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Original Article

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A Comparative Evaluation of Hyperbaric Ropivacaine Versus Hyperbaric Bupivacaine for Lower Limb Surgeries

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Abstract

Background: Anesthesiologists frequently utilize various local anesthetics for intrathecal administration, including isobaric or hyperbaric formulations of ropivacaine, levobupivacaine, and bupivacaine solutions. Among these, hyperbaric local anesthetics like ropivacaine, levobupivacaine, and bupivacaine solutions are particularly prevalent. Aim of this study to compare the clinical efficacy and safety of hyperbaric 0.75% ropivacaine and hyperbaric 0.5% bupivacaine under spinal anaesthesia for lower limb surgeries, focusing on sensory and motor block characteristics. ***Methods:*** A randomized double-blind, prospective study, total 130 patients aged 18-50 undergoing lower limb surgeries. The study excluded patients with unwillingness, psychiatric diseases, emergency surgeries, drug abuse history, medical complications, coagulation disorders, local infections, spinal deformities, heart block or dysrrhythmia, sensory block not achieved till T10 level, and motor block less than 3(BS-3). Patients in the study were categorized into two groups: one receiving 0.75% ropivacaine and the other receiving 0.5% bupivacaine for spinal anaesthesia. The main objective was to investigate the effects of ropivacaine on spinal anaesthesia outcomes. ***Results:*** Total of 130 patients were analyzed, comparing the demographics and clinical parameters between two groups, R and B. The mean age of participants was 40.36±9.76 years, with average weight and height at 66.94±15.53 kg and 164.22±14.79 cm, respectively. Both groups had similar mean surgical durations, 120.74 minutes for group R and 121.01 minutes for group B. While group B exhibited shorter sensory and motor blockade durations, group R showed longer times. Bromage scores were found to be comparable between the two groups. ***Conclusion:*** The study compared ropivacaine and bupivacaine in spinal anesthesia duration, finding no significant difference. Bupivacaine had longer sensory blocking and motor blockage time, while ropivacaine had superior hemodynamic stability.

Keywords: ***Ropivacaine, Hyperbaric Bupivacaine, Lower Limb Surgery, Spinal Anesthesia.***

Introduction

A century ago, a report emphasized the importance of a long-term decision regarding local anesthetics in spinal anesthesia, which sees around 15 million procedures performed annually worldwide. Central neuraxial blockade, a favored technique, is known for its affordability and ease of use, offering muscle relaxation, pain relief, and decreases in blood loss, stress response, and morbidity, particularly in high-risk patients [1,2].

Spinal anesthesia involves the injection of a hyperbaric local anesthetic into the subarachnoid space, leading to total analgesia, relaxed breathing, and muscle relaxation. The injection is typically performed between the third and fourth lumbar vertebrae, below where the spinal cord ends [3]. The density of the anesthetic solution influences the blockade type and patient positioning helps control the flow towards the target area [4]. A "medium" spinal block is appropriate for lower abdominal and leg procedures, utilizing drugs such as bupivacaine, lidocaine, and tetracaine [5].

Anesthesiologists utilize local anesthetics such as isobaric and hyperbaric ropivacaine, levobupivacaine, and bupivacaine for intrathecal application. Nonetheless, the therapeutic efficacy of these anesthetics in non-pregnant patients has only been examined in 16 studies from 1946 to 2017 [2]. The results are cautious due to the limited sample size and significant data heterogeneity. Bupivacaine, an aminoamide molecule introduced in 1963, is recognized as a strong, long-acting local anesthetic [6]. Bupivacaine and etidocaine pose cardiac risks like ventricular depression and collapse, prompting the creation of ropivacaine. While bupivacaine is frequently used in spinal anesthesia, it is more hazardous to the heart and central nervous system than other local anesthetics, being associated with severe cardiovascular injuries [7,8].

The molecular composition of bupivacaine and the recently developed aminoamide local anesthetic ropivacaine is similar [7,8]. Ropivacaine has been shown to be safe and effective in regional anesthetic treatments like brachial plexus block and epidural anesthesia. However, a thorough investigation of intrathecal anesthesia with hyperbaric ropivacaine is still pending [9]. The S-(–)-enantiomer of bupivacaine has fewer side effects than its R-(+)-cousin [6]. This led to the development of "enantiomeric" local anesthetics that are more tolerable and less harmful to the heart and central nervous system. A pure "S" isomer of the propyl analog of bupivacaine was synthesized to produce ropivacaine, a novel amide

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local anesthetic with lower potency, lower lipid solubility, and less harmful effects on the central nervous system and cardiovascular system [10-13]. The study compared the safety and efficacy of isobaric ropivacaine in neuraxial blockade with intrathecal lignocaine. It concluded that ropivacaine acted faster and had a lower risk of causing neurological symptoms, although pressurized preparations were not available due to stability concerns.

Aim of this study to compare the clinical efficacy and safety of hyperbaric 0.75% ropivacaine and hyperbaric 0.5% bupivacaine under spinal anaesthesia for lower limb surgeries, focusing on sensory and motor block characteristics, hemodynamic changes, and potential adverse effects.

Methods

The was Randomized Double blind, Prospective study conducted in Department of Anaesthesiology, Ganesh Shanker Vidyarthi Memorial medical college, Kanpur over a period of one year. Total 130 adult patients aged 18-50 undergoing lower limb surgeries, ASA Class I and II patients, weighing 45kg-80kg, and with heights between 160cm-185cm were included. Exclusion criteria include unwilling patients, psychiatric diseases, emergency surgeries, drug abuse history, medical complications, coagulation disorders, local infection, spinal deformities, heart block or dysrrhythmia, and patients with sensory block not achieved till T10 level and motor block less than 3(BS-3). Patients with coagulation disorders, anticoagulant therapy, or spinal deformities are excluded.

After taking written informed consent patients were divided into two groups by computer generated random numbers.

1. **GROUP (R) (n =65)**: received 3ml of Heavy (0.75%) ropivacaine for spinal anaesthesia.
2. **GROUP (B) (n =65):** received 3ml of Heavy (0.5%) bupivacaine for spinal anaesthesia.

Individuals who underwent lower extremity surgery, a total of 138 ASA I or II patients, were randomly assigned to receive either 3 ml of hyperbaric 0.75% ropivacaine or 3 ml of hyperbaric 0.5% bupivacaine. Eligibility criteria included ages 18 to 50 and height between 160 and 185 cm, with no contraindications for spinal anesthesia. If motor block was below BS 3 and sensory block did not reach T10, general anesthesia was used. Patients were blinded to their treatment group, with the bupivacaine group receiving a standard solution and the ropivacaine group receiving a higher concentration for spinal anesthesia. Each patient was pre-hydrated with a 10 mL/kg crystalloid solution before blockade, which was administered in an upright position at L3-L4 or L4-L5 levels using a 25G Quincke type needle. Post-injection, patients were positioned supine, and sensation was assessed via the pin prick method.

The assessment of sensory blockade was performed at regular intervals until the onset of sensory block. The commencement of a sensory block at the T10 level is considered to be the beginning of the sensory block and is considered sufficient for the surgical treatment. The evaluation of sensory blockage was conducted at 10-minute intervals until the sensory block receded. The patient's sensory blockage was completely reversed when they felt unpleasant sensations at the S1 dermatome level, and the time of occurrence was recorded.

The motor block was assessed using the Modified Bromage Scale (BS 0-3), with BS 0 indicating no motor block and BS 3 indicating complete motor block. The examination of motor block was performed at one-minute intervals until the onset of motor block, mirroring the assessment of sensory block. The Modified Bromage scale employs a numerical score of BS scale-3 to signify the onset of motor block. After the start, the motor block was assessed every ten minutes until full restoration of motor function (BS scale -0). If a patient fails to attain a motor block level of BS scale -3 on the Bromage scale after receiving a spinal anesthetic, they are deemed ineligible for operation.

Prior to anesthesia, cardiovascular parameters such as heart rate and blood pressure were assessed. Blood flow dynamics were measured at 3-minute intervals for the first 30 minutes after spinal medication administration, then at 5-minute intervals for 60 minutes, and finally at 10-minute intervals until the motor block subsided. Hypotension was treated with increased fluid infusion and 6 mg of mephentermine as necessary, while bradycardia was addressed with atropine sulfate (0.6 mg). Patients experiencing discomfort received intravenous midazolam (0.05 mg/kg) and fentanyl (1 mcg/kg) for slight pain, with ketamine (0.25 mg/kg) for recurrent pain. Intraoperative anesthetic quality was assessed on a four-grade scale ranging from 'Excellent' (no additional medication needed) to 'Inadequate' (requiring general anesthesia). A power analysis was performed based on the first 20 patients to assess sensory blockade. Comprehensive medical evaluations, counseling in native languages, and informed consent were obtained, with specific pre-operative medications administered.

The statistical analysis was performed with SPSS version 22nd The data were presented in the form of mean (standard deviation) and percentage (%). The chi-square test was used to compare categorical variables, while the independent t-test was used to assess discrete variables between groups. A p-value of 0.05 was considered statistically significant.

Results

Total of 130 patients were included in a study comparing spinal anaesthesia using 3 ml of heavy (0.75%) ropivacaine versus 3 ml of heavy (0.5%) bupivacaine, with equal distribution of 65 patients in each group. Mean age differed slightly between groups, with group R averaging 40.36±9.76 years and group B 42.16±9.47 years, but the difference was not statistically significant. In terms of weight and height, group R had mean values of 66.94±15.53 kg and 164.22±14.79 cm, while group B had 64.94±9.78 kg and 165.61±8.33 cm, again with no significant differences noted. Gender distribution was fairly similar; group R had 53.62% males and 46.38% females, compared to group B's 55.07% males and 44.93% females. Furthermore, the ASA grade frequencies indicated that group R had 63.77% in grades I and II, while group B showed a slightly higher frequency at 68.12%. Overall, demographic characteristics showed no significant differences between the two groups.

Table 1: Comparison of mean age, weight, height, and frequencies of different ASA grades between groups R and B.

	Group R (n=65)		Group B (n=65)		t	p-Value
	Mean	±SD	Mean	±SD		
Age	40.36	9.76	42.16	9.47	-1.10	0.274
Weight (kg)	66.94	15.53	64.94	9.78	0.91	0.367
Height (cm)	164.22	14.79	165.61	8.33	-0.68	0.497

ASA I	44	63.77	47	68.12	0.13	0.719
ASA II	25	36.23	22	31.88		

The study analyzed surgical duration in two groups, R and B, finding the mean operation time at 120.74 cm for group R and 121.01 cm for group B. Although group B had a lower onset time for sensory blockade, this difference was not statistically significant. However, group B exhibited a significantly longer duration for both sensory and motor blockade compared to group R. These results indicate variability in blockade durations based on the group.

Table 2: comparison of mean duration of surgery, onset time of sensory block, time to peak sensory block, duration of sensory block, time to complete motor blockade, and motor blockade between group R and group B.

	Group R (n=65)		Group B (n=65)		t	p-Value
	Mean	±SD	Mean	±SD		
Duration of Surgery (min)	120.74	13.33	121.01	12.56	-0.12	0.901
Onset time of sensory block (sec)	156.43	38.00	146.10	30.44	1.76	0.080
Time to peak sensory block (min)	14.42	3.03	13.64	3.26	-1.46	0.146
Duration of sensory block (min)	156.87	29.06	211.14	47.57	-8.09	<0.001
Time to complete motor blockade (min)	13.54	2.48	9.30	2.08	10.87	<0.001
Duration of motor blockade (min)	121.49	11.51	176.20	15.18	-23.86	<0.001

Comparison of frequencies of different bromage in between group R and group B. The percentage of Bromage 3, Bromage 2, Bromage 1 and Bromage 0 were 73.91%, 23.19%, 2.90%, and 0.00% in group R and 82.61%, 17.39%, 0.00% and 0.00 in group B, respectively. On the basis of bromage, both groups were comparable.

Table 3: Comparison of frequencies of different bromage in between group R and group B

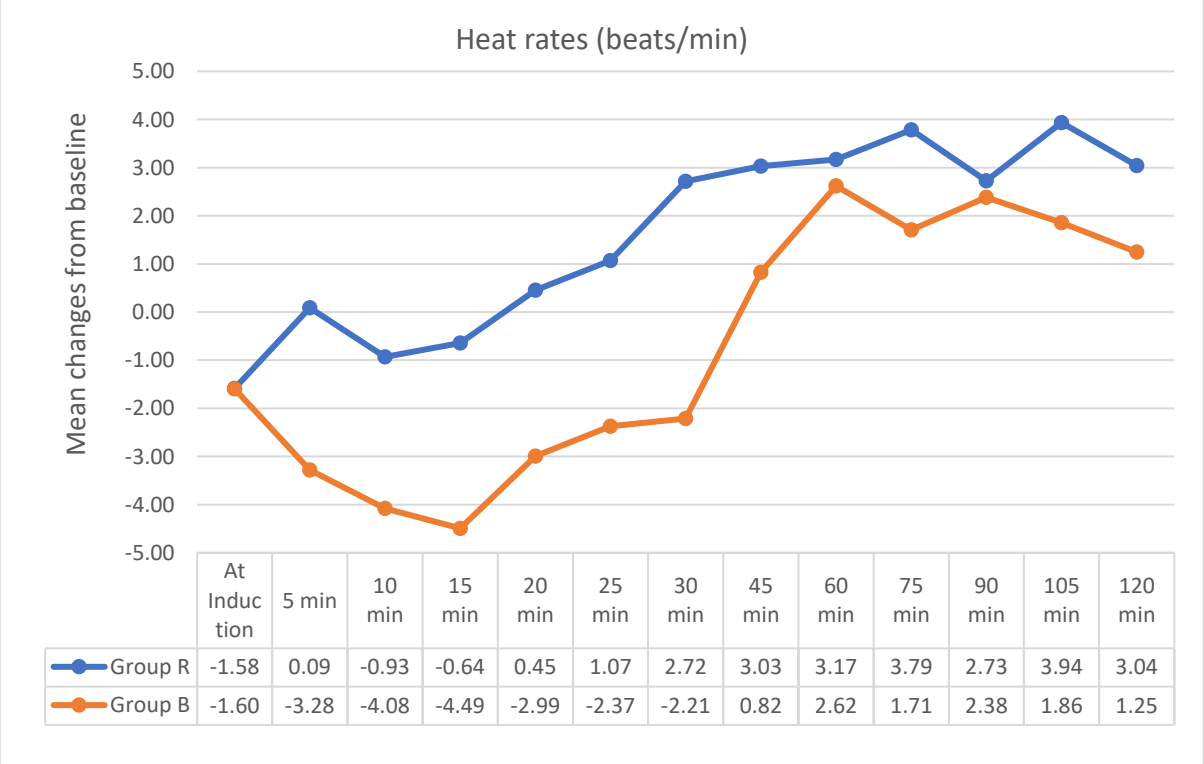
	Group R (n=65)		Group B (n=65)		Chi Sq.	p-Value
	n	%	n	%		
Bromage 3	50	73.91	53	82.61	2.91	0.234
Bromage 2	13	23.19	12	17.39		
Bromage 1	2	2.90	0	0.00		
Bromage 0	0	0.00	0	0.00		

Comparison of frequencies of different complication between group R and group B before Induction to 120 min. The percentage of intra-operative Hypotension, Bradycardia, Nausea, Vomiting and Shivering were 7.25%, 4.35%, 7.25%, 0.00%, and 4.35% in group R and 10.14%, 7.25%, 8.70%, 0.00%, and 7.25%, in group B, respectively. The post-operative vomiting was 1.45% in group R and 2.90% in group B. On the basis of complication, both groups were comparable.

Table 4: Comparison of frequencies of different complication between group R and group B before Induction to 120 min

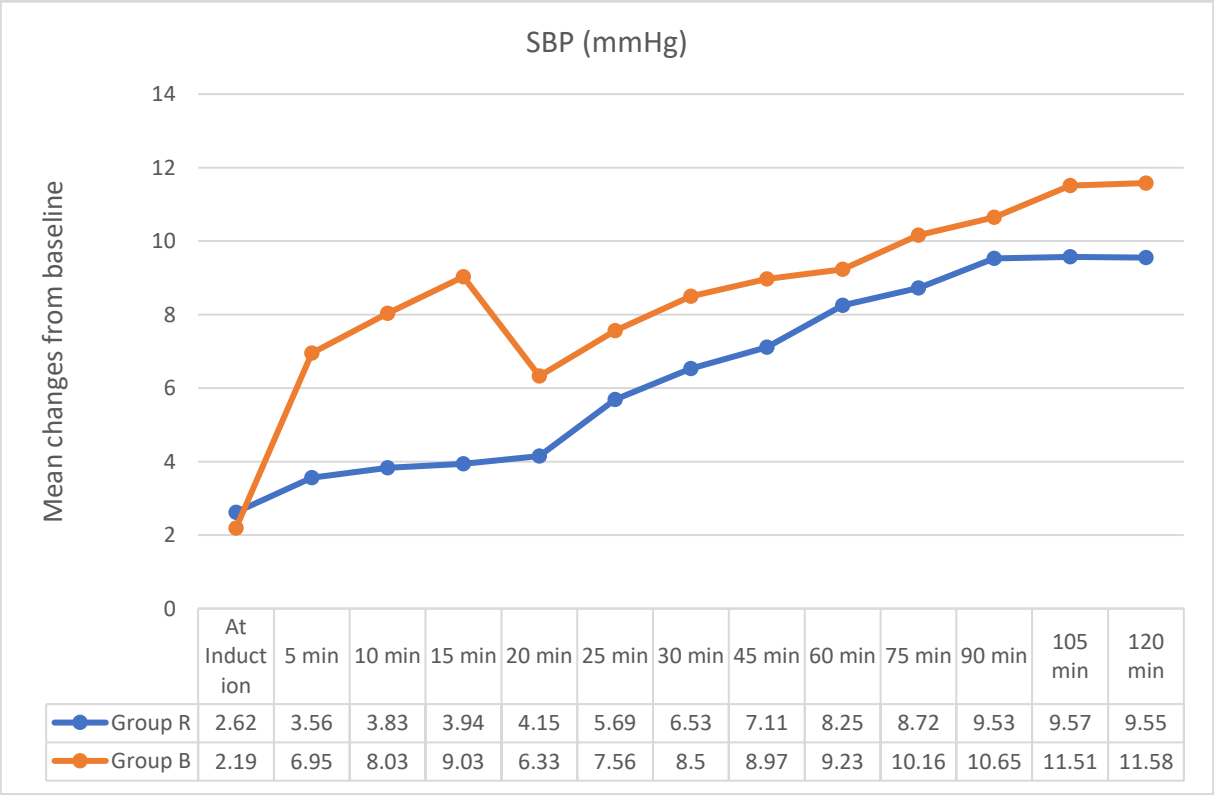
	Group R (n=65)		Group B (n=65)		Chi Sq.	p-Value
	n	%	n	%		
Intraoperative side effects						
Hypotension	5	7.25	7	10.14	0.09	0.763
Bradycardia	3	4.35	5	7.25	0.13	0.716
Nausea	5	7.25	6	8.70	0.08	0.771
Vomiting	0	0.00	0	0.00	-	-
Shivering	3	4.35	5	7.25	0.13	0.716
Postoperative side effects (%)						
Vomiting	1	1.45	2	2.90	0.34	0.559

Show the change in heart rate from baseline to at induction and after induction 5 min to 120 min. (figure 1)



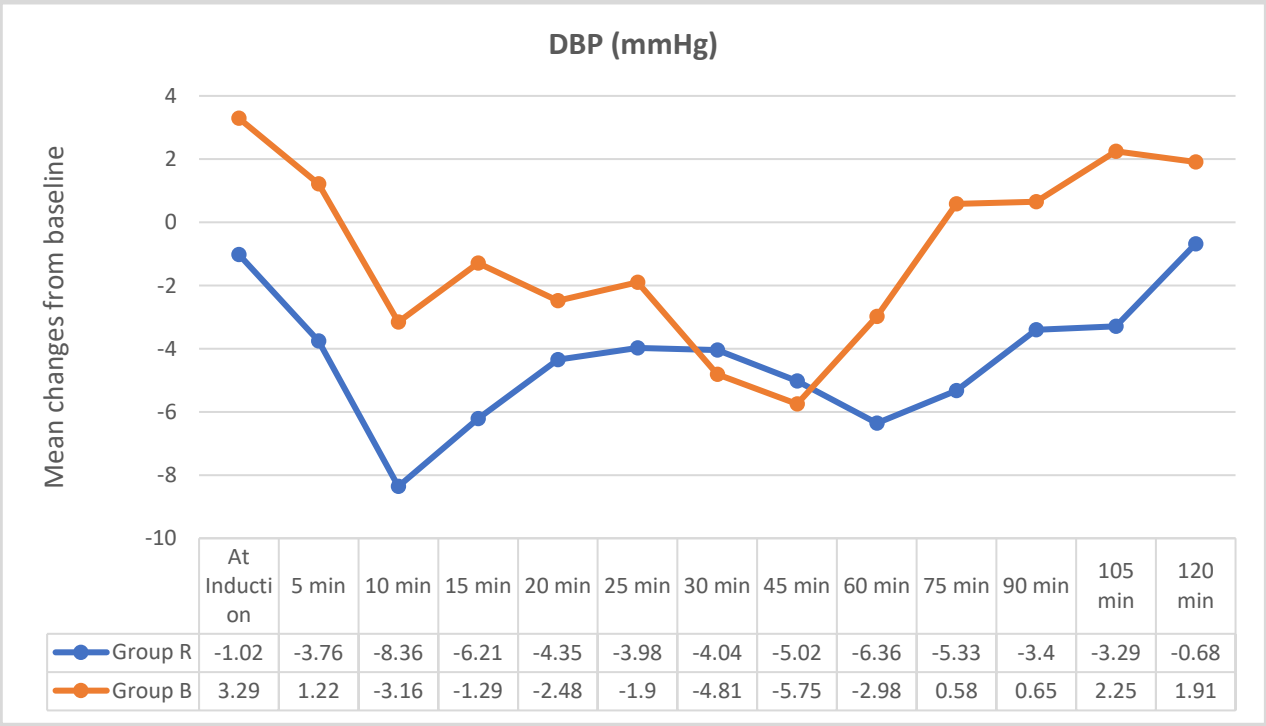
	At Induction	5 min	10 min	15 min	20 min	25 min	30 min	45 min	60 min	75 min	90 min	105 min	120 min
Group R	-1.58	0.09	-0.93	-0.64	0.45	1.07	2.72	3.03	3.17	3.79	2.73	3.94	3.04
Group B	-1.60	-3.28	-4.08	-4.49	-2.99	-2.37	-2.21	0.82	2.62	1.71	2.38	1.86	1.25

Figure 1. Shows the change in heart rate from baseline to at induction and after induction 5 min to 120 min



	At Induction	5 min	10 min	15 min	20 min	25 min	30 min	45 min	60 min	75 min	90 min	105 min	120 min
Group R	2.62	3.56	3.83	3.94	4.15	5.69	6.53	7.11	8.25	8.72	9.53	9.57	9.55
Group B	2.19	6.95	8.03	9.03	6.33	7.56	8.5	8.97	9.23	10.16	10.65	11.51	11.58

Figure 2. Shows the mean % change in SBP from baseline to at induction and after induction 5 min to 120 min



	At Induction	5 min	10 min	15 min	20 min	25 min	30 min	45 min	60 min	75 min	90 min	105 min	120 min
Group R	-1.02	-3.76	-8.36	-6.21	-4.35	-3.98	-4.04	-5.02	-6.36	-5.33	-3.4	-3.29	-0.68
Group B	3.29	1.22	-3.16	-1.29	-2.48	-1.9	-4.81	-5.75	-2.98	0.58	0.65	2.25	1.91

Figure 3. Shows the change in DBP from baseline to at induction and after induction 5 min to 120 min

Discussion

Spinal anesthesia is widely used in orthopedic and abdominal surgeries due to its predictable onset, duration, cost-effectiveness, and reduced bleeding. Common local anesthetics for intrathecal procedures include lignocaine, bupivacaine, levo-bupivacaine, and ropivacaine, with bupivacaine 0.5% heavy being frequently applied. Ropivacaine, a less potent enantiomer of bupivacaine, presents a lower risk of cardiac and neurological damage and provides a shorter duration of sensory and motor blockage [14-16]. Comparative studies of hyperbaric solutions of ropivacaine and bupivacaine have been conducted for various surgical applications.

McNamee *et al.*,[17] revealed that both the ropivacaine and bupivacaine groups experienced a rapid onset of motor and sensory block, with no significant differences noted. However, the ropivacaine group demonstrated a significantly shorter duration of motor block compared to the bupivacaine group. The average age of participants was 40.36±9.76 years for the ropivacaine group and 42.16±9.47 years for the bupivacaine group, with gender parity observed in both groups. In terms of physical characteristics, the ropivacaine group had an average weight of 66.94±15.53 kg and height of 164.22±14.79 cm, while the bupivacaine group averaged 64.94±9.78 kg in weight and 165.61±8.33 cm in height. Notably, the ropivacaine group experienced a longer time to both sensory blockade and full motor blockade, while the bupivacaine group exhibited a reduced duration of sensory blockade. Similarities were found between the two groups in terms of bromage scores.

Research on spinal anesthesia for lower abdominal surgeries indicates that ropivacaine and bupivacaine resulted in similar sensory blockade quality; however, ropivacaine exhibited a delayed onset and a shorter duration of motor blockade [18]. Specifically, Dar *et al.*, found that ropivacaine led to a postponement in both sensory and motor block initiation, with shorter duration effects [19]. Similarly, Adhikari *et al.*,[20] reported comparable sensory blockade features between the two anesthetics, while highlighting that the ropivacaine group experienced quicker recovery of motor function. Overall, the findings suggest that ropivacaine is more effective for these surgical procedures.

A study by Olapour *et al.*,[21] found that administering 15 mg of 1% ropivacaine for cesarean births under spinal anesthesia led to a longer onset time for sensory and motor blockage compared to 10 mg of 0.5% bupivacaine; however, ropivacaine provided a briefer overall blockage duration. Similarly, Chari *et al.* observed that both sensory and motor effects were slower to manifest with ropivacaine, leading to a reduction in motor activity [22]. Purohit *et al.* reported that the ropivacaine group experienced a later onset of sensory and motor characteristics but achieved quicker motor recovery [23]. Kulkarni *et al.* also noted that the onset of sensory effects was delayed in the ropivacaine group, which exhibited a shorter average duration of both sensory and motor blockage compared to the bupivacaine group [24].

Kharat *et al.*,[25] investigated the effects of intravenous administration of 0.5% hyperbaric bupivacaine and ropivacaine during surgery, revealing that bupivacaine had a quicker onset and shorter duration of sensory peak than ropivacaine, although both showed similar diffusion towards the skull. Erturk *et al.* and Bigat *et al.* noted that hyperbaric spinal bupivacaine resulted in a faster onset of sensory blockade at the T-10 level and a longer duration compared to ropivacaine [26,27]. This difference may stem from bupivacaine's higher lipid solubility and marginally greater protein binding, ultimately enhancing its effectiveness as a local anesthetic by increasing its concentration in myelin and adjacent neuronal compartments.

Ropivacaine targets pain neurons not covered in myelin, rather than motor fibers, due to its lower affinity for fat. A quicker recovery with spinal ropivacaine is associated with greater patient satisfaction, although a formal assessment of patient satisfaction is not conducted [28,29].

Research demonstrates that ropivacaine provides improved hemodynamic stability relative to bupivacaine, with fewer instances of hypotension and bradycardia. Although no substantial differences are observed in systolic and diastolic blood pressures between the two groups, a notable increase in heart rate is recorded for the bupivacaine group, as indicated by Mahajan and Patel [18,20,21]. Other studies, including those by Chari *et al.* and Purohit *et al.*, confirm stable hemodynamics in the ropivacaine cohort, while bupivacaine

patients exhibited a greater need for hypotension treatment. Kulkarni *et al.* identified a higher prevalence of low blood pressure among bupivacaine patients, although heart rate changes were similar across both groups [24]. Kharat *et al.* found minimal differences in hemodynamic metrics except for reductions in diastolic and mean pressures [30]. Hypotension emerged as the primary adverse effect across both groups, supplemented by side effects like nausea, bradycardia, and shivering, with the bupivacaine group reporting higher occurrences of these complications, particularly nausea, bradycardia, and tremors compared to ropivacaine. Despite these differences, the overall complications were similar for both anesthetics.

Dar *et al.*,[19] found that hypotension was the main adverse impact in both groups, with varying rates. Kulkarni *et al.*,[24] found that 27.5% of bupivacaine and 20% of ropivacaine participants needed phenylephrine for hypotension treatment. Both groups responded positively to atropine injections, but some experienced slight pain during lumbar puncture, minor post-dural puncture headache, and earlier urination onset in ropivacaine patients. No neurological issues were observed.

Kalbande *et al.*,[31] found that both groups had high incidences of hypotension and bradycardia as side effects. The bupivacaine group had higher incidences but not statistically significant. However, ropivacaine administration via the intrathecal route decreased hypotension compared to bupivacaine. The absence of the R-enantiomer in ropivacaine accounts for this inconsistency. Ropivacaine is a suitable alternative for spinal anesthesia in cardiac and elderly patients with different health conditions due to its less cardiovascular impact and fewer adverse effects. Our sample size is limited, necessitating the use of larger studies for a more precise assessment.

The study compares the efficacy and safety of hyperbaric ropivacaine and hyperbaric bupivacaine for spinal anesthesia in lower limb surgeries. It aims to optimize pain control, reduce side effects, and improve patient outcomes. The findings can guide anesthesiologists in selecting appropriate local anesthetics, potentially leading to shorter recovery times and better patient satisfaction.

Conclusions

A study comparing ropivacaine and bupivacaine revealed no significant differences in spinal anesthesia duration. Bupivacaine provided a longer sensory block but a shorter motor block time. Both anesthetics exhibited similar bromage scales, however, ropivacaine demonstrated superior hemodynamic stability. The main adverse reactions noted were hypotension, nausea, bradycardia, and shivering. Hyperbaric 0.75% ropivacaine resulted in a sensory block that was preferred over motor blocks due to its slow onset and duration, with concentration increases having no impact on motor block patterns.

Declarations

Ethical Clearance

Approved by Institutional ethics committee

Contributorship

All author contributor equally.

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Conflict of interest

There is no conflict of interest among authors.

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No

Contributors

SSY: Concept design, Supervision, Patients enrollment, Patients treatment, Supervision, Case management, Radiological investigations.

PP: Paper writing, Supervision, Patients enrollment, Data collection, supervision, Patients enrollment, Patient treatment, Unit incharge, Supervision, Patients treatment, enrolment.

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