Section: Anaesthesiology & Critical Care

Original Research Article

COMPARING THE EFFECT OF HYPERBARIC BUPIVACAINE WITH HYPERBARIC ROPIVACAINE ON BLOCK CHARACTERISTICS IN PARTURIENTS UNDERGOING CAESAREAN SECTION UNDER SPINAL ANAESTHESIA: A RANDOMISED CLINICAL TRIAL

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ABSTRACT

Background: Effective intraoperative management of anaesthesia during Caesarean section remains a challenge for perioperative physicians. Ropivacaine, a long-acting amide local anaesthetic with lower cardiotoxic potential than bupivacaine, may offer comparable block quality with favourable recovery characteristics. The study aimed to compare the block characteristics and side-effect profiles of 0.5% hyperbaric bupivacaine and 0.75% hyperbaric ropivacaine administered intrathecally in parturients undergoing Caesarean section. **Materials and Methods:** Sixty parturients with ASA physical status I and II, between 18 and 45 years, undergoing Caesarean section under spinal anaesthesia were enrolled and randomly assigned into two groups; Group A (n=30) and Group B (n=30) received 2 ml hyperbaric bupivacaine 0.5%, and 2 ml hyperbaric ropivacaine 0.75% respectively at the L3–L4 interspace. Onset time of sensory block, time to reach T10 sensory level, onset time of motor block, time to complete motor block, duration of motor block, hemodynamic changes, and side effects were recorded and analysed. **Result:** The onset times of both sensory and motor blockade, as well as time to achieve T10 sensory level and complete motor block, were significantly longer in the ropivacaine group ($p < 0.05$). However, ropivacaine demonstrated a significantly shorter duration of motor block, indicating earlier motor recovery ($p < 0.05$). Hemodynamic parameters and incidence of side effects were insignificant between the groups. **Conclusion:** Intrathecal 0.75% hyperbaric ropivacaine provides spinal anaesthesia of comparable quality to 0.5% hyperbaric bupivacaine for Caesarean section, with the added advantage of faster motor recovery and a lower potential for cardiotoxicity. It is a safe and effective alternative for obstetric spinal anaesthesia.

INTRODUCTION

Caesarean section (CS) deliveries have been rising at an alarming pace worldwide.[1] In India, the proportion of CS births rose from 17.2% (NFHS-4, 2015–16) to 21.5% according to the fifth round of the National Family Health Survey (NFHS-5, 2020–21).[2] This rising trend in Caesarean deliveries presents anaesthesiologists with increasingly complex decisions regarding the selection of anaesthetic techniques and pharmacological agents, where the paramount concern is ensuring the safety of both mother and fetus.[3-5] Spinal anaesthesia is the preferred technique for Caesarean section globally due to its rapid onset, cost-effectiveness, simplicity, and provision of effective surgical and postoperative analgesia while facilitating early maternal–neonatal bonding.[6,7] Hyperbaric bupivacaine is the standard intrathecal agent used for obstetric anaesthesia.[8] However, optimal spread of local anaesthetic in cerebrospinal fluid is crucial to achieve adequate

surgical block while minimizing adverse cardiac and neurotoxic effects.

Bupivacaine, a long-acting amide local anaesthetic (LA), remains the most commonly used agent for SA. However, concerns regarding its prolonged action and cardiotoxicity have led to the development of ropivacaine.

Ropivacaine, a pure S-enantiomer, offers several advantages over bupivacaine: reduced cardiotoxicity, shorter duration of action, lower lipid solubility, and a differential blockade profile (sensory > motor), which facilitates earlier motor recovery and postoperative ambulation.[9,10]

Existing literature reveals significant variability in the block characteristics of hyperbaric bupivacaine and hyperbaric ropivacaine. Therefore, this study aims to clarify the comparative block profiles of these two agents, enabling more tailored anaesthetic choices based on patient characteristics and surgical requirements, and the safety profile of intrathecal hyperbaric ropivacaine versus intrathecal hyperbaric bupivacaine in parturients undergoing elective caesarean section.

The present study was designed to evaluate the anaesthetic efficacy of intrathecal hyperbaric ropivacaine 0.75% versus hyperbaric bupivacaine 0.5% in patients undergoing lower segment cesarean section (LSCS). The primary outcome was the onset of sensory block, while secondary outcomes included onset and duration of motor block, duration of sensory block, grade of sensory and motor block, and duration of postoperative analgesia.

MATERIALS AND METHODS

Study design and participants: This prospective, randomized, double-blinded study was conducted at the Regional Institute of Medical Sciences (RIMS), Imphal, from May 2022 to June 2024, after approval from the Research Ethics Board. Sixty ASA I–II parturients, aged 18–45 years, scheduled for elective LSCS under spinal anaesthesia, were enrolled after written informed consent.

Exclusion criteria:

Included hypersensitivity to study drugs, local site infection, bleeding disorders, significant cardiac/respiratory/renal disease, neurological deficits, and spinal deformities.

Sample size and Recruitment: Based on a prior study 4, using two-segment regression time (mean ± SD: 71.4 ± 13.36 min vs 82.4 ± 11.88 min), with α = 0.05 and power 90%, the required sample size was 28 per group. Considering 5% dropout, 30 subjects were recruited per group.

Formula for calculation of sample size: n = (σ12+ σ22)x[Z (1-∝/2) +Z(1-β)]2/ ((M1-M2)2

Where, n = sample size in each group, σ1 = standard deviation of group 1

σ2 = standard deviation of group 2,

M1 = Mean of group 1, M2 = Mean of group 2

and,

Z1-α/2 =1.96,

Z1-β= 0.842 for α value of 0.05 and power of 80%

Z1-β= 1.282 for the power of 90%

Randomization and blinding: Participants were randomly assigned to two equal groups via a computer-generated chart (Graphpad.com). Allocation concealment was ensured using sealed opaque envelopes. Study drugs were prepared in identical syringes by an anaesthesiologist not involved in patient care or data collection. Both the patient and investigator were blinded to group allocation.

- Group A: 2 mL of 0.5% hyperbaric bupivacaine
- Group B: 2 mL of 0.75% hyperbaric ropivacaine

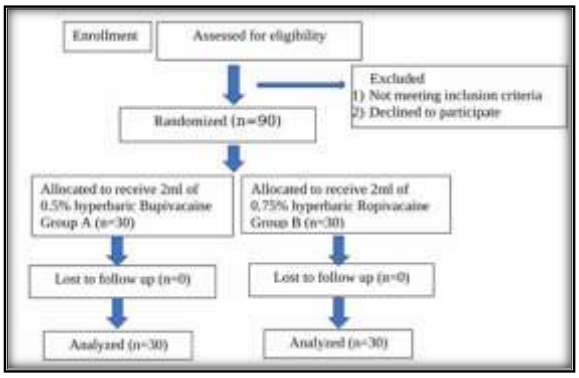

Figure 1: Consort flow diagram for allocation of groups

Procedures: Patients were reassured with a thorough explanation of the procedure, and preoperative assessment for all the participants was done one day before the scheduled surgery and a good rapport was established with the patients. Written informed consent was taken from each participant. Patients were advised to take Tablet Ranitidine 300 mg and Tab Alprazolam 0.25mg orally with a sip of water at 10 pm and thereafter advised to fast overnight or to be kept nil per oral (NPO) for a minimum of 6 hours before surgery. On arrival at the pre-anaesthetic room, intravenous access for all the patients was established with an 18-gauge needle cannula over the forearm and preloaded with Ringer's Lactate (R/L) at 15 ml/kg at least 30 minutes before spinal anaesthesia. Patients were premedicated with Injection Ranitidine 1mg/kg and Injection Ondansetron 0.08mg/kg intravenously as an aspiration prophylaxis, 10-20 minutes before the anaesthetic procedure.

Anaesthesia technique: On arrival at the operating table, patients were connected to Standard multipara monitors (ECG, NIBP, SpO_2). Baseline measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), pulse rate, and SpO_2 of the patients were recorded and placed in the left lateral decubitus position. Under aseptic and antiseptic precautions, dural puncture for spinal anaesthesia was performed at the L3–L4 interspace using a 25-G Quincke needle. After free flow of CSF was confirmed, the study drug was injected over 10 seconds. Then patients were

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turned immediately into a supine position with left uterine displacement, and sensory & motor block was assessed at every two-minute interval up to 30 minutes. The following parameters were noted for assessment of sensory block by the pin-prick method using the Visual analogue scale (VAS) 6,7. 1) onset time of sensory block, 2) Maximum sensory block level, 3) time to maximum cephalic spread, 4) two-segment regression time, and 5) total duration of sensory block. The characteristics of the motor block were also assessed by following observations: 1) the degree of motor block by the Bromage scale, 2) time to maximum degree of block (Bromage grade-3), 3) time to complete regression, grade-0.

After achieving an adequate level of anaesthesia, surgeons were allowed to operate. The time of incision for surgery was noted. Intraoperatively, patients were closely monitored using a multipara monitor for pulse rate, SBP, DBP, MAP, SPO2 at induction 0, 2, 4, 6, 8, 10, 20, 25, 30, 45, 60 minutes. The following observations were noted and intervened as needed. Hypotension (>20% fall of baseline BP) was treated with R/L infusion with or without Injection Mephentermine 3mg. Bradycardia (HR <60 bpm) were treated with the injection of Atropine 0.6mg. SpO2 < 90% with oxygen (O2) at 5L through face mask. Analgesics were supplemented when required. General anaesthesia was kept as a standby if spinal anaesthesia failed.

Post-operative monitoring: The time to completion of surgery and the duration of surgery were noted. In the recovery room, HR, SBP, DBP, SpO2 were monitored at arrival 0, 15, 30, 45, 60 minutes with the help of a multipara monitor. Time taken for regression below L1 and duration of motor block (Bromage scale up to 0) was noted. The total duration of the sensory and motor block is defined as the time interval from intrathecal administration to the point of complete regression of sensory block or to the point at which the Bromage score is back to zero. The patients were shifted to the ward with written instructions to withhold any analgesic or sedative unless there was a complaint of moderate pain and to note down the first time of micturition. Patients were observed for side effects like nausea, vomiting, shivering, hypotension, bradycardia, etc. Time to first rescue analgesic was noted.

Assessments: Sensory block was assessed bilaterally along the midclavicular line using a pinprick method and VAS every 2 min until block stabilisation, then at predefined intervals. Parameters recorded:

- Sensory onset time
- Maximum sensory block level (MSBL)
- Time to peak sensory block level (TPSBL)
- Two-segment regression time
- Total sensory block duration

Motor block was assessed via the Bromage scale:[6,8,11-15]

- 0 = no paralysis
- 1 = inability to raise the extended leg
- 2 = inability to flex the knee
- 3 = inability to flex ankle

Recorded parameters:

- Motor onset time (time to Bromage 1)
- Time to complete motor block (Bromage 3)
- Duration of motor block (Bromage 0)

Haemodynamic (HR, SBP, DBP, MAP, SpO_2) were recorded at baseline and fixed intervals intraoperatively and postoperatively.

Side effects (nausea, vomiting, pruritus, bradycardia, hypotension, respiratory depression) were documented.

Statistical analysis: Data were analyzed using IBM SPSS Statistics v26.0. Continuous variables were expressed as mean ± SD and compared using Student's t-test. Categorical data were compared using the Chi-square test. A p-value <0.05 was considered statistically significant.

Ethical Issues: The study was conducted after obtaining ethical clearance from the Research Ethics Board RIMS, Imphal (REB No-A/206/REB-Comm (SP)/RIMS/2015/903/241/2022) and after being registered at Clinical Trial Registry of India (CTRI No-CTRI/2023/03/051045). Written informed consent of the patients who fulfilled the inclusion criteria was obtained. The collected data were kept password-protected, so only the investigator and the guide had access to the data.

RESULTS

Demographic profile: Comparing the demographic characteristics of two groups, the analysis showed similar (P > 0.05) demographic characteristics between the two groups, i.e., did not differ significantly [Table 1].

Table 1: Demographic profiles of the two groups

Demographic Profiles	Group A (n=30) (%)	Group B (n=30) (%)	t/χ2 value	P – value
Age (yrs)	28.70 ± 1.13	29.97 ± 1.05	0.82	0.415
Weight (kg)	62.27 ± 0.40	61.60 ± 0.27	1.39	0.171
Height (cm)	156.60 ± 0.80	157.40 ± 0.84	0.69	0.494
ASA (grade): II	30 (100.0)	30 (100.0)	0.00	1.000

Block characteristics are summarised in [Table 2]. The mean characteristics, viz., Onset of sensory block (OSB), time to reach T10 level (TT10), time to reach T4-6 level (TT4-6), and onset time of motor block (OMB), were comparatively higher in Group B as compared to Group A. In contrast, the mean characteristics viz. duration of sensory block (DOSB), duration of motor block (DOMB), duration of 2-segment regression time (2SR), and time first rescue analgesic (FRA) were lowered comparatively

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in Group B as compared to Group A. Comparing the mean block characteristics of the two groups, Student's t test showed significantly ($P < 0.05$ or $P < 0.001$) different and higher TT10, TT4-6, and OMB in Group B as compared to Group A. Conversely, the mean DOSB, DOMB, 2SR, and FRA were found significantly ($P < 0.05$ or $P < 0.001$) different and lower in Group B as compared to Group A.

Table 2: Comparison of block characteristics between intrathecal bupivacaine and Ropivacaine

Parameter	Group A: Bupivacaine (n = 30)	Group B: Ropivacaine (n = 30)	p-value
Onset of sensory block (min) (OSB)	1.42 ± 12.1	1.71 ± 14.4	<0.001
Time to reach T10 sensory level (min) (TT10)	5.07 ± 0.03	5.68 ± 0.05	<0.001
Time to reach T4-6 level (min) (TT4-6)	8.45 ± 0.19	9.09 ± 0.17	0.015
Duration of sensory block (min) (DOSB)	169.03 ± 2.30	129.98 ± 1.75	<0.001
Onset of motor block (min) (OBM)	1.52 ± 0.03	2.84± 0.09	<0.001
Duration of motor block (min) (DOMB)	159.44 ± 1.65	121.29± 1.88	<0.001
Duration of 2-segment regression (min) (2SR)	64.25 ± 1.23	59.24 ± 1.56	0.015
First rescue analgesic time (min) (FRA)	144.81 ± 2.24	125.99± 2.31	< 0.001

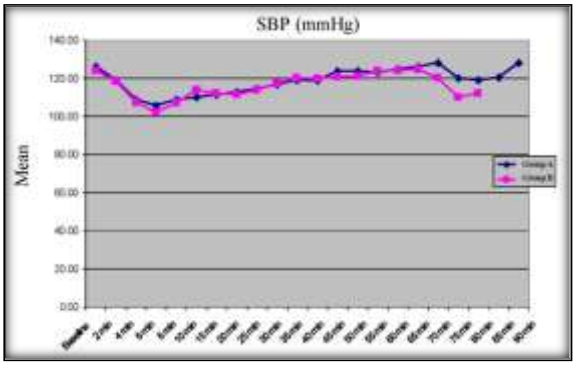

Figure 2: Mean SBP of the two groups over the periods.

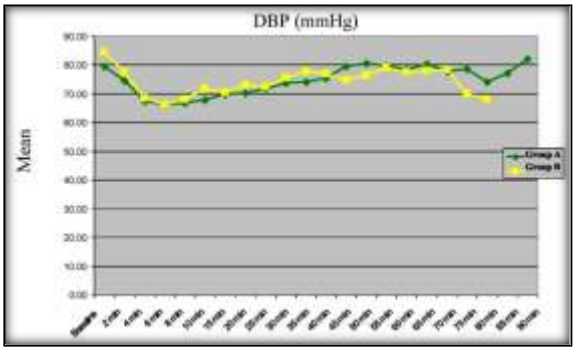

Figure 3: Mean DBP of the two groups over the periods.

Hemodynamic parameters remained largely comparable between the groups during spinal anaesthesia. The Tukey test revealed no significant differences in mean SBP at any time point ($P > 0.05$), with both groups maintaining values within the normal range [Figure 2]. Mean DBP showed a similar pattern [Figure 3], except at 45 min, when Group B exhibited a significantly lower value than Group A ($P < 0.05$). Likewise, mean MAP mirrored SBP and DBP trends [Figure 4], with the only deviation at 30 min, where Group B demonstrated a significantly higher value than Group A ($P < 0.05$). These findings indicate that, aside from brief and isolated variations, both anaesthetic regimens preserved stable and clinically acceptable blood pressure profiles throughout the perioperative period.

In both groups [Table 3], mean HR rose slightly until 6 min, then declined, remaining below baseline except in Group A from 6-70 min. From 8-70 min, HR was consistently lower in Group B, with between-group differences significant ($P < 0.05$–0.001) but within-group changes non-significant ($P > 0.05$); all values remained within the normal range.

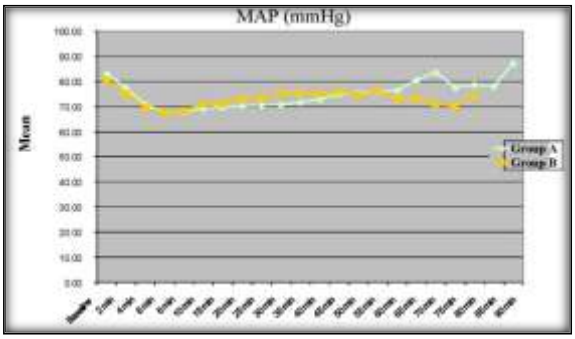

Figure 4: Mean MAP of the two groups over the periods.

Table 3: HR (per minute) of two groups over the periods

Period	Group A (n=30)		Group B (n=30)		P value
	n	Mean ± SE	n	Mean ± SE	
Baseline	30	85.20 ± 1.97	30	86.67 ± 1.97	0.600
2 min	30	84.93 ± 1.34	30	86.47 ± 1.69	0.479
4 min	30	87.03 ± 1.65	30	88.17 ± 1.59	0.623
6 min	30	91.20 ± 1.69	30	88.20 ± 1.84	0.235
8 min	30	93.23 ± 1.13	30	81.27 ± 1.60	< 0.001
10 min	30	92.23 ± 0.91	30	78.53 ± 1.98	< 0.001
15 min	30	92.47 ± 1.41	30	74.20 ± 1.70	< 0.001
20 min	30	91.33 ± 1.44	30	76.67 ± 1.82	< 0.001
25 min	30	91.13 ± 1.49	30	75.00 ± 2.02	< 0.001
30 min	30	90.30 ± 1.20	30	73.67 ± 1.99	< 0.001
35 min	30	89.50 ± 1.18	30	72.73 ± 2.02	< 0.001
40 min	28	89.43 ± 1.24	29	75.97 ± 2.11	< 0.001

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45 min	23	88.22 ± 1.62	23	75.26 ± 2.26	< 0.001
50 min	16	89.75 ± 1.67	13	76.85 ± 3.10	< 0.001
55 min	13	87.92 ± 2.20	9	73.11 ± 2.89	< 0.001
60 min	11	92.00 ± 1.11	5	75.80 ± 4.48	< 0.001
65 min	8	92.00 ± 1.51	5	71.40 ± 2.14	< 0.001
70 min	4	89.00 ± 3.34	3	70.00 ± 3.06	0.010
75 min	2	83.50 ± 1.50	1	85.00 ± 0.00	0.667
80 min	2	84.00 ± 4.00	1	81.00 ± 0.00	0.740
85 min	2	83.50 ± 1.50	0	-	NA
90 mn	1	82.00 ± 0.00	0	-	NA

Table 4: Treatment-associated complications of the two groups

Complications		Group A (n=30) (%)	Group B (n=30) (%)	χ2 value	P value
Nausea	No	23 (76.7)	25 (83.3)	0.42	0.519
	Yes	7 (23.3)	5 (16.7)		
Vomiting	No	25 (83.3)	27 (90.0)	0.58	0.448
	Yes	5 (16.7)	3 (10.0)		
Shivering	No	24 (80.0)	26 (86.7)	0.48	0.488
	Yes	6 (20.0)	4 (13.3)		
Incidence of Hypotension	Once	11 (36.7)	18 (60.0)	3.27	0.195
	Twice	16 (53.3)	10 (33.3)		
	Thrice	3 (10.0)	2 (6.7)		
Incidence of Bradycardia	No	28 (93.3)	30 (100.0)	2.07	0.150
	Yes	2 (6.7)	0 (0.0)		
Incidence of Tachycardia	Nil	29 (96.7)	24 (80.0)	0.447	0.107
	Once	1 (3.3)	3 (10.0)		
	Twice	0 (0.0)	3 (10.0)		
Vasopressor Requirement	Once	11 (36.7)	18 (60.0)	3.27	0.195
	Twice	16 (53.3)	10 (33.3)		
	Thrice	3 (10.0)	2 (6.7)		

The incidence of all recorded complications was marginally lower in Group B than in Group A, except for tachycardia, which was more frequent in Group B. However, χ^2 analysis revealed no statistically significant difference in complication rates between the groups ($P > 0.05$) [Table 4].

DISCUSSION

This study evaluated and compared the efficacy and safety of intrathecal administration of 0.5% hyperbaric bupivacaine and 0.75% hyperbaric ropivacaine in parturients undergoing elective Caesarean Section. The main findings were that ropivacaine produced a slower onset of sensory and motor block, a longer time to achieve complete motor block, and a shorter duration of motor block compared to bupivacaine. There were no significant differences between the groups in haemodynamic parameters, stability, or side-effect profiles.

The slower onset of block observed with ropivacaine is consistent with the findings of Gautier et al,[16] Khaw et al,[17] and Chari et al,[18] and may be attributed to its lower lipid solubility and reduced potency compared with bupivacaine.[19] The faster regression of motor block with ropivacaine, which aligns with the results of earlier studies,[6,7,8,11] is clinically advantageous, as it facilitates early mobilization, reduces the risk of thromboembolic events, and may enhance maternal satisfaction in the postpartum period. The ropivacaine group also showed shorter total sensory block duration and faster rescue analgesia requirements. It also exhibited delayed characteristics of the nerve blocks, such as the onset of sensory and motor blockade, the time taken to reach a T10 sensory block, and the time to achieve complete motor block.

Hemodynamic stability was comparable between the groups, as reflected by similar blood pressure and heart rate trends, which is in line with findings from several studies.[6,9,14,20-20] As noted in a related study by Olapur et al,[6] Group B had a significantly lower heart rate from 8 minutes to 70 minutes compared to Group A when the mean heart rates within and between groups were compared using the Tukey test. Despite this variation, both groups' heart rates under spinal anaesthesia stayed within the usual range. The absence of significant differences in adverse effects—including hypotension, shivering, nausea, and vomiting—indicates that ropivacaine is as safe as bupivacaine for intrathecal use in obstetric patients.

From a safety perspective, ropivacaine—a long-acting amide local anaesthetic—has been shown in both animal and human studies to have less cardiotoxic potential than bupivacaine.[21,22] While our study did not specifically evaluate cardiotoxic events, the established safety profile of ropivacaine may provide additional reassurance in high-risk patients or settings where cardiac complications are a concern.

Overall, our findings support the use of hyperbaric ropivacaine as an effective alternative to hyperbaric bupivacaine for spinal anaesthesia in LSCS, particularly when early postoperative motor recovery is desirable.

Limitations: Modest sample size limits generalizability to broader populations. Cardiotoxicity Specific monitoring is absent, and the use of surrogate endpoints for block regression rather than directly measured.

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CONCLUSION

In elective Caesarean Section, 0.75% hyperbaric ropivacaine provides spinal anaesthesia of equivalent quality to 0.5% hyperbaric bupivacaine, with the advantage of faster motor recovery and comparable hemodynamic and side-effect profiles. Given its lower theoretical cardiotoxicity, ropivacaine may be preferable when early mobilization and safety are priorities. Future large-scale studies in high-risk obstetric groups are encouraged to validate these findings further.

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