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A PROSPECTIVE RANDOMIZED CONTROLLED DOUBLE BLINDED STUDY COMPARING THE EFFICACY OF HYPERBARIC BUPIVACAINE V/S HYPERBARIC ROPIVACAINE IN SUBARCHANOID BLOCK FOR LOWER LIMB SURGERIES

Anesthesiology

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ABSTRACT

Background: The most popular regional anesthesia method is spinal anesthesia because it is simple to administer, affordable, and results in rapid onset of anesthesia and total muscle relaxation. **Materials And Methods:** A total of 60 ASA Grade 1 and 2 patients undergoing lower limb surgeries under spinal anaesthesia were randomly divided into two groups (30 each). Group B received 3ml of 0.5% hyperbaric bupivacaine intrathecally. Group R received 3ml of 0.75% hyperbaric ropivacaine intrathecally. Using a 26G/25G Quincke spinal needle and aseptic precautions, a subarachnoid block was administered between the L3 and L4 space following a clear and free flow of CSF while seated. Hemodynamics, side effects, effectiveness and length of action were observed. Statistical analysis was performed by using SPSS Version 21.0 and $P < 0.05$ was considered to be significant. **Results:** Current results show that, BMI, age, sex, weight did not significantly differ between the two groups. We found that when using Bupivacaine instead of Ropivacaine, the mean onset of sensory block was faster (3.56 vs 4.22 mins), and the duration was longer (267.83 vs 218.17 mins). In comparison to Ropivacaine, the mean onset of motor block was faster (4.73vs5.2mins) and the duration was longer (191.68 vs 165.17 mins) with bupivacaine. **Conclusion:** Hyperbaric Ropivacaine is a safe substitute for Bupivacaine in lower limb surgeries, particularly those that are shorter in duration and that aid in early ambulation. It also reliably produces spinal anaesthesia with less hypotension than Bupivacaine.

KEYWORDS

Spinal Anaesthesia, Bupivacaine, Ropivacaine.

INTRODUCTION

Spinal anaesthesia is part of the modern practice of anaesthesia because of its proven success, predictability, increased patient satisfaction, low complication rate, better pain control than intravenous narcotics, earlier recovery of bowel function, less need for systemic opioids, easier breathing resulting from better pain control and easier participation in physical therapy [1].

An overall 5% hyperbaric lignocaine was preferred medication for intrathecal anaesthesia; however, it has been linked to brief radicular irritation [2]. Since then, spinal anaesthesia has been widely achieved using 0.5% hyperbaric Bupivacaine which offers a long lasting, strong motor block that is typically unnecessary for surgeries on the lower limbs and perineum. A local anaesthetic known as an Ropivacaine an amino amide, was introduced to the market in 1996 which is Bupivacaine's initial S (-) enantiomer. In comparison to Bupivacaine, it is less potent and produces a less intense motor block with short duration [3]. Ropivacaine is less toxic to the central nervous system and cardiovascular system and has been used in a large number of studies for peripheral nerve blocks, epidural blocks, and local infiltration [4].

Regarding the characteristics of intrathecal ropivacaine use, very little is known. of which the number of studies on hyperbaric ropivacaine is significantly lower than that on isobaric ropivacaine [5]. In comparison to isobaric solutions, it is well known that adding dextrose to a local anaesthetic increases its specific gravity and produces more dependable block [6]. Greater cephalad spread and good muscle relaxation results from this, which enhances the anaesthetic profile [7]. In the direction of gravity, hyperbaric solutions produce a more uniform block with a larger spread. As required by the surgery, it aids in achieving block height.

Current study aims to compare the two commonly used medications intrathecal hyperbaric Ropivacaine and intrathecal hyperbaric Bupivacaine with respect to their effects on the onset and duration of motor and sensory block, changes in hemodynamic parameters, and adverse reaction profile in patients undergoing lower limb surgeries under spinal anaesthesia.

MATERIAL AND METHODS

Study Design:
A prospective, randomized, double blind controlled study.

Study Sample:
This Prospective study included 60 American Society of Anaesthesiologists (ASA) Grade I and II patients, regardless of sex, between the ages 21 and 65 who were having lower limb surgeries under spinal anaesthesia. The computerized random table was used to randomly assign 60 patients of any sex to the Ropivacaine (Group R) or Bupivacaine (Group B) groups.

Inclusion Criteria:
The study includes patients scheduled for elective lower limb surgeries under spinal anaesthesia, between 21years to 65 years of age and American Society of Anaesthesiologists (ASA) Grade I and II patients.

Exclusion Criteria:
The study excludes patients with co-morbid conditions like uncontrolled diabetes mellitus, asthma, hypertension, cardiac disease, haematological disease, allergy to local anaesthetics, ASA class III, IV and V, body mass index more than 28kg/m^2, patients having absolute contraindication like raised intracranial pressure, severe hypovolemia, bleeding diathesis and local infection etc. for spinal anaesthesia.

Study Site:
The current study is a single-centre, hospital-based investigation conducted from February 2022 to September 2022 in the Department of Anaesthesia, Yashoda Hospital, Secunderabad, which is accredited by the NABH and NABL.

Anesthesia checks were performed on the patients prior to surgery. A day before the procedure, written informed consent was taken and appropriate fasting guidelines were explained. Before surgery, patients were given clear fluids two hours prior and solids six hours. Alprazolam 0.5 mg and Ranitidine 150 mg tablets were given to patients the night before surgery as a premedication. Thirty minutes prior to anesthesia, an intravenous line was obtained using an 18G/20G cannula and preloaded with 500ml of ringer lactate (10ml/kg body weight). A multi-channel monitor was connected to the patients in order to measure their mean arterial pressure (MAP), non-invasive

blood pressure (NIBP), pulse rate (PR), arterial oxygen saturation (SPO_2), and electrocardiogram (ECG).

A qualified anaesthesiologist administered spinal anaesthesia in sitting position to the patients in L3–L4 area under aseptic precautions with a spinal needle, Quincke tip and 26G/25G. The study drug is injected into the subarachnoid space once the clear and unobstructed flow of CSF has been confirmed. The Group B received 3ml of 0.5% hyperbaric bupivacaine intrathecally and Group R received 3ml of 0.75% hyperbaric ropivacaine intrathecally. Patients were immediately placed in a supine position; the table was kept flat and extra oxygen was administered. Using the pinprick method and a blunt-tipped 27G hypodermic needle, sensory blockade was tested at every 30 seconds for the first 2 minutes, then every minute for the next 5 minutes and every 5 minutes for the next 15 minutes and every 10 minutes for the next 30 minutes and every 15 minutes until the end of the surgery and then every thirty minutes until the sensory block is resolved. All patients were kept under observation using a multi-channel monitor which shown heart rate, ECG, SPO2, systolic and diastolic blood pressure, and mean arterial pressure during the block and peri-operative periods.

Statistical Analysis

The statistical analysis was performed using IBM SPSS V21. Mean ± SD was used to present the quantitative data, Mann-Whitney test was used if the data failed the "Normality test," and the unpaired t-test was used if the data passed. Number (%) was used to present the results of categorical measurements. Fisher's exact test and the Chi-Square test with continuity correction were used to evaluate the associations between the qualitative variables in all two-by-two tables. A *p*-value of less than 0.05 was deemed significant for statistical significance.

RESULTS

Table 1 shows that the current study group's mean age distribution was 58.35±7.25 years and there was no significant difference between the study groups ($p = 0.23$). Out of the total 60 cases, 53.3% were females while 46.7% were males with no significant difference between two study groups (p=0.08). Results also shows that, a total of 21.7% cases were in ASA grade I while 78.3% were in ASA grade II with no significant difference between the study groups (p=0.41). The incidence of hypotension and bradycardia was considerably higher in those treated with Bupivacaine (20%, 10%) than Ropivacaine (3.3%, 0%). Minor variation is recorded in shivering between the individuals treated with Bupivacaine (6.7%) than Ropivacaine (3.3%) These values are statistically insignificant (p=1.0). Results also show that the values recorded for PONV was similar in both the groups which is also statistically insignificant (6.7%, p=1.0).

Table 1: Age, Gender and ASA Grade, Maximum Sensory Block And Adverse Reactions Comparison Among Study Groups

Characteristics	Group		Total	P-value
	Bupivacaine (B)	Ropivacaine (R)		
Age (Mean±SD)	30 (59.73±6.26)	30 (56.97±9.76)	60	0.23
Female	14(46.7%)	21(70.0%)	35(53.3%)	0.08
Male	16(53.3%)	9(30.0%)	25(46.7%)	
Total	30(100%)	30(100%)	60(100%)	
ASA grade				
Grade 1	8(26.7%)	5(16.7%)	13(21.7%)	0.41
Grade 2	22(73.3%)	25(83.3%)	47(78.3%)	
Total	30(100%)	30(100%)	60(100%)	
Adverse reactions				
Bradycardia	3(10%)	0(0%)	3(5.0%)	0.12
Hypotension	6(20.0%)	1(3.3%)	7(11.7%)	<0.05
PONV	2(6.7%)	2(6.7%)	4(6.7%)	1.00
Shivering	2(6.7%)	1(3.3%)	3(5.0%)	1.00

Table 2: Mean Comparison Of BMI, Duration Of Surgery, Sensory Block And Motor Block Characteristics Among Study Groups

Variables	Group	Total number (N)	Mean ±SD	P-value
BMI	Bupivacaine (B)	30	27.21±2.31	0.19
	Ropivacaine (R)	30	26.80±2,12	
Duration of surgery(min)	Bupivacaine (B)	30	167.50±33.26	0.65
	Ropivacaine (R)	30	161.17±23.62	
Sensory block characteristics				
Onset (Min)	Bupivacaine (B)	30	3.56±0.27	<0.01
	Ropivacaine (R)	30	4.22±0.37	
Time for maximum block (Min)	Bupivacaine (B)	30	10.31±0.77	0.06
	Ropivacaine (R)	30	12.02±1.14	
Total duration (min)	Bupivacaine (B)	30	267.83±32.26	<0.01
	Ropivacaine (R)	30	218.17±24.65	
Motor block characteristics				
Onset (min)	Bupivacaine (B)	30	4.73±0.4	<0.01
	Ropivacaine (R)	30	5.20±0.48	
Time for maximum block (min)	Bupivacaine (B)	30	11.34±0.85	0.11
	Ropivacaine (R)	30	12.65±1.25	
Total duration (min)	Bupivacaine (B)	30	191.68±33.46	<0.01
	Ropivacaine (R)	30	165.17±23.66	

Table 3: Comparison Of Changes In Heart Rate And Respiratory Rate Among Study Groups

	Heart rate		P-value	Respiratory rate		P-value
	Bupivacaine Mean±SD	Ropivacaine Mean±SD		Bupivacaine Mean±SD	Ropivacaine Mean±SD	
Base line	85.37±12.25	87.10±9.46	0.81	17.37±2.68	16.33±1.95	0.11
5 mins	79.97±10.80	83.87± 9.93	0.317	17.10±18.47	15.07±1.78	0.187
10 mins	77.93± 11.32	80.50±10.77	0.592	16.40±2.65	15.10±2.01	0.067
15 mins	75.30±10.29	77.67±11.24	0.612	15.70±2.32	15.27±2.16	0.524
20 mins	73.47±9.39	74.83±10.82	0.674	15.07±2.60	15.13±1.94	0.469
25 mins	71.33±9.82	73.70±10.19	0.566	14.73±2.63	15.17±2.10	0.224
30 mins	68.97±9.47	73.00±10.65	0.272	14.40±3.10	14.83±2.32	0.233
45 mins	69.30±8.84	71.07±10.62	0.678	14.07±2.79	15.03±2.14	0.072
60 mins	68.67±9.07	71.60±11.79	0.2	13.87±2.58	14.93±2.50	0.053
75 mins	70.13±10.06	71.27±11.91	0.416	14.17±2.77	15.23±2.31	0.143

90 mins	69.13±8.92	70.03±11.64	0.933	14.33±2.38	15.13±2.57	0.15
120 mins	70.50±9.67	72.43±12.08	0.744	14.27±2.56	15.20±2.46	0.242
150 mins	70.46±9.01	73.70±11.98	0.472	14.69±2.28	15.03±1.69	0.735
180 mins	69.17±4.49	74.46±10.41	0.105	14.33±2.74	15.00±1.77	0.486
210 mins	73.00±6.65	75.00±9.64	0.812	15.60±2.88	14.70±1.34	0.622
240 mins	69.00±7.55	-	0.138	15.33±2.52	-	0.624

Table 4: Comparison Of Changes In Arterial Pressure And Oxygen Saturation Among Study Groups

	Arterial Pressure (AP)		P-value	Oxygen saturation (SpO2)		P-value
	Bupivacaine Mean±SD	Ropivacaine Mean±SD		Bupivacaine Mean±SD	Ropivacaine Mean±SD	
Base line	104.90±5.54	105.33±4.66	0.98	98.43±0.77	98.83±0.53	0.075
5 mins	92.37±10.88	96.37±8.14	0.08	98.37±0.93	98.81±0.99	0.304
10 mins	89.57±12.48	93.03±13.98	0.311	98.30±1.34	99.00±0.69	0.05
15 mins	86.87±12.19	89.83±10.14	0.23	97.77±1.55	98.93±1.78	0.09
20 mins	81.03±11.11	83.27±10.59	0.19	97.371.87	98.87±1.82	0.07
25 mins	78.80±10.47	83.83±10.01	0.12	97.17±2.02	98.83±1.05	0.09
30 mins	79.63±10.21	82.87±15.01	0.21	97.40±1.75	98.50±1.11	0.06
45 mins	75.50±11.54	83.27±11.29	0.16	98.00±1.31	98.63±0.81	0.103
60 mins	77.77±10.35	83.57±9.52	<0.05	98.43±0.86	98.80±0.76	0.26
75 mins	79.17±9.65	84.47±8.73	0.06	98.77±0.50	99.00±0.69	0.297
90 mins	79.80±10.89	85.87±10.33	<0.05	98.70±0.60	99.03±0.67	0.12
120 mins	76.17±9.49	85.13±10.34	<0.05	99.03±0.67	99.00±0.64	0.188
150 mins	77.47±8.92	84.08±9.53	<0.05	98.65±0.49	99.07±0.58	0.017
180 mins	78.10±9.68	84.28±10.09	0.163	98.50±0.51	99.14±0.56	0.07
210 mins	78.46±9.23	84.30±9.40	0.411	98.50±0.53	98.70±0.48	0.07
240 mins	82.90±7.51	83.67	0.787	98.33±0.58	-	0.667

Table 2 explains and the mean BMI was 27 Kg/m^2 with no significant difference between the study groups (p=0.19) and the mean duration of surgery was 167.5 mins in Bupivacaine group and 161.17 mins in Ropivacaine group respectively. The mean onset of sensory block was faster and longer with Bupivacaine as compared to Ropivaciane which is statistically significant (3.56 vs 4.22 mins; p<0.01; 267.83 vs 218.17 mins; p<0.01). Additionally, the results demonstrate that the maximum degree of sensory block achieved was similar in the groups treated with Bupivacaine and Ropivacaine, with no statistical significance. (p=0.78). Mean onset of motor block was faster and duration was longer with Bupivacaine as compared to Ropivaciane (4.73 vs 5.2 mins; p<0.01; 191.68 vs 165.17 mins; p<0.01). However, the values are statistically significant.

Table 3 explains that the mean heart rate at baseline was comparable between Ropivaciane and Bupivacaine groups (p=0.81). The group that received Bupivacaine had a lower mean heart rate during the surgical operation than the group that received Ropivacaine; however, this difference was not statistically significant (p>0.05). Results also shows that, the mean respiratory rate was comparable between Ropivaciane and Bupivacaine groups before and after the surgical procedure (p>0.05).

Table 4 explains that between Ropivaciane and Bupivacaine, the mean arterial pressure at baseline was similar with no significant difference among these two groups (p=0.94). Mean arterial pressure decreased in the bupivacaine group during the procedure compared to the ropivacaine group with slight variations; however, the difference was not statistically significant in majority of cases (p>0.05). There was no significant difference in mean oxygen saturation levels between bupivacaine and ropivacaine groups at baseline or after the surgical procedure (p>0.05).

DISCUSSION

Spinal anaesthesia is the most often used regional anaesthesia technique because it is easy to use, reasonably priced, and produces complete muscle relaxation and anaesthetise quickly. Compared to general anaesthesia, it has less surgical stress and post-operative analgesia. The current single-centric study revealed that the ASA score, BMI, age, and gender of the two groups are equivale (P values >0.05).

The current study's findings correlate with the comparative study of hyperbaric ropivacaine with fentanyl and hyperbaric Bupivacaine in intrathecal block for perineal surgeries [8].

Bupivacaine causes a faster start of sensory block than Ropivacaine, and that the mean duration of the block will be significantly shorter [9]. In the present study, Bupivacaine produced a long lasting and mean onset of sensory block than Ropivaciane. Between Ropivaciane and Bupivacaine, the maximum degree of sensory block attained was statistically significant. In comparison to Bupivacaine, Ropivacaine shows delay on onset of sensory block, a quicker time to regression and a shorter duration of sensory block [10]. In the ropivacaine group, the overall length of sensory block is shorter than in the bupivacaine group [11] and in Bupivacaine group the mean time for the start of sensory block was significantly quicker than in Ropivacaine group [12].

In our study we observed that, the mean onset and duration of motor block was higher with Bupivacaine than Ropivaciane, Previous studies show that, Ropivacaine group experience a delayed start, degree of block, and duration of motor block in comparison to the bupivacaine group. Patients who had Ropivacaine, recovered more quickly in terms of mobilization and found that Group Bupivacaine (B) had considerably longer motor blockade duration than Group Ropivaciane (R)[13]Studies oneffectiveness of hyperbaric Ropivacaine over hyperbaric Bupivacaine in spinal anesthesia, hyperbaric Ropivacaine offers a dependable subarachnoid block with a shorter duration [14]. Our results are consistent with a study shown that for lower limb orthopaedic surgery, hyperbaric Ropivacaine produced appropriate and efficient spinal anaesthetic with a shorter period of sensory and motor block than hyperbaric Bupivacaine[15]

Some studies shown that, when compared to patients getting intrathecal hyperbaric Bupivacaine, patients receiving intrathecal hyperbaric Ropivacaine have shorter durations of sensory block and motor block [16]. When equivalent doses (15mg) of hyperbaric Bupivacaine, Ropivacaine, and Levobupivacaine was administered intrathecally for elective Ropivacaine produced spinal anaesthesia more quickly than the other two medications which shows Ropivacaine's recovery profile is helpful in situations when early mobilization is necessary [17].

Studies shows that Group Ropivaciane were more stable than Group Bupivacaine and in the Bupivacaine group, more patients needed bradycardia and hypotension therapy whereas in Group Ropivaciane, there were no side effects throughout the surgical procedure or the recovery period [18]. The current study shows that there were no significant differences in mean respiratory rate or oxygen saturation between Bupivacaine and Ropivaciane at baseline or during the surgical procedure. Mean heart rate and the mean arterial pressure were lower in the Bupivacaine group during the procedure than in the Ropivacaine group. Bradycardia, hypotension, and shivering were much more common adverse reactions in those treated with Bupivacaine. PONV has the same adverse effect in both groups. Studies revealed that compared to Bupivacaine, Ropivacaine offers more consistent spinal anaesthesia with less hypotension and stable hemodynamic parameters [19].

CONCLUSION

Hyperbaric Ropivacaine provided effective and adequate spinal anaesthesia which is similar to Bupivaciane in terms of extent of block. The hemodynamics were more stable when Ropivacaine was used rather than Bupivacaine, which led to a greater number of people required treatment for bradycardia and hypotension. Hyperbaric Ropivacaine seems to be the go-to anaesthetic agent for lower limb procedures performed under spinal anaesthesia since it produces a short duration of sensory and motor block.

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