Section: Anaesthesia

Original Research Article

COMPARING THE EFFICACY OF HYPERBARIC LEVOBUPIVACAINE 0.5% WITH FENTANYL VERSUS HYPERBARIC BUPIVACAINE 0.5% WITH FENTANYL FOR SUBARACHNOID BLOCK IN PATIENTS UNDERGOING ELECTIVE LSCS

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Abstract

Background: Postoperative analgesia plays a crucial role in the recovery after caesarean section, with spinal anaesthesia being widely used for its rapid and effective blockade. This study compared the efficacy and safety of hyperbaric levobupivacaine 0.5% with fentanyl versus hyperbaric bupivacaine 0.5% with fentanyl for subarachnoid block in elective lower-segment caesarean sections (LSCS). **Materials and Methods:** This double-blind, randomised controlled trial included 156 patients undergoing elective LSCS. Patients were randomly allocated to Group L (n=78) (10 mg of 0.5% hyperbaric levobupivacaine with fentanyl) or Group B (n=78) (10 mg of 0.5% hyperbaric bupivacaine with fentanyl). Spinal anaesthesia was administered aseptically, and the sensory and motor blockade levels were assessed regularly. Intraoperative and postoperative parameters, including analgesia duration, haemodynamic stability, and adverse effects, were assessed. **Result:** The onset of sensory blockade was faster in Group L (4.00±0.99 min) than in Group B (4.80±1.14 min, p<0.001). The time to achieve the highest sensory block was shorter in Group L (7.50±1.87 min vs. 9.00±2.00 min, p<0.001). Sensory block duration was longer in Group L (187.70±20.98 min) than in Group B (179.80±24.28 min, p=0.033). Motor block duration was shorter in Group L (89.00±11.64 min) than in Group B (138.80±26.43 min, p<0.001). Analgesia lasted longer in Group L (221.60±25.52 min) than in Group B (204.30±34.76 min, p=0.001). The incidence of complications, including hypotension, bradycardia, and shivering, showed no significant difference (p>0.05). **Conclusion:** Levobupivacaine provided faster sensory onset, prolonged analgesia, and quicker motor recovery than bupivacaine, with comparable safety. These findings suggest that levobupivacaine may be preferred for caesarean sections, ensuring effective pain relief with reduced motor blockade.

INTRODUCTION

Postoperative analgesia is a vital component of the management of patients undergoing surgery, especially in caesarean sections, where appropriate pain relief is strongly associated with recovery for both the mother and early bonding of the neonate. Spinal anaesthesia has long been used as a landmark in caesarean deliveries because of its effectiveness in facilitating rapid and profound blockade of sensory neurones. However, optimal postoperative pain management continues evolving with new agents and adjuvants that bring about higher analgesic effects with fewer adverse outcomes.[1,2]

During the last couple of years, hyperbaric solutions of levobupivacaine and bupivacaine, sometimes with adjuvants like fentanyl, have gained ground in spinal anaesthesia.[3] Hyperbaric bupivacaine has been a reliable agent for spinal anaesthesia due to its pharmacokinetic profile and predictable block characteristics. However, it is associated with side effects like hypotension, bradycardia, and motor block that can limit utility in certain populations.[4] Levobupivacaine, an amide-type long-acting local anaesthetic, has gained popularity due to significantly less cardiotoxicity and reduced neurotoxic potential compared to bupivacaine.5 When mixed with fentanyl, opioid-enhancing analgesia without prolonging motor blockade, levobupivacaine

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presents an exciting alternative for spinal anaesthesia, especially in obstetric populations.[5]

This study compared the efficacy and safety of hyperbaric levobupivacaine mixed with fentanyl versus hyperbaric bupivacaine mixed with fentanyl in spinal anaesthesia for elective lower-segment caesarean sections. This comparison is critical because, despite recognising the effectiveness of both agents, there is limited direct evidence regarding their performance in terms of sensory and motor blockade, duration of analgesia, and incidence of side effects, particularly in lower-segment caesarean sections. The choice of drugs is therefore crucial.[6]

The main reason for this study was to help design the future of clinical practice in obstetric anaesthesia. This study could guide anaesthetists in choosing the spinal anaesthetic regimen for patients undergoing Lower Segment Caesarean Section (LSCS) based on the comparative efficacy and safety of these two widely used agents. There is a lack of direct comparative studies of levobupivacaine and bupivacaine in the guidelines for spinal anaesthesia in obstetrics within existing evidence.[7] This study fills an important knowledge gap and allows for improvement in patient outcomes through better-tailored anaesthetic care.

Optimal pain management strategies require careful consideration of efficacy and safety in this population. Comparing hyperbaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl, the regimen providing better analgesia with minimal side effects will improve the postoperative experience of patients undergoing elective LSCS.

Aim

This study aimed to compare the analgesic efficacy of hyperbaric levobupivacaine 0.5% with fentanyl versus hyperbaric bupivacaine 0.5% with fentanyl for subarachnoid block in patients undergoing elective LSCS.

MATERIALS AND METHODS

This prospective double-blinded randomised controlled trial included 156 patients and was conducted in the Department of Anaesthesiology, Government Medical College, Omandurar Government Estate, Chennai, for 12 months between September 2022 and April 2024. The Institutional Ethics Committee (33/IEC/GOMC/2022) approved this study before its initiation. Informed consent was obtained from all patients.

Inclusion criteria

The study included patients aged 18 to 35 years, height 145-165 cm, weight 45-70 kg, scheduled for elective lower segment caesarean section under anaesthesia, classified as ASA physical status II, with singleton pregnancy, who consented.

Exclusion criteria

Patients with neurological disorders, cardiovascular, hepatic, renal, or respiratory diseases, coagulopathy, or a history of drug allergies or anaphylaxis related to the study medications were excluded. Contraindications for spinal anaesthesia, including spinal deformities, elevated intracranial pressure, bleeding disorders, and infections at the puncture site, also led to exclusion. Patients with obesity (BMI >30), short stature (<147 cm), twin pregnancies, or those unwilling to participate were excluded from the study.

Methods: Patients were evaluated in the pre-anaesthetic assessment clinic based on the inclusion and exclusion criteria. One day before surgery, the participants were informed about the study procedures and received 50 mg of intravenous Inj. Ranitidine to minimise gastric secretions. The patients were randomly assigned to two groups using the SNOSE method. Group L (n=78) received 10 mg (2 ml) of 0.5% Hyperbaric Levobupivacaine with 10 mcg (0.2 ml) of Inj. Fentanyl for spinal anaesthesia, while Group B (n=78) received 10 mg (2 ml) of 0.5% Hyperbaric Bupivacaine with 10 mcg (0.2 ml) of Inj. Fentanyl.

Patients were moved to the operating table on the day of surgery, and standard monitors were connected to record baseline vital signs. Intravenous access was confirmed, and fluid therapy was initiated. Under aseptic conditions, spinal anaesthesia was administered in the left lateral position using a 25-G spinal needle, delivering 2.2 ml. The patients were placed in the supine position after administering the subarachnoid block. The pinprick method and Modified Bromage Scale were used to assess sensory and motor levels. Intraoperative haemodynamic parameters were also recorded. Postoperatively, sensory and motor levels and pain were evaluated at 0, 1, 2, 3, 4, 5, and 6 h.

Statistical Analysis: Data were presented as mean, standard deviation, frequency, and percentage. Continuable variables were compared using the independent sample t-test. Categorical variables were compared using the Pearson chi-square test. Significance was defined by P values less than 0.05 using a two-tailed test. Data analysis was performed using IBM-SPSS version 21.0.

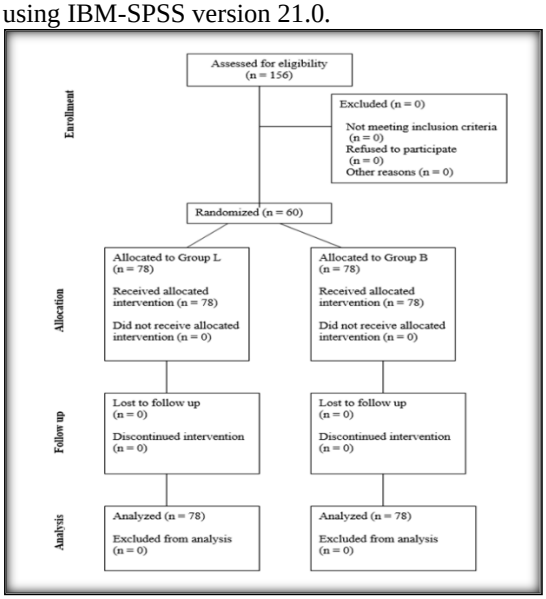

Figure 1: CONSORT flowchart

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RESULTS

Regarding age distribution, most patients belonged to the 20–30 age category, with 79.5% in Group L and 73.1% in Group B, followed by 31–40 years (17.9% in Group L vs. 25.6% in Group B). A small proportion of patients were younger than 20 years (2.6% in Group L vs. 1.3% in Group B), with no significant differences (p=0.449). The mean age was 27.42±3.47 years in Group L and 28.13±3.47 years in Group B, with no significant difference (p=0.206).

The mean weight in Group L was 51.50±8.05 kg and in Group B was 50.60±6.44 kg, with no significant difference (p=0.411). The mean height was 154.90±3.49 cm in Group L and 154.50±3.52 cm in Group B, showing no significant difference (p=0.523). The mean surgery duration was 37.40±1.72 min in Group L and 37.70±1.59 min in Group B, showing no significant difference (p=0.36) [Table 1].

Table 1: Comparison of demographics between groups.

		Mean±SD		P value
		Group L	Group B	
Age (years)	<20	2(2.6%)	1(1.3%)	0.449
	20-30	62(79.5%)	57(73.1%)	
	31-40	14(17.9%)	20(25.6%)	
Age (years)		27.42±3.47	28.13±3.47	0.206
Weight (kg)		51.50±8.05	50.60±6.44	0.411
Height (cm)		154.90±3.49	154.50±3.52	0.523
Duration of surgery (minutes)		37.40±1.72	37.70±1.59	0.36

Regarding ASA grading, most patients were ASA Grade I: 78.2% in Group B and 76.9% in Group L. The remainder were ASA Grade II: 21.8% in Group B and 23.1% in Group L, with no significant difference (p=0.848). The Bromage scale showed significant differences (p<0.001). In Group B, 67.9% of the patients showed complete motor blockade (grade 3), whereas none of the patients in Group A did. were observed in Group L. In Group L, 50% of the patients had partial motor blockade (degree 1), whereas none were observed in Group B. An equal proportion (50%) in Group L and 32.1% in Group B had moderate motor blockade (degree 2) [Table 2].

Table 2: Comparison of ASA grading and Bromage scale between groups

		N (%)		P value
		Group B	Group L	
ASA grading	Grade I	61(78.2%)	60(76.9%)	0.848
	Grade II	17(21.8%)	18(23.1%)	
Bromage scale	Degree 1	0	39(50%)	<0.001
	Degree 2	25(32.1%)	39(50%)	
	Degree 3	53(67.9%)	0	

The onset of sensory blockade was faster in Group L than in Group B (4.00±0.99 vs. 4.80±1.14 min), with a significant difference (p<0.001). The time to achieve the highest sensory block was shorter in Group L (7.50±1.87 minutes) than in Group B (9.00±2.00 minutes), showing a significant difference (p<0.001). The duration of sensory blockade was longer in Group L (187.70±20.98 min) than in Group B (179.80±24.28 min), with a significant difference (p=0.033). The two-segment regression time was comparable between the groups, with Group L at 89.10±13.48 min and Group B at 85.80±14.51 min, with no significant difference (p=0.147).

The onset of motor blockade was 3.20±0.85 min in Group L and 3.30±0.54 min in Group B, with no significant difference (p=0.102). However, the duration of motor blockade was longer in Group B (138.80±26.43 min) than in Group L (89.00±11.64 min), showing a significant difference (p<0.001). The duration of analgesia was longer in Group L (221.60±25.52 min) than in Group B (204.30±34.76 min), showing a significant difference (p=0.001) [Table 3].

Table 3: Comparison of sensory and motor block characteristics between groups

	Mean±SD		P value
	Group L	Group B	
Onset of sensory block (mins)	4.00±0.99	4.80±1.14	<0.001
Time to achieve the highest sensory block (minutes)	7.50±1.87	9.00±2.00	<0.001
Duration of sensory block (minutes)	187.70±20.98	179.80±24.28	0.033
Two-segment regression time (mins)	89.10±13.48	85.80±14.51	0.147
Onset of motor block (mins)	3.20±0.85	3.30±0.54	0.102
Duration of motor block (mins)	89.00±11.64	138.80±26.43	<0.001
Duration of analgesia (mins)	221.60±25.52	204.30±34.76	0.001

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There was no significant difference in the incidence of complications between Group B and Group L. The proportion of patients without complications was comparable between the two groups (69.2% vs. 65.4%, p = 0.608). The incidence of bradycardia (3.8% vs. 6.4%, p = 0.467), hypotension (10.3% vs. 7.7%, p = 0.575), shivering (9% vs. 7.7%, p = 0.772), postoperative nausea and vomiting (PONV) (3.8% vs. 6.4%, p = 0.467), and pruritus (3.8% vs. 6.4%, p = 0.467) did not differ significantly between the groups [Table 4].

Table 4: Comparison of complications between groups

		N (%)		P value
		Group B	Group L	
Complications	None	54(69.2%)	51(65.4%)	0.608
	Bradycardia	3(3.8%)	5(6.4%)	0.467
	Hypotension	8(10.3%)	6(7.7%)	0.575
	Shivering	7(9%)	6(7.7%)	0.772
	PONV	3(3.8%)	5(6.4%)	0.467
	Pruritus	3(3.8%)	5(6.4%)	0.467

Regarding intraoperative systolic pressure changes between the two groups, there was no significant difference at 0 to 35 min (p>0.05) [Figure 2].

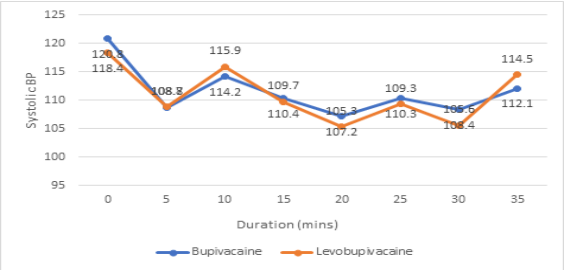

Figure 2: Comparison of intraoperative systolic BP between groups

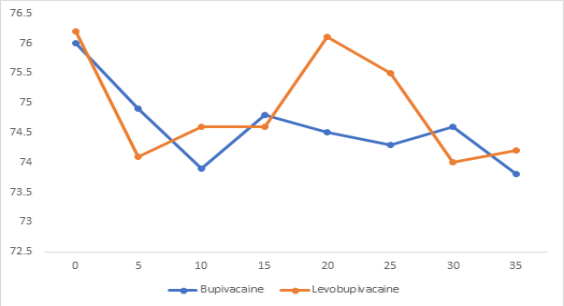

Figure 3: Comparison of intraoperative diastolic BP between groups

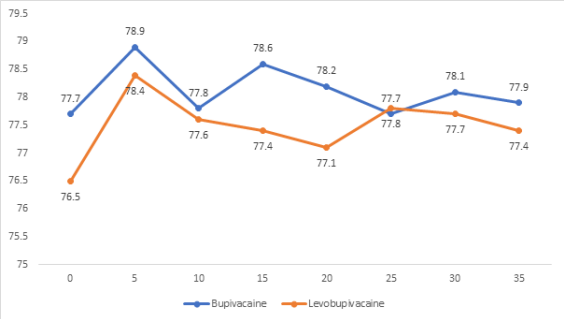

Figure 4: Comparison of intraoperative heart rate between groups

Regarding the changes in intraoperative diastolic blood pressure between the two groups, there was no significant difference at 0 to 35 min (p>0.05) [Figure 3].

Regarding intraoperative heart rate changes between the two groups, there was no significant difference at 0 to 35 min (p>0.05) [Figure 4].

DISCUSSION

In our study, the sensory blockade onset was faster in the levobupivacaine group than in the bupivacaine group. The time to achieve the highest sensory block was shorter, and the blockade duration was longer in the levobupivacaine group. A study by Lakshmi noted a quicker sensory block onset with hyperbaric bupivacaine (1.46 ± 0.18 min) than with isobaric levobupivacaine (2.29 ± 0.30 min). Sensory block duration was greater in the isobaric levobupivacaine group.[8]

Goyal et al. reported faster sensory block onset with hyperbaric bupivacaine (2.30 ± 1.343 minutes) compared to isobaric bupivacaine (6.57 ± 1.794 minutes) and isobaric levobupivacaine (4.57 ± 1.960 minutes).[9] Abd-El Wahab et al. found sensory block onset less with isobaric levobupivacaine (2.93 ± 0.83 minutes) than with hyperbaric bupivacaine (3.95 ± 0.64 minutes).[10] Thakore et al. observed higher sensory block onset and time to the maximum level in the isobaric levobupivacaine group, which had greater sensory block duration.[11]

In our study, the onset of motor blockade was similar in both groups, but the duration was shorter in the levobupivacaine group, indicating faster motor recovery. The two-segment regression time was comparable between the groups. Lakshmi et al. found earlier motor block onset in the hyperbaric bupivacaine group than in the isobaric levobupivacaine group (5.58 ± 0.48 min and 6.07 ± 0.53 min). Block regression time with isobaric levobupivacaine and fentanyl was very long.8 Abd-El Wahab et al. reported motor block initiation at 4.92±0.89 minutes in hyperbaric bupivacaine compared to 4.03 ± 0.83 minutes in isobaric levobupivacaine.[10]

Deori et al. reported that the time to onset of motor block was shorter with hyperbaric bupivacaine (3.28 ± 0.28) than with isobaric levobupivacaine (4.22 ± 0.34). The time for two-segment regression was

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70.27 ± 5.69 minutes for hyperbaric bupivacaine and 76.13 ± 6.55 minutes for isobaric levobupivacaine.[12] Erbay et al. reported time to maximum motor block level was less in the hyperbaric bupivacaine group (7 ± 3 minutes) than the isobaric levobupivacaine group (12 ± 5 minutes).[13] Paul et al. found onset time of motor blockade was shorter in hyperbaric bupivacaine (5.18 ± 0.20 minutes) compared to hyperbaric levobupivacaine (6.37 ± 0.42 minutes) and isobaric levobupivacaine (8.45 ± 0.46 minutes).[14]

In our study, the duration of analgesia was longer in the levobupivacaine group than in the bupivacaine group. Lakshmi et al. reported greater analgesia duration in the isobaric levobupivacaine group.8 Erbay et al. found a shorter onset time in the hyperbaric bupivacaine group compared to isobaric levobupivacaine (305 ± 50 minutes vs. 389 ± 146 minutes).[13] Saha et al. reported longer postoperative analgesia duration in the isobaric levobupivacaine and fentanyl group.[15] Thakore et al. found isobaric levobupivacaine-fentanyl took longer to acquire the required analgesia compared to hyperbaric bupivacaine-fentanyl. The time of postoperative first rescue analgesia was 3.07 ± 0.52 hours for hyperbaric bupivacaine and 2.79 ± 0.67 hours for isobaric levobupivacaine.[11]

In our study, the haemodynamic parameters, including intraoperative systolic and diastolic blood pressure and heart rate changes, showed no significant differences between the groups. Saring et al. reported that spinal-induced hypotension was equivalent in groups of hyperbaric bupivacaine and hyperbaric levobupivacaine, but the bupivacaine group required more vasopressor doses.[16] Karthik et al. reported hypotension was more prevalent in the hyperbaric bupivacaine group than the isobaric levobupivacaine group.[17] Bekkam et al. reported levobupivacaine offers longer sensory and motor blocks with greater haemodynamic stability compared to bupivacaine.[18]

In our study, the intraoperative and postoperative complications were comparable between the two groups. Thakore et al. found no difference between isobaric levobupivacaine and hyperbaric bupivacaine groups regarding complications.[11] Lakshmi et al. reported lesser motor blockade in the isobaric levobupivacaine group compared to hyperbaric bupivacaine.8 Yumnam et al. compared hyperbaric levobupivacaine and bupivacaine at different doses and injection locations, showing no differences in side effects.[19] Saha et al. reported a lower incidence of side effects, especially postoperative pain, and shivering, with isobaric levobupivacaine combined with fentanyl.[15]

Limitations

The sample size limits the generalisability of the findings to broader populations. As a single-centre study, its applicability across multiple hospital settings is constrained. The short follow-up period may not capture long-term outcomes or late complications. Despite randomisation, confounding variables may influence the results due to variations in the anaesthetic response.

CONCLUSION

Our study concluded that levobupivacaine produced a prolonged sensory block, extended postoperative pain relief, and reduced the need for analgesics. It facilitated faster motor recovery, enabling earlier ambulation and minimising immobilisation risks. Levobupivacaine was associated with fewer hypotension and bradycardia incidents, contributing to a safer anaesthetic experience. The superior safety profile and prolonged analgesic effects suggest that levobupivacaine may be an alternative to bupivacaine in obstetric anaesthesia, improving the outcomes of caesarean sections.

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