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To compare the anaesthetic effectiveness and safety of ropivacaine 0.75% with bupivacaine 0.5% for spinal anaesthesia in patients having lower limb orthopedic surgery

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ABSTRACT

Background: Spinal anaesthesia, also known as subarachnoid block, is a fundamental method in the field of contemporary anesthesiology. Spinal anaesthesia is a very safe anaesthetic treatment because it provides deep pain relief, muscular relaxation, and causes fewer systemic and metabolic disruptions.

Aims and objectives: To compare the anaesthetic effectiveness and safety of Ropivacaine 0.75% with Bupivacaine 0.5% for spinal anaesthesia in patients having lower limb orthopaedic surgery.

Materials and methods: A prospective, randomised, double-blinded study was undertaken on 100 adult patients, aged between 18 and 62 years, who were having elective lower limb orthopaedic surgery under spinal anaesthesia. The patients were randomly separated into two equal groups (n = 50) using the odd and even technique. One group was given Ropivacaine (group R), while the other group was assigned Bupivacaine (group B).

Results: In group R, the average length of operation was 102.11±4.15 minutes, whereas in group B it was 105.29±5.22 minutes ($P<0.05$). There was no statistically significant difference seen in any of the groups. In group R (Ropivacaine), the average time for the sensory block to start at the T_{10} level was 2.77±0.36 minutes, whereas in group B (Bupivacaine), it was 3.21±0.39 minutes. The difference between the two groups was statistically significant with a p-value of 0.007. In group R, the time taken to reach the highest degree of sensory block was 8.09±0.77, whereas in group B it was 8.55±0.88. The value of P is 0.23. The average duration of sensory block was shorter in the Ropivacaine group (123.25±5.85 min) compared to the bupivacaine group (179.85±6.88 min; $P = 0.001$). The highest level of sensory block achieved with Ropivacaine was T_5, and with Bupivacaine, it was T_6 (Table 2). The average time it took for a motor block to occur was 4.52±0.56 minutes in group R and 4.89±0.63 minutes in group B. The difference between the two groups was not statistically significant ($P = 0.07$). The duration of motor block recovery in the bupivacaine group was 209.58±5.59 minutes, whereas in the Ropivacaine group it was 151.29±4.82 minutes ($P = 0.001$). Both groups of patients maintained intraoperative stability in terms of heart rate and mean blood pressure.

Conclusion: A hyperbaric solution of Ropivacaine (0.75%) can be utilised to achieve consistent spinal anaesthesia that is equivalent in quality to hyperbaric Bupivacaine (0.5%), but with a shorter duration of sensory and motor block.

Keywords: Ropivacaine, Bupivacaine, Spinal anaesthesia, Lower limb surgery

Introduction

Spinal anaesthesia, also known as subarachnoid block, is a fundamental method in the field of contemporary anesthesiology. Spinal anaesthesia is a very safe anaesthetic treatment because it provides deep pain relief, muscular relaxation, and causes less systemic and metabolic disruptions. Additional benefits include the maintenance of the airway, reduction in blood loss, and the capacity to provide ongoing postoperative pain relief.[1] Spinal or intrathecal anaesthesia has a well-established track record of effectiveness and is gaining popularity, particularly due to the growing number of outpatient procedures and interventions. The ideal spinal anaesthetic should offer both prompt and sufficient surgical anaesthesia, allowing for early mobility and discharge. Bupivacaine is widely used and effectively induces a sufficient sensory and motor blockage.[2] Intrathecal Bupivacaine has a minimal occurrence of postoperative problems. However, it has specific effects on the heart, which are more noticeable with the R-isomer than the S-isomer. The negative consequences have motivated an exploration of medications with reduced toxicity. Recent advancements in local anaesthesia have led to the introduction of newer, longer-acting drugs such as Ropivacaine and levobupivacaine for therapeutic applications.[3] Bupivacaine is a well-recognised regional anaesthetic that has a long-lasting effect. However, it is important to note that, like other amide anaesthetics, it may cause harm to the heart if used in excessive concentrations or if mistakenly injected into the blood vessels.[4,5] Ropivacaine is a prolonged-acting local anaesthetic used for regional anaesthesia. It has a similar chemical structure to Bupivacaine. Unlike Bupivacaine, which is a mixture of both S(+) and S(-) enantiomers, this substance is a pure S(-) enantiomer. It was specifically created to minimise possible toxicity and enhance sensory and motor block characteristics.[6]

Ropivacaine's limited solubility results in enhanced discrimination between sensory and motor fibres since it preferentially blocks sensory nerve fibres over motor fibres. There is a correlation between prompt restoration of

motor function, a reduced occurrence of venous thromboembolism, early mobilisation, and a shorter duration of hospital stay.[7,8] Ropivacaine administered intrathecally was determined to be safe, with a shorter duration of effect and a lower occurrence of temporary neurological symptoms compared to bupivacaine. Additionally, it has a lower risk of causing damage to the heart compared to bupivacaine.[9] In 2004, the European Union authorised the use of Ropivacaine forintrathecal administration.[10] Hyperbaric 0.75% Ropivacaine is a recently developed medication that may be administered intrathecally. Therefore, the purpose of the research was to assess and evaluate the safety and effectiveness of hyperbaric Ropivacaine 0.75% and Bupivacaine 0.5% as anaesthetics in spinal anaesthesia for patients having orthopaedic procedures on the lower leg.

Aims and objectives: To compare the anaesthetic effectiveness and safety of Ropivacaine 0.75% with Bupivacaine 0.5% for spinal anaesthesia in patients having lower limb orthopaedic surgery.

Materials and methods

A prospective, randomised, double-blinded study was undertaken on 100 adult patients, aged between 18 and 62 years, who were having elective lower limb orthopaedic surgery under spinal anaesthesia. The present study has been carried out at the Critical Care, Big Apollo Spectra Hospital, Patna, Bihar, India, in collaboration with the Departments of Anaesthesia, Nalanda Medical College and Hospital, Patna, Bihar, India. The study was carried out over a one-year period, from January 2023 to December 2023. Obtained written informed consent from participants to participate in the present study. Data such as name, age, etc. was recorded. These patients were classified as ASA I and II, and the trial was conducted after obtaining clearance from the institutional review board committee. A comprehensive pre-anesthetic examination was conducted, including all required investigations. The trial excluded individuals who had a documented allergy to any medications, those who had a contraindication to neuraxial block, and those who were unable to provide informed permission. The patients were randomly separated into two equal groups (n = 50) using the odd and even technique. One group was given Ropivacaine (group R), while the other group was assigned Bupivacaine (group B).

Methodology

Prior to the surgery, all patients were given a 150-mg pill of ranitidine and a 0.5-mg tablet of alprazolam. Upon arrival, a thorough evaluation of the peripheral intravenous (IV) condition was conducted using an 18-gauge cannula. The preloading procedure included administering 8–10 mL/kg of Ringer lactate solution within a time frame of 10–15 minutes. Standard equipment, including an electrocardiogram, non-invasive arterial blood pressure monitor, and pulse oximetry (SPO2), was connected in the operating room, and initial readings were recorded. The subarachnoid blocks were conducted with meticulous aseptic measures using a 23G Quincke spinal needle. The procedure was done while the patient was seated, targeting the L3–L4 intervertebral area. Group R was administered 3 mL of hyperbaric 0.75% ropivacaine intrathecally, whereas Group B got 3 mL of hyperbaric 0.5% bupivacaine intrathecally. The patients were promptly placed in a supine position, and measurements of blood pressure (BP), heart rate (HR), and mean arterial pressure (MAP) were recorded. The features of the sensory block were observed using the pinprick technique, while the motor block was assessed using the modified Bromadge scale. The initiation of sensory block was defined as the duration between the administration of the anaesthetic solution and the point at which the feeling of pinpricking at the T10 level was no longer felt. The highest degree of sensory block and the corresponding duration were recorded. The evaluation of motor block was conducted using a modified Bromadge scale, which included instructing the patient to perform flexion movements at the hip, knee, and ankle joints. Grade 0: No paralysis, Grade 1: Inability to raise an extended leg; can bend knees; Grade 2: Inability to bend the knee; can flex the ankle; and Grade 3: No movement.The onset time of motor block was taken as the time to acquire a complete motor block (grade 3) after the intrathecal injection of local anesthetic. Then, the assessment was continued until complete regression of motor block in the lower limbs and sensory block to S1. Vitals parameters such as heart rate, mean arterial pressure, and SPO2 will be recorded at baseline, after spinal anaesthesia, every 2 minutes for 15 minutes, and then at an interval of 15 minutes throughout surgery.

The quality of intraoperative anaesthesia will be assessed using the “four grade scale,” which is defined as:

- Excellent: No supplementary sedative or analgesia is required.
- Good: Only sedatives are required.
- Fair: Both sedatives and analgesia is required, and
- Poor: General anaesthesia and tracheal intubation are required.

Occurrences of complications such as low blood pressure, slow heart rate, feelings of sickness, vomiting, and shivering were documented during and after the surgery, if present. Hypotension, which is characterised by a decrease in systolic blood pressure of more than 20% from the initial level, was managed by administering an intravenous injection of mephentermine at a dosage of 3 mg. Alternatively, intravenous fluids were administered, or a combination of both interventions was used, depending on the specific needs of the patient. Bradycardia, defined as a heart rate below 60 beats per minute, was addressed by administering an intravenous injection of atropine at a dosage of 0.3 mg.

Statistical analysis

Results are provided as the mean value ± standard deviation (SD). The t-test analysis was used to analyse continuous data, while the Chi-square test was used to examine categorical data. The data analysis was conducted using the SPSS programme version 25.0, which is a statistical tool for the social sciences. Results were deemed statistically significant if the p-value was less than 0.05 and highly significant if the p-value was less than 0.001.

Results

Table: 1 displays the demographic characteristics of both groups. The average age in the R group (Ropivacaine) was 43.25 ± 2.96 years, whereas in the B group (Bupivacaine), it was 39.85±3.74 years. Group R consisted of 24 male patients and 26 female patients, whereas Group B included 30 male patients and 20 female patients. Group R consisted of 45 patients classified as ASA I and 5 individuals classified as ASA II. Group B consisted of 42 patients classified as ASA I and 8 individuals classified as ASA II. In group R, the average length of operation was 102.11±4.15 minutes, whereas in group B it was 105.29 ±5.22 minutes (P<0.05). There was no statistically significant difference seen in any of the groups.

Table 1: Demographic Profile of the Patients

Demographic Profile	Group R (Ropivacaine) (n=50)		Group B (Bupivacaine) (n=50)		P-value
	Number	Percentage	Number	Percentage	
Gender					
Male	24	48	30	60	0.19
Female	26	52	20	40	
Age					
Below 20	2	4	4	8	0.23
20-30	11	22	14	28	
30-40	23	46	21	42	
40-50	10	20	8	16	
Above 50	4	8	3	6	
Mean Age in years	43.25±2.96		39.85±3.74		
ASA grade (I/II)					
I	45		42		0.18
II	5		8		
Duration of surgery (min)	102.11±4.15		105.29±5.22		0.32

Table 2: Block characteristics

Efficacy endpoints	Time in minutes				P-value
	Group R		Group B		
	Mean	SD	Mean	SD	
Time required for the onset of sensory block up to T_{10}	2.77	0.36	3.21	0.39	0.007
Time required to achieve the maximum level of sensory block	8.09	0.77	8.55	0.88	0.23
Time required for the onset of motor block (Bromadge scale)	4.52	0.56	4.89	0.63	0.07
Time required to complete recovery from sensory block to S1	123.25	5.85	179.85	6.88	0.001
Time required to recover from motor block (Bromadge 0)	151.29	4.82	209.58	5.59	0.001

In group R (Ropivacaine), the average time for the sensory block to start at the T_{10} level was 2.77±0.36 minutes, whereas in group B (Bupivacaine), it was 3.21±0.39 minutes. The difference between the two groups was statistically significant with a p-value of 0.007 (Table 2). In group R, the time taken to reach the highest degree of sensory block was 8.09±0.77, whereas in group B it was 8.55±0.88. The value of P is 0.23, as seen in Table 2. The average duration of sensory block was shorter in the ropivacaine group (123.25±5.85 min) compared to the

bupivacaine group (179.85±6.88 min; P = 0.001). The highest level of sensory block achieved with ropivacaine was T5, and with bupivacaine, it was T6 (Table 2). The average time it took for a motor block to occur was 4.52±0.56 minutes in group R and 4.89±0.63 minutes in group B. The difference between the two groups was not statistically significant (P = 0.07). The duration of motor block recovery in the bupivacaine group was 209.58±5.59 minutes, whereas in the ropivacaine group it was 151.29±4.82 minutes (P = 0.001) (Table 2).

Table 3: Quality of intraoperative anaesthesia

Grade scale	Group R		Group B	
	Number	Percentage	Number	Percentage
Excellent	37	74	33	66
Good	8	16	9	18
Fair	5	10	8	16
Poor	0	0	0	0

Table :3 shows that the intraoperative quality of anaesthesia was deemed good in 37 patients (74%) in group R and in 33 patients (66%) in group B. The anaesthesia quality was deemed satisfactory in 8 (16%) patients in group R and 9 (18%) patients in group B. There was a fair grade of anaesthesia seen in 5 patients (10%) in group R and 8 patients (16%) in group B.

Table 4: Intraoperative mean blood pressure

Mean blood pressure	Group R		Group B	
	Mean	SD	Mean	SD
Just before induction	98.52	2.52	91.29	2.63
Just after induction	84.36	2.45	93.85	2.15
2 minutes	88.41	2.47	78.63	2.17
4 minutes	82.58	2.15	80.74	2.11
6 minutes	90.47	3.96	84.57	3.25
8 minutes	89.69	2.17	82.72	2.09
10 minutes	92.71	2.18	80.66	1.99
15 minutes	90.52	2.96	80.56	1.78
30 minutes	82.61	1.99	80.32	2.69
45 minutes	88.87	2.11	86.29	2.37
60 minutes	90.67	3.14	78.51	3.33
90 minutes	94.76	3.85	80.61	3.58
120 minutes	82.15	2.05	78.48	1.89

Table: 4 displays the fluctuations in average arterial blood pressure during surgery for both group R and group B at regular intervals. The mean arterial blood pressure of both groups throughout surgery remained constant and similar, with no significant difference observed (P<0.05).Both groups of patients maintained intraoperative stability in terms of heart rate and mean blood pressure, as seen in Tables 4 and 5, respectively.The occurrence of hypotension was prevalent in both groups. Intraoperatively, hypotension was seen in 7 patients (14%) in group R and 11 patients (22%) in group B, necessitating treatment with medicines. During the surgery, shivering was seen in 4 (8%) patients in group R and 8 (16%) patients in group B.

Table 5: Intraoperative mean heart rate

Mean heart rate	Group R		Group B	
	Mean	SD	Mean	SD
Just before induction	83.43	3.96	84.01	3.25
Just after induction	79.62	2.89	81.52	3.33
2 minutes	76.34	2.85	77.83	2.58
4 minutes	80.88	2.61	79.23	2.63
6 minutes	84.29	3.87	81.84	2.47
8 minutes	80.52	2.15	78.28	2.85
10 minutes	78.85	2.09	77.59	1.98
15 minutes	82.44	3.47	80.06	1.69
30 minutes	81.93	3.61	78.57	3.26
45 minutes	79.18	2.15	76.42	2.55
60 minutes	80.79	2.22	77.63	2.89

90 minutes	82.44	1.98	78.44	1.69
120 minutes	80.35	1.86	77.87	2.18

Table 5 displays the average heart rate changes during surgery for group R and group B at certain time intervals. The mean heart rate throughout surgery was constant and similar in both groups, and the observed difference was not statistically significant ($P<0.05$).

Discussion

The typically used local anaesthetics for spinal anaesthesia include lignocaine, bupivacaine, levobupivacaine, and Ropivacaine. Currently, Ropivacaine is being effectively used for spinal anaesthesia. Ropivacaine is well tolerated after intrathecal administration and has a shorter duration of action compared to bupivacaine. Due to its minimal occurrence of temporary neurological symptoms, this characteristic makes it a potential substitute for lignocaine in ambulatory surgery. The decreased lipophilicity of ropivacaine is also linked to a reduced risk of central nervous system toxicity and cardiotoxicity. When compared to bupivacaine, the lower lipid solubility of Ropivacaine suggests that it is more likely to produce a greater differential block of sensory and motor function.[10] Ropivacaine, a recently developed amino-amide local anaesthetic, has a chemical structure comparable to bupivacaine but is about 30–40% less powerful. Extensive research has been conducted on its use for spinal anesthesia.[11] The use of hyperbaric local anaesthetic drugs by intrathecal administration has gained popularity due to their ability to induce consistent block characteristics and dependable spinal anaesthesia. Prior research on isobaric ropivacaine has shown inconsistent or insufficient block patterns for surgical procedures. However, it has been established that the inclusion of glucose in the Ropivacaine solution yields superior outcomes.[9]After undergoing a thorough procedure of securing a patent, doing animal toxicity tests, and completing a clinical phase III study, a 0.75% hyperbaric Ropivacaine was introduced. This Ropivacaine is equally powerful as 0.5% bupivacaine.[12-16] Our research found that the time it took for the sensory block to reach T_{10} was shorter in the Ropivacaine group compared to the bupivacaine group. Ropivacaine, due to its lower lipophilicity, has a reduced ability to enter big, myelinated motor fibres. As a result, it selectively affects the pain-transmitting A delta and C nerves rather than the A beta fibres that are engaged in motor function.[17-19] Therefore, Ropivacaine exhibits a higher degree of specificity in blocking sensory signals compared to the more lipophilic bupivacaine. Kallio et al.[20] conducted a study comparing the effects of hyperbaric and ordinary Ropivacaine. They found that intrathecal administration of hyperbaric Ropivacaine at a dose of 15 mg resulted in a quicker start of action, a higher rate of successful pain relief at the T_{10} dermatome level, and a faster recovery from the block. This is in contrast to previous investigations conducted by Erturket al.[12] and Bigat et al.[10], which reported an earlier sensory start in the bupivacaine group. Our investigation revealed that the Ropivacaine group had a quicker rate of full recovery for both motor and sensory blocks compared to the Bupivacaine group. Parallel findings were shown in the studies conducted by Luck et al.[9] and Whiteside et al.[21]. No statistically significant difference in the intraoperative quality of anaesthesia was seen between the two groups in our investigation. Both organisations provide exceptional anaesthesia services. Osama-Al-Abdulhadiet al.[13] and Luck et al.[9] observed similar findings, as they also discovered no significant disparity in the anaesthesia quality between the Ropivacaine and Bupivacaine groups. There were no significant differences in the complications that occurred during and after the surgery between the two groups. Nevertheless, our research had several constraints. The dosage was not standardised according to age, height, and weight.

Limitations of study: The sample size was small and the duration of the study was short.

Conclusion

A hyperbaric solution of Ropivacaine (0.75%) can be used to achieve consistent spinal anaesthesia that is equivalent in quality to hyperbaric Bupivacaine (0.5%) but with a shorter duration of sensory and motor block.

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