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Hemodynamics and Analgesia of Hyperbaric Bupivacaine vs Hyperbaric Ropivacaine with Fentanyl in Spinal Anesthesia

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Abstract

Introduction: Spinal anesthesia is a preferred technique for infraumbilical surgeries due to its rapid, reliable action and minimal systemic effects. While hyperbaric bupivacaine provides effective sensory and motor blockade, its potential for hypotension and bradycardia has led to interest in alternatives like hyperbaric ropivacaine, which offers comparable anesthesia with potentially better hemodynamic stability. This study aimed to compare the hemodynamic effects and analgesic efficacy of hyperbaric bupivacaine and ropivacaine, both combined with fentanyl, in infraumbilical surgeries.

Methodology: In this randomized, double-blind trial, 70 patients undergoing elective infraumbilical surgeries were allocated equally to receive spinal anesthesia with either hyperbaric bupivacaine 0.5% or hyperbaric ropivacaine 0.75%, both with 25 mcg fentanyl. Sensory and motor block onset times, intraoperative hemodynamics, side effects, and postoperative pain scores via Numeric Rating Scale (NRS) were recorded and analyzed.

Results: Groups were comparable demographically. Bupivacaine had a significantly faster onset of sensory (3.55 ± 0.19 vs 4.10 ± 0.27 min, P<0.001) and motor blockade (6.91 ± 0.25 vs 9.85 ± 0.24 min, P<0.001) and longer time to first rescue analgesia (227.8 ± 8.7 vs 209.9 ± 6.9 min, P<0.001). Although hypotension was more frequent with bupivacaine (42.85% vs 25.71%), differences were not statistically significant. Postoperative pain scores were similar in both groups at all assessed intervals.

Conclusion: Both anesthetics provide effective spinal anesthesia in infraumbilical surgeries. Bupivacaine offers faster block onset and longer analgesia, while ropivacaine presents improved hemodynamic stability, making it suitable for patients needing rapid recovery or cardiovascular caution.

Keywords: ***Spinal anesthesia; Bupivacaine; Ropivacaine; Infraumbilical surgery; Numeric rating scale (NRS)***

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1. Introduction

For infraumbilical procedures, spinal anesthesia is still a fundamental technique because it provides quick, reliable, and efficient surgical anesthetic with little systemic effect. Hyperbaric bupivacaine has long been a popular choice among local anesthetics due to its consistent sensory and motor block [1]. But because of its link to severe bradycardia and hypotension, especially in susceptible patient groups, doctors are looking for substitutes that might have a better safety record. In this respect, hyperbaric ropivacaine has become a viable option [2]. It differs from bupivacaine in that it is less harmful to the heart and central nervous system while still producing efficient spinal blocks [3]. This quality makes ropivacaine especially suitable in ambulatory surgical settings or for day-care surgeries, where early patient discharge is desirable [4]. Furthermore, its favorable hemodynamic profile has broadened its application in elderly and cardiovascularly compromised patients, where excessive drops in blood pressure can have serious consequences [5].

The use of adjuvants, such as the opioid receptor agonist fentanyl, in conjunction with spinal anesthetic has improved postoperative results. Due to its high lipid solubility, fentanyl provides better analgesia during surgery and the early postoperative period without the longer motor block or higher risk of delayed respiratory depression associated with more hydrophilic opioids [6]. In addition to intensifying the block, fentanyl lowers the overall postoperative analgesic need and the frequency of adverse effects like nausea and shivering when taken with ropivacaine or bupivacaine. This improves patient comfort and satisfaction [7].

Ropivacaine, particularly in its hyperbaric formulation, is associated with significantly lower incidences of hypotension and bradycardia during spinal anesthesia, while others confirm its equivalence to bupivacaine in terms of surgical anesthesia quality but highlight differences in recovery times and block regression [8]. These variances underscore the need for direct, head-to-head studies evaluating these agents in a contemporary clinical context, especially with fentanyl as a standardized adjuvant.

Therefore, this study is designed to compare the hemodynamic parameters and analgesic efficacy of hyperbaric ropivacaine with those of hyperbaric bupivacaine, both administered intrathecally with fentanyl, in patients undergoing infraumbilical surgeries.

2. Methodology

This randomized, double-blinded clinical trial was conducted on patients scheduled for elective infraumbilical surgeries under spinal anesthesia within the study period. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI/2022/11/047760). Ethical approval was obtained from the institutional ethics committee, and all participants provided written informed consent.

2.1 Participant flow

Overall, 80 patients were eligible as per criteria. Of these, 10 subjects were excluded due to being unfit for surgery (n=2) or conversion to general anesthesia (n=8). Seventy eligible participants were randomized equally into two groups. Both Group B (bupivacaine) and Group R (ropivacaine) included 35 patients each, all of whom received their allocated intervention. No

patients were lost to follow-up or discontinued the intervention in either group. For analysis, data from 30 patients in each group were included, with no exclusions reported.

2.2 Inclusion and exclusion criteria

Adults of either sex classified as American Society of Anesthesiologists (ASA) physical status Grade I or II, slated for infraumbilical procedures, were eligible. Exclusion criteria included patient refusal, known coagulation disorders, allergy to local anesthetics, severe stenotic valvular heart disease, and uncooperative behavior.

2.3 Group allocation

Using a computer-generated randomization sequence, participants were randomly assigned to one of two groups: Group B received bupivacaine, while Group R received ropivacaine. An impartial anesthesiologist opened sealed, opaque, and sequentially numbered envelopes only before administering anesthesia, ensuring allocation concealment. To reduce bias, both patients and outcome assessors were kept unaware of the group allocation.

2.4 Sample size calculation

Sample size was determined using the formula:

$$N = \frac{\left[Z_{\alpha/2}\sqrt{(r+1)p(1-p)} + Z_{\beta}\sqrt{rp_0(1-p_0) + p_1(1-p_1)}\right]^2}{r(p_0 - p_1)^2}$$

Where:

- Zα/2$Z\alpha/2$: Z-value for significance level (α=0.01)
- Zβ$Z\beta$: Z-value for power (β=0.01)
- p0$p0$: Proportion of complications in Bupivacaine group (66%)
- p1$p1$: Proportion of complications in Ropivacaine group (19%)
- rr: Ratio of population 2 to population 1

The study assumed a 99% confidence interval and 90% power, yielding a calculated sample size of 35 patients per group to ensure adequate power for detecting significant differences with minimal error.

2.5 Preoperative assessment

All patients underwent comprehensive pre-anesthetic evaluation encompassing detailed medical and surgical histories, clinical examination, and vital signs monitoring (blood pressure, heart rate, SpO2). Preoperative investigations included blood grouping, coagulation profiles, viral serology, complete blood counts, ECG, and, when indicated, 2D echocardiography and chest X-ray. Peripheral intravenous access was established with an 18-20 gauge cannula. Patients were preloaded with intravenous crystalloids tailored to their preoperative assessment.

2.6 Intraoperative procedure

In the operating room, continuous monitoring of blood pressure (non-invasive), heart rate (ECG), and oxygen saturation by pulse oximetry was performed at 3-minute intervals for the initial 10 minutes, then every 5 minutes for 20 minutes, followed by every 10 minutes until one hour, and every 15 minutes thereafter until surgery completion. Temperature was monitored with skin probes as needed, and oxygen was administered by facemask at 4-5 L/min.

Patients were positioned sitting, and strict asepsis was maintained with lumbar cleaning using 7.5% povidone-iodine and >70% ethyl alcohol. The L3-L4 intervertebral space was located via palpation. After local infiltration with 2 ml of 2% lignocaine, a 25-gauge spinal needle was inserted using a midline approach. Upon confirmation of free cerebrospinal fluid flow, Group R received 3 ml of 0.75% hyperbaric ropivacaine and Group B received 3 ml of 0.5% hyperbaric bupivacaine; both groups received 25 mcg fentanyl added to the anesthetic, making a total volume of 3.5 ml.

2.7 Monitoring and block assessment

Hemodynamic parameters were closely monitored throughout. Sensory block onset was tested using cold swabs and skin pinching at the T10 dermatome. Motor block onset was evaluated by the time to achieve Bromage score 3. Hypotension, defined as mean arterial pressure below 65 mmHg or a reduction >20% from baseline, was treated with 6 mg IV mephentermine boluses. Bradycardia (heart rate <40 bpm) was managed with 0.6 mg IV atropine. Intravenous fluids were adjusted based on surgical and patient needs.

2.8 Data collection and statistical analysis

Parameters such as sensory and motor block onset times, duration to regression, hemodynamic changes, and adverse events were meticulously recorded. Data were entered into MS Excel and analyzed using SPSS v21.0. Continuous variables were expressed as mean ± standard deviation, and categorical variables as percentages. Associations between categorical variables were tested using Chi-square tests, while unpaired t-tests compared group means. Statistical significance was set at $P<0.05$.

3. Results

There were no significant differences in age or gender distribution between the Bupivacaine group (Group B) and the Ropivacaine group (Group R). The mean age was 39.7 ± 12.6 years in Group B and 44.0 ± 11.7 years in Group R ($P=0.141$). Both groups had a near-equal distribution of male and female patients ($P=0.811$), indicating successful randomization and demographic comparability (TABLE 1).

FIG. 1 demonstrates the trends of mean arterial pressure (MAP) and heart rate (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 anesthesia, the overall trends remained comparable throughout the monitoring period. No clinically significant hemodynamic instability was observed in either group.

TABLE 2 shows Anaesthetic Efficacy and Intraoperative Effects in which Group B exhibited a significantly faster onset of both sensory block (3.55 ± 0.19 min vs 4.10 ± 0.27 min; P<0.001) and motor block (6.91 ± 0.25 min vs 9.85 ± 0.24 min; P<0.001) compared to Group R. The duration of surgery was slightly longer in Group B but not statistically significant (114 ± 51.1 min vs 100.9 ± 46.6 min; P=0.265). The time to first rescue analgesia was significantly prolonged in Group B (227.8 ± 8.7 min) compared to Group R (209.9 ± 6.9 min, P<0.001).

The incidence of intraoperative hypotension was higher in Group B (42.85%) than Group R (25.71%), though this difference was not statistically significant (P=0.131). No cases of post-operative nausea and vomiting (PONV) were reported in either group.

Postoperative pain, measured using the Numeric Rating Scale (NRS), was comparable between the two groups at all measured time points (1 to 24 hours postoperatively). Median NRS scores remained low in both groups, with no statistically significant differences at any time interval (P>0.05 for all comparisons). For example, at 1 hour postoperatively, the NRS scores were 1.0 ± 1.8 in Group B and 0.9 ± 1.7 in Group R (P=0.84); at 24 hours, scores were 2.7 ± 1.0 (Group B) and 2.3 ± 1.4 (Group R), P=0.123 (TABLE 3).

TABLE 1. **Comparison of patient demography between B-group and R-group.**

Variable		**Group B (N=35)**	**Group R (N=35)**	**Statistical Test**	**P value**
Gender	**Male**	17 (48.6%)	18 (51.4%)	Chi-square	0.811
	Female	18 (51.4%)	17 (48.6%)		
Age	**Mean ± SD**	39.7 ± 12.6	44.0 ± 11.7	Unpaired t-test	0.141

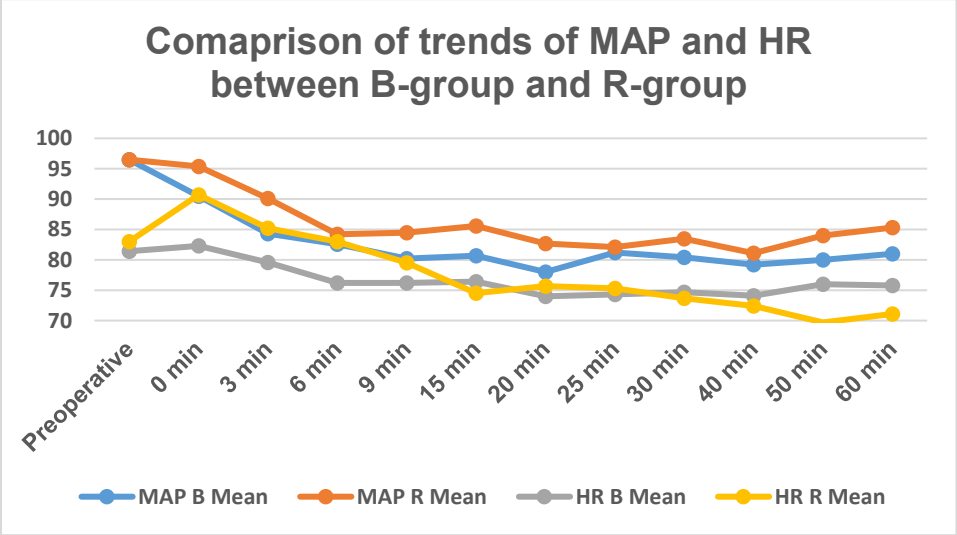

FIG. 1. **Comparison of trends of MAP (Mean Arterial Pressure) and HR (Heart Rate) between B-group and R-group.**

TABLE 2. **Comparison of Anaesthetic Efficacy and Intraoperative Effects of Bupivacaine vs Ropivacaine.**

Parameters	Group B	Group R	p-value
Sensory block			
Onset at T10 (min)	3.55 ± 0.19	4.10 ± 0.27	<0.001*
Motor block			
Onset at T10 (min)	6.91 ± 0.25	9.85 ± 0.24	<0.001*
Duration of Surgery(min)	114 ± 51.1	100.9 ± 46.6	0.265*
Time for first rescue analgesia	227.8 ± 8.7	209.9 ± 6.9	<0.001*
Intraoperative side effects (%)			
Hypotension	15(42.85%)	9(25.71%)	0.131®
PONV (Post-operative Nausea and vomiting)	0(0%)	0(0%)	N/A
*Unpaired t test, ®Chi-square test, p<0.05 is statistically significant			

TABLE 3. **Numeric Rating Scale (NRS) Scores for Postoperative Pain Assessment at Various Time Points in Group B and Group R.**

Time Point	GROUP B Mean ± SD	GROUP R Mean ± SD	P value
Postop-1hr	1.0 ± 1.8	0.9 ± 1.7	0.84
Postop-2hr	2.2 ± 1.9	1.8 ± 1.8	0.446
Postop-4hr	3.3 ± 1.1	3.0 ± 1.3	0.275
Postop-8hr	2.9 ± 1.1	3.1 ± 1.3	0.363
Postop-12hr	2.9 ± 1.3	2.7 ± 1.2	0.704
Postop-24hr	2.7 ± 1.0	2.3 ± 1.4	0.123

4. Discussion

Our findings are supported by several studies that show bupivacaine causes both sensory and motor blocks to occur more quickly than ropivacaine. In a prospective, randomized research conducted by Bhat et al. [9], bupivacaine demonstrated a substantially longer duration and a faster onset for both sensory and motor blockage. Jaafarpour et al. [8] conducted a systematic review and meta-analysis and found that ropivacaine's slightly slower onset supports its use in cases where early ambulation is desired, while bupivacaine is linked to a faster sensory and motor block onset at the expense of more frequent cardiovascular effects.

A meta-analysis by Anand et al. concluded data from 8 randomized controlled trials (RCTs) selected from 119 studies, rigorously assessing sensory and motor block characteristics, analgesic duration, and side effect profiles of hyperbaric

bupivacaine versus hyperbaric ropivacaine in cesarean sections. The meta-analysis demonstrated that the onset of sensory blockade between the two agents showed no statistically significant difference (P=0.1586), indicating comparable efficacy in the initiation of sensory anesthesia. This finding aligns with the present study and multiple prior investigations showing similar sensory-block onset times, as seen in infraumbilical and other regional anesthesia procedures [3]. In line with our findings of longer block duration and analgesia with bupivacaine, this systematic analysis done by Nair et al [10]. emphasizes that low doses (4 mg - 5 mg) of hyperbaric bupivacaine with unilateral positioning allow for successful spinal anesthetic and quicker recovery for knee arthroscopy. Similar to this review, ropivacaine's shorter duration and good safety profile were supported by the fact that neither adjuvant addition nor ropivacaine significantly improved recovery time. Both findings highlight the necessity for standardized RCTs to improve clinical procedures by emphasizing the importance of balancing dosage and location to maximize anesthesia while reducing adverse effects and delayed recovery.

Although it may not always approach statistical significance, our results showing ropivacaine is linked to less hypotensive episodes are in line with previous research. In their systematic review and meta-analysis, Jaafarpour et al. [8] found that ropivacaine offers more stable intraoperative hemodynamics than bupivacaine, with a lower risk of bradycardia and hypotension. According to Sorout et al. [11], patients undergoing lower limb orthopedic procedures who received ropivacaine experienced noticeably less bradycardic and hypotensive episodes. The lower, although statistically insignificant, incidence of hypotension in our ropivacaine group (25.71%) compared to the bupivacaine group (42.85%) supports these findings and emphasizes the advantage of ropivacaine for patients who are at cardiovascular risk or for whom a speedy recovery after surgery is essential.

Comparative trials and reviews support our findings that bupivacaine, as opposed to ropivacaine, postpones the requirement for rescue analgesia. In lower limb orthopedic anesthesia, for example, Sorout et al. [11] reported a substantially longer duration to first analgesic necessity for bupivacaine compared to ropivacaine (205.1 vs. 152.7 min; $p<0.001$). Nevertheless, most research, including ours, show that the two medications' actual levels of pain alleviation, as determined by NRS and VAS, are comparable despite these time discrepancies.

In line with our findings, investigations using standardized pain assessment measures such as the Numeric Rating Scale (NRS) and Visual Analogue Scale (VAS) found no significant differences in early or late postoperative pain control between bupivacaine and ropivacaine. Suddapally et al. [12] found that the two anesthetics had equivalent analgesic efficacy despite changes in block length. Similarly, Garg et al. [13] found comparable postoperative pain scores across different time points, demonstrating that when properly dosed, both medications provide excellent pain relief.

5. Conclusion

Both Bupivacaine and Ropivacaine provided good sensory and motor block during infraumbilical surgery, but Bupivacaine had a faster block onset and a longer duration until the first rescue analgesia. The postoperative pain assessments were similar between groups, with no significant difference in safety or efficacy other than block onset and analgesia duration. Ropivacaine, however, offers better hemodynamic stability and a more favourable safety profile, making it suitable for shorter surgeries and patients requiring quicker recovery.

6. Limitations of the Study

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

7. Acknowledgement

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