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Original Research

Comparative Evaluation of Intrathecal Hyperbaric 0.5% Bupivacaine with Fentanyl and Isobaric 0.75% Ropivacaine with Fentanyl for Infraumbilical and Lower Limb Surgery: A Prospective Randomized Double-Blind Trial

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ABSTRACT

Background: Spinal anesthesia is widely used for infraumbilical and lower limb surgeries due to its cost-effectiveness, simplicity, and ability to provide profound analgesia with minimal metabolic alterations. Bupivacaine, though effective, has been associated with prolonged motor block and cardiovascular effects. Ropivacaine, a newer alternative, provides a differential block with minimal motor blockade, potentially allowing early ambulation. The addition of fentanyl enhances the anesthetic effect while reducing the required local anesthetic dose. This study aims to compare the efficacy and safety of hyperbaric 0.5% bupivacaine with fentanyl and isobaric 0.75% ropivacaine with fentanyl in spinal anesthesia.

Methods: A prospective, randomized, double-blind study was conducted on 66 ASA I-II patients aged 20–60 years undergoing infraumbilical and lower limb surgeries. Patients were allocated into two groups: Group A received intrathecal hyperbaric 0.5% bupivacaine (3 ml) with fentanyl (25 mcg), and Group B received intrathecal isobaric 0.75% ropivacaine (3 ml) with fentanyl (25 mcg). Sensory and motor block onset, duration, hemodynamic stability, and perioperative complications were assessed.

Results: Both groups achieved adequate sensory blockade for surgery. Group A (bupivacaine) had a faster onset of sensory and motor blockade but also a longer duration of motor block. Group B (ropivacaine) exhibited a shorter motor block duration, allowing for earlier ambulation while maintaining effective analgesia. Hemodynamic parameters remained stable in both groups, with a lower incidence of hypotension in the ropivacaine group.

Conclusion: Isobaric 0.75% ropivacaine with fentanyl provides comparable surgical anesthesia to hyperbaric 0.5% bupivacaine with fentanyl but offers a shorter motor block duration, making it a preferable option for procedures requiring early ambulation. The study supports the use of ropivacaine as a safer alternative with minimal hemodynamic alterations.

Keywords: Spinal Anesthesia, Bupivacaine, Ropivacaine, Fentanyl, Infraumbilical Surgery, Lower Limb Surgery, Motor Block, Sensory Block, Hemodynamic Stability.

INTRODUCTION

Since the introduction of spinal anesthesia in 1898 by Dr. August Bier, who described the intrathecal administration of cocaine, spinal anesthesia is preferred over general anesthesia, particularly in surgical procedures of the lower abdomen and lower limbs. The main reasons for extensive use of spinal anesthesia in general are simplicity of equipment, low cost, profound analgesia, adequate muscle relaxation, less blood loss, and fewer metabolic alterations.[1]

General anesthesia does not abolish the stress response completely. The local anesthetic, when used intrathecally or epidurally, largely abolishes the response, particularly in lower abdominal operations. Spinal anesthesia has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anesthetic, but it comes with the consideration that there is a need to relieve the psychological distress of being immobile for a longer period of time after lower abdominal surgeries, and hence this study was conducted to know the characteristics of given drugs.[1]

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Bupivacaine has been in clinical use for more than 30 years and is available commercially as a racemic mixture containing equal proportions of the S (-) and R (-) isomers. It is widely used because of its long duration of action and beneficial ratio of sensory to motor block. However, bupivacaine is also associated with a number of side effects, including motor weakness, urinary retention, and cardiovascular and central nervous system toxicity.[1]

Ropivacaine is a new, long-acting amino-amide local anesthetic. The reason for introducing ropivacaine was to reduce the duration of hospital stay, which is becoming more important, especially for in-patients. Therefore, in operations performed under spinal anesthesia, early ambulation because of a shorter duration of motor block is considered desirable. Ropivacaine produces a greater degree of differential block at low concentration and a property of producing frequency-dependent block, offering considerable clinical advantage in providing analgesia with minimum motor blockade.[1,2] Opioid analogues have been used as additives in spinal anesthesia to improve the onset of action, prolong the duration of block, and improve the quality of perioperative analgesia. 6-9 Fentanyl (a lipophilic opioid) has a rapid onset and short duration of action following intrathecal administration. The co-administration of opioids reduces the total dose of local anesthetics required for anesthesia and significantly prolongs the duration of complete and effective analgesia without prolonging the duration of motor block. It prolongs the duration and reduces analgesic requirement in the early postoperative period following spinal block.[3]

AIMS AND OBJECTIVES

This study aims to evaluate and compare the safety and efficacy of intrathecal hyperbaric 0.5% bupivacaine with fentanyl and isobaric 0.75% ropivacaine with fentanyl for perioperative anesthesia and analgesia in infraumbilical and lower limb surgeries. The primary objectives include assessing sensory and motor block characteristics, such as onset, time to reach T10, quality, regression, total duration, and the timing of rescue analgesia, along with the overall duration of surgery. Secondary objectives focus on evaluating hemodynamic stability and perioperative complications to determine the optimal anesthetic choice for enhanced patient outcomes.

MATERIALS AND METHODS

This prospective, randomized, double-blind study was conducted in the Department of Anesthesiology at a tertiary care hospital from September 2022 to July 2024, following approval from the institutional ethics committee. The study included patients aged 20 to 60 years scheduled for elective infraumbilical and lower limb surgeries under spinal anesthesia, requiring a sensory block level up to T10 and an expected surgical duration of 90 to 120 minutes.

Inclusion and Exclusion Criteria

This study included ASA grade I and II patients aged 20–60 years, weighing 40–70 kg, scheduled for elective infraumbilical, urological, or orthopedic surgeries under spinal anesthesia, with an expected duration of 90–120 minutes. Patients provided written informed consent and were randomly assigned to two groups: Group A received intrathecal hyperbaric 0.5% bupivacaine (3 ml) with fentanyl (0.5 ml), while Group B received intrathecal isobaric 0.75% ropivacaine (3 ml) with fentanyl 25 mcg (0.5 ml). Exclusion criteria included patient refusal, contraindications to spinal anesthesia (local infection, bleeding disorders, vertebral deformities, or allergies to study drugs), significant comorbidities (ischemic heart disease, uncontrolled hypertension or diabetes, severe hepatic, renal, respiratory, or CNS disorders), ASA grade III and IV status, and pregnancy or lactation.

Sample Size Calculation

To determine the sample size for a study comparing the incidence of hypotension between two groups-Group A (bupivacaine) and Group B (ropivacaine)-the following assumptions were drawn from Arun Kumar R. et al. (2020).[4]

Proportion in Group A (P1): 56.7%, proportion in Group B (P2): 23.3%, effect size (P1 - P2): 33.4%, power (1 - β): 80%, Alpha (α, 2-sided): 5%

Using the formula for sample size estimation based on the difference in proportions, the required sample size is calculated as 33 per group. Thus, a total of 66 subjects were included across both groups.

Data Collection Tools

The data collection tools utilized in this study encompassed a variety of clinical, monitoring, and laboratory instruments to ensure comprehensive evaluation. Clinical assessment tools included detailed history and physical examination records to document patient health status, alongside the Modified Bromage Scale (grades 0–3) for assessing motor block and a pinprick test using a 24G needle to evaluate sensory block at specific dermatomes. Monitoring equipment consisted of a multipara monitor capturing ECG (Electrocardiogram), NIBP (Non-Invasive Blood Pressure), and pulse oximetry (SpO2) for real-time vital sign tracking, supplemented by ECG and 2D echocardiogram machines when clinically indicated. Laboratory tests comprised a complete hemogram (hemoglobin, total and differential leukocyte count, and platelet count); blood grouping with Rh typing; random blood sugar; KFT (Kidney Function Tests), LFT (Liver Function Tests), and a coagulation profile for patients over 40 or as required. Procedure-specific tools included a 23/25 G Quincke's spinal needle for lumbar puncture and a stopwatch or clock to precisely record time intervals such as the onset and duration of blocks. Documentation was facilitated through consent forms and structured observation charts to systematically log intraoperative and postoperative variables.

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Data Collection Procedure

The data collection procedure was methodically executed across preanesthetic, intraoperative, and postoperative phases to ensure accuracy and consistency. In the preanesthetic phase, a thorough evaluation was conducted, involving the collection of patient history, clinical examination findings, and results from relevant investigations like hemogram, blood sugar, and organ function tests; baseline vital signs (pulse, blood pressure, SpO2) were recorded in the preanesthetic room, followed by securing intravenous access with an 18/20 G cannula and initiating preloading with Ringer's lactate (10 ml/kg) over 30 minutes. During the intraoperative phase, patients were connected to standard monitors (ECG, NIBP, pulse oximeter) in the operating theatre, where baseline vitals were re-recorded; spinal anesthesia was administered at the L2-L3 or L3-L4 interspace using a 23/25 G Quincke's needle with 3.5 ml of drug injected at 0.2 ml/sec, marking the injection time as "0 hour"; sensory block onset was assessed every 1 minute at L1 and every 2 minutes at T10 using the pinprick test, while motor block onset and quality were evaluated every 2 minutes (then every 15 minutes) via the Modified Bromage Scale; vital signs and complications such as hypotension or bradycardia were continuously monitored, with interventions (e.g., vasopressors, atropine) documented, alongside the total duration of surgery from skin incision to closure. In the postoperative phase, patients were observed in the PACU (Post Anaesthesia Care Unit) for 6 hours, with hourly recordings of vital signs; the total duration of sensory and motor blocks, time to first rescue analgesia (marked by administration of tramadol 100 mg IV), and any postoperative complications (e.g., urinary retention, headache) were meticulously noted, along with corresponding treatments, ensuring a comprehensive dataset for analysis.

Statistical Analysis

The data collected in this study were systematically coded and analyzed using the statistical software STATA, version 10.1 (2011), developed by StataCorp, Texas, USA. Descriptive statistics were employed to summarize the data, with quantitative variables expressed as means and standard deviations, providing a clear overview of central tendencies and variability. For qualitative or categorical variables, frequencies and percentages were calculated to represent their distribution across the study groups. Proportions of categorical hemodynamic parameters were estimated as percentages for each group, accompanied by 95% confidence intervals to quantify the precision of these estimates. Inferential statistics were applied to assess differences between groups, with p-values derived from hypothesis testing procedures used to determine statistical significance, thereby facilitating robust conclusions regarding the study outcomes.

RESULTS

Table 1 compares age, gender, and weight between Group A (bupivacaine) and Group B (ropivacaine). The mean age (42.58 vs. 41.12 years, p =0.563), weight (66.48 vs. 67.85 kg, p =0.420), and gender distribution (42.4% vs. 45.5% female, p =0.804) show no statistically significant differences, indicating comparable baseline demographics across the groups.

Parameter	Group	Mean /N	SD/%	P-Value
Age (in years)	Group A	42.58	9.96	0.563
	Group B	41.12	10.38	
Weight (Kg)	Group A	66.48	6.77	0.420
	Group B	67.85	6.87	
Gender (Female)	Group A	14	42.4%	0.804
	Group B	15	45.5%	
Gender (Male)	Group A	19	57.6%	
	Group B	18	54.5%	
Total	Group A	33	100%	
	Group B	33	100%	

Table 1: Comparison of Demographic Characteristics (Age, Gender, Weight)

Table 2 compares preoperative vital signs (HR [Heart Rate], SBP [Systolic Blood Pressure], DBP [Diastolic Blood Pressure], MAP [Mean Arterial Pressure], and Spo2 [Oxygen Saturation]) between the groups. No significant differences were observed (P-values > 0.05), except for a discrepancy in the text noting HR significance (P=0.009), which conflicts with the table's P=0.209, suggesting a potential error in the original document. Otherwise, preoperative vitals are comparable.

Parameter	Group	Mean /N	SD/%	P-Value
HR(bpm)	Group A	77.45	7.34	0.209
	Group B	79.36	7.58	
SBP(mmHg)	Group A	127.91	9.72	0.256
	Group B	130.58	9.17	

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DBP(mmHg)	Group A	80.73	6.48	0.213
	Group B	78.82	5.84	
MAP(mmHg)	Group A	96.79	6.68	0.649
	Group B	96.07	6.06	
SpO2 (%)	Group A	97.70	1.07	0.823
	Group B	97.64	1.11	

Table 2: Comparison of Pre-Operative Vital Signs

Table 3 presents intraoperative HR, SBP, DBP, and MAP at selected time points (2, 11, 17, and 90 min). HR remains comparable ($P > 0.05$), while significant differences in SBP, DBP, and MAP occur at 11 and 17 min ($P < 0.001$), with Group A (bupivacaine) showing lower values than Group B (ropivacaine). By 90 min, differences diminish, suggesting overall hemodynamic stability is maintained across the surgery.

Time	Parameter	Group A Mean (SD)	Group B Mean (SD)	P-Value
2 min	HR (bpm)	79.97 (10.86)	78.24 (8.18)	0.468
	SBP (mmHg)	127.91 (9.72)	125.03 (9.77)	0.291
	DBP (mmHg)	71.94 (8.17)	72.73 (4.93)	0.637
	MAP (mmHg)	89.95 (5.17)	87.43 (5.16)	0.052
11 min	HR (bpm)	92.24 (12.77)	91.27 (12.58)	0.757
	SBP (mmHg)	104.61 (10.49)	115.27 (6.72)	<0.001
	DBP (mmHg)	62.58 (9.06)	68.55 (5.62)	0.002
	MAP (mmHg)	76.59 (6.61)	82.06 (4.54)	<0.001
17 min	HR (bpm)	94.33 (9.46)	93.88 (7.70)	0.831
	SBP (mmHg)	101.67 (6.25)	111.79 (6.65)	<0.001
	DBP (mmHg)	60.12 (8.34)	70.21 (4.53)	<0.001
	MAP (mmHg)	79.30 (6.17)	84.07 (4.22)	0.001
90 min	HR (bpm)	91.79 (8.89)	90.48 (8.01)	0.534
	SBP (mmHg)	115.00 (6.33)	110.88 (6.79)	0.013
	DBP (mmHg)	72.33 (4.40)	74.15 (6.11)	0.170
	MAP (mmHg)	86.56 (3.65)	86.39 (3.98)	0.864

Table 3: Comparison of Intraoperative Hemodynamic Parameters (HR, SBP, DBP, MAP)

Table 4 compares intraoperative SpO2 and respiratory rate. No significant differences were observed at any time point ($P>0.05$), indicating that both groups maintained stable oxygenation and respiratory function throughout the procedure, with mean values consistently near 97.5% for SpO2 and 12.8 bpm for respiratory rate.

Time	Parameter	Group A Mean (SD)	Group B Mean (SD)	P-Value
2 min	SpO2 (%)	97.64 (1.17)	97.42 (1.06)	0.443
	Resp. Rate (bpm)	12.85 (0.83)	12.88 (0.78)	0.879
17 min	SpO2 (%)	97.61 (1.32)	97.45 (1.06)	0.610
	Resp. Rate (bpm)	12.88 (0.86)	12.94 (0.79)	0.766
50 min	SpO2 (%)	97.70 (1.21)	97.42 (1.06)	0.334
	Resp. Rate (bpm)	12.88 (0.78)	12.82 (0.85)	0.763
90 min	SpO2 (%)	97.61 (1.32)	97.45 (1.06)	0.610
	Resp. Rate (bpm)	12.88 (0.70)	12.85 (0.76)	0.866

Table 4: Comparison of Intraoperative Respiratory Parameters (SpO2, Respiratory Rate)

Table 5 summarizes blockade characteristics. Group A (bupivacaine) exhibits significantly faster onset of sensory (122.27 vs. 171.27 sec) and motor blocks (293.82 vs. 537.12 sec) and longer motor block duration (140.55 vs. 109.88 min, $P<0.001$). Sensory block duration is comparable ($P=0.370$), while regression to L1 is longer in Group B ($P=0.020$), highlighting bupivacaine's quicker and more prolonged effects.

Parameter	Group	Mean	SD	P-Value
Onset of Sensory Block (sec) (L1)	Group A	122.27	34.47	<0.001
	Group B	171.27	39.56	
Sensory Block to T10 (sec)	Group A	292.55	39.17	<0.001
	Group B	339.36	26.66	
Onset of Motor Block (sec)	Group A	293.82	75.27	<0.001

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	Group B	537.12	69.57	
Total Duration Sensory Block (min)	Group A	162.00	23.50	0.370
	Group B	157.48	16.57	
Total Duration Motor Block (min)	Group A	140.55	26.74	<0.001
	Group B	109.88	9.11	
2-Segment Regression to L1 (min)**	Group A	70.76	3.37	0.020
	Group B	74.76	9.10	
Table 5: Comparison of Blockade Characteristics				

Table 6 compares motor block quality and complications. Motor block quality is similar (P=0.897), with most patients achieving excellent blocks (84.8% vs. 81.8%). Complications (bradycardia, hypotension, etc.) show no significant differences (P>0.05), though hypotension is more frequent in Group A (18.2% vs. 9.1%), suggesting comparable safety profiles.

Parameter	Group	N	%	P-Value
Quality of Motor Block				0.897
Poor	Group A	2	6.1%	
	Group B	3	9.1%	
Excellent	Group A	28	84.8%	
	Group B	27	81.8%	
Satisfactory	Group A	3	9.1%	
	Group B	3	9.1%	
Complications				
Bradycardia	Group A	2	6.1%	<0.500
	Group B	2	6.1%	
Hypotension	Group A	6	18.2%	<0.230
	Group B	3	9.1%	
Shivering	Group A	1	3.0%	<0.500
	Group B	1	3.0%	
Vomiting	Group A	2	6.1%	<0.300
	Group B	1	3.0%	
Nil	Group A	22	66.7%	
	Group B	26	78.8%	
Table 6: Comparison of Motor Block Quality and Complications				

Table 7 focuses on postoperative HR, SBP, MAP, and motor block at 1 hour. HR is significantly higher in Group A (P=0.001), while SBP and MAP show no difference (P>0.05). All Group A patients had Grade 3 motor block vs. 81.8% in Group B, indicating denser initial block in Bupivacaine, with differences fading later.

Parameter	Group	Mean /N	SD/%	P-Value
HR (1 hr., bpm)	Group A	92.79	10.03	0.001
	Group B	83.64	10.92	
SBP (1 hr., mmHg)	Group A	120.42	8.75	0.120
	Group B	114.70	18.81	
MAP (1 hr., mmHg)	Group A	90.72	5.17	0.356
	Group B	89.69	3.74	
	Group A			
	Group B			
Modified Bromage (1 hr.)				
Grade 3	Group A	33	100%	
	Group B	27	81.8%	
Grade 2	Group A	0	0%	
	Group B	6	18.2%	
Table 7: Comparison of Postoperative Parameters (HR, SBP, MAP, Modified Bromage Scale at 1 hr.)				

DISCUSSION

This randomized, double-blind study compared the efficacy of hyperbaric 0.5% bupivacaine (15 mg) with fentanyl (25 µg) versus isobaric 0.75% ropivacaine (22.5 mg) with fentanyl (25 µg) for spinal anesthesia in infraumbilical and lower limb surgeries, conducted

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from September 2022 to July 2024. The study aimed to assess differences in sensory and motor block characteristics, hemodynamic effects, and perioperative outcomes.

Bupivacaine remains the most commonly used local anesthetic for spinal anesthesia, known for its prolonged sensory and motor blockade, whereas ropivacaine offers a shorter motor block duration, facilitating early ambulation-a key factor in reducing hospital stay.[3] Equipotent doses were selected based on prior studies indicating bupivacaine's potency as 1.4 to 1.68 times that of ropivacaine.[2] Fentanyl, a lipophilic opioid, was added to enhance onset, prolong sensory block, and improve analgesia without extending motor block duration.[3]

Demographically, the groups were comparable in age (Group A: 42.58 ± 9.96 years; Group B: 41.12 ± 10.38 years, P=0.563), gender (Group A: 42.4% female; Group B: 45.5% female, P=0.804), and weight (Group A: 66.48 ± 6.77 kg; Group B: 67.85 ± 6.87 kg, P=0.420), consistent with findings by R. Arun Kumar et al.[4] and V. R. R. Chari et al.[5] Surgical duration was also similar (Group A: 100.97 ± 10.27 min; Group B: 103.97 ± 11.11 min, P=1.000).[4,6]

Sensory block onset to L1 was significantly faster with bupivacaine (122.27 ± 34.47 sec) than ropivacaine (171.27 ± 39.56 sec, P < 0.001), corroborated by Pathania et al.[7] and Madhu K R et al.[8] Time to reach T10 was also quicker in Group A (292.55 ± 39.17 sec) versus Group B (339.36 ± 26.66 sec, P < 0.001), aligning with Abbas et al.[9] and Koltka et al.[2] Motor block onset was faster in Group A (293.82 ± 75.27 sec) than Group B (537.12 ± 69.57 sec, P < 0.001), consistent with V. R. R. Chari et al.[5] and Sangeeta Varun et al.[3] However, motor block quality was excellent in both groups, with no significant difference.[6,8,10,11]

Total sensory block duration was similar (Group A: 162 ± 23.50 min; Group B: 157.48 ± 16.57 min, P=0.370), while motor block duration was longer with bupivacaine (140.55 ± 26.74 min) than ropivacaine (130.15 ± 13.85 min, P=0.005).[5,7,12] Two-segment regression to L1 was prolonged in Group B (74.76 ± 9.10 min) versus Group A (70.76 ± 3.37 min, P=0.002),[5,11] though Ravi Teja Vallabha et al.[12] reported the opposite, possibly due to lower doses. Time to first rescue analgesia was comparable (Group A: 165 min; Group B: 162 min), with fentanyl likely contributing to this equivalence.[2,13]

Hemodynamically, preoperative heart rate (Group A: 77.45 ± 7.34 bpm; Group B: 79.36 ± 7.58 bpm, P = 0.209) and intraoperative variations were not significantly different.[3,5] However, bupivacaine caused a greater fall in SBP, DBP, and MAP, particularly at 11–17 minutes post-induction (e.g., SBP at 11 min: Group A: 104.61 ± 10.49 mmHg; Group B: 115.27 ± 6.72 mmHg, P<0.001), consistent with Madhu K R et al.[8] This may reflect bupivacaine's peak effect and fentanyl's additive impact.[3,8]

Perioperative complications (e.g., hypotension, bradycardia, nausea, shivering) showed no significant intergroup differences, aligning with Kalpana R Kulkarni et al.,[14]and Osama al-Abdulhadi et al.[15] Postoperative recovery, assessed via the Modified Bromage Scale, indicated faster motor regression in Group B.[16,17]

Bupivacaine offers faster sensory and motor block onset and longer motor block duration, while ropivacaine provides a shorter motor block and prolonged two-segment regression, supporting early ambulation. Both agents, with fentanyl, deliver comparable analgesia and safety profiles, making ropivacaine a viable alternative for reducing recovery time.

CONCLUSION

This study demonstrates that intrathecal isobaric ropivacaine (0.75%, 22.5 mg) combined with fentanyl (25 µg) provides effective spinal anesthesia for infraumbilical and lower limb surgeries. While there was a statistically significant delay in the onset and upper level of sensory block compared to hyperbaric bupivacaine (0.5%, 15 mg) with fentanyl (25 µg), the quality of sensory and motor blockade achieved with ropivacaine was adequate and comparable to that of bupivacaine. Notably, the mean duration of motor block and the time to patient mobilization were shorter with ropivacaine, facilitating earlier ambulation. Changes in vital parameters, including heart rate and blood pressure, were similar between the two agents, indicating comparable hemodynamic stability. The shorter recovery profile of ropivacaine enhances patient safety and supports its use as a viable alternative to bupivacaine in elective infraumbilical and lower limb surgeries. Thus, ropivacaine offers an optimal balance of anesthesia and analgesia, promoting faster recovery and early rehabilitation without compromising efficacy.

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