



Comparison of ultrasound-guided suprainguinal fascia iliaca block and lumbar erector spinae plane block in hip fracture: A single-blind randomized controlled trial

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ABSTRACT

Objective: Hip fractures are common in older adults and are associated with increased morbidity and mortality. Although multimodal anesthesia with peripheral nerve blocks is recommended, the superiority of specific block methods remains unclear. This study compared the postoperative analgesic efficacy of the suprainguinal fascia iliaca block (SFIB) and lumbar erector spinae plane block (LESPB) in patients who underwent hip fracture surgery.

Material and Methods: This single-center, single-blind, randomized controlled trial was conducted at a university hospital (Marmara University Faculty of Medicine, İstanbul, Türkiye) between August 2022 and May 2023. Patients received SFIB, LESPB, or no block before spinal anesthesia. No block-related complications were observed. Postoperative analgesia was provided using patient-controlled intravenous morphine, with tramadol administered as rescue analgesia for NRS pain scores above 4. The primary outcome was 24-hour total opioid consumption. Secondary outcomes included opioid consumption at 6 and 48 hours, pain scores, rescue analgesia requirements, and time to discharge from the intensive care unit and hospital.

Results: A total of 63 patients (mean age 78.5±14.0 years; 46 females and 17 males) with American Society of Anesthesiologists I-III undergoing hip fracture surgery were randomized to SFIB (n=23), LESPB (n=22), or control (n=22). During the first 24 hours, opioid consumption was higher in the control group [18 (9-24.5); p=0.002]. Post-hoc analysis showed a significant difference between the control and SFIB groups [6 (4-9); p<0.001]. The LESPB [13 (5-22)] and control groups were comparable (p>0.016).

Conclusion: SFIB provided the greatest reduction in postoperative opioid use during the first 24 hours after hip fracture surgery. While LESPB appears to be an alternative to SFIB, it produced a reduction in opioid consumption similar to that observed in the control group. Suprainguinal FIB should be prioritized as a component of multimodal analgesia for these surgeries.

Keywords: Erector spinae plane block, hip surgery, opioid consumption, postoperative analgesia, suprainguinal fascia iliaca block

INTRODUCTION

The majority of hip fractures occur in older adults, with over 30% of patients aged ≥85 years (1). A hip fracture is a fracture of the proximal femur extending up to 5 cm below the lesser trochanter (2). These fractures require careful anesthetic management because patients are often of advanced age, frail, and have multiple comorbidities, in addition to experiencing moderate-to-severe postoperative pain.

Several hip fracture guidelines recommend regular use of paracetamol, avoidance of non-steroidal anti-inflammatory drugs (NSAIDs), titration of opioids, including codeine, and application of peripheral nerve blocks (3-7). The susceptibility to the harmful effects of opioids and NSAIDs increases with age (8). Many elderly patients with hip fractures have chronic conditions that these analgesics could worsen, including cardiovascular disease, coagulopathy, decreased renal function, hiatal hernia, a history of gastric or duodenal erosions, vertigo, diverticulitis, or cognitive impairment. Peripheral nerve blocks, as part of regional anesthesia, have been linked to reduced pain, fewer severe opioid-related adverse events, and improved rehabilitation and functional recovery (9-11). Despite these advantages, there is limited high-quality evidence comparing the effectiveness and establishing the superiority of various peripheral nerve blocks in older adults (7,8,12).

The suprainguinal fascia iliaca block (SFIB), as demonstrated by Hebbard et al. (13), spreads more cephalad than the infrainguinal FIB, affecting the terminal branches of the lumbar plexus more proximally. This reliably blocks the femoral, lateral femoral

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cutaneous, and obturator nerves, as well as the articular branches of the hip, providing effective analgesia for hip fractures (14,15).

The erector spinae plane block was first described by Forero et al. (16). Recent studies have suggested that the lumbar ESPB (LESPB) can provide analgesia for the hip by blocking the lumbar plexus (17). A meta-analysis of five randomized controlled trials (RCTs) showed a significant reduction in opioid consumption with LESPB in hip arthroplasty and arthroscopy, although patients with hip fractures were not included (18). At the time of this study, evidence for LESPB in patients with hip fractures was primarily limited to case series, although it showed promise in providing effective analgesia (19-21). Future RCTs are needed to evaluate LESPB to inform guideline recommendations for hip fractures.

We designed a RCT to compare ultrasound-guided suprainguinal FIB and lumbar ESPB for postoperative analgesia in patients with proximal femur fractures. We hypothesized that LESPB would provide analgesia similar to that of SFIB. The primary outcome was the total opioid consumption over 24 h. Secondary outcomes included opioid consumption at 6 and 48 h, pain scores, need for rescue analgesia, and time to discharge from the intensive care unit (ICU) and hospital.

MATERIAL and METHODS

Study Design

Ethics

The randomized trial was conducted after receiving approval from the Institutional Committee (Marmara University Faculty of Medicine Clinical Research Ethics Committee, reference number 09.2022.254, approval date: April 11, 2022) in accordance with the principles outlined in the Declaration of Helsinki. The trial was registered at clinicaltrials.gov (NCT05642975). Written informed consent was obtained from all the patients included in the study. The CONSORT checklist was used for the enrollment and allocation of patients, and the flow chart is shown in Table 1.

Between August 2022 and May 2023, patients aged 18-100 years who underwent unilateral hip fracture surgery under spinal anesthesia and had an American Society of Anesthesiologists (ASA) physical status classification of I-III were included in the study. The exclusion criteria were as follows: Refusal to enroll, request for withdrawal from the study, inability to provide informed consent, contraindications to the local anesthetic agents used, severely impaired renal or hepatic function, bleeding diathesis, chronic corticosteroid use or regular use of strong opioids (e.g., morphine, fentanyl, oxycodone, or methadone), any condition preventing operation of the patient controlled analgesia (PCA) system, and psychiatric disorders.

The study included three groups: the SFIB group, LESPB group, and control group. Patients were randomized using computer-generated block randomization sequences. The allocation was concealed using a password-protected electronic system. Blocks were performed by two authors (EGO, BB) who were not involved in the data collection or analysis. Postoperative assessments were conducted by a blinded member of the pain management team. Outcome assessors and the statistician were blinded to the group allocation.

Anesthesia Management

All patients received a standardized anesthesia protocol (Figure 1). In the operating room, patients underwent standard monitoring using electrocardiography, invasive blood pressure measurement, and pulse oximetry. After confirming hemodynamic stability, intravenous crystalloid infusion was initiated. Supplemental oxygen was administered via a nasal cannula, and intravenous fentanyl (50 µg) was given prior to patient positioning.

Ultrasound Guided Blocks

SFIB

In the SFIB group, an ultrasound-guided suprainguinal FIB was performed on the ipsilateral side of the surgical site, using the technique described by Hebbard et al. (13). The patient was positioned supine, and a 12-4 MHz linear ultrasound probe (Sparq Ultrasound, Philips, USA) was used. The probe was placed over the inguinal ligament, near the anterior superior iliac spine, and oriented in the parasagittal plane. It was then moved inferomedially along the inguinal ligament to visualize the bow-tie sign. The iliacus muscle was identified centrally, with the sartorius and internal oblique muscles forming the wings of the bow-tie view, with the fascia iliaca between them. The deep circumflex iliac artery, located just above the fascia iliaca and 1-2 cm above the inguinal ligament, serves as an important anatomical landmark for needle insertion. A 22-G, 80-mm needle (SonoPlex®; Pajunk Medizintechnologie, Geisingen, Germany) was inserted. After confirming the needle position, 30 mL of 0.25% bupivacaine was injected.

LESPB

Patients in the LESPB group were positioned laterally. An ultrasound-guided lumbar ESPB was performed ipsilateral to the surgical site, with needle advancement directed cephalad from the sacrum. The transverse processes of L3-L5 and the erector spinae muscles were identified using ultrasonography.

Table 1. CONSORT flowchart

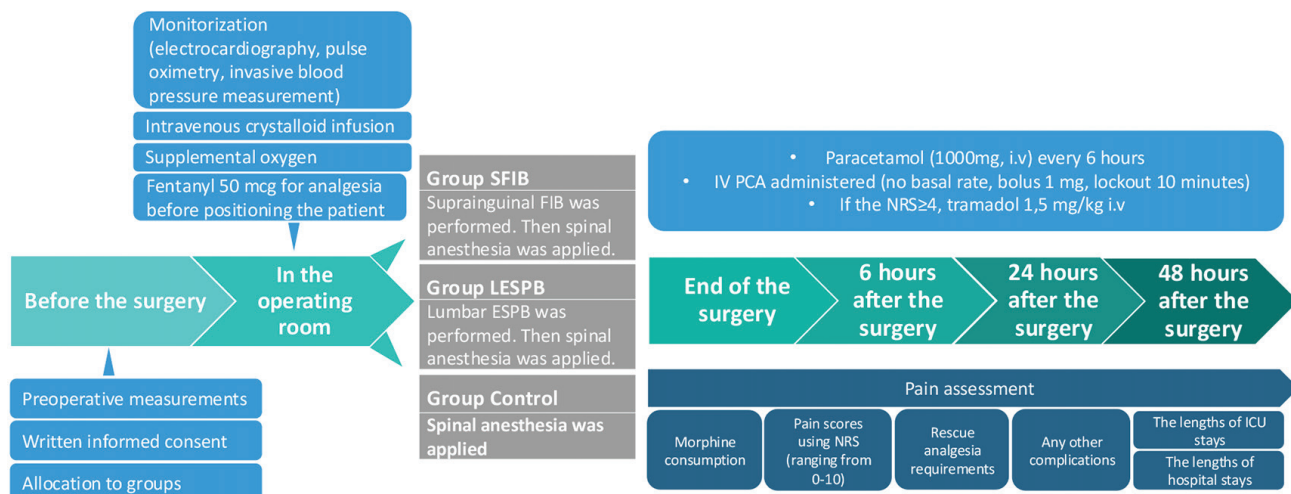
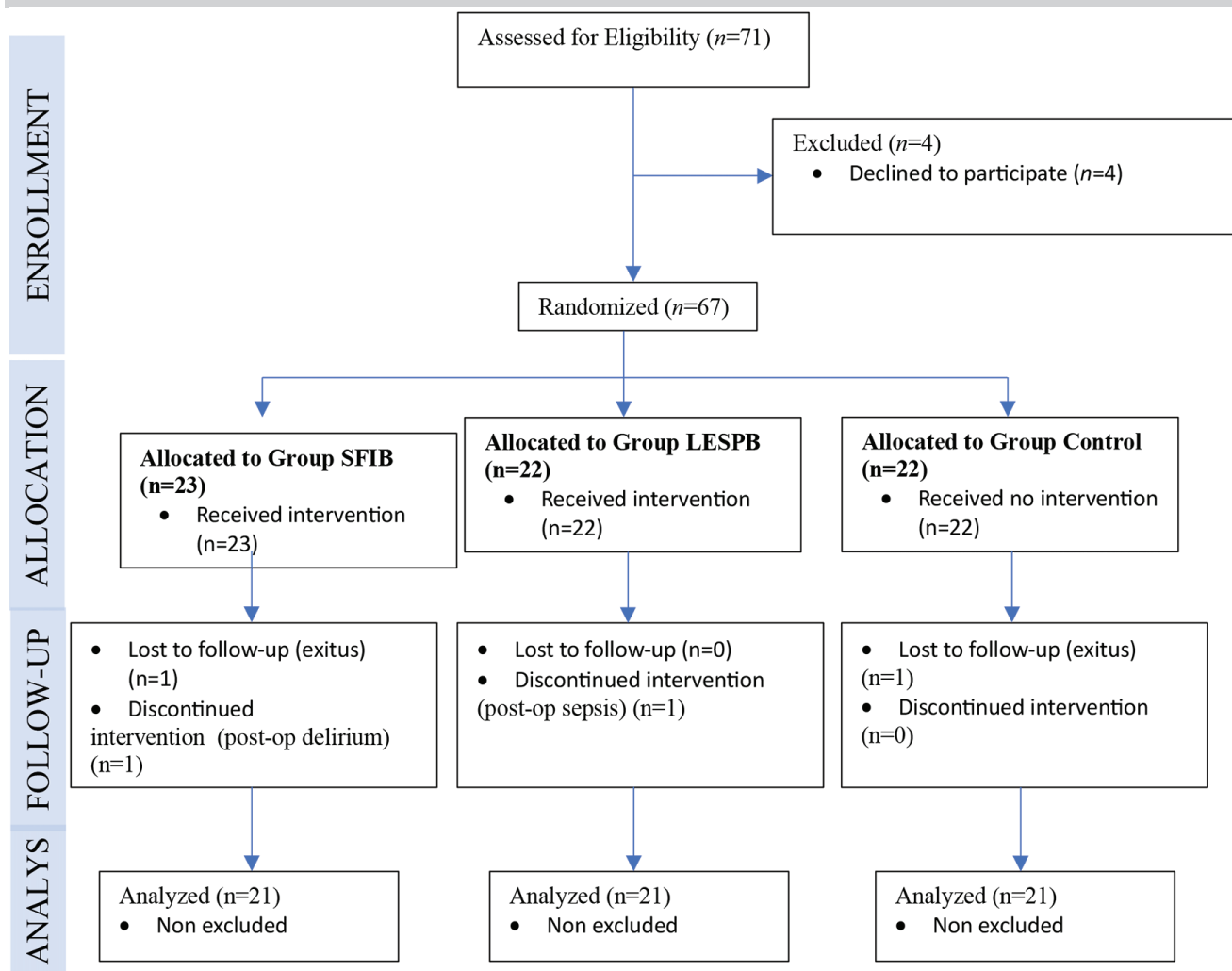


Figure 1. Standardized anesthesia protocol.

IV: Intravenous, PCA: Patient-controlled analgesia, SFIB: Suprainguinal fascia iliaca block, LESP: Lumbar erector spinae plane block, ICU: Intensive care unit, FIB: Fascia iliaca block, NRS: Numeric rating scale

The curved 6-2 MHz transducer was initially placed on the mid-vertebral line in the sagittal plane and then shifted laterally to visualize the erector spinae muscle and the L3 transverse process. A 100 mm, 21 G needle (Sonoplex® Pajunk Medizintechnologie, Germany) was directed in-plane, with the tip advanced to the fascial plane anterior to the erector spinae muscle at the lateral edge of the transverse process. A total volume of 40 mL of 0.25% bupivacaine was injected. Correct placement was confirmed by the cranial and caudal spread of local anesthetic from the injection site, which dissected the plane between the transverse processes and the erector spinae muscles.

Control Group

In the control group, the same preoperative and postoperative analgesia protocols were applied without blocks. In all groups, spinal anesthesia was administered to patients in the lateral position using 2.5 mL of 0.5% heavy bupivacaine at the L3-L4 level.

After performing both nerve blocks, a pinprick test was used to confirm an adequate sensory blockade in the targeted regions. In the SFIB, the dermatomal areas corresponding to the femoral, obturator, and lateral femoral cutaneous nerves were evaluated. For the lumbar erector spinae plane block, sensory assessment included the dermatomes corresponding to L1-L5 on the anterior, medial, and lateral aspects of the thighs. Block-related and postoperative complications were monitored as safety outcomes. Postoperative analgesia was provided via PCA with intravenous morphine (no basal infusion; 1-mg bolus; 10-minute lockout interval). All patients received scheduled intravenous paracetamol (1000 mg every 6 hours). If the numeric rating scale (NRS) score exceeded 4, tramadol (1.5 mg/kg IV) was administered as rescue analgesia.

Data Collection

Intraoperative demographic data, baseline characteristics, fracture type, and type and duration of surgery were recorded. Postoperatively, at 0, 6, 24, and 48 hours, an independent investigator blinded to group allocation assessed morphine consumption, NRS pain scores (0-10 scale), rescue analgesia requirements, and any complications. ICU and hospital lengths of stay were also documented. Total opioid consumption was calculated by summing the amount of morphine delivered via IV PCA and the dose of rescue tramadol after conversion to intravenous morphine milligram equivalents (MME).

Sample Size

The sample size was calculated based on a pilot study. In our single-center preliminary study (unpublished), with 10 patients in each group, the mean opioid consumption in the first 24 h postoperatively was 9.8 ± 6.1 , 10.2 ± 4.9 , and 10.87 ± 4.1 in the SFIB, LESPB, and control groups, respectively. We anticipated

that perioperative analgesia would result in a 20% reduction in opioid consumption compared with the control group; this reduction was considered significant, with a standard deviation of 5.1. Using G*Power 3.1, a minimum sample size of 19 patients per group was calculated, with a power of 0.80, an alpha level of 0.05, and an effect size of 0.43 for an ANOVA comparing the three groups (22). Considering possible dropouts, the study was designed to include 21 patients in each group.

Statistical Analysis

Statistical analysis of the study data was conducted using the statistical package SPSS version 27 (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.). To compare anesthesia method groups with respect to categorical variables, the chi-square and Fisher's exact tests were employed when necessary. The distribution of continuous variables was assessed using the Shapiro-Wilk test. As the data were not normally distributed, non-parametric tests were applied. Statistical significance was set at $p < 0.05$. In cases where a statistically significant difference was detected in the Kruskal-Wallis test, the post-hoc pairwise comparisons between groups were examined using the Mann-Whitney U test. Post-hoc pairwise comparisons were performed using the Bonferroni correction; significance was set at $p < 0.016$ ($0.05/3$ comparisons).

RESULTS

As shown in Table 1, 71 patients with ASA I-III, all presenting with hip fractures, were initially assessed for eligibility. Four patients were subsequently excluded because they declined to participate, and 67 were enrolled. Follow-up for two patients was terminated because of death within the first 24 h postoperatively: One patient in the SFIB group due to pulmonary embolism and one patient in the control group due to myocardial infarction. Additionally, follow-up for another patient from the LESPB group was discontinued due to sepsis within the first 24 h postoperatively; this patient had preexisting immunosuppression. Follow-up for one additional patient in the SFIB group was discontinued because of postoperative delirium, which complicated assessment of consciousness in the ICU. However, all other patients, both in the ICU and the ward, remained conscious, cooperative, and oriented and were actively using the PCA device, which allowed assessment of pain.

The baseline characteristics and demographics are presented in Table 2. These characteristics, including body mass index (body mass index, kg/m^2), ASA status, sex, surgery time, fracture type, and type of surgery, were comparable among the study groups. The patients' ages ranged from 55 to 100 years, with a mean age of 78.5 ± 14.0 years. All procedures were completed uneventfully; no complications related to SFIB, LESPB, or spinal anesthesia were observed.

The average NRS scores remained below 4 at all time intervals and were comparable across study groups (Table 3). This finding indicates that the predefined analgesic target of maintaining NRS scores below 4 throughout the study period was achieved.

Regarding our primary outcome (Figure 2), 24-hour total opioid consumption was significantly higher in the control group [18 (9-24.5)] than in the SFIB group [6 (4-9)] ($p<0.001$). Opioid consumption were higher in the control group during the first 6 h ($p=0.021$) and the 6-24 h interval ($p=0.01$) (Table 4). Post-hoc analysis during these periods showed significant differences between the control and SFIB groups (0-6 h, $p=0.008$; 6-24 h,

$p=0.002$). The LESP and control groups were comparable ($p>0.016$).

The clinical outcomes, including ICU admission, duration of hospital stay, and rescue analgesia details, are presented in Table 3. The duration of ICU stay was 0.18 ± 0.59 , 0.65 ± 2.91 , and 1.19 ± 5.02 days for the SFIB, LESP, and control groups, respectively; these differences were not statistically significant. Similarly, the total hospitalization durations were 6.68 ± 4.16 , 9.20 ± 9.42 , and 6.19 ± 4.45 days for the SFIB, LESP, and control groups, respectively, with no significant variation among the groups.

Table 2. Demographics and surgical characteristics of the participants

			SFIB	LESPB	Control	p-value
Age (years)		82 (73.5-87)	79 (75-87)	82 (71-87)	82 (79-87)	0.76 ^a
BMI (kg/m ²)		24.6 (22.9-28.9)	24.1 (23.1-28.3)	24.5 (22.5-28.5)	25.0 (23.0-29.3)	0.83 ^a
ASA	1	0	0 (0)	0 (0)	0 (0)	0.54 ^b
	2	24	7 (33.3)	9 (42.9)	8 (38.1)	
	3	39	14 (66.7)	12 (57.1)	13 (61.9)	
Sex	Female	46	17 (81.0)	13 (61.9)	16 (76.2)	0.26 ^c
	Male	17	4 (19.0)	8 (38.1)	5 (23.8)	
Type of fracture	Femoral neck fracture	22	8 (38.1)	8 (38.1)	6 (28.6)	0.15 ^b
	Intertrochanteric fracture	35	9 (42.9)	11 (52.4)	15 (71.4)	
	Subtrochanteric fracture	6	4 (19.0)	2 (9.5)	0 (0.0)	
Type of surgery	Open reduction	14	6 (28.6)	4 (19.0)	4 (19.0)	0.33 ^b
	Closed reduction	26	5 (23.8)	9 (42.9)	12 (57.2)	
	Arthroplasty	23	10 (47.6)	8 (38.1)	5 (23.8)	
Surgery time (min)		120 (96.5-130)	110 (95-160)	120 (105-130)	120 (90-130)	0.66 ^a

^a: Kruskal-Wallis test, ^b: Fisher's exact test, ^c: Chi-square test, ASA: American Society of Anesthesiologists, BMI: Body mass index, SFIB: Suprainguinal fascia iliaca block, LESP: Lumbar erector spinae plane block.

Summary statistics are reported as median (interquartile range), mean \pm standard deviation, or number (%).

Table 3. Postoperative clinical outcomes

	SFIB	LESPB	Control	p-value
Block failures [n (%)] ^a	0 (0)	0 (0)	NA	NA
NRS scores ^b				
0 h	0 (0-1)	0 (0-1)	0 (0-2)	0.50
6 th h	1 (0-2)	1 (0-2)	1 (1-3)	0.42
24 th h	1 (0-1)	1 (1-2)	2 (2-3)	0.02
48 th h	1 (1-2)	1 (1-1)	1 (1-2)	0.07
ICU stay time (day) ^b	0.18 \pm 0.59	0.65 \pm 2.91	1.19 \pm 5.02	0.85
Hospital stay time (day) ^b	6.68 \pm 4.16	9.20 \pm 9.42	6.19 \pm 4.45	0.41
Rescue analgesia requirement				
0-6 h	1 (4.76%)	4 (19.04%)	5 (23.81%)	
6-24 h	2 (9.52%)	5 (23.81%)	9 (42.86%)	
24-48 h	1 (4.76%)	1 (4.76%)	4 (19.04%)	

^a: Fisher's exact test, ^b: Kruskal-Wallis test [Bonferroni-adjusted significance threshold for NRS scores, $p<0.016$ (0.05/3 comparisons)], NA: Not applicable, ICU: Intensive care unit, NRS: Numeric rating scale.

Summary statistics are reported as median (interquartile range), mean \pm standard deviation, or number (n).

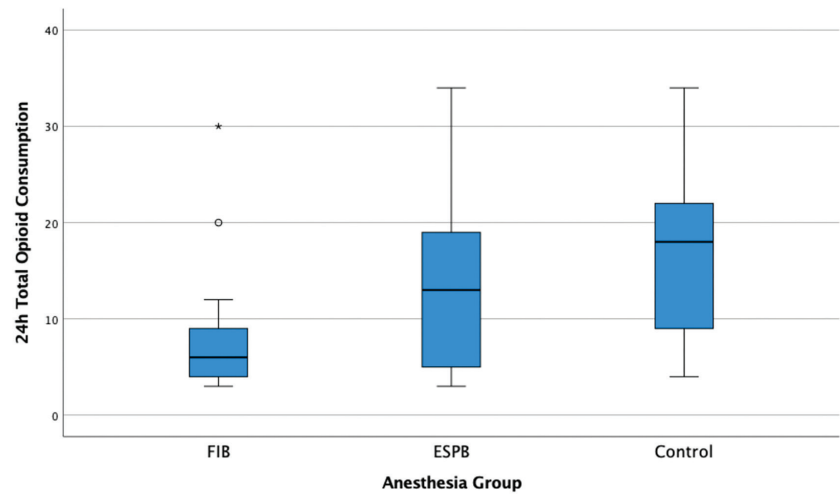


Figure 2. Intravenous opioid consumption during the 24 hours after surgery. Opioid consumption was presented as morphine milligram equivalents. The whiskers are the two lines outside the box that extend to the highest and lowest observations, respectively.

SFIB: Suprainguinal fascia iliaca compartment block, ESPB: Erector spinae plane block, FIB: Fascia iliaca block

Table 4. Postoperative total opioid consumption (MME). Total opioid consumption (milligrams in intravenous morphine equivalents) in the first 48 h after surgery was summarized as the median (interquartile range). Medians from separate time intervals were not additive; therefore, total values were calculated from individual patient-level cumulative opioid consumption

Total opioid consumption (MME)	SFIB	LESPB	Control	Overall p ^a	SFIB vs. LESPB (p, 95% CI) ^b	SFIB vs. control (p, 95% CI) ^b	LESPB vs. control (p, 95% CI) ^b
0-6 h	3 (1.5-4)	5 (2.5-12)	5 (3-13)	0.021	0.041 (-3, 1)	0.008 (-8.5, -0.5)	0.560 (-5, 2)
6-24 h	3 (2-6)	5 (3-12)	7 (4.5-14.5)	0.010	0.156 (-6, 1)	0.002 (-9, -1)	0.158 (-8, 2)
24-48 h	4 (1-5)	4 (1.5-10)	5 (3-11)	0.198	0.156 (-7, 1)	0.03 (-7, 0)	0.56 (-5, 4)
24 h total	6 (4-9)	13 (5-22)	18 (9-24.5)	0.002	0.045 (-12, 2)	<0.001 (-16, -3)	0.222 (-14, 4)

^a: Kruskal-Wallis test, ^b: Mann-Whitney U test [Bonferroni-adjusted significance threshold, $p < 0.016$ (0.05/3 comparisons)], MME: Morphine milligram equivalents, CI: Confidence interval, SFIB: Suprainguinal fascia iliaca block, LESPB: Lumbar erector spinae plane block. Summary statistics are reported as median (interquartile range), mean \pm standard deviation, or number.

DISCUSSION

This RCT demonstrated that SFIB significantly reduced postoperative opioid requirements in the first 24 hours after hip fracture surgery. Post-hoc analyses revealed a significant reduction in postoperative opioid consumption in the SFIB group compared with the control group, whereas opioid consumption between the LESPB and control groups was similar during the first 24 h.

Hip fractures require careful attention because frail elderly patients experience moderate-to-severe pain. Over the years, guidelines, consensus reports, and reviews for hip fracture repair have recommended the implementation of multimodal analgesia during the perioperative period. This approach includes the regular use of paracetamol, avoidance of NSAIDs, and the addition of peripheral nerve blocks to general or spinal anesthesia to minimize opioid requirements for hip fracture repair (2,4,5,7,23). The use of SFIB in hip fracture surgeries has been demonstrated to enhance pain control and reduce opioid

requirements (2-4,24). The LESPB, a relatively recent block, was first described by Forero et al. (16). Its analgesic efficacy in the hip region has been demonstrated in recent studies, although it has not yet been included in the guidelines. This study aimed to compare the analgesic efficacy of LESPB and SFIB.

In this three-group RCT, the primary endpoint—total opioid consumption over 24 hours—was lowest in patients receiving SFIB. Notably, SFIB requires a lower local anesthetic volume than LESPB, which may offer an additional clinical advantage. In elective total hip arthroplasty, patients who received LESPB exhibited lower opioid consumption during the first 8 h compared with those who did not receive the block. In contrast, between 8 and 48 hours postoperatively, opioid consumption and pain scores were similar (25). However, another study demonstrated that adding LESPB to the multimodal analgesia protocol for hip arthroplasty did not significantly affect opioid consumption or analgesic efficacy at 12 and 24 hours postoperatively (26).

In a study comparing SFIB with LESPb for hip analgesia in elective total hip arthroplasties, both blocks produced comparable reductions in postoperative pain scores and opioid requirements. Flaviano et al. (27) noted the absence of a control group in their study, which may have resulted in insufficient power to detect a difference in the primary outcome, despite calculating an appropriate sample size. In our three-group study, results in the SFIB and LESPb groups were statistically similar; however, opioid consumption was significantly reduced in the SFIB group compared with the control group, while opioid consumption in the LESPb group was similar to that in the control group. A comparison against a true control group provides a more meaningful assessment of clinical efficacy.

Studies evaluating LESPb in hip operations have primarily been conducted in patients undergoing elective hip arthroplasty. Patients undergoing surgery for hip fractures differ from those undergoing other surgeries because they are typically older, frailer, often require urgent surgery, and frequently have concomitant soft-tissue trauma. Therefore, selecting appropriate perioperative pain-control protocols based on the type of surgery is necessary, given the variability in postoperative pain management across procedures. Most studies demonstrating the effectiveness of LESPb in patients with hip fractures comprise case reports (28).

Our study aimed to achieve effective pain control. In comparing NRS scores, we observed that scores remained below 4 at all time intervals across groups, indicating successful achievement of our initial pain control goal. Comparison of opioid consumption would be unreliable in the presence of inadequate pain control. Thus, we believe that assessing the amount of opioids required for pain control would provide a more accurate representation of the effectiveness of multimodal analgesia.

Although in our study the length of hospital stay among groups was comparable, a REDUCE registry-dependent cohort study involving 178,757 patients aged ≥ 60 years with hip fractures demonstrated that the use of preoperative FIB or femoral block shortened hospitalization duration (29). The length of hospital stay was evaluated as one of the secondary endpoints in our study, and the sample size for this parameter may have been insufficient.

Our study had several strengths. Including a third control group when comparing SFIB and LESPb in hip fracture surgeries enabled a more reliable assessment of block performance and minimized comparison bias. Having all interventions performed by two experienced clinicians and using a standardized assessment protocol conducted by a blinded evaluator minimized both selection and observer biases.

Study Limitations

One limitation of this study is its single-center design. Additionally, patients were not blinded to the blocks because they were conscious during the perioperative period. In future studies, a double-blind design could be implemented using sham blocks; however, this would require a double-injection protocol because the two blocks require different positions. In this study, we chose a single-blind protocol to avoid the risk of infection associated with double injections. The volumes applied differed between the two block groups. This variation was due to one block being a compartment block and the other being fascial-plane block. These volumes were selected based on recommendations for minimal effective volumes reported in the regional anesthesia literature. Consequently, the LESPb group received a higher total dose of bupivacaine, and we cannot exclude the possibility that the observed analgesic benefit in this group is attributable to the higher dose. Future studies should investigate optimal dosing strategies to more accurately evaluate comparative efficacy.

Across the patient groups, postoperative analgesia was provided via IV-PCA to allow more precise follow-up. Opioid consumption can be reduced through oral multimodal analgesia. Mobilization duration was not included in the data collection because it varied with fracture type and surgical procedure among patients with hip fractures. Longer-term follow-up studies should be planned to assess the effects of reduced opioid consumption on functional status and mortality.

CONCLUSION

In conclusion, this study hypothesized that SFIB and LESPb would exhibit similar postoperative analgesic efficacy in patients undergoing hip fracture surgery. However, SFIB provided superior analgesic efficacy compared with LESPb. While LESPb seems to be an alternative to SFIB, it demonstrated a similar reduction in opioid consumption as that in the control group. As a component of multimodal analgesia for these surgeries, suprainguinal FIB should be prioritized.

Ethics

Ethics Committee Approval: The randomized trial was conducted after receiving approval from the Institutional Committee (Marmara University Faculty of Medicine Clinical Research Ethics Committee, reference number 09.2022.254, approval date: April 11, 2022) in accordance with the principles outlined in the Declaration of Helsinki. The trial was registered at clinicaltrials.gov (NCT05642975).

Informed Consent: Written informed consent was obtained from all the patients included in the study.

Footnotes

Author Contributions

Concept - E.G.Ö., Ö.Ö.; Design - E.G.Ö., Ö.Ö.; Data Collection or Processing - B.B.Ö.; Analysis or Interpretation - B.B.; Literature Search - E.G.Ö., B.B.Ö.; Writing - E.G.Ö., B.B., Ö.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

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