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Comparative Study Of 0.5% Hyperbaric Levobupivacaine, 0.75% Hyperbaric Ropi-Vacaine And 0.5% Hyperbaric Bupivacaine With Add On Fentanyl In Subarachnoid Block For Lower Limb Surgeries.

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Abstract

Introduction: Hyperbaric bupivacaine, levobupivacaine, and ropivacaine are commonly used intrathecal local anaesthetic agents for lower limb orthopaedic surgeries. Their sensory and motor block characteristics influence postoperative recovery and analgesia. Aim: Comparison of the sensory and motor block characteristics of 0.5% hyperbaric levobupivacaine with fentanyl, 0.75% hyperbaric ropivacaine with fentanyl, and 0.5% hyperbaric bupivacaine with fentanyl in orthopaedic surgeries under subarachnoid block in terms of onset, sensory level, and duration of sensory and motor block. ***Methods:*** A prospective randomized double-blind study was conducted on 195 patients undergoing lower limb orthopaedic surgeries under subarachnoid block. Patients were equally allocated into three groups B,R&L receiving 0.5% hyperbaric levobupivacaine with fentanyl, 0.75% hyperbaric ropivacaine with fentanyl, and 0.5% hyperbaric bupivacaine with fentanyl. Onset and duration of sensory and motor block, duration of analgesia, haemodynamic parameters, and adverse effects were assessed. ***Results:*** The onset of sensory block was comparable among Group B (4.86 ± 1.06 min), Group R (4.95 ± 1.42 min), and Group L (4.58 ± 1.10 min) (p=0.194). Duration of sensory block was significantly shorter in Group R (101.00 ± 10.72 min) compared to Group B (107.00 ± 12.52 min) and Group L (105.69 ± 11.07 min) (p=0.008). Duration of motor block and analgesia were also significantly shorter in Group R (p=0.001). Haemodynamic parameters and adverse effects were comparable among the groups. ***Conclusion:*** Hyperbaric ropivacaine provides earlier motor recovery with comparable haemodynamic stability and may be preferred when early postoperative mobilization is desired.

Keywords: Subarachnoid block; Hyperbaric bupivacaine; Hyperbaric ropivacaine; Hyperbaric levobupivacaine; Fentanyl; Lower limb orthopaedic surgery.

INTRODUCTION

Spinal anaesthesia is widely preferred for lower limb orthopaedic surgeries because of its rapid onset, effective sensory blockade, reduced perioperative complications, and good postoperative analgesia. [1,2] Hyperbaric bupivacaine has traditionally been the most commonly used intrathecal local anaesthetic agent; however, it is associated with prolonged motor blockade and increased cardiovascular and central nervous system toxicity. [3,4-7] Levobupivacaine and ropivacaine, the pure S(-) enantiomers developed as safer alternatives, demonstrate lower cardiotoxicity and neurotoxicity while maintaining effective sensory blockade.[8,9] Levobupivacaine provides block characteristics similar to bupivacaine, whereas ropivacaine produces less intense motor blockade with faster recovery, making it useful for ambulatory and lower limb surgeries.[8,9] Addition of intrathecal fentanyl enhances sensory blockade and postoperative analgesia without significantly prolonging motor block. [2] However, limited studies have directly compared hyperbaric ropivacaine, hyperbaric levobupivacaine, and hyperbaric bupivacaine in spinal anaesthesia for lower limb surgeries. Therefore, the present study was undertaken to compare the sensory and motor block characteristics of 0.5% hyperbaric levobupivacaine with fentanyl (25 mcg), 0.75% hyperbaric ropivacaine with fentanyl (25 mcg), and 0.5% hyperbaric bupivacaine with fentanyl (25 mcg) in orthopaedic surgeries under subarachnoid block in terms of onset, highest sensory level, and duration of sensory and motor blockade.

MATERIALS AND METHODS

Study design: Prospective, randomized, double-blind interventional study.

Study period: 12 Months

Place of study: Department of Anaesthesiology, Tertiary Care Teaching Hospital.

Study population: Adult patients aged 18–65 years, ASA physical status I–III, undergoing lower limb orthopaedic surgeries under subarachnoid anaesthesia.

Sample size: 195 patients.

Inclusion Criteria:
- Age 18–65 years.
- ASA physical status I–III.
- Scheduled for lower limb orthopaedic surgeries under subarachnoid anaesthesia.

Exclusion Criteria:
- Refusal for subarachnoid block.
- Known allergy to local anaesthetic agents.
- Coagulopathy.
- Infection at the injection site.
- Spinal deformity (e.g., scoliosis, kyphoscoliosis).
- Pre-existing neurological disease.
- Inability to comprehend sensory and motor block assessment.
- Failed subarachnoid block requiring conversion to general anaesthesia.

Study Variable:
This prospective, randomized, double-blind interventional study was conducted in the Department of Anaesthesiology of a tertiary care teaching hospital, after obtaining approval from the Institutional Ethics Committee (vide approval number IEC/2023/145, Ref no DMCH/IEC/2023/287 Dated 15 December 2023). It was done according to the principles of the declaration of Helsinki, 2013 and Good Clinical practice guidelines.

A total of 195 adult patients aged 18–65 years, belonging to ASA physical status I–III and scheduled for lower limb orthopaedic surgeries under subarachnoid anaesthesia, were included in the study. Patients refusing subarachnoid block , those with known allergy to local anaesthetic agents, coagulopathy, infection at the injection site, spinal deformities (scoliosis, kyphoscoliosis or similar deformities), pre-existing neurological disease, inability to comprehend sensory and motor block assessment, and failed subarachnoid block requiring conversion to general anaesthesia were excluded from the study.
Sample size was calculated using the formula:

$$n = \frac{(\sigma_1^2 + \sigma_2^2)(Z_\alpha + Z_\beta)^2}{(m_1 - m_2)^2}$$

where Z_αwas taken as 1.96 at 95% confidence interval and Z_βas 0.842 for 80% power. Based on the findings of Casati et al., the calculated sample size was 59 patients per group. To account for possible dropouts and exclusions, 65 patients were included in each group, making a total sample size of 195 patients.

All patients underwent detailed pre-anaesthetic evaluation one day prior to surgery. Routine investigations including haemogram and coagulation profile were performed, and standard fasting guidelines according to ASA recommendations were followed.

In the operating room, standard monitoring including non-invasive blood pressure, electrocardiography, and peripheral oxygen saturation was established and baseline parameters were recorded. Intravenous access was secured and preloading with intravenous fluids was initiated prior to administration of subarachnoid block.

Patients were randomly allocated into three groups using computer-generated randomization. Allocation concealment was done using sealed envelopes opened by an independent anaesthesiologist responsible for preparation of the study drug. Group B received 2.5 mL of 0.5% hyperbaric bupivacaine with fentanyl 25 mcg (0.5 mL), Group R received 2.5 mL of 0.75% hyperbaric ropivacaine with fentanyl 25 mcg (0.5 mL), and Group L received 2.5 mL of 0.5% hyperbaric levobupivacaine with fentanyl 25 mcg (0.5 mL) intrathecally. The total volume administered in all groups was 3 mL.

A designated anaesthesiologist prepared the study drug in a coded 5 mL syringe and handed it over to another anaesthesiologist administering the block, who remained blinded to the study medication. Under strict aseptic precautions and with the patient in sitting position, local infiltration was performed using 2 mL of 2% lignocaine.

A 26-gauge Quincke spinal needle was inserted through the midline approach. After confirmation of free flow of cerebrospinal fluid, the study drug was administered intrathecally at a rate of 0.2 mL/s. Immediately after injection, patients were placed supine with the operating table maintained in a neutral position.

Haemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and peripheral oxygen saturation were recorded at baseline, 2, 4, 6, 8, 10, and 15 minutes after administration of subarachnoid block and subsequently at 15-minute intervals. Sensory block was assessed bilaterally along the midclavicular line using pinprick method with a sterile 26G needle. Surgery was commenced after attainment of sensory block up to T10 dermatome.

The onset of sensory block was defined as the time from intrathecal injection to loss of pain sensation at T10 dermatome. Duration of sensory block was defined as the time interval between intrathecal injection and regression by two dermatomes from the highest sensory level achieved. Motor block was assessed using the Modified Bromage Scale at 2, 4, 6, 8, 10, and 15 minutes and subsequently at 15-minute intervals.

The onset of motor block was defined as the time from intrathecal injection to attainment of Grade 1 motor block, while duration of motor block was defined as the time from intrathecal injection until return to Grade 0. Modified Bromage Scale grading was as follows: Grade 0 – full motor function; Grade 1 – unable to raise extended leg but able to flex knee; Grade 2 – unable to flex knee with preserved ankle movement; and Grade 3 – complete motor block.

Patients were monitored intraoperatively for hypotension, bradycardia, and hypoxemia. Hypotension was defined as systolic blood pressure below 90 mmHg or a reduction greater than 20% from baseline and was managed with intravenous fluids and ephedrine 6 mg boluses. Bradycardia, defined as heart rate below 60 beats/minute, was treated using intravenous atropine 0.6 mg. Hypoxemia, defined as peripheral oxygen saturation below 90%, was managed with supplemental oxygen and ventilatory support when required.

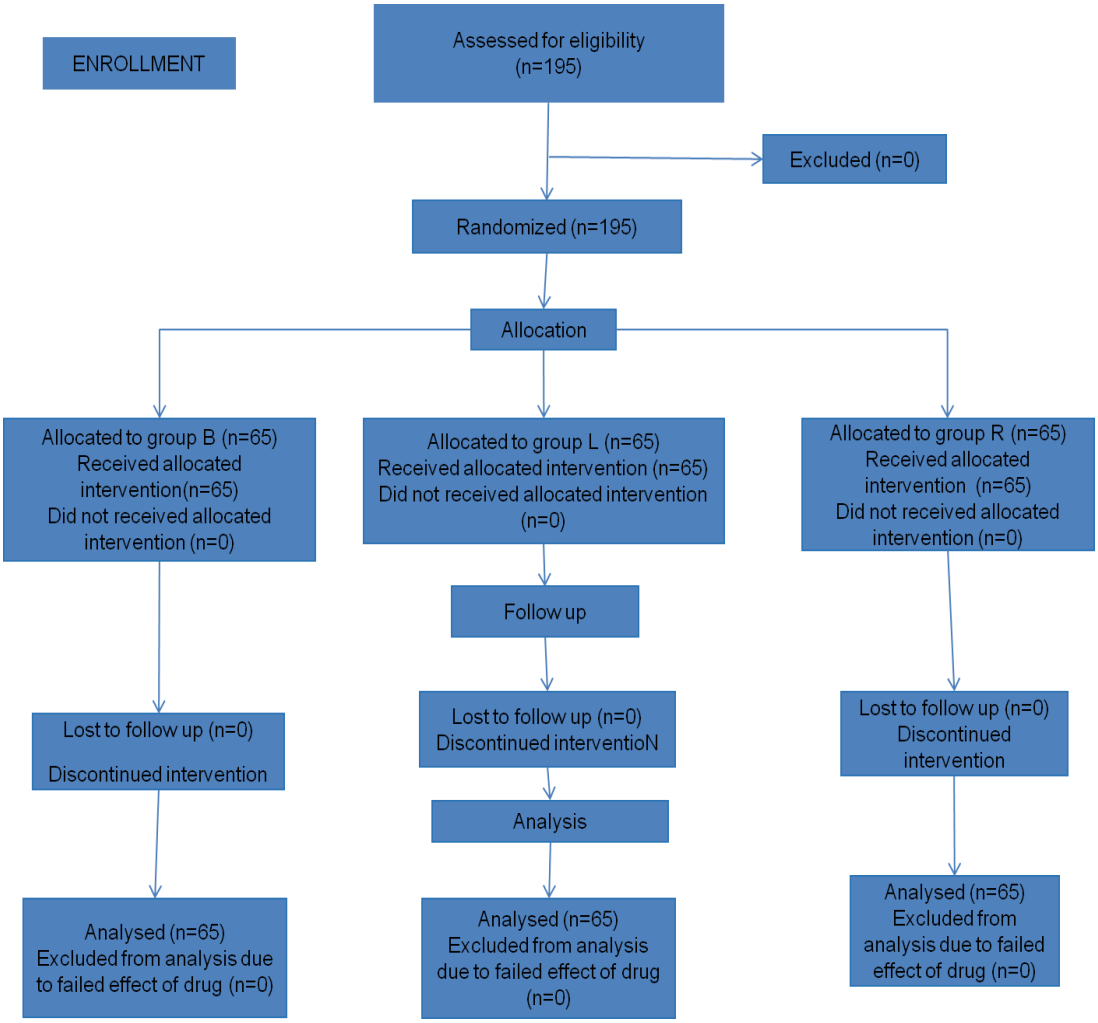
In the post-anaesthesia care unit, haemodynamic parameters along with sensory and motor block characteristics were monitored every 15 minutes until complete regression of both blocks. Postoperative pain assessment was performed using the Numerical Rating Scale (NRS), where 0 represented no pain and 10 represented worst imaginable pain. Pain assessment was initiated immediately upon arrival in the post-anaesthesia care unit and repeated hourly for the first six postoperative hours. Intravenous tramadol 100 mg was administered when NRS score exceeded 4, and the time to first analgesic request was documented.

The primary outcomes of the study were onset of sensory block and onset of motor block. Secondary outcomes included highest level and duration of sensory block and duration of motor block.

Data were summarized using mean ± standard deviation, median, range, frequencies, and percentages as appropriate. Normality of distribution was assessed using the Kolmogorov–Smirnov test. Quantitative variables were compared using the Kruskal–Wallis test followed by post hoc Tukey's test where applicable.

Categorical variables were analysed using chi-square test or Fisher's exact test. A p-value <0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 21 (SPSS Inc., Chicago, IL, USA).

Consort Flow Chart.



RESULTS

Table 1: Baseline characteristics of study participants

Parameter	Group B	Group R	Group L	p-value
Age (years), mean ± SD	42.72 ± 13.34	41.68 ± 12.89	40.02 ± 14.14	0.514
Male/Female	46/19	44/21	47/18	0.842
BMI (kg/m²), mean	27.20	27.09	26.88	>0.05
ASA I, n (%)	25 (38.5%)	31 (47.7%)	24 (36.9%)	0.372
ASA II, n (%)	20 (30.8%)	18 (27.7%)	27 (41.5%)	
ASA III, n (%)	20 (30.8%)	16 (24.6%)	14 (21.5%)	
Duration of surgery (min), mean ± SD	104.62 ± 33.22	100.85 ± 33.84	111.15 ± 36.44	0.230

Table 2: Comparison of sensory block characteristics among study groups

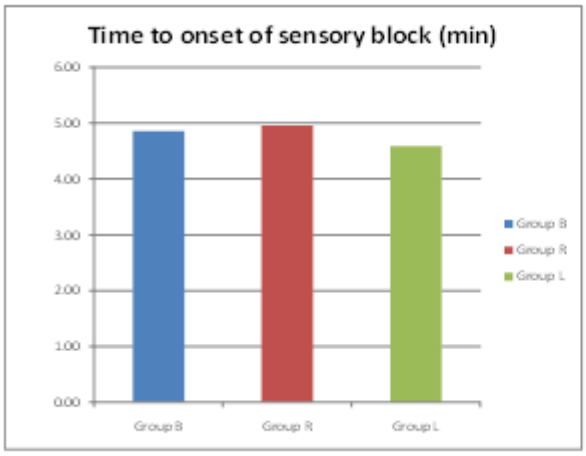
Parameter	Group B	Group R	Group L	p-value
Onset of sensory block (min), mean ± SD	4.86 ± 1.06	4.95 ± 1.42	4.58 ± 1.10	0.194
Duration of sensory block (min), mean ± SD	107.00 ± 12.52	101.00 ± 10.72	105.69 ± 11.07	0.008
Maximum sensory level T4, n (%)	19 (29.2%)	28 (43.1%)	23 (35.4%)	
Maximum sensory level T6, n (%)	45 (69.2%)	36 (55.4%)	41 (63.1%)	0.602
Maximum sensory level T8, n (%)	1 (1.5%)	1 (1.5%)	1 (1.5%)	

Table 3: Comparison of motor block characteristics and duration of analgesia among study groups

Parameter	Group B	Group R	Group L	p-value
Onset of motor block (min), mean ± SD	2.31 ± 1.07	2.34 ± 1.20	2.09 ± 0.55	0.301
Time to complete motor regression (min), mean ± SD	167.77 ± 12.06	132.23 ± 13.75	166.23 ± 14.95	0.001
Duration of analgesia (min), mean ± SD	191.23 ± 15.18	155.08 ± 14.83	189.15 ± 17.49	0.001

Table 4: Comparison of adverse effects among study groups

Adverse effect	Group B	Group R	Group L	p-value
Hypotension, n (%)	26 (40.0%)	28 (43.1%)	24 (36.9%)	0.774
Bradycardia, n (%)	0 (0.0%)	3 (4.6%)	1 (1.5%)	0.168
Nausea/Vomiting, n (%)	5 (7.7%)	13 (20.0%)	9 (13.8%)	0.127
Vasopressor requirement, mean ± SD	7.76 ± 2.77	6.56 ± 1.78	7.86 ± 3.25	0.101



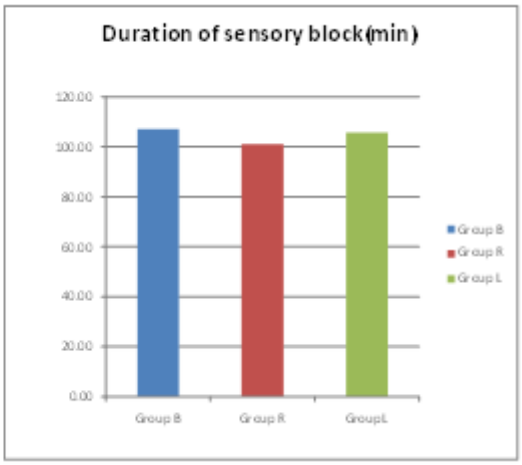
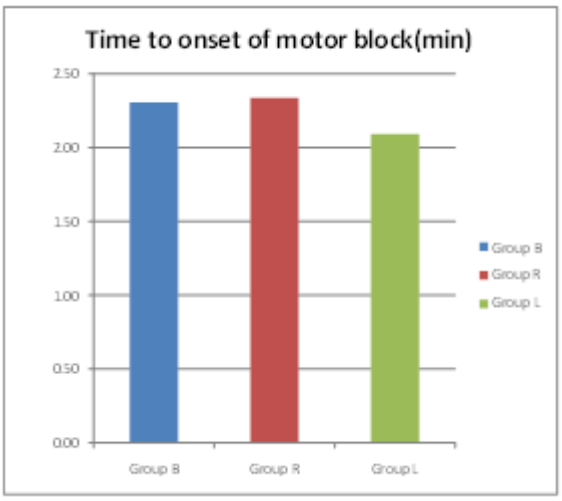


Figure 2a: Comparison of Study Groups According to Onset of Sensory Block (Minutes)

Figure 2b: Comparison of Study Groups According to Duration of Sensory Block (Minutes)



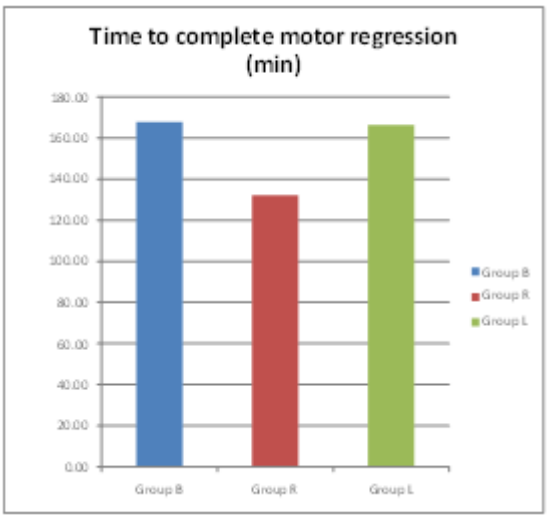


Figure 3a: Comparison of Study Groups According To Time Required For Onset of Motor Block (Minutes)

Figure 3b: Comparison of Study Groups According to Duration of Motor Block (Minutes)

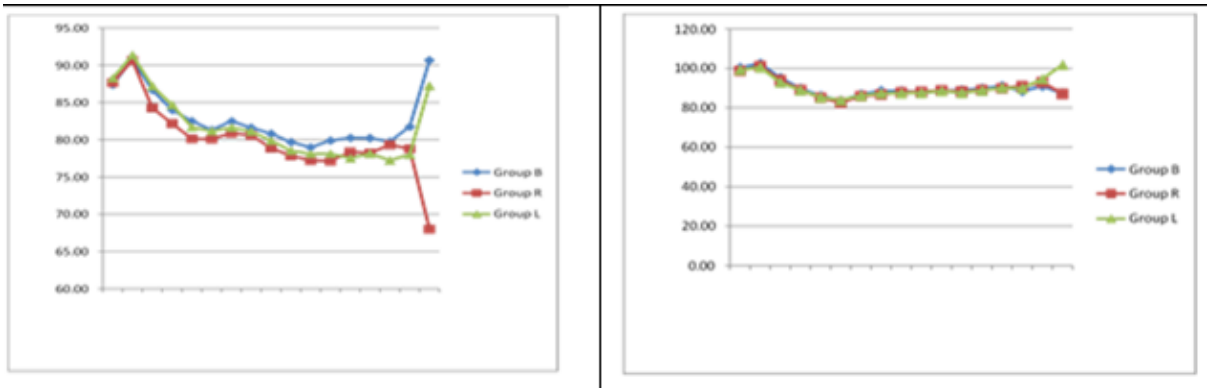


FIGURE 4a: Trends Of Intra-Operative HR Values In Three Group

Figure 4b: Trends Of Intra-Operative Mean Arterial Pressure (MAP) Values In All Three Groups

A total of 195 patients were enrolled and randomized equally into three groups: Group B (hyperbaric bupivacaine with fentanyl), Group R (hyperbaric ropivacaine with fentanyl), and Group L (hyperbaric levobupivacaine with fentanyl), with 65 patients in each group. The participant recruitment and allocation process is illustrated in Figure 1.

The baseline demographic and clinical characteristics of the study population are summarized in Table 1. The three groups were comparable with respect to demographic profile, ASA grading, BMI, and duration of surgery, with no statistically significant intergroup differences observed ($p > 0.05$).

Sensory block characteristics among the study groups are presented in Table 2 Fig 2. The mean onset time of sensory block was comparable among the three groups, with no statistically significant difference ($p = 0.194$). However, duration of sensory block differed significantly among the groups ($p = 0.008$). Group B demonstrated significantly longer duration of sensory block compared to Group R ($p = 0.003$), while no significant difference was observed between Group B and Group L ($p = 0.516$). T6 was the most commonly achieved sensory level in all groups, and no statistically significant difference was observed in the maximum sensory level attained ($p = 0.602$).

Motor block characteristics and duration of analgesia are summarized in Table 3 Fig 3 . The onset of motor block was comparable among all groups ($p = 0.301$). Time to complete motor regression was significantly shorter in Group R compared to Group B and Group L ($p = 0.001$). Similarly, duration of analgesia was significantly shorter in Group R, whereas Groups B and L demonstrated comparable duration of postoperative analgesia.

Adverse effects and haemodynamic parameters are summarized in Table 4 and Figure 4, respectively. No statistically significant intergroup differences were observed with respect to incidence of hypotension, bradycardia, nausea/vomiting, or vasopressor requirement ($p > 0.05$). Haemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure remained comparable among the three groups throughout the intraoperative and postoperative periods.

DISCUSSION

The present randomized controlled study was conducted to compare the sensory and motor block characteristics of 0.5% hyperbaric bupivacaine, 0.75% hyperbaric ropivacaine, and 0.5% hyperbaric levobupivacaine with (adjuvant) fentanyl in patients undergoing lower limb orthopaedic surgeries under subarachnoid anaesthesia. Parameters including onset and duration of sensory and motor block, haemodynamic changes, duration of analgesia, and adverse effects were evaluated among the three groups.The doses of the study drugs were selected based on the findings of Lee et al., who evaluated the ED50 of intrathecal bupivacaine, levobupivacaine, and ropivacaine for lower limb surgeries.[10] Kallio et al. also reported that the potency of ropivacaine is lower than bupivacaine for both sensory and motor blockade.[11] Based on these findings, commercially available concentrations nearest to the effective doses were used in the present study.

The demographic profile including age, gender distribution, BMI, ASA physical status, and duration of surgery was comparable among the three groups, minimizing the influence of confounding factors on the study outcomes. Similar demographic comparability has been reported in previous comparative studies evaluating intrathecal local anaesthetic agents such as Casati et al. [12] In the present study, onset of sensory block was comparable among all three groups, with no statistically significant difference observed. Similar findings were reported by Luck et al. comparing hyperbaric bupivacaine, levobupivacaine, and ropivacaine for spinal anaesthesia.[13] However, Gupta et al. and Kalbande et al.

observed a significantly faster onset of sensory block with hyperbaric bupivacaine compared to ropivacaine.[14,15] Gohil et al., in contrast, reported faster onset with ropivacaine.[16] Differences in baricity, opioid additives, dosages, and methods used for assessment of sensory block onset may explain these variations among studies.The maximum sensory level attained was comparable among the groups, with T6 being the most commonly achieved level. Similar findings were reported by Garaniya et al. [17] Athar et al., using isobaric preparations, observed lower dermatomal spread, suggesting the influence of baricity on sensory block characteristics.[18]

The duration of sensory block was significantly longer in the bupivacaine and levobupivacaine groups compared to the ropivacaine group. Similar findings have been reported by Luck et al., Gupta et al., and Kalbande et al., who demonstrated earlier sensory regression with ropivacaine. [13-15] The onset of motor block was comparable among all three groups in the present study. Similar findings were reported by Garaniya et al. [17] However, Luck et al., Gupta et al. observed delayed onset of motor block with ropivacaine.[13,14] These differences may be explained by variation in grading systems and definitions used for motor block assessment across studies. The duration of motor block was significantly shorter in the ropivacaine group compared to the bupivacaine and levobupivacaine groups. Similar observations have been reported by Luck et al., Gohil et al., Garaniya et al., and Athar et al. [13,16,17,18] The shorter duration of motor blockade observed with ropivacaine may be due to its lower lipophilicity and reduced penetration into large myelinated motor fibres, resulting in greater sensory-motor differentiation. This property makes ropivacaine advantageous in daycare procedures requiring early mobilization.

The duration of analgesia was significantly shorter in the ropivacaine group, whereas bupivacaine and levobupivacaine provided prolonged postoperative analgesia. Similar findings have been reported by Luck et al. [13] Haemodynamic parameters and incidence of adverse effects including hypotension, bradycardia, and nausea/vomiting were comparable among all three groups, indicating satisfactory haemodynamic stability and safety profile of the study drugs.

CONCLUSION

The present study demonstrated that 0.5% hyperbaric bupivacaine, 0.75% hyperbaric ropivacaine, and 0.5% hyperbaric levobupivacaine with fentanyl provided comparable onset of sensory and motor blockade and similar intraoperative haemodynamic stability in patients undergoing lower limb orthopaedic surgeries under subarachnoid anaesthesia. However, hyperbaric bupivacaine and levobupivacaine were associated with longer duration of sensory block, motor block, and postoperative analgesia compared to hyperbaric ropivacaine. In contrast, ropivacaine demonstrated earlier regression of motor blockade and faster recovery while maintaining an acceptable safety profile. The incidence of adverse effects including hypotension, bradycardia, and nausea/vomiting was comparable among the three groups. Therefore, hyperbaric ropivacaine may be a suitable alternative in procedures where early postoperative mobilization is desirable, whereas hyperbaric bupivacaine and levobupivacaine may be preferred when prolonged anaesthesia and analgesia are required.

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