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Original Article

Anaesthesia Section

Comparison of Hyperbaric Ropivacaine (0.75%) with Hyperbaric Bupivacaine (0.5%) for Spinal Anaesthesia in Lower Limb Surgeries: A Randomised Clinical Study

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ABSTRACT

Introduction: Spinal anaesthesia, also known as subarachnoid block, is the most commonly used anaesthetic technique for lower limb and lower abdominal surgeries due to its good safety profile and high success rate. Hyperbaric bupivacaine has long been the preferred agent for spinal anaesthesia. However, ropivacaine is less potent and has a shorter duration of action compared to bupivacaine.

Aim: To compare hyperbaric ropivacaine (0.75%) with hyperbaric bupivacaine (0.5%) for spinal anaesthesia in patients undergoing lower limb surgeries.

Materials and Methods: This single-blinded randomised clinical study was conducted in the Department of Anaesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore, Madhya Pradesh, India, over a period of 12 months from 1st October 2022 to 30th September 2023. A total of 80 patients aged between 18 and 60 years, posted for lower limb surgeries, were enrolled and randomly allocated into two groups: Group R: Patients receiving 3 mL of hyperbaric ropivacaine (0.75%); Group B: Patients receiving 3 mL of hyperbaric bupivacaine (0.5%). The onset and duration of sensory and motor blockade, haemodynamic parameters, vasopressor and fluid requirements and the incidence of adverse effects were recorded in all patients. Statistical analysis was performed using the independent t-test, Chi-square test and Fisher's-exact test. A p-value<0.05 was considered statistically significant.

Results: The demographic profile of patients with respect to age, gender, Body Mass Index (BMI), American Society of Anaesthesiologists (ASA) grade and duration of surgery was comparable between the two groups (p>0.05). The mean onset time of sensory and motor block in Group R was significantly longer than in Group B (6.25±6.22 min vs 3.50±0.93 min and 11.82±2.85 min vs 8.44±0.91 min, respectively; p<0.05). Conversely, the mean duration of sensory and motor block in Group R was significantly shorter compared to Group B (174.62±22.17 min vs 225.12±19.03 min and 143.50±21.67 min vs 192.35±17.88 min, respectively; p<0.0001). Ropivacaine demonstrated better haemodynamic stability than bupivacaine. The incidence of hypotension was significantly lower in Group R compared to Group B (p<0.05).

Conclusion: The present study indicates that hyperbaric ropivacaine (0.75%) may be preferred over hyperbaric bupivacaine (0.5%) for lower limb surgeries, as it provides a shorter duration of motor blockade and better haemodynamic stability.

Keywords: Analgesia, Bradycardia, Haemodynamic monitoring, Hypotension, Subarachnoid block

INTRODUCTION

Spinal anaesthesia is one of the most commonly used anaesthetic techniques in current practice, owing to its favourable safety profile and high success rate. It is widely employed for lower limb and lower abdominal surgeries [1].

Hyperbaric bupivacaine is extensively used for spinal anaesthesia; however, it is associated with several disadvantages and adverse effects, including hypotension, bradycardia and cardiovascular and central nervous system toxicity [2,3]. To overcome these limitations and improve patient care, there has been a continued search for newer local anaesthetic agents with reduced cardiovascular and central nervous system toxicity, while ensuring early recovery and discharge [4].

Ropivacaine, a pure S-enantiomer of bupivacaine, was developed to address these concerns [4,5]. Hyperbaric ropivacaine has pharmacological properties similar to hyperbaric bupivacaine [6,7] but exhibits significantly lower cardiovascular toxicity [8,9]. Ropivacaine has been widely studied for local infiltration, epidural anaesthesia and peripheral nerve blocks. Hyperbaric ropivacaine 0.75% is a relatively newer formulation approved for intrathecal use [10].

However, data on the intrathecal use of ropivacaine remain limited, particularly regarding comparisons between hyperbaric ropivacaine 0.75% and hyperbaric bupivacaine 0.5% [11-13]. Most previous studies have evaluated hyperbaric ropivacaine in infra-umbilical surgeries [14,15]. Therefore, this single-blinded study was undertaken to compare hyperbaric ropivacaine (0.75%) with hyperbaric bupivacaine (0.5%) in terms of safety and efficacy in lower limb surgeries.

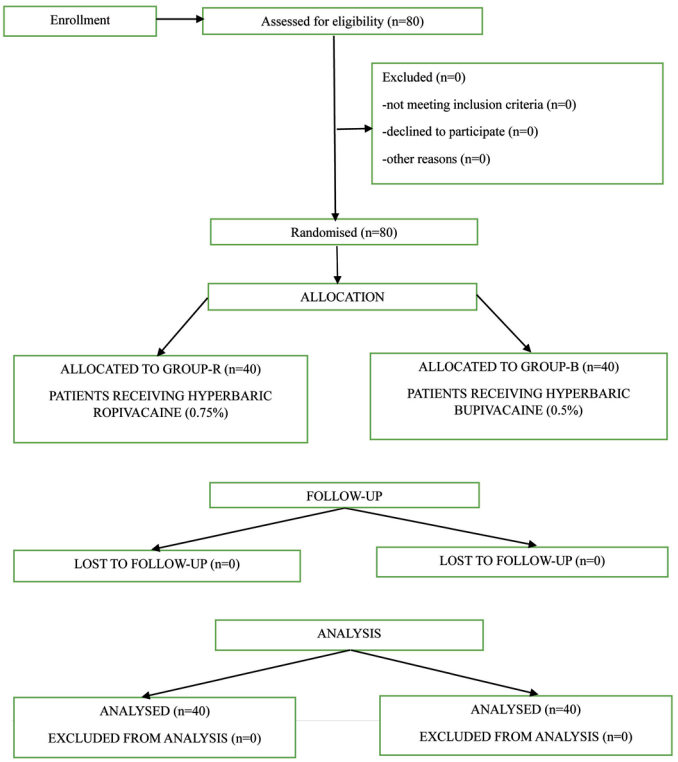
The primary objective of the present study was to compare the onset and duration of sensory and motor blockade between the two groups. Secondary objectives included comparison of haemodynamic changes, total vasopressor and fluid requirements and the incidence of adverse effects.

MATERIALS AND METHODS

The present single-blinded (participants blinded) randomised clinical study was conducted in the Department of Anaesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore, Madhya Pradesh, India, over a period of 12 months from 1st October 2022 to 30th September 2023 following approval from the Institutional Ethics and Scientific Review Committee (Ethical Approval No.: EC/MGM/OCT-22/04).

Sample size calculation: Sample size estimation was performed with the assistance of a statistician using G*Power software version 3.1.9.4, with a confidence level of 95% and a power of 90% for two groups using an unpaired t-test. Mean and standard deviation values (15.4±4 and 15.57±5.25) were derived from a previously published similar study [1]. The calculated sample size was 38 patients per group. To account for potential data loss, a total of 80 patients were enrolled, with 40 patients allocated to each group.

Randomisation and group allocation: Patients were randomly allocated to either group using a computer-generated randomisation sequence [Table/Fig-1]:



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) diagram of study.

1. Group R: Patients receiving hyperbaric ropivacaine (0.75%)
2. Group B: Patients receiving hyperbaric bupivacaine (0.5%)

Inclusion criteria: Patients aged 18-60 years of either gender, belonging to ASA physical status I or II and scheduled for lower limb surgeries were included in the study.

Exclusion criteria: Patients who refused consent; had a BMI >35 kg/m^2; had coagulopathy or bleeding disorders; spinal deformities; cardiovascular disease; known allergy to study drugs; hypovolaemia, hypotension, or shock; or psychiatric illness were excluded.

Study Procedure

A thorough pre-anaesthetic evaluation was performed for all patients prior to surgery. Patients were informed about the entire procedure and written informed consent was obtained. Upon arrival in the operating theatre, patients were connected to multiparameter monitors and baseline vital parameters—Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Pulse Rate (PR) and Oxygen Saturation (SpO_2)—were recorded. A peripheral intravenous line was secured using an 18-gauge cannula and intravenous fluid (Ringer's lactate) was initiated at a rate of 15 mL/kg.

After briefly re-counselling patients regarding the anaesthesia procedure, painting and draping were performed under full aseptic precautions. Subarachnoid block was administered using a 25-gauge Quincke spinal needle at the L3-L4 interspinous space via the midline approach in the sitting position. According to group allocation, either 3 mL (22.5 mg) [16] of hyperbaric ropivacaine (0.75%) or 3 mL (15 mg) [17] of hyperbaric bupivacaine (0.5%) was injected into the intrathecal space using the barbotage technique.

Sensory blockade was assessed using the pin-prick method. The time interval from intrathecal injection to achievement of a T10 sensory level was recorded and considered the onset time of sensory block. Motor blockade was assessed using the Modified Bromage Scale. The time from intrathecal injection to attainment of Modified Bromage Scale grade 4 was recorded as the onset time of motor block.

Haemodynamic parameters were monitored every five minutes for the first 30 minutes and thereafter every 15 minutes until the completion of surgery. Hypotension was defined as a fall in MAP of more than 20% from baseline or an absolute MAP value of less than 65 mmHg and was managed with fluid boluses (200 mL of Ringer's lactate) and bolus doses of vasopressor (mephentermine) when required. The total requirement of fluid boluses and vasopressors was recorded. Bradycardia was defined as a heart rate less than 60 beats per minute and was treated with intravenous atropine 0.6 mg.

The duration of sensory block (time from onset of sensory block to return of a Visual Analogue Scale score of 3) and motor block (time from onset of motor block to return to Modified Bromage Scale score 1) was recorded. Patients were followed postoperatively until the Visual Analogue Scale score exceeded 3, which marked the end of the study period. Injection tramadol 1 mg/kg was administered thereafter for analgesia. Any adverse effects, including hypotension, bradycardia, urinary retention, nausea, vomiting, or allergic reactions, were recorded throughout the study period and managed appropriately according to standard protocols.

STATISTICAL ANALYSIS

Data entry was performed using Microsoft Excel and final statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) software. The independent t-test was used for quantitative variables, while the Chi-square test was applied for qualitative variables. Fisher's-exact test was used when the expected cell value was less than five. A p-value<0.05 was considered statistically significant. Final data were presented in the form of tables and graphs.

RESULTS

The demographic profile of patients with respect to age, gender, Body Mass Index (BMI), American Society of Anaesthesiologists (ASA) grade and duration of surgery was comparable between the two groups (p>0.05) [Table/Fig-2].

Demographic characteristics	Group R (n=40)	Group B (n=40)	p-value
Age (years)	39.6±14.55	36.97±11.53	0.374‡
Female	10 (25%)	7 (17.50%)	0.412†
Male	30 (75%)	33 (82.50%)	
Body mass index (kg/m^2)	23.48±1.71	24.07±1.63	0.118‡
ASA grade I	33 (82.50%)	30 (75%)	0.412†
ASA grade II	7 (17.50%)	10 (25%)	
Duration of surgery (minutes)	104.75±13.15	108.75±25.31	0.379‡

[Table/Fig-2]: Comparison of age (years), gender, BMI, ASA grade and duration of surgery between group R and B. (Mean±SD).
‡Independent t-test; †Chi-square test

The mean onset time of both sensory and motor block in Group R was significantly longer than in Group B (p<0.05). Conversely, the mean duration of sensory and motor block in Group B was significantly longer compared to Group R (p<0.0001) [Table/Fig-3].

Parameters	Group R (n=40)	Group B (n=40)	p-value
Onset of sensory block {T10} (minutes)	6.25±6.22	3.5±0.93	0.007‡
Onset of motor block {Modified Bromage Scale Grade 4} (minutes)	11.82±2.85	8.44±0.91	<0.0001‡
Duration of sensory block (minutes)	174.62±22.17	225.12±19.03	<0.0001‡
Duration of motor block (minutes)	143.5±21.67	192.35±17.88	<0.0001‡

[Table/Fig-3]: Comparison of onset and duration of sensory and motor blockade between group R and B.
‡Independent t-test

The mean±SD pulse rate (beats per minute) in patients of Group R at 5, 10, 15, 20, 25, 30, 75, 90, 105, 120, 135, 150, 165 and 180 minutes was significantly higher compared to Group B (p<0.05) [Table/Fig-4].

Systolic Blood Pressure (SBP) (mmHg)	Group R (n=40)	Group B (n=40)	p-value
At baseline	126.3±12.92	121.62±9.46	0.069‡
At 5 minutes	122.4±13.28	117.8±7.06	0.058‡
At 10 minutes	116.1±13.6	110.82±6.8	0.032‡
At 15 minutes	111.62±15.38	104.18±10.85	0.015‡
At 20 minutes	110.88±17.59	101.38±12.68	0.007‡
At 25 minutes	110.9±14.44	103.55±12.71	0.018‡
At 30 minutes	111.2±12.89	107.98±9.16	0.201‡
At 45 minutes	112.82±14.15	111.4±8.8	0.59‡
At 60 minutes	113.8±14.57	112.85±7.78	0.717‡
At 75 minutes	115.78±12.57	114.82±7.92	0.687‡
At 90 minutes	117.42±12.07	115.48±8.78	0.411‡
At 105 minutes	118.68±11.99	117.05±7.29	0.467‡
At 120 minutes	120.25±11.33	117.48±7.52	0.201‡
At 135 minutes	120.75±9.69	118.48±6.69	0.225‡
At 150 minutes	121.92±9.67	120.02±6.84	0.314‡
At 165 minutes	122.35±9.12	120.85±6.91	0.41‡
At 180 minutes	123.75±9.89	121.18±7.43	0.192‡

[Table/Fig-5]: Comparison of Systolic Blood Pressure (SBP) (mmHg) between Group R and B.
‡Independent t-test

The mean±SD Systolic Blood Pressure (SBP) in Group R at 10, 15, 20 and 25 minutes was significantly higher than in Group B (p<0.05). No statistically significant difference in SBP was observed at other time intervals [Table/Fig-5].

Similarly, the mean±SD diastolic blood pressure (DBP) in Group R at 10, 15, 20 and 25 minutes was significantly higher compared to Group B (p<0.05), with no significant differences at other time points [Table/Fig-6].

The mean±SD mean arterial pressure (MAP) in Group R at 10, 15, 20 and 25 minutes was significantly higher than in Group B (p<0.05), while no significant difference was observed at the remaining intervals [Table/Fig-7].

Mean Oxygen Saturation (SpO_2) remained stable and within clinically acceptable limits in both groups throughout the study period, with no statistically significant difference between the groups (p>0.05) [Table/Fig-8].

The mean total requirement of intravenous fluids (Ringer's lactate) was significantly higher in Group B compared to Group R (p<0.0001) [Table/Fig-9].

A significantly lower proportion of patients in Group R (27.5%) required vasopressor support (mephentermine) for the

Diastolic Blood Pressure (DBP) (mmHg)	Group R (n=40)	Group B (n=40)	p-value
At baseline	81.38±8.56	78.55±7.35	0.117‡
At 5 minutes	78.32±8.74	76.05±6.48	0.19‡
At 10 minutes	74.3±11.21	70.08±6.79	0.046‡
At 15 minutes	70.42±8.5	66.38±8.04	0.032‡
At 20 minutes	68.9±10.6	63.42±10.3	0.022‡
At 25 minutes	70.42±9.01	64.65±10.01	0.008‡
At 30 minutes	70±7.54	68.47±7.18	0.357‡
At 45 minutes	70.78±7.37	71.53±6.54	0.632‡
At 60 minutes	72.2±8.22	73.2±5.96	0.535‡
At 75 minutes	73.38±6.76	74±6.36	0.671‡
At 90 minutes	74.25±6.22	74.92±6.73	0.643‡
At 105 minutes	75.5±6.45	76.38±5.27	0.508‡
At 120 minutes	76.28±6.4	76.72±5.24	0.732‡
At 135 minutes	77.25±5.97	77.62±5.09	0.763‡
At 150 minutes	78.1±6.24	78.42±5.71	0.809‡
At 165 minutes	79.75±5.94	79.35±5.88	0.763‡
At 180 minutes	80.53±5.98	80.42±5.51	0.938‡

[Table/Fig-6]: Comparison of Diastolic Blood Pressure (DBP) (mmHg) between Group R and B.
‡Independent t-test

Mean Arterial Pressure (MAP) (mmHg)	Group R (n=40)	Group B (n=40)	p-value
At baseline	96.3±9.66	92.65±7.45	0.062‡
At 5 minutes	92.32±9.31	90.08±5.31	0.189‡
At 10 minutes	87.85±10.1	83.82±6.64	0.039‡
At 15 minutes	84.22±10.96	79.35±9.63	0.038‡
At 20 minutes	82.72±12.82	76.05±11.85	0.018‡
At 25 minutes	83.35±10.77	78.45±10.72	0.045‡
At 30 minutes	83.3±9.8	81.8±7.49	0.444‡
At 45 minutes	84.8±10.24	84.75±7.46	0.98‡
At 60 minutes	86.18±10.43	85.9±6.68	0.889‡
At 75 minutes	87.75±10.05	87.7±6.55	0.979‡
At 90 minutes	88.62±7.86	88.38±6.76	0.879‡
At 105 minutes	89.75±7.58	89.78±5.94	0.987‡
At 120 minutes	90.68±7.31	90.38±5.41	0.835‡
At 135 minutes	91.48±6.56	91.15±5.24	0.807‡
At 150 minutes	92.7±6.55	92.22±5.43	0.725‡
At 165 minutes	94±6.21	93.2±5.84	0.555‡
At 180 minutes	95.1±7.12	94.22±5.77	0.548‡

[Table/Fig-7]: Comparison of Mean Arterial Pressure (MAP) (mmHg) between Group R and B.
‡Independent t-test

SpO_2 (%)	Group R (n=40)	Group B (n=40)	p-value
At baseline	97±0.6	97±0	1‡
At 5 minutes	98.65±0.48	98.68±0.53	0.825‡
At 10 minutes	99.08±0.27	99.18±0.45	0.228‡
At 15 minutes	99±0	99±0	1‡
At 20 minutes	99.2±0.46	99.32±0.47	0.237‡
At 25 minutes	99±0	99±0	1‡
At 30 minutes	99±0	99±0	1‡
At 45 minutes	99.05±0.32	99.2±0.41	0.069‡
At 60 minutes	99.02±0.28	99.15±0.43	0.125‡
At 75 minutes	98.92±0.27	98.98±0.16	0.312‡
At 90 minutes	98.7±0.69	98.9±0.55	0.153‡
At 105 minutes	98.5±0.51	98.68±0.47	0.115‡
At 120 minutes	97.85±0.83	98.15±0.89	0.124‡

At 135 minutes	97.4±0.67	97.7±0.72	0.058‡
At 150 minutes	97.22±0.53	97.48±0.64	0.061‡
At 165 minutes	97.25±0.59	97.4±0.59	0.259‡
At 180 minutes	97.05±0.22	97.08±0.27	0.649‡

[Table/Fig-8]: Comparison of SpO_2 (%) between Group R and B.
‡ Independent t-test

Total requirement of fluids (RL) (mL)	Group R (n=40)	Group B (n=40)	p-value
Mean±SD	863.75±233.97	1106.25±197.16	<0.0001‡

[Table/Fig-9]: Comparison of total requirement of fluids (RL) (ml) between Group R and B.
‡ Independent t-test

management of hypotension compared to Group B (55%) (p=0.026) [Table/Fig-10].

Total requirement of vasopressor (Mephentermine) (mg)	Group R (n=40)	Group B (n=40)	p-value
0	29 (72.50%)	18 (45%)	0.026*
3	2 (5%)	3 (7.5%)	
6	3 (7.50%)	11 (27.50%)	
9	5 (12.50%)	8 (20%)	
12	1 (2.50%)	0	
Total	40 (100%)	40 (100%)	

[Table/Fig-10]: Comparison of total requirement of vasopressor (Mephentermine) (mg) between Group R and B.
*Fisher's-exact test

The incidence of hypotension was significantly lower in Group R compared to Group B (p=0.012). Additionally, Group R showed a significantly lower incidence of urinary retention compared to Group B (p=0.032). Other adverse effects were comparable between the two groups and were not statistically significant (p>0.05) [Table/Fig-11].

Adverse effects	Group R (n=40)	Group B (n=40)	p-value
Hypotension	11 (27.50%)	22 (55%)	0.012†
Bradycardia	6 (15%)	11 (27.50%)	0.172†
Urinary retention	5 (12.50%)	13 (32.50%)	0.032†
Nausea and vomiting	3 (7.50%)	5 (12.50%)	0.712*
Allergic reaction	0	0	NA

[Table/Fig-11]: Comparison of adverse effects between Group R and B.
*Fisher's-exact test, †Chi-square test.

DISCUSSION

Spinal anaesthesia is the most commonly used regional anaesthetic technique for lower limb surgeries [18]. It offers several advantages, including ease of administration, avoidance of airway manipulation, predictable onset and duration of anaesthesia and excellent intraoperative analgesia [19]. Various local anaesthetic agents have been used intrathecally for spinal anaesthesia. To date, hyperbaric bupivacaine has been the preferred agent; however, it is associated with cardiotoxic and neurotoxic effects [20].

Ropivacaine, a pure S-enantiomer of bupivacaine, is structurally similar to bupivacaine, differing only by the substitution of a propyl side chain in place of the butyl group present in bupivacaine. This structural difference accounts for its lower lipid solubility [21], reduced toxicity and a greater degree of motor-sensory differentiation [22,23].

In the present study, the mean onset time of both sensory and motor block in Group R was significantly longer compared to Group B (p<0.05). Conversely, the mean duration of sensory and motor block in Group B was significantly longer than in Group R (p<0.0001). Gaikwad DM et al., compared hyperbaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5% in patients undergoing elective infra-umbilical surgeries and reported a significant delay in the onset of sensory (p<0.001) and motor block (p<0.001), along with a shorter duration of sensory (p<0.001) and motor block (p<0.001) in the ropivacaine group [12]. Similarly, Kalbande JV et al., compared the efficacy and safety of subarachnoid block using hyperbaric ropivacaine (0.75%) versus hyperbaric bupivacaine (0.5%) in infra-umbilical surgeries and observed a slower onset and shorter duration of motor block in the ropivacaine group compared to the bupivacaine group (p<0.001) [13].

The mean pulse rate was significantly higher in Group R at most time intervals (p<0.05), except at baseline, 45 minutes and 60 minutes, where although the heart rate was higher in Group R compared to Group B, the difference was not statistically significant. Chatterjee S et al. and Adhikari P et al., also reported statistically significant differences in heart rate at various time intervals during the assessment period (p<0.05) [17,18].

Mean Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP) in Group R at 10, 15, 20 and 25 minutes were significantly higher compared to Group B (p<0.05), while these parameters were comparable between the two groups at all other time intervals. Chatterjee S et al., reported significantly lower MAP values at various time intervals in the bupivacaine group compared to the ropivacaine group (p<0.05) [17]. In contrast, Kalbande JV et al., concluded that haemodynamic changes were not statistically significant when hyperbaric bupivacaine (0.5%) was compared with an equipotent dose of hyperbaric ropivacaine (0.75%) (p>0.05); however, MAP and heart rate were consistently higher in the ropivacaine group throughout the study period [13].

The total requirement of intravenous fluids (Ringer's lactate) and vasopressor (mephentermine) was significantly higher in Group B compared to Group R (p<0.05). Whiteside JB et al., also observed a significantly greater requirement for vasopressor (ephedrine) in the bupivacaine group, with 14 patients (70%) requiring intervention compared to only three patients (15%) in the ropivacaine group (p=0.001) [4].

Bradycardia and hypotension were the most commonly observed adverse effects. Although the incidence of bradycardia was higher in the bupivacaine group, the difference was not statistically significant between the two groups (p=0.172). However, bupivacaine was associated with a significantly higher incidence of hypotension (p=0.012), necessitating treatment in a greater number of patients. Adhikari P et al., compared the efficacy and safety of intrathecal ropivacaine (0.75%, isobaric) versus intrathecal bupivacaine (0.5%, isobaric) in lower abdominal surgeries and concluded that hypotension and bradycardia occurred more frequently with bupivacaine, rendering ropivacaine more haemodynamically stable (p<0.05) [18].

Urinary retention was significantly more frequent in the bupivacaine group (p=0.032). Gaikwad DM et al., also reported a significantly higher incidence of delayed micturition in the bupivacaine group compared to the ropivacaine group (p<0.05) [12]. No allergic reactions were observed in patients from either group.

Limitation(s)

The limitations of the present study include its single-centre design and the inclusion of only ASA physical status grade I and II patients.

CONCLUSION(S)

Ropivacaine demonstrates a delayed onset and shorter duration of both sensory and motor block compared to bupivacaine. Patients in the ropivacaine group exhibited greater perioperative haemodynamic stability and required fewer fluids and vasopressors for the management of hypotension compared to those receiving bupivacaine. Additionally, ropivacaine was associated with fewer adverse effects. In conclusion, hyperbaric ropivacaine (0.75%) is comparable to hyperbaric bupivacaine (0.5%) in terms of the quality

of spinal anaesthesia. Its advantages of shorter motor blockade duration and superior haemodynamic stability make ropivacaine a suitable alternative to bupivacaine for short-duration lower limb surgeries.

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