Original Research Paper

Volume - 15 | Issue - 05 | May - 2025 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

COMPARATIVE STUDY OF 0.75% HYPERBARIC ROPIVACAINE, 0.75% HYPERBARIC ROPIVACAINE WITH DEXMEDETOMIDINE, AND 0.5% HYPERBARIC BUPIVACAINE IN SPINAL ANAESTHESIA FOR ELECTIVE SURGERY: A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND INTERVENTIONAL STUDY

Vidya Sagar Chaubey — PG Resident, Department of Anaesthesiology, 4th floor, Room No. 418, Bharat Ratna late Shri Atal Bihari Vajpayee memorial Medical College, Rajnandgaon, Chhattisgarh 491441 India.

Durga Kashyap Kosam* — Professor & HOD, Department of Anaesthesiology, 4th floor, Room No. 418, Bharat Ratna late Shri Atal Bihari Vajpayee memorial Medical College, Rajnandgaon, Chhattisgarh 491441 India. *Corresponding Author

Smriti Bandhu — Associate Professor, Department of Anaesthesiology, 4th floor, Room No. 418, Bharat Ratna late Shri Atal Bihari Vajpayee memorial Medical College, Rajnandgaon, Chhattisgarh 491441 India.

Daleena Nelson — PG Resident, Department of Anaesthesiology, 4th floor, Room No. 418, Bharat Ratna late Shri Atal Bihari Vajpayee memorial Medical College, Rajnandgaon, Chhattisgarh 491441 India.

ABSTRACT **Introduction:** Spinal anaesthesia facilitates lower limb and abdominal surgeries with rapid onset and fewer complications compared to general anaesthesia. Although hyperbaric bupivacaine (0.5%) is the standard despite its cardiotoxicity risks, alternatives such as hyperbaric ropivacaine and dexmedetomidine may improve block quality. This study compared intrathecal 0.75% hyperbaric ropivacaine (with and without 3 mcg dexmedetomidine) and 0.5% hyperbaric bupivacaine for block characteristics, analgesia, haemodynamic stability, and adverse events in elective surgeries. **Methods:** Seventy-five ASA I-II patients (18-65 years) undergoing elective lower abdominal or limb surgeries were enrolled in a randomised trial at B.R.L.S.A.B.V.M Medical College from April to July 2024. Patients were divided into three groups (n=25): Group R (3 mL 0.75% hyperbaric ropivacaine + 0.5 mL NS), Group RD (3 mL 0.75% hyperbaric ropivacaine + 3 mcg dexmedetomidine in 0.5 mL NS), and Group B (3 mL 0.5% hyperbaric bupivacaine + 0.5 mL NS). Outcomes included sensory/motor block parameters, rescue analgesia, haemodynamic parameters, and adverse events. Data were analysed using ANOVA, Tukey's test, Chi-square test, and Kruskal-Wallis test ($p<0.05$). **Results:** Group RD exhibited faster sensory block onset to T10 (2.55 ± 1.1 min vs. 2.94 ± 1.14 min [Group B] vs. 3.07 ± 1.28 min [Group R]; p=0.272) and motor block (1.37 ± 0.45 min vs. 1.69 ± 0.53 min vs. 1.87 ± 0.85 min; p=0.023), with longer sensory block (202.2 ± 28.8 min vs. 174 ± 36.6 min vs. 175.8 ± 32.4 min; p=0.0045) and motor block duration (381 ± 125.4 min vs. 237.6 ± 47.4 min vs. 235.2 ± 34.2 min; $p<0.001$). Time to first rescue analgesia was longest in Group RD (421.8 ± 66 min) compared to Group B (379.2 ± 52.2 min) and Group R (341.4 ± 58.8 min; $p<0.001$). Haemodynamic declines were similar ($p>0.05$), with manageable adverse events (hypotension: 16% vs. 28% vs. 20%; p=0.574). **Conclusion:** Intrathecal 0.75% hyperbaric ropivacaine with dexmedetomidine provides superior block characteristics and postoperative analgesia with minimal instability. Hyperbaric ropivacaine alone is suitable for shorter procedures with faster recovery.

KEYWORDS : Spinal anaesthesia, hyperbaric bupivacaine, hyperbaric ropivacaine, dexmedetomidine

INTRODUCTION

Spinal anaesthesia is a cornerstone of regional anaesthesia, widely used for lower abdominal, perineal, and lower limb surgeries due to its rapid onset, effective sensory and motor blockade, and fewer systemic effects compared to general anaesthesia (Ghimire & Gyawali, 2019). By injecting a local anaesthetic into the cerebrospinal fluid, it delivers profound analgesia, muscle relaxation, and autonomic suppression, making it ideal for procedures like caesarean deliveries, orthopaedic surgeries, and urological interventions (Whiteside et al., 2003). Its advantages include reduced risk of pulmonary aspiration, no airway manipulation, faster mobilisation, and cost-effectiveness, particularly valuable across healthcare settings (Kanazi et al., 2006).

Hyperbaric bupivacaine (0.5%) has been the gold standard for spinal anaesthesia due to its potency, consistent block profile, and prolonged duration (Camorcia et al., 2005). The addition of dextrose increases its baricity, ensuring reliable cephalad spread and predictability, crucial for extended surgeries (Whiteside et al., 2003). However, bupivacaine's cardiotoxicity, linked to its racemic mixture of S- and R-enantiomers, poses risks of severe cardiac arrhythmias and myocardial depression, especially with intravascular injection (Graf et al., 2002). Its prolonged motor blockade can also delay recovery, making it less ideal for ambulatory surgeries (Ravipati et al., 2017).

These drawbacks have driven exploration of alternatives like ropivacaine, a pure S-enantiomer with reduced lipid solubility and lower cardiotoxic potential (Luck et al., 2008). Compared to bupivacaine, ropivacaine offers a safer profile, preferential sensory blockade, and faster motor recovery (Kulkarni et al., 2014). Its hyperbaric formulation (0.75%) optimises intrathecal spread, supporting its use in both inpatient and outpatient settings (Shashikala et al., 2019). Its shorter duration and lower incidence of transient neurological symptoms enhance its appeal for day-care procedures (Luck et al., 2008).

Adjuvants are often used to enhance spinal anaesthesia, prolong analgesia, and reduce local anaesthetic doses, minimising toxicity (Yektaş et al., 2014). Dexmedetomidine, a potent α2-adrenergic agonist, improves block characteristics without respiratory depression, unlike opioids (Rahimzadeh et al., 2018). By inhibiting norepinephrine release in the spinal cord, it provides sedation, analgesia, and sympatholysis, extending sensory and motor blockade at low doses with minimal side effects (Kanazi et al., 2006).

While studies have compared bupivacaine with isobaric ropivacaine or adjuvants, data on hyperbaric ropivacaine with dexmedetomidine versus bupivacaine are limited (Chatterjee et al., 2014). Preliminary evidence suggests dexmedetomidine enhances ropivacaine's block profile (Singh et al., 2015), but comprehensive studies on hyperbaric formulations are scarce. This study evaluated intrathecal 0.75% hyperbaric ropivacaine with 3 µg dexmedetomidine against ropivacaine alone and 0.5% hyperbaric bupivacaine in elective lower abdominal and limb surgeries, assessing block onset, duration, analgesia, haemodynamic stability, and adverse effects.

MATERIALS & METHODS

This prospective, randomised, double-blind study was conducted at B.R.L.S.A.B.V.M. Medical College, Rajnandgaon, India, from April to July 2024. Approved by the Institutional Scientific and Ethics Committees and registered with the Clinical Trials Registry of India (CTRI/2024/03/064896), it followed the Declaration of Helsinki. Seventy-five ASA I-II patients (18-65 years) scheduled for elective lower abdominal, or limb surgeries were enrolled after providing informed consent. Exclusion criteria included refusal, ASA >II,

neuropathy, sepsis, allergies, bleeding disorders, major cardiorespiratory disease, and pregnancy.

Sample size was calculated based on motor block duration differences from Ravipati et al. (2017) and Kulkarni et al. (2014), targeting 90% power and α=0.05, yielding 25 patients per group (total n=75). Patients were randomised into three groups (n=25 each) using a computer-generated code:

- Group R: 3 mL 0.75% hyperbaric ropivacaine + 0.5 mL normal saline (NS).
- Group RD: 3 mL 0.75% hyperbaric ropivacaine + 3 mcg dexmedetomidine in 0.5 mL NS.
- Group B: 3 mL 0.5% hyperbaric bupivacaine + 0.5 mL NS.

Double-blinding was ensured by an independent anaesthesiologist preparing identical, unlabelled syringes. Preoperative preparation included a xylocaine sensitivity test, NPO guidelines, and premedication. Spinal anaesthesia was administered at L3-L4 or L4-L5 with a 25/26G Quincke needle, injecting 3.5 mL over 10-15 seconds. Sensory block was assessed via pinprick (onset to T10, maximum level, regression to L1), and motor block via the Modified Bromage Scale (onset to Bromage 1, complete block to Bromage 3, recovery to Bromage 0). Haemodynamic parameters, adverse events, and analgesia requirements were monitored. Data were analysed using SPSS 29.0 with ANOVA, Tukey's test, Chi-square, and Kruskal-Wallis tests ($p<0.05$).

RESULTS

Demographic and surgical variables were comparable across groups (Table 1). Mean ages were 37.04 ± 9.62 (RD), 39 ± 13.58 (B), and 38.64 ± 14.46 (R) years (p=0.845), with similar sex distribution, BMI, ASA status, and surgery duration (p>0.05).

Table 1: Demographic And Surgical Characteristics

Parameter	Group RD (n=25)	Group B (n=25)	Group R (n=25)	p-value
Age (years)	37.04±9.62	39±13.58	38.64±14.46	0.845
Height (cm)	160.2±5.55	160.56±6.43	160±6.63	0.949
Weight (kg)	54.71±5.87	55.92±9.97	58.24±10.87	0.390
BMI (kg/m²)	21.38±2.36	21.59±2.9	22.73±3.17	0.199
Surgery Duration (min)	72±34.06	59.6±24.36	57.4±28.55	0.171
Male/Female	19/6	20/5	17/8	0.610
ASA I/II	2/23	4/21	5/20	0.474

(kg = kilograms, cm = centimetres, BMI = Body Mass Index, min = minutes; p < 0.05 = significant, p < 0.001 = highly significant, p > 0.05 = not significant) ASA: American Society of Anaesthesiologists.

Spinal Block Characteristics:

Sensory Block (Table 2): Group RD had the fastest onset to T10 (2.55 ± 1.1 min) versus Group B (2.94 ± 1.14 min) and Group R (3.07 ± 1.28 min; p=0.272). Time to T4 was quickest in Group RD (6.62 ± 1.26 min) versus Group B (8.31 ± 2.26 min; p=0.002) and Group R (8.74 ± 2.1 min; p=0.001). Maximum level reached T4 in 40% of Group RD versus 16% (B) and 12% (R; p=0.03). Duration to L1 was longest in Group RD (202.2 ± 28.8 min) versus Group B (174 ± 36.6 min; p=0.004) and Group R (175.8 ± 32.4 min; p=0.003).

Table 2: Characteristics Of Sensory Blockade:

Group	Mean±SD	P (One-way Anova)	Group Comparison	P
Time for onset of sensory block to T10 (Min)				
Group RD (n=25)	2.55±1.1	0.272	RD compared to B	0.224
Group B (n=25)	2.94±1.14		RD compared to R	0.130
Group R (n=25)	3.07±1.28		B compared to R	0.706
Time for maximal level of sensory block (T4) (Min)				
Group RD (n=25)	6.62±1.26	0.0004	RD compared to B	0.002
Group B (n=25)	8.31±2.26		RD compared to R	0.0001
Group R (n=25)	8.74±2.1		B compared to R	0.488
Time for two segment sensory regression (Min)				
Group RD (n=25)	123±27	0.104	RD compared to B	0.167
Group B (n=25)	113.4±21		RD compared to R	0.370
Group R (n=25)	131.4±38		B compared to R	0.042
Time for sensory regression to T10 (Min)				
Group RD (n=25)	153.6±35.4	0.130	RD compared to B	0.063
Group B (n=25)	131.4±46.2		RD compared to R	0.320
Group R (n=25)	144±32.4		B compared to R	0.269
Time for sensory regression to L1 (Min)				
Group RD (n=25)	202.2±28.8	0.0045	RD compared to B	0.004
Group B (n=25)	174±36.6		RD compared to R	0.003
Group R (n=25)	175.8±32.4		B compared to R	0.850

(One way ANOVA ; p < 0.05 = significant, p < 0.001 = highly significant, p > 0.05 = not significant)

Motor Block (Table 3): Onset to Bromage 1 was fastest in Group RD (1.37 ± 0.45 min) versus Group B (1.69 ± 0.53 min; p=0.026) and Group R (1.87 ± 0.85 min; p=0.0136). Complete block (Bromage 3) times were similar (p=0.104), but duration was longest in Group RD (381 ± 125.4 min) versus Group B (237.6 ± 47.4 min; p<0.0001) and Group R (235.2 ± 34.2 min; p<0.0001).

Table 3: Characteristics Of Motor Blockade

Group	Mean±SD	P (One-way Anova)	Group Comparison	P
Time for Onset of Motor Block (MBG-1) (Min)				
Group RD (n=25)	1.37±0.45	0.023	RD compared to B	0.026
Group B (n=25)	1.69±0.53		RD compared to R	0.0136
Group R (n=25)	1.87±0.85		B compared to R	0.373
Time for complete Motor blockade (MBG-3) (Min)				
Group RD (n=25)	3.88±0.74	0.104	RD compared to B	0.13
Group B (n=25)	4.44±1.7		RD compared to R	0.012
Group R (n=25)	4.7±1.49		B compared to R	0.560
Total duration of motor blocked (Min)				
Group RD (n=25)	381±125.4	<0.001	RD compared to B	<0.0001
Group B (n=25)	237.6±47.4		RD compared to R	<0.0001
Group R (n=25)	235.2±34.2		B compared to R	0.838

(MBG = Modified Bromage Scale, One way ANOVA ; p < 0.05 = significant, p < 0.001 = highly significant, p > 0.05 = not significant).

Analgesia (Table 4): Time to first rescue analgesia was longest in Group RD (421.8 ± 66 min) versus Group B (379.2 ± 52.2 min; p=0.0147) and Group R (341.4 ± 58.8 min; p<0.001). Analgesic consumption was similar (p=0.14).

Table 4: Time To First Rescue Analgesia After Skin Closure (min)

Group	Mean±SD	P (One-way Anova)	Group Comparison	P
Time to first rescue analgesia after skin closure (Min)				
Group RD (n=25)	421.8±66	<0.001	RD compared to B	0.0147
Group B (n=25)	379.2±52.2		RD compared to R	< 0.0001
Group R (n=25)	341.4±58.8		B compared to R	0.020

(One way ANOVA ; p < 0.05 = significant, p < 0.001 = highly significant, p > 0.05 = not significant)

Adverse Events (Table 5): Hypotension occurred in 16% (RD), 28% (B), and 20% (R; p=0.574); bradycardia in 8%, 12%, and 4% (p=0.580); shivering in 16%, 24%, and 16% (p=0.704); and nausea/vomiting in 0%, 12%, and 8% (p=0.223). No neurological or hypersensitivity reactions were noted.

Table 5: Adverse Events

Complications	Group RD (n = 25)	Group B (n = 25)	Group R (n = 25)	P (Chi-square test)
Hypotension	4 (16 %)	7 (28%)	5 (20%)	0.574
Bradycardia	2 (8%)	3 (12%)	1 (4%)	0.580
Shivering	4 (16 %)	6(24%)	4 (16%)	0.704
Nausea & Vomiting	0	3(12%)	2(8%)	0.223
Pruritus And Urticaria	0	0	0	NA
Hypersensitivity Reaction	0	0	0	NA
Bronchospasm	0	0	0	NA

(Chi-square test ; $p < 0.05$ = significant, $p < 0.001$ = highly significant, $p > 0.05$ = not significant)

Haemodynamics: HR, SBP, DBP, and MAP declined intraoperatively ($p<0.05$ within groups) but were comparable between groups ($p>0.05$). RR and SpO_2 remained stable.

DISCUSSION

This study demonstrates that combining 3 µg dexmedetomidine with 0.75% hyperbaric ropivacaine (Group RD) significantly enhances spinal anaesthesia compared to hyperbaric ropivacaine (Group R) or bupivacaine (Group B) alone, offering faster block onset, extended sensory and motor blockade, prolonged postoperative analgesia, and a favourable safety profile. These findings position this combination as a valuable option for elective lower abdominal and limb surgeries, aligning with efforts to optimise anaesthesia for intraoperative efficacy and postoperative recovery, particularly in settings requiring extended surgical duration or effective pain management (Ghimire & Gyawali, 2019; Whiteside et al., 2003).

The faster sensory (2.55±1.1 min) and motor (1.37±0.45 min) block onset in Group RD compared to Group B (2.94±1.14 min; 1.69±0.53 min) and Group R (3.07±1.28 min; 1.87±0.85 min) highlights dexmedetomidine's synergistic effect with ropivacaine. As an α2-adrenergic agonist, dexmedetomidine likely enhances neural blockade by inhibiting nociceptive transmission in the spinal cord's dorsal horn (Kanazi et al., 2006). Gupta et al. (as cited in Chatterjee et al., 2014) reported a sensory onset of 1.67 min with isobaric ropivacaine plus 5 µg dexmedetomidine, slightly faster than our findings, possibly due to the higher dose used. Kulkarni et al. (2014) noted bupivacaine's sensory onset at T10 was marginally quicker than ropivacaine's (p=0.034), consistent with our Group B versus Group R results, yet Group RD's performance surpassed both, underscoring dexmedetomidine's potentiating role.

Group RD's prolonged sensory block duration (202.2±28.8 min) compared to Group B (174±36.6 min) and Group R (175.8±32.4 min) emphasises dexmedetomidine's ability to extend analgesia. This duration is shorter than Shashikala et al.'s (2019) 356.67 min for ropivacaine with dexmedetomidine, likely due to differences in sensory regression endpoints (L1 versus S2) or patient cohorts. Camorcia et al. (2005) reported bupivacaine's sensory duration at approximately 240 min, longer than our Group B, possibly reflecting variations in hyperbaricity or dosing. The motor block duration in Group RD (381±125.4 min) significantly exceeded Group B (237.6±47.4 min) and Group R (235.2±34.2 min), raising considerations for clinical use. While beneficial for prolonged surgeries, extended motor blockade may delay ambulation, a drawback in ambulatory settings (Latwal et al., 2020). Singh et al. (2015) observed a motor block duration of 382 min with isobaric ropivacaine plus 10 µg dexmedetomidine, closely matching our Group RD, suggesting dexmedetomidine's dose-dependent effect on motor block prolongation. This warrants further investigation into optimal dosing to balance block duration with recovery needs.

The extended time to first rescue analgesia in Group RD (421.8±66 min) compared to Group B (379.2±52.2 min) and Group R (341.4±58.8 min) reflects dexmedetomidine's robust postoperative analgesic effect, with 88% of Group RD patients requiring only paracetamol within 2 hours. Rahimzadeh et al. (2018) reported 496.63 min with bupivacaine plus 5 µg dexmedetomidine, supporting dexmedetomidine's efficacy. In contrast, Group R's analgesia duration (341.4 min) exceeds Chatterjee et al.'s (2014) 190.8 min for ropivacaine, likely due to our hyperbaric formulation enhancing block consistency. The similar analgesic consumption across groups (p=0.14) indicates that while dexmedetomidine delays pain onset, early postoperative needs may not differ significantly, consistent with Gupta et al.'s observations (as cited in Chatterjee et al., 2014).

Hyperbaric ropivacaine alone (Group R) showed comparable block quality to bupivacaine (Group B) but with faster motor recovery, supporting its role in ambulatory surgery. Whiteside et al. (2003) found ropivacaine's sensory block reached T7 versus bupivacaine's T5, but our study achieved T4 across groups, likely due to higher glucose concentration (80 mg/ml) enhancing cephalad spread. Dar et al. (2015) reported ropivacaine's motor block duration (126 min) shorter than bupivacaine's (174 min), aligning with our Group R versus Group B findings, reinforcing ropivacaine's suitability for rapid recovery.

Haemodynamic stability was comparable across groups, with Group RD exhibiting a transient systolic BP decrease (2-120 min, $p<0.01$), likely due to dexmedetomidine's sympatholytic effects (Kanazi et al., 2006). Intergroup differences diminished after 15 minutes, suggesting similar safety profiles, as seen in Latwal et al.'s (2020) study. Adverse events, including hypotension (16% RD, 28% B, 20% R) and bradycardia (8% RD, 12% B, 4% R), were less frequent in Group RD, though not significant ($p>0.05$). This aligns with Kulkarni et al.'s (2014) similar side effect profiles but contrasts with Yektaş et al.'s (2014) higher hypotension rates with dexmedetomidine. The absence of neurological or hypersensitivity reactions supports ropivacaine's safer toxicity profile compared to bupivacaine (Graf et al., 2002).

Limitations include the fixed 3 µg dexmedetomidine dose, potentially suboptimal for varying patient characteristics like height or weight. The small sample size (n=75) and ASA I-II restriction limit generalisability to higher-risk groups. Surgical duration variability (15-150 min) may have influenced outcomes, despite group comparability (p=0.17). Lack of surgeon satisfaction data on block quality and short-term follow-up (2 hours) are gaps. Future research should investigate dexmedetomidine dose-ranging (2-5 µg), patient-specific dosing, extended analgesia (e.g., 24 hours), and ASA III inclusion to enhance applicability.

Clinically, Group RD suits prolonged surgeries (e.g., orthopaedic, complex abdominal) by reducing intraoperative supplementation and postoperative opioids. Group R's rapid recovery fits ambulatory settings, meeting efficiency demands. Group B, while effective, is less favourable due to prolonged motor block and toxicity risks. These findings advance personalised anaesthesia strategies, optimising efficacy, safety, and recovery.

CONCLUSIONS

The intrathecal application of 0.75% hyperbaric ropivacaine in conjunction with 3 mcg dexmedetomidine has been shown to surpass the efficacy of using hyperbaric ropivacaine or bupivacaine alone. This combination facilitates a swift onset of anaesthesia, extends the duration of both sensory and motor blockade, and ensures prolonged postoperative pain relief, all while maintaining stable haemodynamic parameters and minimal adverse effects. This anaesthetic approach is particularly beneficial for elective surgeries of the lower limbs and abdomen that necessitate prolonged anaesthetic coverage. In contrast, hyperbaric ropivacaine alone offers similar effectiveness with a reduced recovery time, making it suitable for outpatient procedures. Bupivacaine, despite its limitations, remains a dependable choice. These results underscore the importance of tailoring anaesthetic selection to the specific duration of the surgical procedure and the recovery goals of the patient, thereby optimising perioperative management.

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