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Research Article

Spinal Anaesthesia for Elective Surgery: A Prospective Randomized Comparison of Hyperbaric Ropivacaine and Hyperbaric Bupivacaine

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Abstract

Background: Spinal anaesthesia is widely used for lower abdominal and lower limb surgery. Bupivacaine remains the gold standard intrathecal agent; however, its cardiotoxicity profile has driven interest in safer alternatives. Ropivacaine, a pure S-(-)-enantiomer with lower lipophilicity, offers theoretical advantages of reduced cardiovascular and central nervous system toxicity with a faster recovery profile.

Hypothesis: Hyperbaric Ropivacaine 15 mg provides clinically non-inferior anaesthesia to hyperbaric Bupivacaine 15 mg with a superior recovery profile (shorter sensory and motor block duration) and comparable haemodynamic stability.

Objective: To compare the onset, spread, duration of sensory and motor block, and haemodynamic effects of equidose (15 mg) hyperbaric Ropivacaine versus hyperbaric Bupivacaine for spinal anaesthesia in elective lower abdominal, perianal, and lower limb surgery.

Methods: In this prospective, randomized, double-blind study, 60 ASA I–II patients were allocated to receive either 3 ml of 0.5% hyperbaric Bupivacaine (Group B, n=30) or 3 ml of 0.5% hyperbaric Ropivacaine (Group R, n=30). Sensory and motor block characteristics and haemodynamic parameters were recorded at standardized intervals.

Results: Both groups were demographically comparable. Onset of maximum sensory block was similar (Group B: 9.10±3.90 min vs Group R: 10.87±5.37 min; p=0.150). Bupivacaine produced significantly faster maximum motor block (8.70±3.19 vs 13.10±4.40 min; p<0.001). Ropivacaine demonstrated significantly faster five-segment sensory regression (116.00±29.72 vs 143.50±18.76 min; p<0.001), regression to S2

(154.00±27.84 vs 186.00±18.73 min; p<0.001), and complete motor block regression (149.00±30.75 vs 183.50±19.96 min; p<0.001). Incidence of hypotension and bradycardia did not differ significantly between groups.

Conclusions: Equidose hyperbaric Ropivacaine produces clinically adequate spinal anaesthesia with a significantly shorter duration of sensory and motor block and comparable haemodynamic stability compared with hyperbaric Bupivacaine. It represents a suitable alternative when early ambulation is desirable.

Keywords: spinal anaesthesia; ropivacaine; bupivacaine; hyperbaric; subarachnoid block; motor block; sensory block; regional anaesthesia

1. Introduction

Spinal anaesthesia (SA), or subarachnoid block (SAB), involves the injection of a local anaesthetic into the cerebrospinal fluid (CSF) to achieve neuraxial blockade of the spinal nerve roots. First described clinically by August Bier in 1898, it has become one of the most widely practised anaesthetic techniques globally, particularly for lower abdominal, perineal, and lower limb procedures [1,2].

The popularity of spinal anaesthesia stems from its simplicity, reliability, profound sensory analgesia, excellent muscle relaxation, reduced intraoperative blood loss, and minimal preoperative preparation requirements [3]. Bupivacaine—a racemic mixture of its enantiomers—has been the intrathecal agent of choice for decades, providing consistent sensory and motor blockade. However, Bupivacaine carries a well-documented risk of cardiac and central nervous system (CNS) toxicity, primarily mediated through its relatively high lipophilicity and non-stereoselective sodium channel blockade [4].

These concerns prompted the development of single-enantiomer local anaesthetics. Ropivacaine, the pure S-(-)-enantiomer of 1-propyl-2,6-pipecoloxylidide, was introduced into clinical practice in 1996 [5]. Compared with Bupivacaine, Ropivacaine is less lipophilic (partition coefficient: 2.9 vs 27.5), exhibits greater differential sensory–motor blockade, and has a more favourable toxicity profile [6,7]. While its epidural efficacy is well established, data on intrathecal Ropivacaine in equal milligram doses to Bupivacaine remain limited, particularly for non-obstetric elective surgery [5,8].

Commercially available hyperbaric Ropivacaine is not yet widely accessible; published studies have used investigator-prepared hyperbaric solutions, and results vary with respect to onset, spread, and duration of block. Resolving the comparative clinical profile of equidose hyperbaric Ropivacaine and Bupivacaine is therefore of practical importance for anaesthetic decision-making, especially in day-case settings where rapid motor recovery facilitates early discharge.

The present study was designed to compare the onset, maximum spread, duration of sensory and motor block, and haemodynamic stability of 15 mg hyperbaric Ropivacaine versus 15 mg hyperbaric Bupivacaine in ASA I–II patients undergoing elective lower abdominal, perianal, and lower limb surgery under spinal anaesthesia.

2. Hypothesis, Aims, and Objectives

2.1 Research Hypothesis

Intrathecal administration of 15 mg hyperbaric Ropivacaine provides clinically adequate and safe spinal anaesthesia for lower abdominal, perianal, and lower limb surgery, with a shorter duration of sensory and motor block and comparable haemodynamic stability when compared with an equidose of hyperbaric Bupivacaine.

2.2 Primary Aim

To compare the safety and efficacy of equidose (15 mg) hyperbaric Ropivacaine (0.5%) and hyperbaric Bupivacaine (0.5%) as sole intrathecal agents for elective surgery.

2.3 Specific Objectives

- To compare the onset time and maximum level of sensory block between the two groups.
- To compare the onset time and maximum grade of motor block (Modified Bromage Scale) between the two groups.
- To compare the duration of sensory block (five-segment regression and regression to S2) between the two groups.
- To compare the duration of motor block (regression by one Bromage grade and complete regression) between the two groups.
- To compare the incidence and severity of haemodynamic complications (hypotension and bradycardia) between the two groups.

3. Materials and Methods

3.1 Study Design and Ethics

This was a prospective, randomized, double-blind, parallel-group controlled trial conducted in the Department of Anaesthesiology, Manipal Hospital, Bangalore, India, from January 2016 to March 2018. The study was approved by the Institutional Review Committee (IRC), and written informed consent was obtained from all participants. The trial was conducted in accordance with the Declaration of Helsinki.

3.2 Sample Size

Using a formula for a two-tailed test with $\alpha = 0.05$ (type I error), $\beta = 0.20$ (type II error), and 80% power to detect a 35% difference between groups, a minimum sample size of 25 per group was calculated. To allow for withdrawals and to improve statistical power, 30 patients per group (n=60 total) were enrolled.

3.3 Inclusion and Exclusion Criteria

Inclusion criteria: ASA physical status grade I or II; aged 18–60 years; scheduled for elective lower abdominal, perianal, or lower limb surgery under spinal anaesthesia; body weight ≥40 kg.

Exclusion criteria: Patient refusal; acute cardiovascular or respiratory disease; spinal deformity or previous spinal surgery; bleeding disorder or anticoagulant therapy; caesarean section; known hypersensitivity to amide-type local anaesthetics; psychiatric illness or any condition that may interfere with clinical assessment; emergency surgery.

3.4 Randomization and Blinding

Patients were allocated to one of two groups using a computer-generated random number table. The allocation sequence was concealed in sealed, opaque envelopes opened by a designated anaesthetic nurse immediately before drug preparation. The anaesthesiologist performing the block and the observer assessing the block were blinded to group allocation. Hyperbaric solutions of identical volume (3 ml) and appearance were prepared aseptically by a third anaesthesiologist not involved in patient assessment.

3.5 Drug Preparation

Group B (n=30): 3 ml of commercially available 0.5% hyperbaric Bupivacaine (5 mg/ml in 80 mg/ml dextrose).

Group R (n=30): 3 ml of 0.5% hyperbaric Ropivacaine prepared aseptically by combining 2 ml of commercially available 0.75% isobaric Ropivacaine with 1 ml of 25% dextrose, yielding a final concentration of 5 mg/ml Ropivacaine in 83 mg/ml dextrose. A fresh 10 ml ampoule of 25% dextrose was used for each patient to maintain sterility.

3.6 Anaesthetic Technique

All patients received intravenous preloading with 500 ml of isotonic saline or Ringer's lactate solution. Standard monitoring was applied: ECG, pulse oximetry (SpO_2), and non-invasive blood pressure. Supplemental oxygen was administered at 4 l/min via face mask throughout the procedure.

With the patient in the sitting or lateral decubitus position under strict aseptic conditions, the subarachnoid space was identified at the L2–L3 or L3–L4 interspace using a 25-gauge Quincke spinal needle. After confirming free CSF flow, the allocated drug was injected at a rate of approximately 0.2 ml/s. The patient was then repositioned supine.

3.7 Outcome Measurements

Sensory block was assessed bilaterally by loss of pinprick sensation using a 23-gauge hypodermic needle. Motor block was graded by the Modified Bromage Scale (0 = no block; 1 = inability to raise extended leg but able to move knees and feet; 2 = inability to raise extended leg and move knees, but able to move feet; 3 = complete motor block). Block characteristics were assessed every 3 minutes for the first 20 minutes and every 15 minutes thereafter until complete resolution.

The following endpoints were recorded: (i) time to maximum sensory block level; (ii) highest dermatomal level of sensory block; (iii) time to five-segment regression of sensory block; (iv) time to regression of sensory block to S2; (v) time to maximum motor block (Bromage 3); (vi) time to regression of motor block by one Bromage grade; (vii) time to complete motor block regression (Bromage 0).

Haemodynamic parameters (HR, SBP, DBP, MAP) were recorded at 0, 5, 10, 20, 30, 40, 50, and 60 minutes after injection. Hypotension was defined as SBP < 90 mmHg and was treated with intravenous Mephentermine 6 mg. Bradycardia was defined as HR < 60 beats/min and treated with intravenous Atropine 0.3 mg.

3.8 Statistical Analysis

Data were analysed using SPSS (version 20) and Microsoft Excel. Continuous variables are reported as mean ± standard deviation (SD). Between-group comparisons of continuous variables were performed using the independent samples t-test. Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. A p-value < 0.05 was considered statistically significant, with a 95% confidence interval.

4. Results

4.1 Demographic Data

Sixty patients completed the study (Group B n=30, Group R n=30). There were no statistically significant differences between the groups in age (p=0.458), sex distribution (p=0.766), weight (Group B: 68.77±9.44 kg vs Group R: 68.40±13.09 kg; p=0.901), height (Group B: 165.73±4.79 cm vs Group R: 164.43±6.26 cm; p=0.370), or ASA grade (p=0.297). The groups were thus well matched at baseline (Table 1).

Table 1. Demographic and baseline characteristics

Variable	Group B (Bupivacaine) n=30	Group R (Ropivacaine) n=30	p-value
Age (years), mean±SD	43.10±11.52	44.97±11.34	0.458
Sex (M/F)	23/7	22/8	0.766
Weight (kg), mean±SD	68.77±9.44	68.40±13.09	0.901
Height (cm), mean±SD	165.73±4.79	164.43±6.26	0.370
ASA I/II	19/11	15/15	0.297

4.2 Sensory Block Characteristics

The mean time to maximum sensory block level was 9.10±3.90 min in Group B and 10.87±5.37 min in Group R (p=0.150), indicating no significant difference in onset. The most common maximum dermatomal level was T8 in Group B (36.7%) and T10 in Group R (36.7%).

Time to five-segment regression was significantly shorter in Group R (116.00±29.72 min) than Group B (143.50±18.76 min; p<0.001). Similarly, time to complete sensory regression to S2 was significantly shorter in Group R (154.00±27.84 min) compared with Group B (186.00±18.73 min; p<0.001) (Table 2).

Table 2. Sensory and motor block characteristics (mean ± SD)

Parameter	Group B	Group R	p-value
Time to max sensory block (min)	9.10 ± 3.90	10.87 ± 5.37	0.150 (NS)
5-segment sensory regression (min)	143.50 ± 18.76	116.00 ± 29.72	<0.001*
Regression to S2 level (min)	186.00 ± 18.73	154.00 ± 27.84	<0.001*
Time to max motor block (min)	8.70 ± 3.19	13.10 ± 4.40	<0.001*
Motor regression by 1 grade (min)	146.50 ± 23.53	97.00 ± 26.64	<0.001*
Complete motor regression (min)	183.50 ± 19.96	149.00 ± 30.75	<0.001*

**Statistically significant (p<0.001); NS = not significant*

4.3 Motor Block Characteristics

All patients in both groups achieved complete motor block (Bromage grade 3). The onset of maximum motor block was significantly faster in Group B (8.70±3.19 min) than Group R (13.10±4.40 min; p<0.001). Motor block regression by one Bromage grade was significantly earlier in Group R (97.00±26.64 min) than Group B (146.50±23.53 min; p<0.001). Complete motor block regression was also significantly faster in Group R (149.00±30.75 min) than Group B (183.50±19.96 min; p<0.001).

4.4 Haemodynamic Parameters

Heart rate did not differ significantly between groups at any time point (all p>0.05). Systolic blood pressure (SBP) was higher in Group R at baseline and throughout the monitoring period (p<0.05 at most time points), reflecting higher baseline values in that group. Diastolic blood pressure did not differ significantly between groups. Mean arterial pressure (MAP) was significantly higher in Group R at 5, 20, 30, and 40 minutes post-injection (p<0.05 each). Both groups showed slight reductions in SBP and MAP following block establishment that resolved without sequelae.

Clinical hypotension (SBP <90 mmHg) occurred in 1 patient in Group B (3.3%) and 2 patients in Group R (6.7%; p=1.000). Bradycardia was observed in 4 patients in Group B (13.3%) and 6 patients in Group R (20.0%; p=0.488). All episodes were successfully managed with Mephentermine (6 mg IV) and Atropine (0.3 mg IV) respectively. When haemodynamic events captured outside scheduled monitoring intervals were pooled, Group B demonstrated a greater total number of hypotensive episodes (7 vs 5 patients) and fewer total bradycardic episodes (4 vs 7 patients) than Group R, though between-group differences remained non-significant.

No patient in either group developed clinically relevant neurological sequelae, backache, or other late complications.

5. Discussion

The present study demonstrates that intrathecal administration of 15 mg hyperbaric Ropivacaine provides clinically adequate spinal anaesthesia for elective lower abdominal, perianal, and

lower limb surgery, with a significantly shorter duration of both sensory and motor block compared with an equidose of hyperbaric Bupivacaine, while maintaining a comparable haemodynamic safety profile.

The onset times for sensory block were similar between the two drugs, consistent with findings reported by Mantouvalou et al. [5] and Kulkarni et al. [31], both of whom observed slightly faster onset with Bupivacaine that did not reach clinical significance. The maximum dermatomal spread also did not differ significantly, which is consistent with prior comparisons employing equal volumes and concentrations [21].

The superior recovery profile of Ropivacaine observed in this study—particularly the earlier regression of motor block by one grade (97 vs 146 min) and complete motor regression (149 vs 184 min)—corroborates findings from Kulkarni et al. [31] (Ropivacaine 120 vs Bupivacaine 190 min) and Casati et al. [18] (166 vs 190 min). This is mechanistically attributable to Ropivacaine's lower lipophilicity (partition coefficient 2.9 vs 27.5 for Bupivacaine), which limits penetration into large myelinated motor fibres and accelerates redistribution from neural tissue [47]. The resulting differential sensory–motor blockade is a clinically desirable feature in day-case and ambulatory surgical settings where early mobilization reduces the risk of venous thromboembolism and shortens recovery unit occupancy.

With regard to haemodynamic stability, the incidence of clinically defined hypotension and bradycardia did not differ significantly between groups, which is consistent with data from Whiteside et al. [21] and Luck et al. [46], who reported less hypotension with Ropivacaine. In the current study, the overall hypotensive burden (including events outside scheduled monitoring windows) was actually numerically greater in Group B, though statistical significance was not reached, possibly because of the limited monitoring frequency and modest sample size.

The higher baseline SBP values in Group R likely reflect between-group variation at enrollment rather than a drug effect, and both groups showed comparable relative reductions in MAP post-injection. The absence of statistically significant differences in MAP overall supports the conclusion that equidose hyperbaric Ropivacaine does not confer inferior haemodynamic stability.

It is noteworthy that commercially available hyperbaric Ropivacaine remains unavailable in many countries, requiring investigator-prepared solutions. The technique described herein—combining 0.75% isobaric Ropivacaine with 25% dextrose—is consistent with established protocols [31,33] and produced a reliable block in all patients.

6. Novel Contributions

The present study adds to the existing literature in several important respects:

- This is among a limited number of studies to compare equidose (15 mg vs 15 mg) hyperbaric Ropivacaine and Bupivacaine in a non-obstetric, mixed surgical population encompassing lower abdominal, perianal, and lower limb procedures—a combination not extensively examined in prior controlled trials.
- The study characterises haemodynamic events both within scheduled monitoring intervals and at unscheduled time points (prompted by patient symptoms), providing a more complete picture of the haemodynamic profile than interval-only monitoring and revealing that Group B accumulated a greater total number of hypotensive episodes.
- The use of five-segment sensory regression (rather than the more conventional two- or four-segment regression) as an endpoint allows a more comprehensive characterisation of offset kinetics across the dermatomes relevant to the surgical procedures studied.

- The study provides confirmatory evidence that aseptically prepared hyperbaric Ropivacaine (0.75% isobaric + 25% dextrose) is a safe, effective, and reproducible formulation in the absence of a licensed commercial preparation.
- The data support a clinical rationale for preferring hyperbaric Ropivacaine over Bupivacaine specifically in patients in whom earlier motor recovery facilitates postoperative physiotherapy, early ambulation, or same-day discharge—a context of growing relevance as day-surgery volumes increase globally.

7. Limitations

Several limitations of this study must be acknowledged:

- Single-centre design: The trial was conducted at a single tertiary-care institution in Bangalore, India. The findings may not be generalizable to populations with differing demographics, comorbidity profiles, or anaesthetic practice environments.
- Restricted ASA grade: Only ASA I–II patients were enrolled. The safety and efficacy profiles of hyperbaric Ropivacaine in higher-risk patients (ASA III–IV), including those with significant cardiovascular disease, remain to be established.
- Age range: Patients aged 20–60 years were included. The pharmacodynamics of intrathecal Ropivacaine in elderly patients (>60 years), in whom CSF volume is reduced and block spread may differ, or in paediatric populations, are not captured by this study.
- Non-commercial hyperbaric Ropivacaine: Hyperbaric Ropivacaine is not commercially available; the study preparation required meticulous aseptic technique and introduces a source of variability in baricity between batches. Standardisation would be facilitated by a licensed formulation.
- Haemodynamic monitoring intervals: Blood pressure and heart rate were recorded at pre-specified intervals (0, 5, 10, 20, 30, 40, 50, and 60 min). Haemodynamic instability occurring between measurement points may have been missed, potentially underestimating the true incidence of hypotension and bradycardia in both groups. Continuous non-invasive haemodynamic monitoring would provide more complete data.
- No assessment of post-operative analgesia duration, time to first analgesic request, or patient satisfaction scores, which are increasingly recognised as important patient-centred outcomes.
- No long-term neurological follow-up: Although no acute neurological sequelae were observed, formal neurological assessment at 24 hours, one week, and one month was not performed.
- Relatively small sample size: While the study met its pre-specified power calculation, the sample size limits the precision of secondary outcome estimates and the ability to detect differences in rare adverse events.

8. Conclusions

This randomised controlled trial demonstrates that 15 mg of investigator-prepared hyperbaric Ropivacaine (0.5%) provides clinically effective and safe spinal anaesthesia for elective lower abdominal, perianal, and lower limb surgery. At equidose:

- Onset of sensory block is comparable between hyperbaric Ropivacaine and hyperbaric Bupivacaine.
- Hyperbaric Bupivacaine produces a significantly faster onset of motor block.
- Hyperbaric Ropivacaine produces a significantly shorter duration of both

sensory and motor block, favouring earlier patient mobilisation.

- The haemodynamic safety profiles of the two agents are comparable, with no statistically significant differences in the incidence of hypotension or bradycardia.

These findings support the use of hyperbaric Ropivacaine as an alternative to Bupivacaine for spinal anaesthesia when shorter block duration and earlier motor recovery are clinically desirable. Future research should evaluate hyperbaric Ropivacaine in high-risk patients, in elderly populations, and within formal enhanced-recovery protocols.

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