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INTRATHECAL HYPERBARIC BUPIVACAINE VERSUS HYPERBARIC ROPIVACAINE FOR SPINAL ANAESTHESIA IN CAESAREAN SECTION: A RANDOMIZED CONTROLLED TRIAL FROM NORTHEAST INDIA

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ABSTRACT

Background: Spinal anaesthesia (SA) is the preferred technique for elective caesarean section (CS), offering rapid onset, reliable surgical conditions, and avoidance of airway manipulation [1–4]. Hyperbaric bupivacaine remains standard but is associated with prolonged motor block and hypotension [3,6]. Ropivacaine, a pure S-enantiomer with lower cardiotoxicity and relative sensorymotor dissociation, may facilitate earlier mobilization with a comparable sensory profile [7–9]. **Methods:** In this single-blinded, randomized controlled trial conducted at Agartala Government Medical College & GBP Hospital, parturients (ASA I–II; 18–40 years; ≥37 to <42 weeks; height 145–165 cm; weight 45–95 kg) scheduled for elective CS were allocated 1:1 to receive intrathecal hyperbaric bupivacaine 0.5% 12 mg (2.4 mL) or hyperbaric ropivacaine 0.75% 18 mg (2.4 mL). Randomization used variable blocks with sequentially numbered opaque sealed envelopes; participants were blinded. Primary outcomes were onset and duration of sensory block (to T6; regression to T10) and motor block (Bromage 3 onset; regression to 0). Secondary outcomes included duration of effective analgesia (to first rescue at VAS ≥ 4), intra-/postoperative haemodynamics (HR, SBP, DBP, MAP, SpO_2), and adverse effects. Statistical analysis employed t-tests and chisquare/Fisher's exact tests ($p<0.05$). Ethics approval Ref. No. F.4(6-13)/AGMC/…/2022/21,857 (09Jan-2023); CTRI/2024/05/067399.

Results: Sixty-six parturients were analysed (33/group). Groups were comparable at baseline (age 26.6 ± 5.8 vs 28.0 ± 13.3 y; weight 68.9 ± 8.8 vs 68.0 ± 7.7 kg; height 151.4 ± 2.7 vs 147.6 ± 2.4 cm; all $p>0.05$). Ropivacaine produced faster onset of sensory block to T6 (4.18 ± 0.59 vs 6.05 ± 0.70 min; $p = 0.001$) and faster motor block onset (8.33 ± 1.33 vs 9.39 ± 0.87 min; $p = 0.01$). Regression was faster with ropivacaine for both sensory (to T10: 135.1 ± 7.5 vs 156.5 ± 10.0 min; $p = 0.001$) and motor block (149.3 ± 10.5 vs 176.1 ± 10.5 min; $p = 0.025$). Duration of effective analgesia was shorter

with ropivacaine (136.3 ± 7.9 vs 158.6 ± 13.4 min; p = 0.003). Haemodynamics were similar between groups intra- and postoperatively without clinically meaningful differences. Intraoperative adverse events (nausea, vomiting, shivering, hypotension, bradycardia) were numerically fewer in the ropivacaine group; differences were not statistically significant.

Conclusion: Intrathecal hyperbaric ropivacaine (18 mg) provided a comparable sensory block with significantly earlier onset and faster motor recovery than hyperbaric bupivacaine (12 mg) in elective CS, enabling earlier ambulation and potentially enhancing postoperative throughput—without compromising haemodynamic stability or safety.

Keywords: caesarean section; spinal anaesthesia; ropivacaine; bupivacaine; hyperbaric; motor recovery; haemodynamics; randomized trial.

INTRODUCTION

Spinal anaesthesia (SA) is the dominant technique for elective caesarean section (CS) owing to rapid onset, high reliability, avoidance of airway instrumentation, and facilitation of immediate maternal–neonatal contact and early breastfeeding [1–3]. Compared with general anaesthesia, SA limits aspiration risk and reduces systemic analgesic exposure while allowing the mother to remain awake during delivery [2,3]. Optimal SA for CS requires a consistent sensory block to at least T4 with stable haemodynamics; higher blocks may precipitate sympathectomy-related hypotension and bradycardia [4,14–16].

Hyperbaric 0.5% bupivacaine is widely used for CS because of dense, long-lasting sensory analgesia; however, its prolonged motor blockade may delay postoperative mobilization and extend postanaesthesia care unit (PACU) time [3,6]. Moreover, dose-dependent hypotension is common during neuraxial anaesthesia in parturients because of reduced venous return and decreased systemic vascular resistance [14]. These limitations have spurred interest in alternative agents with a more favourable motor profile.

Ropivacaine, a long-acting amide local anaesthetic formulated as the pure S-enantiomer, is less lipophilic than bupivacaine, exhibits a lower propensity for cardiotoxicity and central nervous system toxicity, and tends to produce relatively less intense motor block at equipotent doses [7,8,20]. Pharmacodynamically, the smaller motor fibre penetration of ropivacaine may preserve differential sensory analgesia, potentially enabling earlier mobilization without compromising intraoperative conditions [7–9]. Evidence from peripheral nerve blocks and epidural infusions supports a motorsparing effect with comparable analgesia [7,8]. Intrathecally, several comparative studies in obstetric and non-obstetric surgery suggest that hyperbaric ropivacaine may achieve similar sensory levels with faster recovery of motor function than bupivacaine, though findings are not uniform across doses and baricity.

In resource-constrained public hospitals, especially in low- and middle-income settings, agents that provide reliable anaesthesia while enabling efficient turnover and early ambulation are advantageous. The present randomized, single-blinded trial from a teaching hospital in Northeast India was designed to compare hyperbaric ropivacaine (0.75%, 18 mg) with hyperbaric bupivacaine (0.5%, 12 mg) for intrathecal anaesthesia in elective CS. We hypothesized that ropivacaine would demonstrate comparable sensory anaesthesia with faster recovery of motor block and similar haemodynamic stability. We also evaluated onset characteristics, duration of effective analgesia, intra- and postoperative haemodynamics, and adverse events. By reporting pragmatic outcomes with equipotent volumes and clinically relevant dosing in parturients, we aim to inform drug selection for SA in CS in similar practice environments [6–9].

MATERIALS AND METHODS Study design, setting, ethics, and registration

Single-blinded, randomized controlled trial conducted at Agartala Government Medical College & GBP Hospital, Agartala, India (January 2023–June 2024). Institutional Ethics Committee approval Ref. No. F.4(6-13)/AGMC/Medical Education/IEC Approval/2022/21,857 (09-Jan-2023). Trial registration: CTRI/2024/05/067399. Written informed consent was obtained from all participants.

Participants

Inclusion criteria: ASA I–II parturients, age 18–40 years, height 145–165 cm, weight 45–95 kg, term pregnancy (≥37 and <42 weeks), scheduled for elective CS, consenting.

Exclusion criteria: emergency CS; known hypersensitivity to amide local anaesthetics; infection at puncture site; preterm or post-term gestation; ASA > II; foetal anomalies; contraindications to neuraxial block (coagulopathy, raised intracranial tension, etc.).

Randomization, allocation concealment, and blinding

Participants were randomized in a 1:1 ratio using variable block randomization. Allocation concealment used sequentially numbered opaque sealed envelopes. Parturients were blinded to group assignment; the anaesthetist administering the block was necessarily unblinded, while outcome assessment followed standardized protocols.

Interventions

All patients fasted ≥8 h, received premedication (ondansetron 4 mg IV and omeprazole 40 mg IV 2 h pre-op), and were preloaded with 1 L Ringer's lactate 15–20 min pre-block. Standard monitors (ECG, NIBP, SpO_2) were applied. With the patient sitting, a midline L3–4 puncture was performed under asepsis. Study drugs (2.4 mL total volume) were injected intrathecally:

- **Group B (Bupivacaine):** 0.5% hyperbaric bupivacaine 12 mg (2.4 mL).
- **Group R (Ropivacaine):** 0.75% hyperbaric ropivacaine 18 mg (2.4 mL).

Patients were positioned supine immediately; oxygen 4 $L \cdot min^{-1}$ via facemask was administered.

Outcomes and assessments

- **Sensory block** assessed by pin-prick (27G) in the mid-clavicular line at 1-min intervals until T6 (Grades: 0 sharp; 1 dull; 2 anaesthesia). *Onset* defined as time from injection to Grade-2 sensation at T6; *duration* defined by regression to T10.
- **Motor block** graded by modified Bromage (0–3). *Onset* defined as time to Bromage 3; *duration* by regression to Bromage 0. Patients failing to achieve T6 and Bromage 3 were excluded.
- **Analgesia duration**: time from sensory onset to first rescue analgesia (VAS ≥ 4).
- **Haemodynamics** (HR, RR, SBP, DBP, MAP, SpO_2) recorded at 0, 3, 6, 9, 12, 15, 20, 30, 45, 60 min intraoperatively; then every 30 min to 3 h and hourly to 6 h; then 2-hourly to 12 h postoperatively. • **Adverse events**: hypotension (SBP < 90 mmHg), bradycardia (HR < 60 min^{-1}), respiratory depression (RR < 10 or SpO_2 < 90%), nausea, vomiting, shivering. Treatments followed departmental protocols (e.g., mephentermine 6 mg IV for hypotension; atropine 0.6 mg IV for bradycardia; ondansetron 4 mg IV for nausea; tramadol 50 mg IV for shivering). ADRs were reported as per national guidelines.

Sample size and statistics

Based on prior effect estimates (means 33 vs 24; SDs 16 vs 9; α=0.05; power 80%), 33 per group (N=66) were required. Data are presented as mean ± SD or n (%). Between-group comparisons used

independent-samples t-tests for continuous variables and chi-square/Fisher's exact tests for categorical variables (SPSS). Two-sided $p<0.05$ was significant.

RESULTS Participant flow and baseline characteristics

Of 66 randomized parturients, all completed follow-up and were analysed (Figure 1). Baseline characteristics were comparable between groups with no clinically important differences in age, weight, or height (Table 1).

Block characteristics and analgesia

Ropivacaine produced a significantly faster *sensory onset* to T6 (4.18 ± 0.59 vs 6.05 ± 0.70 min; p=0.001) and *motor onset* to Bromage 3 (8.33 ± 1.33 vs 9.39 ± 0.87 min; p=0.01). *Regression* was faster with ropivacaine for both **sensory** (to T10: 135.12 ± 7.55 vs 156.46 ± 9.97 min; p=0.001) and **motor** block (149.30 ± 10.52 vs 176.09 ± 10.46 min; p=0.025) (Table 2). The **duration of effective analgesia** was shorter in the ropivacaine group (136.30 ± 7.91 vs 158.63 ± 13.41 min; p=0.003) (Table 2). Collectively, these findings indicate comparable surgical anaesthesia with earlier recovery using ropivacaine.

Haemodynamics

Intraoperative and postoperative trends in HR, RR, SBP/DBP, MAP, and SpO_2 were broadly similar between groups across the prespecified time points, with no clinically meaningful or sustained differences (Figure 2; Tables 3, 4 provide representative summaries). Transient between-timepoint pvalue fluctuations did not translate into treatment-directional instability. No episodes of respiratory depression were recorded.

Adverse events

Intraoperative adverse events (nausea, vomiting, shivering, hypotension, bradycardia) were numerically fewer with ropivacaine; differences were not statistically significant (Table 3). Postoperative adverse events were rare and similar (Table 4). No serious adverse drug reactions occurred.

TABLES AND FIGURES

TABLE 1. BASELINE CHARACTERISTICS

Variable	Bupivacaine (n=33)	Ropivacaine (n=33)	Mean difference	p-value
Age (years)	26.58 ± 5.84	28.03 ± 13.27	1.45	0.56
Weight (kg)	68.91 ± 8.79	68.03 ± 7.70	0.87	0.66
Height (cm)	151.41 ± 2.65 (n=32)	147.64 ± 2.42	3.77	0.38

TABLE 2. INTRAOPERATIVE BLOCK CHARACTERISTICS AND ANALGESIA

Outcome	Bupivacaine	Ropivacaine	Mean difference	pvalue
Sensory onset to T6 (min)	6.05 ± 0.70	4.18 ± 0.59	2.26	0.001
Motor onset (Bromage 3) (min)	9.39 ± 0.87	8.33 ± 1.33	1.06	0.01
Sensory regression to T10 (min)	156.46 ± 9.97	135.12 ± 7.55	21.33	0.001

Motor block duration to Bromage 0 (min)	176.09 ± 10.46	149.30 ± 10.52	26.78	0.025
Duration of effective analgesia (min)	158.63 ± 13.41	136.30 ± 7.91	22.33	0.003

TABLE 3. INTRAOPERATIVE ADVERSE EVENTS (N, %)

Event	Bupivacaine	Ropivacaine	p-value
Nausea	9 (27.3%)	3 (9.1%)	0.05
Vomiting	8 (24.2%)	3 (9.1%)	0.09
Shivering	4 (12.1%)	5 (15.2%)	0.50
Hypotension	10 (30.3%)	5 (15.2%)	0.14
Bradycardia	9 (27.3%)	8 (24.2%)	0.77

TABLE 4. POSTOPERATIVE ADVERSE EVENTS (TO 12 H)

Event	Bupivacaine	Ropivacaine
Nausea	0	1
Vomiting	0	0
Shivering	0	0
Hypotension	1	1
Bradycardia	0	0

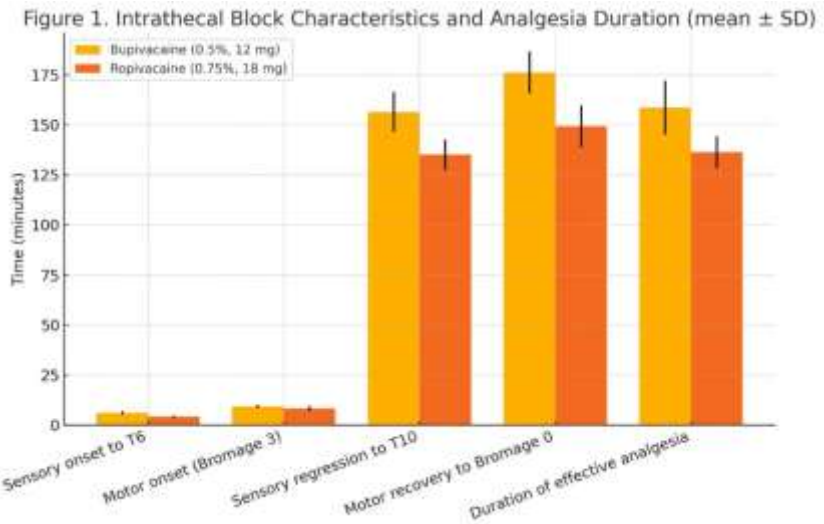

Figure 1. Intrathecal block characteristics and analgesia duration (mean ± SD)

Compares sensory onset, motor onset, sensory regression, motor recovery, and durationof effective analgesia between groups.

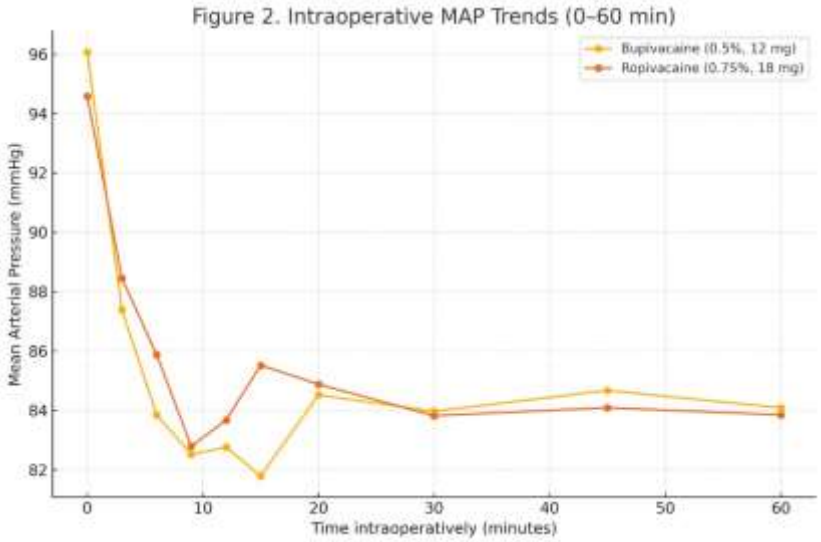

Figure 2. Intraoperative mean arterial pressure (MAP) trends (0–60 min)

Shows overlapping MAP time courses for both groups.

DISCUSSION

This randomized controlled trial demonstrates that intrathecal hyperbaric ropivacaine 0.75% (18 mg) provides rapid onset of surgical anaesthesia for elective CS with significantly faster recovery of both sensory and motor block compared with hyperbaric bupivacaine 0.5% (12 mg). Haemodynamic profiles were comparable between groups, and adverse events were not increased with ropivacaine. These findings align with several comparative studies showing that ropivacaine achieves adequate intrathecal analgesia with earlier motor recovery—an attribute with practical implications for early ambulation, PACU throughput, and patient satisfaction [1-8,9].

Our sensory outcomes complement earlier dose-finding work indicating that the minimum effective intrathecal dose of hyperbaric ropivacaine for CS is higher than that of bupivacaine (relative potency ratio ~0.8) [11-12]. Using a fixed 2.4 mL volume with clinically standard concentrations (18 mg ropivacaine vs 12 mg bupivacaine), we observed faster onset and earlier regression with ropivacaine, consistent with its lower lipid solubility and motor-sparing profile [13,14]. Faster motor recovery has been repeatedly reported for ropivacaine in obstetric and orthopaedic populations, sometimes with similar or slightly shorter sensory duration versus bupivacaine depending on dose/baricity and use of adjuvants [15]. Our data expand this literature in an Indian teaching-hospital context, using hyperbaric formulations without intrathecal opioids—an approach relevant to centres aiming to minimize opioidrelated side effects.

Haemodynamic stability is central in obstetric anaesthesia due to pregnancy-related physiological changes predisposing to sympathectomy-induced hypotension [14–16]. In our trial, group differences in HR, MAP, and SpO_2 across time points were not clinically meaningful, and hypotension requiring vasopressor boluses did not differ significantly. Several trials have reported similar or slightly more stable haemodynamics with ropivacaine, potentially due to less intense sympathetic block at equipotent sensory levels [17]. Our results support the view that ropivacaine is at least non-inferior to bupivacaine in this respect.

The shorter duration of effective analgesia with ropivacaine reflects its faster regression and may be viewed as a trade-off for earlier mobilization. In institutions prioritizing Enhanced Recovery After Surgery (ERAS) pathways for CS, a shorter motor block can be advantageous, provided postoperative multimodal analgesia is protocolized (e.g., paracetamol/NSAIDs and, where suitable, neuraxial or

wound infiltration adjuncts) [9]. Selective addition of intrathecal fentanyl or morphine could be considered to extend analgesia if policy allows, though that was outside our trial's scope [18].

Strengths include randomized allocation, standardized techniques, granular haemodynamic monitoring, and pragmatic dosing reflective of routine practice. Limitations are a modest sample size (powered for block characteristics, not rare adverse events), absence of neonatal outcomes (e.g., Apgar scores, umbilical blood gases), and evaluation of only one dose per agent without adjuvants. We also did not assess maternal satisfaction or time-to-ambulation as formal endpoints. Future research could examine dose-response curves for hyperbaric ropivacaine in CS, compare isobaric vs hyperbaric ropivacaine, and integrate intrathecal adjuvants to optimize the sensory-motorhaemodynamic balance [6].

In summary, our findings reinforce growing evidence that hyperbaric ropivacaine is a suitable alternative to hyperbaric bupivacaine for SA in CS, offering reliable anaesthesia with materially faster motor recovery and no compromise in maternal haemodynamics or safety [19,20].

CONCLUSION

In elective caesarean section, intrathecal hyperbaric ropivacaine 0.75% (18 mg) yielded rapid onset, adequate surgical anaesthesia, and significantly faster regression of sensory and motor block than hyperbaric bupivacaine 0.5% (12 mg), with comparable haemodynamic stability and low adverseevent rates. The shorter motor block translated into a practical advantage for early mobilization and PACU efficiency, at the cost of a modestly shorter analgesia duration that can be addressed with standardized multimodal analgesia. These data support hyperbaric ropivacaine as an effective, safe, and workflow-friendly alternative to bupivacaine for spinal anaesthesia in caesarean delivery.

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