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CLINICAL TRIAL REPORT

Effect of Fascia Iliaca Compartment Block with Liposomal Bupivacaine on the Quality of Recovery After Hip Fracture Surgery: A Prospective, Randomized, Controlled Clinical Study

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Purpose: To investigate the effect of a fascia iliaca compartment block with liposomal bupivacaine on the quality of recovery after hip fracture surgery.

Patients and Methods: Seventy patients who underwent hip fracture surgery were randomized 1:1 to either the liposomal bupivacaine group (LB group) or ropivacaine group (R group). The LB and R groups received 0.333% liposomal bupivacaine and 0.375% ropivacaine, respectively, for fascia iliaca compartment block. The Quality of Recovery-15 (QoR-15) was assessed at 72 hours postoperatively. We performed between-group comparisons of the highest Numerical Rating Scale (NRS) score during activities at 0–24 hours, 24–48 hours and 48–72 hours postoperatively, amount of opioid consumption within 72 hours postoperatively, recovery time for muscle strength grades II and III, postoperative time to first mobilization, postoperative length of hospital stay, incidence of postoperative adverse reactions, and scores for patient satisfaction with pain relief.

Results: Compared to the R group, the LB group had significantly higher QoR-15 scores and lower opioid consumption at 72 hours postoperatively. There was no significant between-group difference in the highest NRS score during activity within 24 hours postoperatively. However, the LB group had lower NRS scores than the R group within the 24–48 and 48–72 hours postoperatively. The postoperative time to first mobilization was significantly shorter in the LB group than in the R group. However, there were no significant between-group differences in the recovery time for grade III muscle strength, postoperative length of hospital stay, incidence of adverse reactions, and pain satisfaction scores.

Conclusion: Fascia iliaca compartment block with liposomal bupivacaine can significantly improve the quality of postoperative recovery and reduce opioid consumption in patients undergoing hip fracture surgery.

Keywords: compartment block, postoperative analgesia, quality of recovery

Introduction

With the aging global population, the incidence of hip fractures among older adults has risen substantially owing to car accidents and falls. Artificial femoral head replacement and total hip arthroplasty are the most commonly used treatments for hip fractures. Notably, pain from hip fracture and inadequate early postoperative analgesia directly affect the treatment outcomes and prognosis.[1] Fascia iliaca compartment block (FICB) refers to the injection of local anesthetic into the fascia iliaca to block the femoral nerve, obturator nerve, and lateral femoral cutaneous nerve, which provides

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anesthesia and analgesia for lower extremity surgery. Recent evidence has indicated that FICB can provide effective postoperative analgesia in older patients undergoing hip fracture surgery.[2,3]

With advancements in surgical modalities and anesthetic techniques, perioperative quality of recovery (QoR) is not only assessed based on surgical success or discharge rates;[4] instead, it has increasingly become "patient-centered", focusing on patient safety, comfort, and overall quality of recovery during the perioperative period. The Quality of Recovery-15 (QoR-15) is a validated 15-item scale that assesses the quality of recovery following surgery and anesthesia.[5,6] FICB with ropivacaine has been shown to provide extended analgesia and improved QoR scores at 24 hours postoperatively in older adults undergoing hip fracture surgery.[7]

Nerve blocks play a crucial role in perioperative multimodal analgesia by enhancing analgesia and reducing the need for opioids. Currently, local anesthetics commonly used in clinical practice are limited by their duration of action, which often necessitates catheter placement, repeated drug administrations,[8] or the addition of adjuvants. However, their use is limited by issues, such as exudates, infections, and the potential side effects of adjuvants. Currently, nerve blocks are performed using a single local anesthetic, leading to increased use of opioids after the anesthetic effect subsides. However, opioid consumption can adversely affect the early postoperative QoR.[9]

Ropivacaine is a long-acting local anesthetic that has demonstrated effectiveness in subcutaneous infiltration; epidural, intrathecal, and peripheral nerve block procedures; and postoperative analgesia.[10] Liposomes consist of lipid molecules featuring a hydrophilic head and two hydrophobic tails arranged in various configurations. Unilamellar vesicles are formed from a single outer bilayer (essentially a hollow sphere) and can encapsulate drugs within their internal cavity.[11] Liposomal bupivacaine is a novel local anesthetic that prolongs drug release by encapsulating bupivacaine in liposomes, which allows a duration of action of up to 72 h.[12] Clinical trials have investigated the efficacy of liposomal bupivacaine in providing intraoperative and postoperative analgesia, including for bunionectomy, prostatectomy, colorectal surgery, orthopedic surgery, and thoracic surgery.[13–15] Although liposomal bupivacaine has demonstrated a favorable safety profile and ability to reduce postoperative opioid consumption, its application in FICB to improve QoR after hip fracture surgery remains to be established. Additionally, there have been inconsistent reports regarding the effectiveness of liposomal bupivacaine for local blocks and postoperative pain management.[16] This study aimed to investigate the effect of FICB with liposomal bupivacaine on the QoR after hip fracture surgery.

Materials and Methods

Seventy patients who underwent hip fracture surgery at The People's Hospital of Baoan Shenzhen between June 1, 2023 and March 31, 2025 were randomly treated with liposomal bupivacaine (Jiangsu Hengrui Pharmaceuticals Co., Ltd., Lianyungang, Jiangsu, China) (LB group, n = 35) or ropivacaine (R group, n = 35) groups. The inclusion criteria were as follows: age 60–85 years, American Society of Anesthesiologists (ASA) grade II–III, and history of artificial femoral head replacement or total hip arthroplasty. The exclusion criteria were as follows: allergy to local anesthetics, abnormal coagulation function, severe cardiopulmonary disease before surgery, hepatic and renal insufficiency, morbid obesity, skin damage, infection in the groin area, history of chronic pain, inability to cooperate with the Numerical Rating Scale (NRS) assessment, and history of opioid abuse.

This single-center, randomized, double-anonymized, controlled trial was registered with the Chinese Clinical Trial Registry (ChiCTR2400094257, 12/19/ 2024) and was approved by the Ethics Committee of the People's Hospital of Baoan Shenzhen in June 2023 (Ethics Approval No. BYL20230301-1). This study adhered to the Declaration of Helsinki, and all participants provided written informed consent. Patients were randomly assigned (via the anonymous selection of random numbers in sealed envelopes) to either the LB or R group. The suprainguinal approach was more likely to block the lateral femoral cutaneous and obturator nerves successfully.[17] Accordingly, all participants received an ultrasonography -guided supra-inguinal fascia iliaca compartment block (US-SIFICB) using a high-frequency Linear Array Probe (M9, Mindray Inc., Shenzhen, China). Here, a 40-mL volume of the drug solution can effectively stain the femoral nerve, lateral femoral cutaneous nerve, and obturator nerve, with a significant reduction in opioid consumption and postoperative complications, especially pain during passive and active movements.[18–20]

At the commencement of the study, the appropriate dose of liposomal bupivacaine for FICB was not established. Therefore, we adopted a dosage based on its application in interscalene brachial plexus blocks.[21] Currently, a dose of

133 mg of liposomal bupivacaine, which had been initially applied as the dosage, has been shown to provide effective analgesia via FICB in older patients undergoing total hip arthroplasty.[22] The LB group, as the experimental group, received 0.333% liposomal bupivacaine (133 mg liposomal bupivacaine concentrate diluted to 40 mL with 0.9% sodium chloride [NaCl] solution), while the R group received 40 mL of 0.375% ropivacaine. All block procedures were performed by three anesthesiologists trained in US-SIFICB. Postoperative pain management and assessment were conducted by the same anesthesiologist (researcher), who was professionally trained and not involved in surgical anesthesia. Physicians who performed the blocks were aware of the local anesthetics used; however, the patients and researchers were anonymized.

After screening, the patients underwent hip fracture surgery under conventional endotracheal intubation combined with intravenous inhalational general anesthesia. Twenty minutes before the end of the surgery, a single bolus of sufentanil (0.1–0.2 μg/kg) was administered for pain transition. At the end of surgery, US-SIFICB was performed in the oblique sagittal plane. Briefly, patients were placed in the supine position. After palpating the anterior superior iliac spine (ASIS), the probe was sagittally positioned medial to the ASIS and tilted slightly laterally. The structures identified in the ultrasonographic image (Figure 1A) showed the hyperechoic iliac bone, the iliacus muscle above it, and the hyperechoic iliac fascia covering the muscle. Using an in-plane technique, a 22-gauge needle was advanced in the caudal-to-cephalad direction to penetrate the iliac fascia, followed by injection of the anesthetic injection. A successful block was confirmed via ultrasonographic visualization of the hypoechoic expansion beneath the iliac fascia with cephalad spread (Figure 1B). Images were saved in the patients' records; and intermittent aspiration was performed during the local anesthetic injection. After emergence, the endotracheal tube was removed, and the patient was transfer to the post-anesthesia care unit (PACU) for continued monitoring and care. Adverse events (nausea, vomiting, tachycardia, bradycardia, dizziness, headache, and drowsiness) were treated immediately. The most severe adverse event is local anesthetic systemic toxicity, which is characterized by metallic taste, tinnitus, lip numbness, or arrhythmias. In this study, mild adverse events were not treated; however, more severe adverse events were treated using appropriate symptomatic medication (if the intervention was halfway completed, it was immediately terminated). Patients with allergic reactions received standard clinical treatment for acute allergies. Starting from PACU admission, all patients received intravenous patient-controlled analgesia (PCA) as postoperative rescue analgesia titrated with intravenous sufentanil (sufentanil 100 μg + 0.9% sodium chloride [NaCl], diluted to 100 mL). The PCA parameters were as follows: no initial dose, no background infusion, a bolus dose of 2 mL, a lockout interval of 5 min, and a maximum hourly

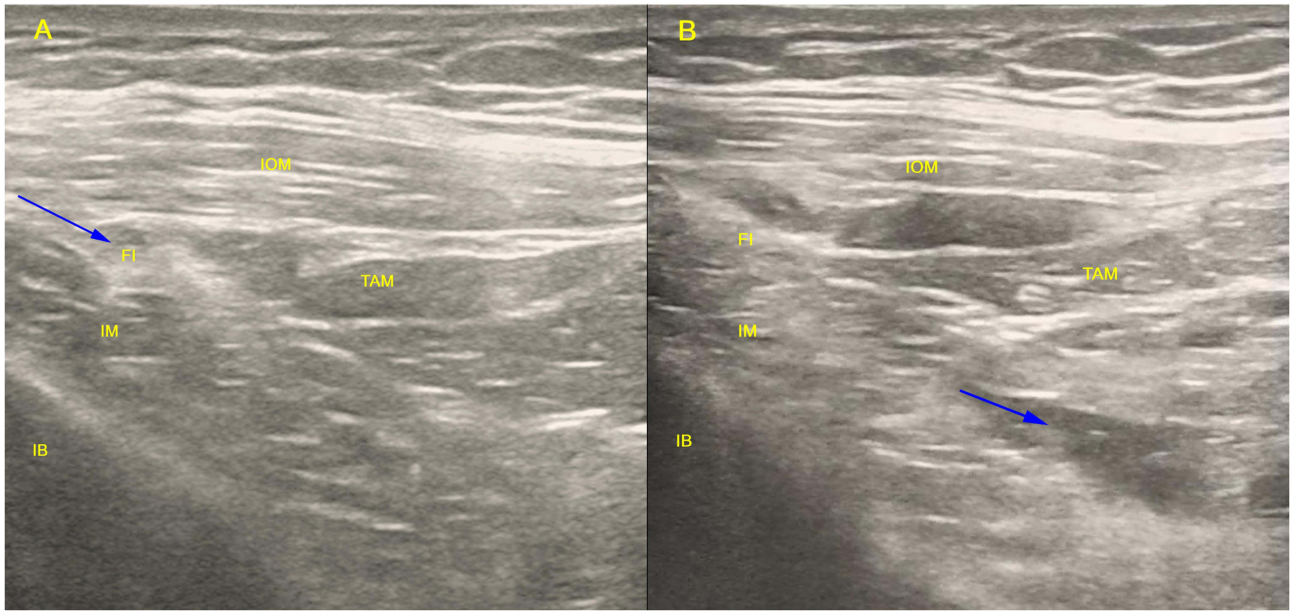

Figure 1 Ultrasonography before and after FICB. (**A**) Preprocedural ultrasonography. The blue arrow indicates the simulated needle insertion path and the target injection area. (**B**) Postprocedural ultrasonography. The area indicated by the arrow shows depot formation of the medication.
Abbreviations: FICB, Fascia iliaca compartment block; IB, Iliac bone; IM, Iliacus muscle; FI, Fascia iliaca; IOM, Internal oblique muscle; TAM, Transversus abdominis muscle.

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dose of 20 mL. In the case of an NRS pain score >3, additional titrated intravenous sufentanil was administered to maintain an NRS score ≤3 prior to returning to the ward. The same trained anesthesiologist conducted follow-up pain severity assessments at 24, 48, and 72 hours postoperatively. The study indicated a significant decrease in the maximal pain scores (NRS) up to 72 hours postoperatively when using liposomal bupivacaine for transversus abdominis plane blocks.[23] Therefore, the highest pain scores during movement were recorded along with the total opioid consumption within 72 hours postoperatively. Adverse reactions, including dizziness, nausea and vomiting, hypotension, and arrhythmia, were also documented (Figure 2).

Observation Indicators

Primary Indicator

The primary outcome was the QoR-15 score at 72 hours postoperatively. A higher score indicated better recovery quality.

Secondary Indicators

The secondary outcomes included the highest NRS score recorded at 24, 48, and 72 hours postoperatively; opioid consumption within 72 hours postoperatively; recovery times for muscle strength grades II (where limbs can move parallel to the bed) and III (where limbs can be lifted off the bed); time to the first mobilization; length of postoperative hospital stay; incidence of adverse reactions; and scores for patient satisfaction with pain relief. Satisfaction scores were rated as follows: 5 = very satisfied, 4 = satisfied, 3 = neutral, 2 = dissatisfied, and 1 = very dissatisfied.

Termination Criteria

The study was automatically terminated at the end of the follow-up period (72 hours postoperatively). Other termination criteria were as follows: (1) voluntary withdrawal from the study, which did not affect their future treatment, (2)

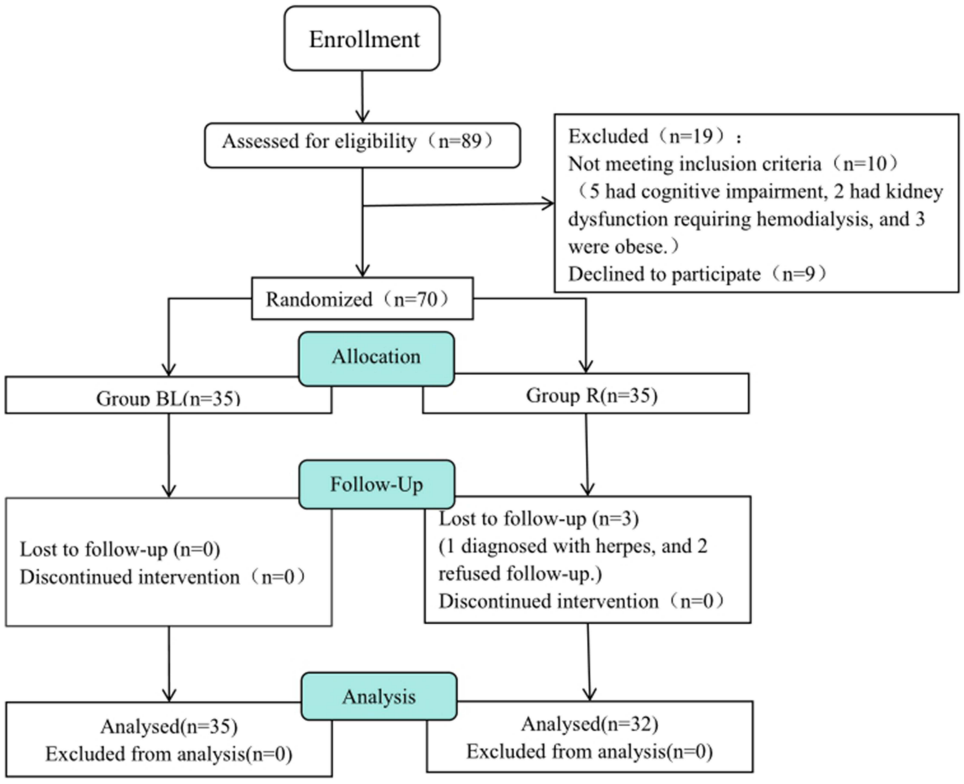

Figure 2 Flow diagram.

cancellation of surgery for any reason, (3) use of medications that violate the protocol requirements during the observation period, and (4) occurrence of severe adverse events during the observation period. The Ethics Committee approved any deviation from the study protocol.

Statistical Analyses

All statistical analyses were performed using the SPSS software (version 22.0). Normally distributed data were expressed as the mean ± standard deviation, with between-group comparisons made using the *t* test. Variance homogeneity was assessed using Levene's test, and a corrected *t* test was used for comparisons between groups with unequal variances. Non-normally distributed data were expressed as M (Q1, Q3) and analyzed using the Mann–Whitney U statistic. Count data are expressed as rates (%), with between-group comparisons using chi-square tests or Fisher's exact tests. Statistical significance was set at $P < 0.05$.

The Shapiro–Wilk test was used to assess the normality of data distribution prior to statistical analysis of the QoR-15 score at 72 h postoperatively. A difference of 8 points in the QOR-15 score is widely considered the minimal clinically important difference for perioperative interventions.[24] Accordingly, the sample size was estimated with $\alpha = 0.05$ and $1 - \beta = 0.8$, which indicated a minimal sample size of $n = 62$ (assuming $\delta = 8$). Considering a maximum data loss rate of 10% (due to surgical cancellations, loss of follow-up, and withdrawal of consent), we planned to include 70 patients (35 in each group). Among them, one patient in the R group dropped out of the study due to unbearable pain resulting from long blisters that were postoperatively diagnosed as herpes on the lateral calf, which hindered QoR assessment. Additionally, two patients in the R group voluntarily requested withdrawal from the experiment. Accordingly, these patients were excluded from the per-protocol analysis due to incomplete endpoint data. Regarding the missing values in the data, we performed a sensitivity analysis using the multiple imputation method, and the resulting conclusions were consistent with the experimental results. Consequently, 32 and 35 patients in the R and LB groups, respectively, were included in the final analysis.

Results

There were no significant between-group differences in age, sex, body mass index, ASA grade, or the ratio of underlying diseases ($P > 0.05$; Table 1).

The LB group had a significantly higher QoR-15 score at 72 hours postoperatively than the R group ($P < 0.05$). None of the participants was taking nonsteroidal anti-inflammatory drugs. Opioid consumption was significantly lower in the LB group compared to the R group ($P < 0.05$). In contrast, postoperative length of hospital stay did not show a significant

Table 1 Demographic and Clinical Characteristic

	LB Group (n=35)	R Group (n=32)	*P* value
Age (years, $\bar{x}$± s)	68.57±5.44	70.34±7.21	0.26
Gender (male/female)	20/15	16/16	0.63
BMI (kg/m^2, $\bar{x}$± s)	23.60±2.80	22.94±2.54	0.32
ASA Grading Ratio (II/III)	26/9	21/11	0.44
Hypertension (n)	13	11	0.81
Diabetes (n)	5	3	0.81
Cerebrovascular disease (n)	7	4	0.62
Cardiovascular disease (n)	2	3	0.92
Total or femoral hip arthroplasty	26/9	25/7	0.72

Note: All subjects were ASA class II or III.
Abbreviations: BMI, Body mass index; ASA, American Society of anesthesiologists.

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Table 2 Postoperative Outcomes

Item	LB Group (n=35)	R Group (n=32)	*P* value
QoR-15	124.00±8.63	118.69±10.90	0.03
Opioid use (μg sufentanil)	24 (12, 65)	52.5 (25, 87)	0.04
Postoperative hospital stay (days)	8 (5, 12)	8 (5.63, 14)	0.44
NRSmax 0–24h	3 (2, 4)	3 (2, 3)	0.57
NRSmax 24–48h	3 (2, 5)	5 (4, 6)	< 0.01
NRSmax 48–72h	2 (2, 3)	5 (4, 6)	< 0.01
Analgesic satisfaction score (1–5)	5 (4, 5)	5 (4, 5)	0.14
Muscle strength recovery time (h)			
Grade II	29 (25, 30)	21.5 (16.25, 26)	< 0.01
Grade III	37 (32, 42)	36.5 (30.5, 42)	0.66
Time to first postoperative mobilization (h)	28 (27, 45)	33 (31, 46)	< 0.01

Note: Muscle strength recovery time was assessed using the Manual Muscle Testing Grading Scale.
Abbreviation: NRSmax, The highest NRS score.

Table 3 The Incidence of Adverse Reactions

	LB Group (n=35)	R Group (n=32)	*P* value
Dizzy	7	9	0.44
Nausea and vomiting	7	6	0.90
Low blood pressure	0	0	N/A
Arrhythmia	1	0	N/A

Note: Data are presented as total number (n).

difference between the groups ($P > 0.05$). There was no significant between-group difference in the highest NRS score within 24 hours postoperatively ($P>0.05$). However, the LB group had significantly lower NRS scores within 24–48 h and 48–72 hours postoperatively than the R group ($P < 0.05$) (Table 2).

The recovery time for grade II muscle strength was significantly longer in the LB group than in the R group ($P<0.05$). However, there was no significant between-group difference in the recovery time of grade III muscle strength ($P>0.05$). Additionally, the time to the first postoperative mobilization was significantly shorter in the LB group than in the R group ($P < 0.05$;Table 2).

There were no significant between-group differences in the incidence of adverse events ($P>0.05$; Table 3).

Discussion

Our findings indicate that FICB with liposomal bupivacaine improved the QoR after hip fracture surgery and promoted quick recovery. This is consistent with a previous report that the use of single liposomal bupivacaine transversus abdominis plane block provides superior early postoperative recovery quality in comparison to bupivacaine.[25]

Older patients with hip fractures usually experience severe pain during their activities of daily living. Inadequate pain control can delay postoperative ambulation, which may lead to long-term functional impairment and increased opioid consumption.[1] Pacira, a pharmaceutical company, found that 90% of patients would consider the risk of opioid substance use disorder and its adverse effects when selecting postoperative analgesics. Additionally, opioid use has been shown to

adversely affect the quality of early postoperative recovery, with 79% of patients preferring nonopioids. In the present study, there was no significant between-group significant difference in the highest NRS score within 24 hours postoperatively. However, it was significantly lower in the LB group than in the R group within the 24–48 hours and 48–72 hours postoperatively periods ($P < 0.05$). This may be attributed to differences in the pharmacological effects of bupivacaine liposomes and ropivacaine, with the former exhibiting a longer duration of action. The LB group showed significantly reduced opioid consumption within 72 hours postoperatively ($P < 0.05$). Collectively, these findings indicate that liposomal bupivacaine provides long-acting analgesia, reduces patient dependence on opioids, and facilitates rapid recovery.

Early mobilization is crucial for the postoperative rehabilitation of patients with hip fractures; furthermore, it is a vital component of the ERAS pathway.[26] It reduces postoperative complications, accelerates functional ambulation recovery, and has a positive impact on multiple patient-reported outcomes.[27] Our study revealed no significant between-group difference in the time to recover grade III muscle strength. However, the LB group had a significantly shorter time to first postoperative ambulation than the R group. This suggests that the long-lasting analgesic effects of liposomal bupivacaine promoted earlier mobilization for rehabilitation, which may reduce the risk of infections and pressure ulcers associated with prolonged bed rest as well as complications, such as deep vein thrombosis and pulmonary embolism in the lower limbs.

Another study on full-term pregnant women undergoing elective cesarean section under spinal anesthesia found that liposomal bupivacaine plus bupivacaine HCl reduced total opioid consumption within 72 hours compared to bupivacaine HCl alone; however, this combination regimen appeared to increase the incidence of adverse reactions.[28] Other similar studies have suggested that liposomal bupivacaine may offer advantages over standard bupivacaine in terms of reducing pain severity and opioid consumption during the early postoperative period, in patients undergoing total knee arthroplasty.[29] This is consistent with our findings of reduced opioid usage within 72 hours postoperatively in the LB group. A previous study reported the occurrence of adverse events, such as nausea and sleep disturbance, due to pain.[30] Similarly, we observed adverse events, such as sinus bradycardia in one patient, which was listed as an adverse event in the drug's prescription information. Nonetheless, there was no significant between-group difference in the incidence of adverse reactions, indicating that both regimens can be safely used for hip fracture surgery in these patients.

Notably, a previous study indicated that liposomal bupivacaine for brachial plexus blocks did not improve pain scores compared to bupivacaine alone.[31] However, the previous study was not designed to observe a difference in pain scores at 24 hours postoperatively, which may have limited its ability to detect differences at that time point. A strength of our study was the use of the QoR-15 score to evaluate the postoperative quality of recovery.

This study has some limitations. First, this was a single-center study, which may have resulted in bias due to inter-institutional differences in diagnostic criteria, treatment levels, and population characteristics. Second, this study had a small sample size, which reduces the statistical power and may have led to false-negative results. Third, the exclusion of dropouts may have affected the generalizability of the results. Further studies are required to confirm the safety and efficacy of these drugs.

Conclusion

Compared to 0.375% ropivacaine, FICB with 0.333% liposomal bupivacaine can reduce opioid usage, significantly improve the quality of postoperative recovery, and promote rapid recovery in patients undergoing hip fracture surgery. This technique shows promising prospects for clinical application.

Data Sharing Statement

The authors can provide the original data for this study. If you have any further inquiries regarding the data, please contact the corresponding author (Bin Zheng). Any information we share will be deidentified.

Ethics Approval and Informed Consent

This single-center, randomized, double-anonymized, controlled trial was registered with the Chinese Clinical Trial Registry (ChiCTR2400094257, 12/19/ 2024) and approved by the Ethics Committee of the People's Hospital of Baoan Shenzhen in June 2023 (Ethics Approval No. BYL20230301-1). This study adhered to the Declaration of Helsinki, and all participants provided written informed consent. Patients were randomly assigned (via anonymous selection of random numbers in sealed envelopes) to either the LB or R group.

Consent for Publication

All authors have given their explicit consent for the publication of this article.

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Disclosure

The authors report no conflicts of interest in this work.

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