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Original Research Article

To compare the effects and efficacy of 0.5% hyperbaric levobupivacaine with fentanyl versus 0.5% hyperbaric bupivacaine with fentanyl for subarachnoid block in elderly patients undergoing elective surgeries

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ABSTRACT

Background: Spinal anesthesia is widely used in elderly patients undergoing lower abdominal or lower limb surgeries. Bupivacaine is associated with cardiovascular and central nervous system toxicity, prompting the adoption of levobupivacaine, its S(–)-enantiomer, as a safer alternative to bupivacaine.
Methods: A randomised, double-blind study was conducted amongst 80 ASA grade I/II patients aged 60-75 years scheduled for elective infraumbilical and lower limb surgeries. Patients were randomly assigned to group L (levobupivacaine 0.5%, 3 ml + fentanyl 25 µg) and group B (bupivacaine 0.5%, 3 ml + fentanyl 25 µg).
Results: The onset of sensory block was significantly faster in group B (2.66±0.56 minutes) than in group L (3.25±0.68 minutes; $p<0.001$). However, sensory block duration was prolonged in group L (303.38±20.44 minutes) compared to group B (263.13±14.55 minutes; $p<0.001$). Similarly, motor block occurred earlier in group B (2.59±0.61 minutes) than in group L (3.15±0.56 minutes; $p<0.001$), but the motor block lasted longer in group L (172.88±19.44 minutes) than in group B (144.63±15.25 minutes; $p<0.001$). Group L demonstrated superior haemodynamic stability. Conversely, side effects were more frequent in group B.
Conclusions: Compared to hyperbaric bupivacaine with fentanyl, hyperbaric levobupivacaine with fentanyl provided a longer duration of sensory and motor blockade, enhanced haemodynamic stability, and fewer adverse effects. Levobupivacaine thus appears to be a safer and more effective option for older adult patients undergoing elective surgeries.

Keywords: Bupivacaine, Elderly, Fentanyl, Infraumbilical, Levobupivacaine, Subarachnoid block

INTRODUCTION

Anesthesia has advanced significantly with reduced complications. Although general anesthesia (GA) is common, it involves multiple drugs and higher risks. Local anaesthetics enable reversible regional blocks, allowing surgery with less pain and discomfort.[1,2] The use of regional anesthesia has reduced GA related complications, such as nausea, airway injury, hypoxia, and aspiration risk. It improves postoperative pain control, lowers opioid use and side effects, shortens hospital stays, decreases readmissions, enhances patient satisfaction and recovery, and reduces blood loss, urinary retention, and ileus.[3,4]

Though spinal anesthesia has evolved significantly, common risks include post-dural puncture headaches, incomplete block requiring GA, and limited duration

unless supplemented with an adjuvant, epidural anesthesia or sedation.[5]

Bupivacaine is a long-acting amide anesthetic used in spinal, epidural, and nerve blocks. It contains equal amounts of R(+) and S(−) enantiomers. Due to concerns about CNS and cardiovascular side effects, safer alternatives like ropivacaine and levobupivacaine have been developed.[6]

Levobupivacaine is a pure S(−)-enantiomer of bupivacaine with a long duration of action and similar anaesthetic and analgesic effects. It provides better haemodynamic stability, reducing the risks of hypotension, bradycardia, arrhythmias, and CNS toxicity. Its onset is slightly slower, and the motor block is less intense, benefiting outpatient use and early mobilisation. It is a safer, effective alternative, especially in high-risk or obstetric cases, with fewer serious adverse events, than racemic bupivacaine.[7,8]

Fentanyl is a potent synthetic opioid used intrathecally (10-25 µg) in regional anesthesia to enhance sensory block and analgesia with minimal motor effect. Its rapid onset and short duration make it suitable for short procedures. Side effects such as pruritus, nausea, and respiratory depression are dose-dependent and less common at low doses. It is often combined with local anesthetics to improve outcomes.[9,10]

Levobupivacaine toxicity is rare and usually manageable. However, it has not fully replaced bupivacaine, and its use in spinal anesthesia for elderly patients has not been extensively studied.[11] Hyperbaric bupivacaine and levobupivacaine, which are denser than cerebrospinal fluid, are used in spinal anesthesia to achieve consistent and precise sensory blocks owing to their predictable and variable diffusion patterns.[12-14] Nevertheless, comparative studies of the two drugs are lacking in the literature. The present study primarily aimed to assess the haemodynamic effects, quality, and duration of sensory and motor blockade of levobupivacaine compared with those of intrathecal bupivacaine in elderly patients undergoing elective surgery. Second, we compared the total duration of analgesia and the side effect profiles of the two drugs.

METHODS

A prospective, interventional, randomised, double-blinded trial was conducted at Paras Hospital, Gurugram from December 2023 to December 2024. The institutional scientific ethical committee approved this study. Eighty patients of both sexes, with a height of 145-180 cm, weight of 50-75 kg, aged 60-75 years, American Society of Anesthesiologists (ASA) grade I/II, and undergoing elective surgery were included. Patients who refused to consent, required emergency surgery, had contraindications to subarachnoid block (thrombocytopenia/coagulopathy, elevated ICP, meningitis, or local site infection), or had known allergies to the study drugs were excluded.

Sample size

Taking into consideration the study by Thakore et al, and assuming 99% power and 95% confidence interval, the minimum sample size required was calculated to be 40 in each group.[15]

Methodology of the study

Patients were randomly assigned to two equal groups (n=40) using a computer-generated table with allocation concealed in opaque, sealed envelopes overseen by an independent investigator. This double-blind study ensured that both the patients and anaesthesiologists were unaware of the group assignments. Intrathecal drugs were prepared by an independent anaesthesiologist who was not involved in the administration or monitoring, and a separate blinded anaesthesiologist performed the injections.

On the procedure day, after confirming nil by mouth, standard ASA monitoring was established, and baseline readings were taken. An intravenous line was placed, and the patients were preloaded with Ringer's lactate (10 ml/kg) or normal saline (10 ml/kg for diabetics) for 15 minutes. Under aseptic conditions, spinal anesthesia was administered at the L3-L4 interspace with the patient in a sitting position. A total of 3.5 ml intrathecal solution was injected using a 25-G Quincke needle: group L received 3 ml (15 mg) of 0.5% hyperbaric levobupivacaine with 25 µg fentanyl, and group B received 3 ml (15 mg) of 0.5% hyperbaric bupivacaine with 25 µg fentanyl. The patients were then positioned supine with a slight head-down tilt to achieve a T10 block level.

Data collection and assessment

Intraoperative monitoring involved regular recordings of blood pressure, heart rate, oxygen saturation, and respiratory rate at 2, 5, 10, and 15 minutes, and then every 15th minute interval until completion of the procedure. Postoperative monitoring was conducted at 30-minute intervals or until rescue analgesia was provided. The sensory block onset and level was evaluated bilaterally using the pinprick technique along the midclavicular line. This was performed every 2 minutes after the intrathecal injection until three consecutive readings stabilised and once more at the end of the surgery.

Outcome measures

The primary outcomes included sensory and motor block characteristics (Bromage scale 3) and haemodynamic stability. The secondary outcomes were analgesia duration, side effects, and safety of the study drugs. Motor block onset was defined as the time to reach Bromage scale 1 and maximum block as the time to achieve Bromage 3.[16] The duration of the motor block was recorded from

injection to full recovery (Bromage 0). Analgesia duration was defined as the time from injection to the first rescue analgesia request or VAS>3, assessed every 30 minutes up to 300 minutes after injection. Rescue analgesia was initiated with i.v. diclofenac (75 mg), followed by tramadol (1 mg/kg i.v.), if needed. Side effects such as hypotension, bradycardia, nausea, and pruritus were monitored perioperatively. Post-surgery, patients were observed during recovery.

Statistical analysis

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 21 (IBM Inc.). Descriptive statistics were reported for all variables. The summarised data were presented in tables and graphs. Data were typically normally distributed, as tested using the Shapiro-Wilk W test ($p>0.05$). An independent t-test was used to compare age, haemodynamic parameters, onset, and duration. For the VAS score, a non-parametric test, the Mann-Whitney U test was used to compare two independent groups. A chi-square test was used to measure the categorical variables. Statistical significance was set at $p<0.05$.

RESULTS

A prospective, interventional, randomised, double-blinded study was conducted involving 80 adult patients, aged 60-75 years. The enrolment of participants is shown in Figure 1.

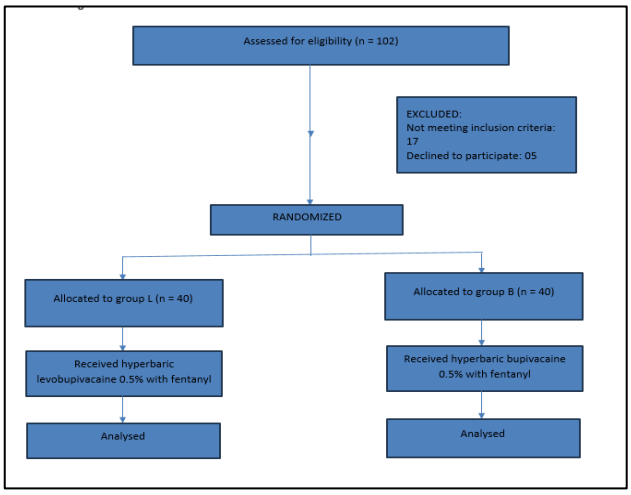

Figure 1: The CONSORT flow chart.

Table 1: Demographic and anthropometric parameters.

		Group L (n=40) (%)	Group B (n=40) (%)	P value
Age (mean±SD) (years)		67.78±4.39	67.9±4.64	0.902*
Gender	Female	21 (52.5)	13 (32.5)	0.056#
	Male	19 (47.5)	27 (67.5)	
ASA	I	5 (12.5)	2 (5)	0.216#
	II	35 (87.5)	38 (95)	
Anthropometric measures (mean±SD)	Weight (kg)	64.68±8.49	63.3±6.91	0.431*
	Height (m^2)	163.88±8.03	163.9±7.81	0.989*
	BMI (kg/ m^2)	24.08±2.8	23.58±2.31	0.366*

*Independent t test, #Chi square test

Groups L and B were comparable in terms of age, sex, ASA status, weight, height, and BMI with no significant difference between the groups (Table 1).

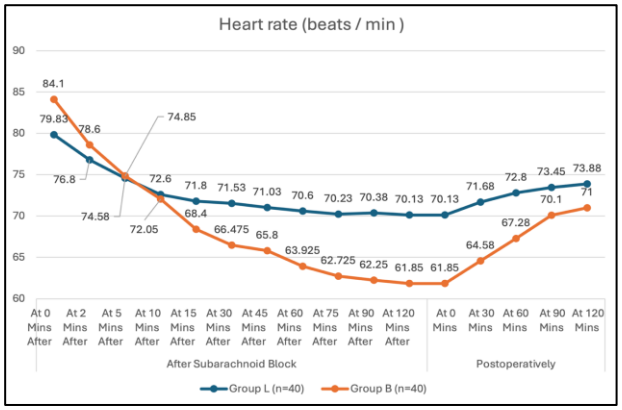

Figure 2: Comparison of heart rate (beats/minute) between the two study groups.

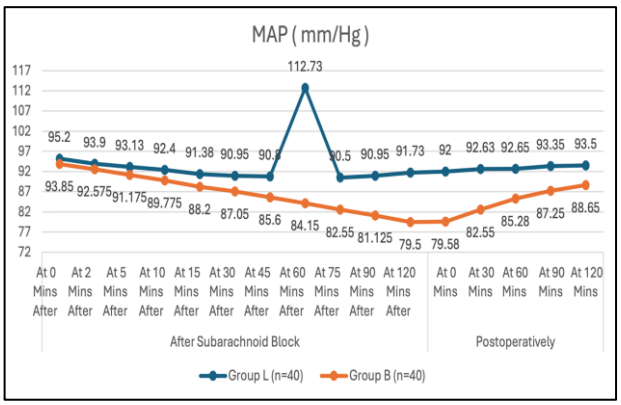

Figure 3: Comparison of MAP (mm/Hg) between the two study groups.

At baseline, group L had a significantly lower heart rate than group B (79.83±6.44 versus 84.10±6.26 beats/minute; $p=0.004$). The heart rates were similar at 2, 5, and 10

minute. From 30 minutes onwards, group L maintained significantly higher heart rates than group B (p≤0.001), a trend that continued postoperatively, with group L showing better haemodynamic stability over time (Figure 2).

Following spinal anesthesia, group L generally maintained a higher mean arterial pressure (MAP) than group B. Initial differences at 0 and 2 minutes were not significant, but from 5 to 45 minutes, group L showed a significantly higher MAP (p≤0.023). A likely outlier at 60 minutes disrupted this trend, but significance resumed from 75 to 120 minutes (p=0.001). Postoperatively, group L had a significantly higher MAP at 0, 30, and 60 min (p=0.001), with differences equalising at 90 and 120 minutes (Figure 3).

The baseline respiratory rates were 16.78±0.70 (group L) and 16.90±0.78 (group B) breaths/minute (p=0.452), with no significant differences intraoperatively up to 75 minutes. At 90 and 120 minutes post-SAB, the rates remained comparable (17.32±0.69 versus 17.30±0.62; p>0.05). Postoperatively, the respiratory rates were similar at 0, 30, and 60 min. However, at 90 and 120 postoperatively, small but statistically significant differences appeared (p=0.001). Overall, respiratory function remained stable in both the groups (Figure 4).

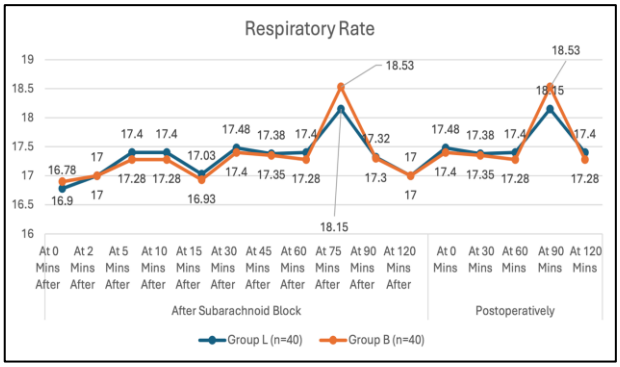

Figure 4: Comparison of respiratory rate between the two study groups.

Table 2: Comparison of sensory and motor blockage.

	Group L	Group B	P value
Maximum sensory dermatomal level N (%)			
T10	37 (92.5)	35 (87.5)	0.356*
T8	3 (7.5)	5 (12.5)	
Maximum motor blockage N (%)			
B3	40 (100)	40 (100)	-*
Time to first postoperative analgesic demand (minutes) (mean±SD)	217.75±8.44	233.38±13.35	0.001#
Time of onset of sensory block (minutes) (mean±SD)	4.33±1.04	1.003±0.66	0.001#
Onset to T10 sensory blockade (minutes) (mean±SD)	5.83±1.7	2.64±0.81	0.001#
Onset of motor blockage (minutes)	6.61±1.72	3.56±0.83	0.001#
Motor blockade duration (minutes)	177.58 ± 8.46	223.05±12.51	0.001#

* Chi Square test, #Independent t test.

Most patients reached a maximum sensory block at T10 (92.5% in group L and 87.5% in group B), with no significant difference (p=0.356). All patients achieved a complete motor block (Bromage 3). Group B had a significantly longer duration of analgesia (233.38±13.35 minute) than group L (217.75±8.44 minute; p=0.001). Sensory block onset was faster in group B (1.00±0.67 minute) than in group L (4.33±1.04 minutes; p=0.001). The time to T10 level and motor block onset were also quicker in group B (2.64±0.81 minutes and 3.57±0.84 minutes, respectively) than in group L (5.83±1.70 minutes and 6.61±1.72 minutes, respectively; p=0.001), indicating the faster action of bupivacaine with fentanyl. Group B showed a significantly longer motor blockade duration (223.05±12.52 minutes) than group L (177.58±8.46 minutes; p=0.001), indicating a prolonged motor block effect with bupivacaine (Table 2).

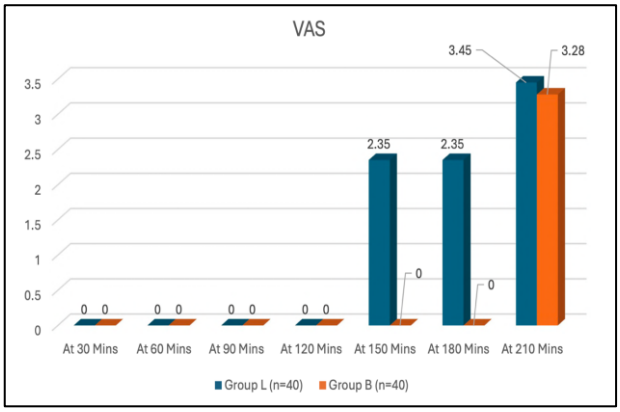

Figure 5: Comparison of the mean VAS between the two study groups.

VAS scores were zero in both groups up to 120 min postoperatively. At 150 and 180 minutes, group L had

significantly higher pain scores than group B (p=0.001). At 210 min, pain increased in both groups without a significant difference (3.45±0.55 versus 3.28±0.45; p=0.071), indicating superior early postoperative analgesia in group B (Figure 5).

Adverse effects were minimal, with nausea occurring in 2.5% of group L and 10% of group B patients, a difference that was not statistically significant (p=0.179), indicating similar safety profiles for both anaesthetic regimens.

DISCUSSION

Demographic characteristics

In the current study, both groups were statistically comparable in terms of age, sex distribution, ASA grade, and physical characteristics.

Heart rate

Group L showed significantly higher mean heart rates from 30 to 120 min post-SAB. Shah et al reported fewer bradycardia episodes with bupivacaine plus fentanyl than with bupivacaine alone.[17] Likewise, Grewal et al reported lower bradycardia rates with levobupivacaine-fentanyl than with bupivacaine.[18] These findings confirm that levobupivacaine with fentanyl offers better heart rate stability post-SAB.

VAS scores and analgesic demand

Both groups had a VAS score of 0 at 30 and 60 minutes post-surgery. At 150 and 180 minutes, group L's pain increased to 2.35±0.74, while group B remained at zero (p=0.001). By 210 minutes, pain levels increased in both groups without significant differences (group L: 3.45±0.55; group B: 3.28±0.45; p=0.071), showing better early analgesia in group B.

Thus, in the present study, bupivacaine-fentanyl produced a significantly faster onset of sensory and motor blocks than levobupivacaine-fentanyl. This aligns with findings by Thakore et al and Erbay et al, though Savio et al reported faster sensory onset with levobupivacaine in cesarean sections.[15,19,20]

Duration of motor blockade

In this study, group B (bupivacaine + fentanyl) had a significantly longer motor blockade duration than group L (levobupivacaine + fentanyl). Similar studies by Grewal et al reported shorter motor block and quicker recovery with levobupivacaine-fentanyl, along with less hemodynamic instability compared to bupivacaine-fentanyl.[15,18,21]

Nausea and other side effects

In the present study, nausea occurred in 2.5% and 10% of the patients in groups A and B, respectively, with no significant difference (p=0.179). The timing of postoperative nausea was also similar between the groups (p=0.401), indicating comparable safety. These findings align with previous reports of minimal side effects for levobupivacaine with fentanyl by Shah and Khobragade et al.[17,22]

Time to analgesic demand

In this study, the time to the first postoperative analgesic request was similar between the two groups. This finding contrasts with that of Erbay et al, who reported a longer duration of analgesia with levobupivacaine plus fentanyl. These differences may stem from variations in drug dosage, baricity, and the surgical procedures.

The sample size was small in this study. It was a single-centre study that included only ASA I and II patients aged 60-75 years, limiting the generalisability of the results to other populations and settings. Follow-up was limited to the immediate postoperative period, preventing the assessment of long-term complications, neurological outcomes and delayed analgesic needs.

CONCLUSION

Hyperbaric bupivacaine with fentanyl led to a markedly quicker onset of sensory and motor block, as well as longer postoperative analgesia compared to levobupivacaine. However, levobupivacaine demonstrated better hemodynamic stability, fewer fluctuations in blood pressure and heart rate, and fewer side effects like nausea. Therefore, while bupivacaine may be favored for rapid onset and prolonged analgesia, evobupivacaine offers a safer and more stable alternative for elderly patients where cardiovascular safety is essential.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee (PHPL/HR-COMM/2023/183)

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