausea and vomiting, our present study showed statistically significant increase in spinal group in comparison with FICB. Karaarslan et al. corroborated our findings, demonstrating that the incidence of side effects linked

to spinal anesthesia, including hypotension, bradycardia, nausea, and vomiting, is elevated with central block in comparison to peripheral block [18].

Conclusion: Fascia iliaca block might be regarded as a talented alternative anesthetic approach to Spinal anesthesia with better hemodynamic parameters in cases who were undergone transfemoral thrombectomy undergone for CLI. It might be owing to restricted precautions regarded as the 1st choice over SA for cases on per surgical anticoagulants.

Decelerations

The authors state that they have no financial or non-financial relationships and no conflicts of interest.

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