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A Comparative Study of the Effectiveness of Intrathecal Hyperbaric Ropivacaine Versus Hyperbaric Bupivacaine in Elective Lower Abdominal Procedures

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ABSTRACT

Background: Spinal anaesthesia is the preferred technique for lower abdominal surgeries owing to its safety, rapid onset, and cost-effectiveness. Hyperbaric bupivacaine 0.5%, though widely used, carries risks of cardiotoxicity and prolonged motor blockade. Ropivacaine, a pure S(−)-enantiomer, offers a wider safety margin with comparable sensory block.
Objective: To compare the block characteristics, haemodynamic stability, and rescue analgesia requirements of intrathecal 0.75% hyperbaric ropivacaine versus 0.5% hyperbaric bupivacaine in patients undergoing elective lower abdominal procedures.
Methods: A randomised, single-blind, interventional study was conducted on 86 ASA I–II patients. Group A (n = 43) received 3 ml of 0.75% hyperbaric ropivacaine; Group B (n = 43) received 3 ml of 0.5% hyperbaric bupivacaine intrathecally. Sensory and motor block characteristics, haemodynamic parameters, and VAS scores were recorded.
Results: All primary and secondary block parameters were comparable between groups. No statistically significant difference was observed in onset of sensory block (p = 0.265), peak sensory level (p = 0.382), two-segment regression (p = 0.651), onset of motor block (p = 0.207), or complete motor recovery (p = 0.664). Haemodynamic parameters and VAS scores were similar throughout.
Conclusion: 0.75% hyperbaric ropivacaine provides a safe and effective alternative to 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower abdominal surgery, with equivalent block quality and superior cardiotoxicity profile.

Keywords: Spinal anaesthesia; Hyperbaric ropivacaine; Hyperbaric bupivacaine; Sensory block; Motor block; Lower abdominal surgery.

INTRODUCTION

Spinal anaesthesia, or sub-arachnoid block (SAB), remains the technique of choice for lower abdominal, orthopaedic lower limb, gynaecological, and urological procedures. The injection of a small volume of local anaesthetic directly into the cerebrospinal fluid (CSF) produces rapid, reliable anaesthesia with minimal systemic disturbance, good muscle relaxation, and excellent cost-effectiveness.[1–3] Compared with general anaesthesia, spinal techniques eliminate airway instrumentation, reduce the risk of pulmonary aspiration, and facilitate early ambulation—key advantages for day-care surgical settings.[4]

The gold-standard intrathecal agent for several decades has been 0.5% hyperbaric bupivacaine. However, being a racemic 50:50 mixture of S and R enantiomers, it carries recognised risks of cardiotoxicity—particularly from the R-enantiomer—as well as a tendency to produce prolonged motor blockade that may delay patient discharge and rehabilitation.[5–6] These

limitations have intensified the search for safer alternatives that preserve the desirable sensorimotor characteristics of bupivacaine.

Ropivacaine, a relatively newer, long-acting amide local anaesthetic, is formulated as the enantiomerically pure S(−)-form. This confers significantly reduced cardiotoxicity and less affinity for cardiac sodium channels compared with its racemic counterpart.[7] Clinical evidence indicates that ropivacaine produces sensorimotor dissociation—preferentially blocking pain-transmitting Aδ and C fibres over the larger Aβ motor fibres—which may translate into shorter motor block duration and earlier mobilisation.[8–10] The present study was therefore designed to evaluate whether 0.75% hyperbaric ropivacaine can serve as a clinically comparable and safer substitute for 0.5% hyperbaric bupivacaine in elective lower abdominal surgeries under spinal anaesthesia.

MATERIALS AND METHODS

Study Design and Setting

A prospective, randomised, single-blind interventional study was conducted in the Operation Theatre and PACU of ESI PGIMSR, ESIC Medical College, Joka, Kolkata over a period of 15 months, following approval by the Institutional Ethics Committee.

Sample Size

Sample size was calculated using Cochran's formula, assuming a prevalence of hypotension of 40% in the ropivacaine group and 20% in the bupivacaine group, at 95% confidence interval and 80% power. The minimum required sample was 78 patients; with a 10% attrition correction, a total of 86 patients were enrolled.

Inclusion and Exclusion Criteria

Inclusion criteria: Written informed consent; ASA physical status I or II; age 18–65 years; patients scheduled for elective lower abdominal surgery under subarachnoid block.
Exclusion criteria: Refusal or inability to consent; any contraindication to SAB; patients undergoing caesarean section; anticipated surgery duration exceeding 2 hours; known allergy to local anaesthetics.

Randomisation and Drug Administration

Eighty-six patients meeting the eligibility criteria were randomly assigned to two equal groups by simple single-blind randomisation. Group A (Ropivacaine; n = 43) received 3 ml of 0.75% hyperbaric ropivacaine (7.5 mg/ml) intrathecally. Group B (Bupivacaine; n = 43) received 3 ml of 0.5% hyperbaric bupivacaine (5 mg/ml) intrathecally. All patients were kept fasting per standard guidelines and premedicated with oral pantoprazole 40 mg 12 hours prior to surgery. On arrival to the operating room, intravenous access was secured with an 18G cannula; injection ondansetron 4 mg IV and injection pantoprazole 40 mg IV were administered. Standard monitoring (ECG, pulse oximetry, non-invasive blood pressure) was applied. Sub-arachnoid block was performed under strict aseptic conditions in the sitting position using a 25G Quincke spinal needle at the L3–L4 interspace via the midline approach.

Outcome Assessments

Sensory block was assessed bilaterally by temperature sensation (warm/cold cotton swabs) along the mid-clavicular line, graded on a three-point scale (2 = normal, 1 = reduced, 0 = absent). Motor block was assessed using the Modified Bromage Scale (Grade 0 = no loss; Grade 3 = inability to flex ankle). Intraoperative and postoperative haemodynamic parameters (pulse, SBP, DBP, MAP, SpO2, RR) were recorded at regular intervals. Hypotension (SBP fall >20%) was managed with IV fluid bolus and injection mephentermine; bradycardia (HR < 50 bpm) was treated with injection atropine 0.6 mg IV. Post-operative pain was assessed using the Visual Analogue Scale (VAS) at recovery and at 30, 60, 90, and 120 minutes.

Statistical Analysis

Data were tabulated in Microsoft Excel and analysed using SPSS v.24. Continuous variables are expressed as mean ± standard deviation (SD); categorical variables as frequency and percentage. Independent samples t-test was used for continuous data and chi-square test for categorical data. A p-value ≤ 0.05 was considered statistically significant.
Ethical Approval: This study was approved by the Institutional Ethics Committee and was registered with the Clinical Trials Registry–India (CTRI) under registration number CTRI/2024/01/062018.

RESULTS

Demographic and Baseline Characteristics

Both groups were comparable in age (Ropivacaine: 48.05 ± 8.40 years vs. Bupivacaine: 48.23 ± 7.41 years; p = 0.914), sex distribution (male 62.8% vs. 58.1%; p = 0.659), weight (57.79 ± 11.05 kg vs. 60.07 ± 5.39 kg; p = 0.227), height (158.95 ± 6.90 cm vs. 164.42 ± 4.78 cm; p = 0.106), and ASA grading (p = 0.281). Baseline haemodynamic parameters (pulse, SBP, DBP, MAP, SpO2, respiratory rate) were also statistically similar between the two groups (all p > 0.05; Table 1).

Table 1: Baseline Demographic and Haemodynamic Characteristics

Parameter	Ropivacaine (n=43)	Bupivacaine (n=43)	p-value
Age (years) – Mean ± SD	48.05 ± 8.40	48.23 ± 7.41	0.914
Sex (Male / Female)	27 / 16 (62.8%/37.2%)	25 / 18 (58.1%/41.9%)	0.659
Weight (kg) – Mean ± SD	57.79 ± 11.05	60.07 ± 5.39	0.227
Height (cm) – Mean ± SD	158.95 ± 6.90	164.42 ± 4.78	0.106
ASA I / II	24 / 19 (55.8%/44.2%)	19 / 24 (44.2%/55.8%)	0.281
Baseline Pulse (bpm)	73.56 ± 8.29	69.88 ± 9.91	0.066
Baseline SBP (mmHg)	130.77 ± 9.73	127.91 ± 10.07	0.184
Baseline DBP (mmHg)	68.93 ± 4.22	72.56 ± 7.55	0.228
Baseline SpO2 (%)	99.98 ± 0.15	99.56 ± 0.50	0.365

NS = Not significant (p > 0.05)

Block Characteristics

The key block characteristics are summarised in Table 2 and illustrated in Figure 1. The onset of sensory block was marginally delayed in Group A (7.48 ± 0.44 min) compared to Group B (6.94 ± 0.13 min), though this difference was not statistically significant (p = 0.265). Similarly, the time to reach peak sensory level was 13.83 ± 0.30 min in Group A versus 12.96 ± 0.13 min in Group B (p = 0.382). Time to two-segment regression was slightly prolonged in the Bupivacaine group (106.95 ± 0.09 min vs. 100.72 ± 1.78 min; p = 0.651). First complaint of pain (Group A: 260.09 ± 1.09 min; Group B: 265.03 ± 0.12 min; p = 0.703) and first rescue analgesia (268.63 ± 1.62 min vs. 267.99 ± 0.14 min; p = 0.861) were comparable. Onset of motor block was 9.30 ± 0.16 min in Group A and 8.30 ± 0.13 min in Group B (p = 0.207); complete motor recovery was equivalent at 227.37 ± 1.43 min vs. 224.00 ± 0.16 min (p = 0.664). No statistically significant difference was observed for any block parameter.

Table 2: Comparison of Block Characteristics (Mean ± SD)

Parameter	Ropivacaine Mean ± SD	Bupivacaine Mean ± SD	p-value	Significance
Onset of sensory block (min)	7.48 ± 0.44	6.94 ± 0.13	0.265	NS
Time to peak sensory level (min)	13.83 ± 0.30	12.96 ± 0.13	0.382	NS
Two-segment regression (min)	100.72 ± 1.78	106.95 ± 0.09	0.651	NS
First complaint of pain (min)	260.09 ± 1.09	265.03 ± 0.12	0.703	NS
First rescue analgesia (min)	268.63 ± 1.62	267.99 ± 0.14	0.861	NS
Onset of motor block (min)	9.30 ± 0.16	8.30 ± 0.13	0.207	NS
Complete motor recovery (min)	227.37 ± 1.43	224.00 ± 0.16	0.664	NS

NS = Not significant (p > 0.05). Independent t-test applied.

Figure 1: Comparison of Block Characteristics – Ropivacaine vs Bupivacaine

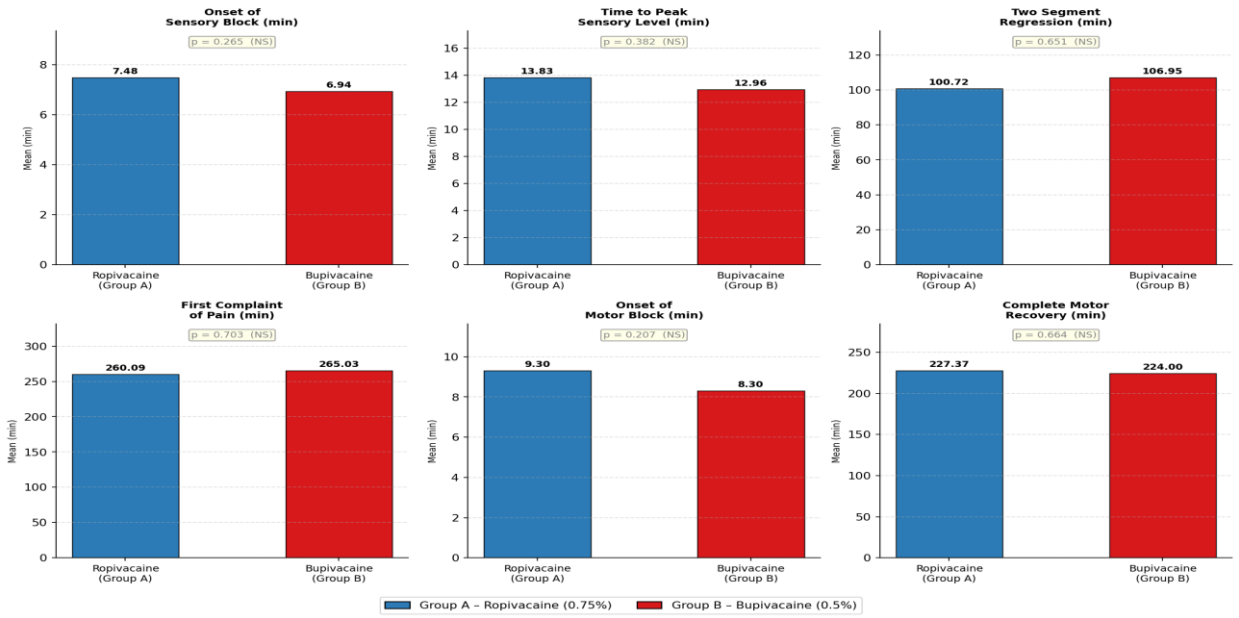

Figure 1: Bar graph comparing mean block characteristics (in minutes) between Group A (Ropivacaine) and Group B (Bupivacaine). All comparisons were statistically non-significant (NS, p > 0.05).

Haemodynamic Parameters and Adverse Effects

Intraoperative and postoperative haemodynamic parameters including pulse rate, SBP, DBP, MAP, respiratory rate, and SpO2 were stable and comparable between the groups at all measured time points (all $p > 0.05$). Only 2 patients in Group A (Ropivacaine) required additional medications intraoperatively versus 6 patients in Group B (Bupivacaine), though this difference was not statistically significant. VAS scores at end of surgery and at 30, 60, 90, and 120 minutes postoperatively were marginally lower in the Ropivacaine group; however, no statistically significant difference was noted and scores improved progressively with time in both groups.

DISCUSSION

This study was undertaken to address the need for safer intrathecal agents with equivalent efficacy to bupivacaine for lower abdominal surgeries. Regional anaesthesia has the potential to provide excellent operating conditions and prolonged postoperative analgesia.[11] Bupivacaine, an amino-amide compound, has been the long-acting local anaesthetic agent of choice; however, its strong binding to cardiac sodium channels leads to prolonged inhibition of normal conduction, making toxicity potentially life-threatening.[12] Ropivacaine, developed specifically to address this concern, is structurally similar to bupivacaine but available as a pure S-enantiomer with a demonstrably greater safety margin.[13–14]

Our demographic data corroborate findings by Latwal et al., who reported no statistically significant difference in age, sex, ASA status, weight, or height between ropivacaine and bupivacaine groups.[15] In our study, the onset of sensory block was marginally later in the ropivacaine group (7.48 vs. 6.94 min), consistent with reports by Latwal et al. (6.28 vs. 4.07 min, $p < 0.05$) and Nema et al., both of whom noted faster onset with bupivacaine.[15],[16] The slightly slower onset of ropivacaine is attributable to its lower lipophilicity relative to bupivacaine.

The time to peak sensory level was also marginally prolonged in Group A (13.83 vs. 12.96 min), corroborating the findings of Chari et al.[17] and Bansal et al.[18] Two-segment regression was slightly faster in the ropivacaine group (100.72 vs. 106.95 min), in agreement with Swetha Purohit et al., who reported significantly faster sensory regression with ropivacaine (157.44 ± 17.78 min vs. 180.60 ± 23.06 min; $p < 0.001$).[19] Motor block onset was marginally delayed in Group A (9.30 vs. 8.30 min), consistent with Latwal et al. and Nema et al.[15],[16] Complete motor recovery was equivalent in both groups, a finding that contrasts with several studies where ropivacaine showed shorter motor block—a potentially favourable property for day-care settings.[20–23] Haemodynamic stability was maintained equally in both groups throughout the intraoperative and postoperative periods, confirming the safety profile of hyperbaric ropivacaine for spinal anaesthesia.

SUMMARY

This randomised interventional study compared 0.75% hyperbaric ropivacaine and 0.5% hyperbaric bupivacaine in 86 ASA I–II patients undergoing elective lower abdominal surgery under spinal anaesthesia. The two groups were demographically homogeneous. All block parameters—onset and peak of sensory block, two-segment regression, first complaint of pain, first rescue analgesia, onset and recovery of motor block—showed no statistically significant intergroup difference. Haemodynamic parameters and postoperative VAS scores were equally well maintained. Fewer patients in the ropivacaine group required supplemental medications intraoperatively, though this did not reach statistical significance.

CONCLUSION

0.75% hyperbaric ropivacaine is a safe and effective alternative to routinely used 0.5% hyperbaric bupivacaine for spinal anaesthesia in elective lower abdominal surgeries. It provides comparable sensory and motor block characteristics, adequate surgical anaesthesia, stable haemodynamics, and similar analgesic duration. Its pharmacological advantage of lower cardiotoxicity and CNS toxicity—owing to its pure S-enantiomer formulation and reduced lipophilicity—renders it a clinically valuable option. The primary limitations of ropivacaine remain its higher cost and limited availability at peripheral healthcare centres. Larger multicentre randomised trials are recommended to further establish its role.

Limitations

1. Relatively small sample size. 2. Single-centre study, limiting generalisability. 3. Hospital-based recruitment may introduce selection bias. 4. Blinding was single rather than double.

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