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Anaesthesia Section

Analgesic Efficacy of Hyperbaric Ropivacaine versus Hyperbaric Bupivacaine with Fentanyl in Infraumbilical Surgeries under Spinal Anaesthesia: A Double-blinded Randomised Clinical Trial

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ABSTRACT

Introduction: Spinal anaesthesia is a preferred technique for infraumbilical surgeries because of its rapid onset, reliable action, and minimal systemic effects. Although hyperbaric bupivacaine provides effective sensory and motor blockade, its association with hypotension and bradycardia has prompted interest in alternatives such as hyperbaric ropivacaine, which offers comparable anaesthesia with potentially better haemodynamic stability.

Aim: To compare the haemodynamic effects and analgesic efficacy of hyperbaric bupivacaine and hyperbaric ropivacaine, both combined with fentanyl, in patients undergoing infraumbilical surgeries under spinal anaesthesia.

Materials and Methods: This randomised, double-blind clinical trial included 70 patients undergoing elective infraumbilical surgeries over a period of two years at Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim, India. Patients were equally allocated to receive spinal anaesthesia with either hyperbaric bupivacaine 0.5% or hyperbaric ropivacaine 0.75%, both combined with 25 µg fentanyl. Sensory and motor block onset times, intraoperative haemodynamic parameters, side-effects, and postoperative pain scores assessed using the Numeric Rating Scale (NRS) . Data were compared between groups using the unpaired Student's t-test, with p-value <0.05 considered statistically significant.

Results: The mean age was 39.7±12.6 years in Group B and 44.0±11.7 years in Group R (p-value=0.141). Bupivacaine demonstrated a significantly faster onset of sensory blockade (3.55±0.19 vs 4.10±0.27 minutes; p-value <0.001) and motor blockade (6.91±0.25 vs 9.85±0.24 minutes; p-value <0.001), as well as a longer time to first rescue analgesia (227.8±8.7 vs 209.9±6.9 minutes; p-value <0.001). Although hypotension occurred more frequently in the bupivacaine group (42.85% vs 25.71%), the difference was not statistically significant. Postoperative pain scores were comparable between the two groups at all assessed time intervals.

Conclusion: Both anaesthetic agents provided effective spinal anaesthesia for infraumbilical surgeries. Hyperbaric bupivacaine offered a faster onset of block and longer duration of analgesia, whereas hyperbaric ropivacaine demonstrated better haemodynamic stability, making it a suitable option for patients requiring rapid recovery or those with cardiovascular risk factors.

Keywords: Haemodynamics, hypotension, Opioid

INTRODUCTION

Spinal anaesthesia remains a fundamental technique for infraumbilical procedures, as it provides rapid, reliable, and effective surgical anaesthesia with minimal systemic effects. Hyperbaric bupivacaine has long been a popular local anaesthetic due to its consistent sensory and motor blockade [1]. However, its association with significant hypotension and bradycardia, particularly in susceptible patient populations, has prompted the search for safer alternatives. In this context, hyperbaric ropivacaine has emerged as a viable option [2].

Ropivacaine differs from bupivacaine in that it is less cardiotoxic and less neurotoxic while still producing effective spinal blocks [3]. These properties make ropivacaine especially suitable for ambulatory and day-care surgeries, where early patient discharge is desirable [4]. Furthermore, its favourable haemodynamic profile has expanded its use in elderly patients and those with cardiovascular compromise, in whom excessive reductions in blood pressure may have serious consequences [5].

The addition of adjuvants such as fentanyl, an opioid receptor agonist, to spinal anaesthetics has been shown to improve intraoperative and postoperative analgesia. Due to its high lipid solubility, fentanyl enhances intraoperative analgesia and provides effective early postoperative pain relief without prolonging motor blockade or increasing the risk of delayed respiratory depression associated with more hydrophilic opioids [6]. When combined with bupivacaine or ropivacaine, fentanyl enhances the quality of the block, reduces postoperative analgesic requirements, and decreases the incidence of adverse effects such as nausea and shivering, thereby improving patient comfort and satisfaction [7].

Several studies have reported that hyperbaric ropivacaine is associated with a lower incidence of hypotension and bradycardia during spinal anaesthesia, while providing surgical anaesthesia comparable to bupivacaine, albeit with differences in block regression and recovery times [8]. These variations highlight the need for direct comparative studies evaluating these agents in contemporary clinical settings, particularly when fentanyl is used as a standardised adjuvant.

A randomised double-blind study involving 60 patients undergoing major lower limb orthopaedic surgeries demonstrated that ropivacaine-fentanyl (15 mg + 25 µg) provided a similar duration of sensory blockade but significantly shorter motor block recovery (242.8 vs 268 minutes) and better haemodynamic stability compared

to bupivacaine-fentanyl [9]. Another study comparing hyperbaric ropivacaine and bupivacaine (15 mg each) concluded that ropivacaine provided reliable spinal anaesthesia of shorter duration, making it advantageous in cases requiring early mobilisation [10]. Plain bupivacaine (10 mg) has been reported to produce longer recovery profiles than ropivacaine, with or without the addition of sufentanil [11].

A 2025 study on infraumbilical surgeries found that 0.75% hyperbaric ropivacaine combined with fentanyl allowed faster motor recovery [12]. Similarly, hyperbaric ropivacaine 0.75% was shown to be a comparable alternative to hyperbaric bupivacaine 0.5% in lower limb orthopaedic surgeries, with a faster onset and shorter duration of block [13]. Despite the widespread use of both agents, there remains a paucity of data directly comparing their haemodynamic effects and analgesic efficacy in hyperbaric formulations, particularly when combined with fentanyl, in infraumbilical surgeries.

The present study aimed to compare the haemodynamic effects and analgesic efficacy of hyperbaric bupivacaine and hyperbaric ropivacaine, both combined with fentanyl, in infraumbilical surgeries. The primary objective was to compare haemodynamic parameters between the two regimens, while the secondary objectives included assessment of analgesic efficacy using NRS scores, sensory and motor block characteristics, adverse haemodynamic effects, and intraoperative complications.

MATERIALS AND METHODS

This randomised, double-blinded clinical trial was conducted at Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim, India over a period of 24 months (November 2022 to October 2024), prospectively registered with the Clinical Trials Registry of India (CTRI/2022/11/047760), with ethical approval from the Institutional Ethics Committee (SMIMS/IEC/2022-111) and all participants provided written informed consent before enrollment.

Sample size calculation: The sample size was calculated using the formula for comparing two proportions:

$$n=\frac{(r+1)\,(p^*)\,(1-p^*)\,(Z_\beta+Z_{\alpha/2})^2}{r(p_1-p_2)^2}$$

Where:

- $Z_{\alpha/2}^\circ$ = 2.576 (Z-value for 99% confidence level, α = 0.01, two-tailed)
- Z_β° = 1.282 (Z-value for 90% statistical power, β = 0.10)
- p_1° = 0.66 (proportion of haemodynamic complications in the hyperbaric bupivacaine group, based on previous literature) [14]
- p_2° = 0.19 (proportion of haemodynamic complications in the hyperbaric ropivacaine group, based on previous literature) [14];
- $p^{*\circ} = (p_1 + p_2)/2 = 0.425$ (pooled proportion)
- $r^\circ = 1$ (ratio of sample sizes, equal allocation)
- Effect size $(p_1 - p_2) = 0.47$

Substituting these values:

$$n=\frac{(1+1)\,(0.425)\,(0.575)\,(1.282+2.576)^2}{1(0.47)^2}$$

$$n=\frac{(2)(0.425)(0.575)(14.525)}{0.2209}=\frac{6.05}{0.2209}\approx 27.4$$

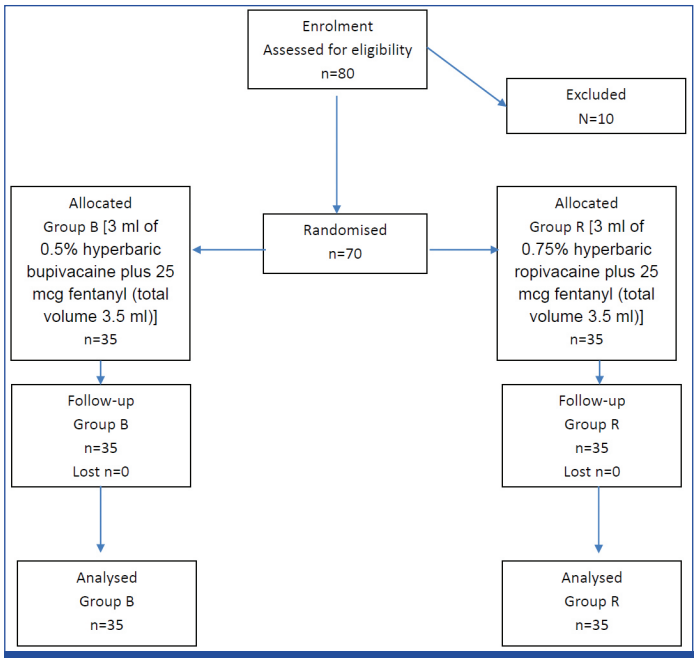
Accounting for a 10% potential dropout rate, the calculated sample size was 35 patients per group, yielding a total of 70 patients.

Inclusion criteria: Adults of either sex classified as American Society of Anaesthesiologists (ASA) physical status Grade I or II, scheduled for infraumbilical procedures, were included in the study.

Exclusion criteria: Patient refusal, known coagulation disorders, allergy to local anaesthetics, severe stenotic valvular heart disease, and uncooperative behaviour were excluded from the study.

Group Allocation and Blinding

As shown in [Table/Fig-1], 80 patients were assessed for eligibility, 10 were excluded, and 70 were randomised equally into Group B (bupivacaine) and Group R (ropivacaine). There were no losses to follow-up, and all 35 patients in each group completed the study.



[Table/Fig-1]: CONSORT flow diagram.

Participants were randomly assigned to one of the two groups using a computer-generated randomisation sequence with a 1:1 allocation ratio, prepared by an independent statistician who was not involved in patient enrolment, clinical management, or outcome assessment. Allocation concealment was ensured by having an impartial anaesthesiologist, who was not involved in patient care, open sealed, opaque, sequentially numbered envelopes immediately before spinal anaesthesia administration. Both patients and outcome assessors, including those recording pain scores and recovery parameters, were blinded to group allocation to minimise bias.

Study Procedure

Preoperative assessment included a detailed medical and surgical history, clinical examination, and measurement of vital signs (blood pressure, heart rate (HR), SpO_2, and respiratory rate). Peripheral intravenous access was established, and patients were preloaded with intravenous crystalloids (Hartmann's solution or normal saline) at 10 mL/kg body weight. In the operating room, continuous non invasive blood pressure monitoring, electrocardiography, and pulse oximetry were performed at 3-minute intervals for the first 10 minutes, then every 5 minutes for 20 minutes, every 10 minutes until one hour, and every 15 minutes thereafter. After strict aseptic preparation of the lumbar region (7.5% povidone-iodine followed by >70% ethyl alcohol) and local infiltration with 2 mL of 2% lignocaine, spinal puncture was performed at the L3-L4 intervertebral space using a 25-gauge spinal needle via the midline approach.

Group R received 3 mL of 0.75% hyperbaric ropivacaine plus 25 µg fentanyl (total volume 3.5 mL).

Group B received 3 mL of 0.5% hyperbaric bupivacaine plus 25 µg fentanyl (total volume 3.5 mL) [15].

Haemodynamic parameters (systolic blood pressure, diastolic blood pressure, Mean Arterial Pressure (MAP), and HR) were recorded at baseline (0), 3, 6, 9, 15, 20, 25, 30, 40, 50, and 60 minutes intraoperatively. Sensory block onset (time to reach T10 dermatome using cold discrimination), motor block onset (Bromage scale 3), and time to complete motor recovery (Bromage scale 0) were noted.

Postoperative pain was assessed using NRS (NRS: 0-10) at 1, 2, 4, 8, 12, and 24 hours.

STATISTICAL ANALYSIS

Data quality was ensured through screening for consistency and completeness before entry into Microsoft Excel and organisation into a master chart. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 21.0. Continuous variables (age, Body Mass Index (BMI), haemodynamic parameters, block onset/recovery times, pain scores) were expressed as mean±standard deviation, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were examined using the Chi-square test, and continuous variables between groups were compared using the unpaired Student's t-test. A p-value <0.05 was considered as statistically significant.

RESULTS

There were no significant differences in age or gender distribution between group B and group R. The mean age was 39.7±12.6 years in Group B and 44.0±11.7 years in Group R (p-value =0.141) [Table/Fig-2].

Variable		Group B n (%)	Group R n (%)	p-value
Gender	Male	17 (48.6)	18 (51.4)	0.811*
	Female	18 (51.4)	17 (48.6)	
Age (years)	Mean±SD	39.7±12.6	44.0±11.7	0.141#
ASA Grade	I	25 (71.4)	22(62.9)	0.610*
	II	10 (28.6)	13 (37.1)	

[Table/Fig-2]: Comparison of patient demography between group B and group R.
*Chi-square #Unpaired t-test

[Table/Fig-3] demonstrates the trends of MAP and HR over time for both groups. Both groups had similar baseline MAP and HR values preoperatively. Although MAP and HR declined over time in both groups after spinal anaesthesia, the overall trends remained comparable throughout the monitoring period. No clinically significant haemodynamic instability was observed in either group.

Time point	Heart rate Group B	Heart rate Group R	Heart rate p-value	MAP Group B	MAP Group R	MAP p-value
Preoperative	81.4	83	0.659	96.5	96.5	1
0 min	82.3	90.7	0.062	90.5	95.4	0.13
3 mins	79.6	85.2	0.156	84.3	90.1	0.083
6 mins	76.2	83	0.068	82.6	84.2	0.637
9 mins	76.2	79.5	0.373	80.2	84.5	0.198
15 mins	76.4	74.5	0.603	80.7	85.6	0.14
20 mins	74	75.7	0.624	78	82.7	0.121
25 mins	74.3	75.3	0.768	81.2	82.1	0.768
30 mins	74.7	73.7	0.756	80.4	83.5	0.268
40 mins	74.1	72.4	0.653	79.2	81.1	0.551
50 mins	76	69.7	0.103	80	84.5	0.14
60 mins	75.8	71.1	0.233	81	85.3	0.143

[Table/Fig-3]: Comparison of trends of Mean Arterial Pressure (MAP) and Heart Rate (HR) between group B and group R.

[Table/Fig-4] shows that group B (bupivacaine) had a significantly faster onset of sensory (3.55±0.19 minutes) and motor block (6.91±0.25 minutes) compared to group R (ropivacaine; 4.10±0.27 minutes and 9.85±0.24 minutes, respectively; both p-value <0.001). The time to first rescue analgesia was longer in group B (227.8±8.7 minutes) than in group R (209.9±6.9 minutes; p-value <0.001). Intraoperative hypotension was more frequent in Group B (42.85% vs. 25.71%), but this difference was not statistically significant. No cases of postoperative nausea or vomiting were observed in either group.

Parameters	Group B	Group R	p-value
Sensory block			
Onset at T10 (mins)	3.55±0.19	4.10±0.27	<0.001*
Motor block			
Onset at T10 (mins)	6.91±0.25	9.85±0.24	<0.001*
Duration of surgery (mins)	114± 51.1	100.9±46.6	0.265*
Time for first rescue analgesia (mins)	227.8±8.7	209.9±6.9	<0.001*
Intraoperative side-effects (%)			
Hypotension	15 (42.85)	9 (25.71)	0.131®
Post-operative Nausea and Vomiting (PONV)	0	0	N/A

[Table/Fig-4]: Comparison of anaesthetic efficacy and intraoperative effects of Bupivacaine vs Ropivacaine.
*Unpaired t-test, ®Chi-square test, p<0.05 is statistically significant

Postoperative pain, assessed using the NRS, was low and comparable in both groups at all time points from 1 to 24 hours postoperatively, with no statistically significant differences observed between Group B and Group R (p-value >0.05 for all comparisons) [Table/Fig-5].

Time point	Group B Mean±SD	Group R Mean±SD	p-value#
Postop-1 h	1.0±1.8	0.9±1.7	0.84
Postop-2 hrs	2.2±1.9	1.8±1.8	0.446
Postop-4 hrs	3.3±1.1	3.0±1.3	0.275
Postop-8 hrs	2.9±1.1	3.1±1.3	0.363
Postop-12 hrs	2.9±1.3	2.7±1.2	0.704
Postop-24 hrs	2.7±1.0	2.3±1.4	0.123

[Table/Fig-5]: Numeric Rating Scale (NRS) scores for postoperative pain assessment at various time points in group B and group R.
#Unpaired t-test

DISCUSSION

In the present study, bupivacaine demonstrated a significantly faster onset of both sensory block (3.55±0.19 minutes) and motor block (6.91±0.25 minutes) compared to ropivacaine (4.10±0.27 and 9.85±0.24 minutes, respectively; both p-value <0.001). These findings are consistent with multiple published studies comparing these agents. Danelli G et al., reported similar results in caesarean deliveries, with faster motor block onset following bupivacaine (8±2 minutes) compared to ropivacaine (12±5 minutes) [16]. A meta-analysis by Anand R et al., similarly documented a delayed onset of complete motor blockade with ropivacaine, although sensory onset times were comparable between the two agents [3]. The pharmacological basis for this difference relates to the lipophilicity and chemical structure of these local anaesthetics.

An important finding of this study was the prolonged time to first rescue analgesia in the bupivacaine group (227.8±8.7 minutes) compared to ropivacaine (209.9±6.9 minutes; p-value <0.001). This differential duration of approximately 18 minutes reflects the established longer duration of action of bupivacaine. Similar findings have been reported in the literature. McNamee DA et al., found a median sensory block duration of 3.5 hours in the bupivacaine group versus 3.0 hours in the ropivacaine group (p-value <0.0001) [17]. Anand R et al., also confirmed this pattern, documenting significantly shorter sensory regression times and analgesia duration with ropivacaine compared to bupivacaine [3].

Both study groups maintained comparable baseline MAP and HR preoperatively, with similar haemodynamic trends throughout the monitoring period. However, intraoperative hypotension was numerically more frequent in Group B (42.85%) compared to

Group R (25.71%), although this difference did not reach statistical significance (p-value=0.131). This observation aligns with the study by Hashemian M et al., which demonstrated that ropivacaine reduces the incidence of hypotension during spinal anaesthesia compared to bupivacaine in caesarean sections. The authors attributed this to ropivacaine's lower lipophilicity and reduced autonomic blockade [18]. Furthermore, Sorout D et al., concluded that while bupivacaine is suited for long-duration surgeries, ropivacaine is preferable for shorter procedures or for patients with cardiovascular risks due to its enhanced haemodynamic stability [19]. These findings suggest that in haemodynamically vulnerable populations, ropivacaine may offer clinical advantages despite its shorter duration of action.

Postoperative pain, assessed using the NRS, demonstrated comparable pain relief between both groups at all time points from 1 to 24 hours (p-value >0.05 for all comparisons). Mean NRS scores ranged from 1.0 to 3.3 in group B and 0.9 to 3.1 in group R.

In contrast, Danelli G et al., found that median 24-hour morphine consumption was higher in ropivacaine recipients (5 mg; range 0-18 mg) compared to bupivacaine recipients (2 mg; range 0-7 mg) (p p-value <0.01), suggesting longer-lasting analgesia with bupivacaine [16]. However, Olapour A et al., , using higher doses for caesarean delivery, reported comparable pain control between the groups [20]. These discrepancies may relate to differences in patient populations, surgical procedures, rescue medication protocols, and analgesic regimens employed across studies.

Bhat SN et al., noted that while ropivacaine showed faster onset of sensory regression, the duration of motor blockade was significantly shorter in the ropivacaine group, with excellent analgesia and stable haemodynamics [21]. However, the prolonged duration of bupivacaine action makes it preferable for longer procedures. Lim Y et al., demonstrated that intrathecal 2.5 mg bupivacaine significantly prolonged the duration of labour analgesia compared with ropivacaine or levobupivacaine [22].

Other studies highlight potential advantages of ropivacaine. Gohil PJ et al., reported that ropivacaine 0.75% produced faster sensory block onset (2.6±0.53 minutes) compared to bupivacaine 0.5% (3±0.56 minutes; p-value=0.006), although this contradicts the findings of the present study [13]. Nagaraju A et al., found that ropivacaine provided better haemodynamic stability, fewer adverse effects, and prolonged analgesia in epidural applications, making it a safer alternative despite faster onset times in their study [23]. Spoorthi KC, reported the time to first rescue analgesia in the bupivacaine group as 409.71±85.15 minutes versus 445.71±77.74 minutes in the ropivacaine group (p-value=0.0069), though the statistical significance was questioned. This contrasts with the present study, which showed an advantage with bupivacaine (227.8±8.7 vs. 209.9±6.9 minutes) [24]. These differences may reflect variations in dosing protocols, patient populations, and definitions of adequate analgesia requiring intervention.

This study suggests that hyperbaric ropivacaine with fentanyl is a clinically useful alternative to hyperbaric bupivacaine with fentanyl for infraumbilical surgeries, with potential advantages in haemodynamic stability and recovery. Future research should confirm these results in larger and higher-risk populations and refine optimal dosing regimens.

Limitation(s)

The moderate sample size may limit the generalisability of the findings, and exclusion of patients with higher ASA grades restricts applicability to high-risk populations. Variability in surgical procedures and anaesthetic dosing could introduce confounding factors.

CONCLUSION(S)

Both bupivacaine and ropivacaine provided effective sensory and motor block during infraumbilical surgery. Bupivacaine demonstrated faster block onset and a longer duration until the first rescue analgesia. Postoperative pain assessments were similar between groups, with no significant differences in safety or efficacy other than block onset and analgesia duration. Ropivacaine, however, offers better haemodynamic stability and a more favourable safety profile, making it suitable for shorter surgeries and for patients requiring quicker recovery.

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