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Original Research Article

Comparison of 0.5% Hyperbaric Ropivacaine and 0.5% Hyperbaric Buprenorphine for Elective Surgery under Spinal Anaesthesia

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Abstract

Background: Bupivacaine is 40% more powerful than the recently developed ropivacaine. Spinal anesthesia produced hyperbaric with ropivacaine, and dextrose is reported to be effective (SA). In this investigation, the clinical effectiveness of 0.5% bupivacaine and 0.5% ropivacaine for SA was compared at equivalent hyperbaric dosages.

Methods: A total of n=60 cases were allotted randomly in two groups of n=30 each with Group I receiving intrathecal 15 mg (3 ml) of 0.5% Hyperbaric Bupivacaine. And group II received intrathecal 15 mg (3 ml) of 0.5% Hyperbaric Ropivacaine which is prepared aseptically immediately before injection by adding 1 ml (250 mg) of autoclaved 25% dextrose ampoule (10 ml) to 2 ml of a commercially available sterile preservative-free isobaric solution of 0.75% Ropivacaine.

Results: Both groups were comparable in the distribution of cases by weight, and height. The onset of sensory block was earlier in group II as compared to group I however, the peak time to sensory block was more in group II as compared to group I, and the duration of sensory block was considerably greater in group II as compared to group I the details have been given in table 1. As far as the motor block is concerned the onset of the motor block was earlier in group II and the duration of the motor block was also significantly longer in group II.

Conclusion: Both groups had a sensory and motor block that began almost simultaneously. Hypotension and bradycardia complications were less common in the ropivacaine group. In terms of block quality, ropivacaine is equivalent to the widely used hyperbaric 0.5% bupivacaine (in 8% glucose), but because of its quicker recovery time, it is a helpful drug for spinal anesthesia during procedures of moderate length.

Keywords: Hyperbaric Bupivacaine, Ropivacaine, Spinal Anesthesia.

Introduction

For spinal anesthesia use of lignocaine was done initially and later state 5% lignocaine heavy was used which caused transient neurological symptoms and it was withdrawn from regular use. Since then, Bupivacaine has been the most widely used drug for spinal anesthesia. However, some patients who received bupivacaine developed life-threatening arrhythmias which were refractory to treatment. Since then, Bupivacaine has been the most widely used drug for Spinal anesthesia.

Therefore, newer, safer local anesthetic drugs began. An important aspect of this cardiotoxicity is that it is related to the stereospecificity of Bupivacaine with the 'S' isomer having very less cardiotoxic potential compared to the 'R' form. To overcome this side effect, Ropivacaine a long-lasting drug with less cardiotoxicity was discovered. Ropivacaine, a more recent amino-amide local anesthetic (LA) drug with a chemical structure comparable to bupivacaine but 30–40% less strong, has been extensively researched for spinal anesthesia (SA). [1-4] The early research assessed the effectiveness and security of isobaric ropivacaine for a neuraxial blockade. [5,6] When compared to intrathecal lignocaine, intrathecal ropivacaine was found to be less likely to cause transient neurological symptoms (TNS) and to act with a shorter half-life than bupivacaine. [7,8] Due to the predictable block properties and dependable SA that hyperbaric LA agents produce, their intrathecal application has grown in popularity. [3,4] Due to the difficulties in preserving the pharmacological stability of hyperbaric solutions for therapeutic application, only isobaric formulations of ropivacaine are now commercially accessible. This prospective randomized control study compared the clinical efficacy and safety of 0.5% Ropivacaine (made hyperbaric by the addition of a desired dose of dextrose from autoclaved 10 ml ampoule of 25% dextrose) with commercial hyperbaric 0.5% Bupivacaine using equal doses (15 mg) and to assess the suitability of Ropivacaine as an alternative to Bupivacaine for the intermediate duration of surgeries under Spinal Anesthesia.

Material and Methods

This prospective controlled study was done in the Department of Anesthesia, Institutional Ethical Approval was obtained for the study. Written consent was taken from all the cases of the study.

Inclusion criteria

1. Patients undergoing elective abdominal surgeries.
2. Belonging to ASA I and II categories
3. Aged 25 – 50 years.
4. Males and Females
5. With informed consent

Exclusion criteria

1. Patients with coagulopathy, spinal deformities
2. Patients with infections
3. History of seizures and neurological deficits
4. Severe renal, hepatic, respiratory, and cardiovascular disease

Patients included in this study underwent pre-anesthetic evaluation which included the following. History of underlying comorbid illnesses like Diabetes, Hypertension, Bronchial asthma, Renal failure, and Seizures. Previous history of surgery and any anesthesia exposure noted. History of any allergy to drugs noted. Physical Examination: General examination of consciousness, orientation, head-to-toe examination, and vital signs are assessed. Height and weight are noted. Systemic examination of the Cardiovascular system, respiratory system, central nervous system, and abdominal examination was done. A local examination of the spine and assessment of the airway was done. Investigations: Complete hemogram (Hb%, RBC count, WBC count, Differential count, Platelet count) Random blood sugar, Blood urea, Serum creatinine. Serum electrolytes**,** bleeding time, Clotting time**,** Urine albumin, sugar. ECG, Chest X-ray, Echo (if necessary). Patients who satisfied the inclusion criteria are explained about the nature of the study and anesthetic technique and informed written consent was obtained.

A total of n=60 cases were allotted randomly in two groups of n=30 each with Group I receiving intrathecal 15 mg (3 ml) of 0.5% Hyperbaric Bupivacaine. And

group II received intrathecal 15 mg (3 ml) of 0.5% Hyperbaric Ropivacaine which is prepared aseptically immediately before injection by adding 1 ml (250 mg) of autoclaved 25% dextrose ampoule (10 ml) to 2 ml of a commercially available sterile preservative-free isobaric solution of 0.75% Ropivacaine. Under strict aseptic precautions, the patient is in a sitting position, the lumbar region is painted and draped. L3-L4 intervertebral space is identified by using Tuffier's line. Then the skin is infiltrated with 2 ml of 2% lignocaine. By midline approach 25 G Quincke's needle is inserted into subarachnoid space. After confirming the free flow of clear CSF, 15 mg of 0.5% Hyperbaric Bupivacaine / Ropivacaine is administered.

Monitoring: The patient's Pulse rate, Systolic Blood pressure, Diastolic blood pressure, mean arterial pressure, saturation, and respiratory rate are observed at 1, 3, 5, 10, 15, 30, 45, 60, 75, 90, and 120 mins after the subarachnoid blockade. Common side effects which are observed after sub-arachnoid block are hypotension and bradycardia. Hypotension is defined as a drop in systolic blood pressure of more than 20% from baseline (or) systolic BP of less than 90 mm of hg. It is managed with Inj. Ephedrine intravenously in increments of 6 mg as necessary. Bradycardia is defined as a heart rate of <60/min and is managed with Inj. Atropine 0.6 mg. Respiratory depression is defined as a respiratory rate of <8/min (or) oxygen saturation of <85% and it is managed with bag and mask ventilation or endotracheal intubation and IPPV if needed. Sensory Block: Time of onset (Time taken to attain T10 dermatome level). Time to Peak Sensory block. (Time taken to attain T6 dermatome level). Duration of the block. (Time of regression upto L1 dermatomal level) Motor Block: Time to complete motor block. (Time taken to achieve Bromage score 3) The degree of motor block is assessed by a modified Bromage scale at 5 mins intervals. 0 =able to raise straight leg against resistance i.e. no detectable motor block. 1=unable to raise straight leg but able to flex the knee. 2=unable to flex knee but able to flex ankles. 3= unable to move hip, knee, or ankle. Duration of motor block. (Time of regression to Bromage score 0)

Results

A total of n=50 cases of elective surgeries were included in the study based on the inclusion and exclusion criteria. They were randomly allotted into two groups. The age range of group I was from 21 – 48 years and the age range of group II was 22 – 45 years. The mean age of group I was 35.5 ± 5.5 years and group II were 38.25 ± 4.5 years. The p-values were 0.125 hence both groups were comparable in age group distribution.

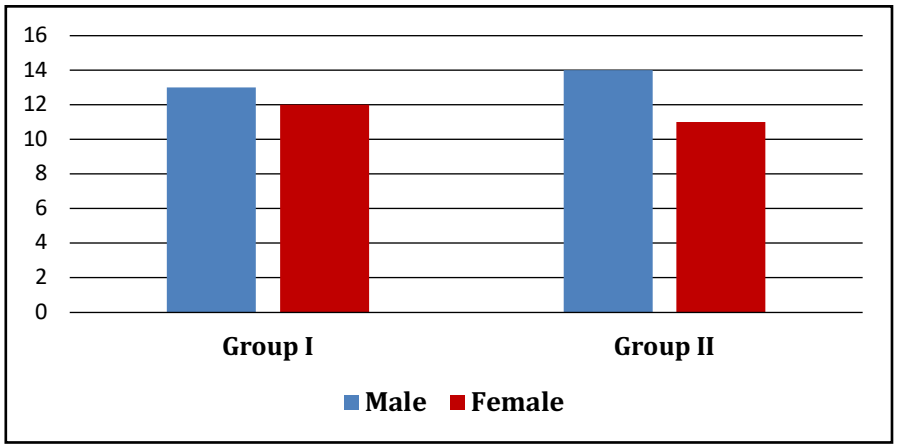

Figure 1: Sex-wise distribution of cases in the study

Both the groups were comparable in the distribution of cases by weight, and height. The onset of sensory block was earlier in group II as compared to group I however, the peak time to sensory block was more in group II as compared to group I, and the duration of sensory block was considerably greater in group II as compared to group I the details have been given in table 1. As far as the motor block is concerned the onset of the motor block was earlier in group II and the duration of the motor block was also significantly longer in group II.

Table 1: Values of parameters recorded in two groups of cases in the study.

Parameter	Group I	Group II	P values
Weight in Kgs	52.33 ± 10.5	55.36 ± 9.8	0.258
Height in cms	152.64 ± 5.5	150.36 ± 4.5	0.158
Time to sensory block in minutes	4.11 ± 0.88	3.14 ± 0.57	0.025*
Time to peak sensory block in minutes	13.55 ± 1.2	14.85 ± 1.5	0.014*
Duration of sensory block in minutes	155.30 ± 3.7	191.33 ± 6.1	0.001*
Time to complete motor block	14.27 ± 1.66	11.37 ± 1.12	0.031*
Duration of motor block in minutes	123.85 ± 4.22	190.64 ± 7.21	0.025*

*Significant

The variations in pulse rates between the groups found the pulse rate in group II was significantly higher in group II from the duration of 5 minutes to block to 120 minutes depicted in table 2.

Table 2: Comparison of the mean pulse rate between the groups

Pulse Rate (BPM)	Group I	Group II	P values
Preoperative	78.22 ± 04.52	84.33 ± 04.33	0.136
1 minute	74.36 ± 05.30	85.60 ± 09.68	0.067
5 minutes	75.83 ± 09.02	82.97 ± 13.22	0.019*
10 minutes	79.60 ± 13.66	86.32 ± 16.28	0.031*
15 minutes	81.33 ± 15.63	89.67 ± 20.36	0.026*
30 minutes	81.50 ± 15.99	90.17 ± 18.74	0.011*
60 minutes	80.35 ± 14.20	90.23 ± 15.99	0.015*
120 minutes	81.36 ± 13.67	89.33 ± 11.98	0.017*

*Significant

There were not many significant hemodynamic variations in both groups as far as the systolic blood pressure is concerned. However, the overall mean values of blood pressure were slightly higher in group I as compared to group II although the values were not found to be significant the details have been depicted in table 3.

Table 3: Comparison of the mean SBP (mmHg) between the groups

Systolic Blood Pressure (mmHg)	Group I	Group II	P values
Preoperative	125.36 ± 10.36	123.67 ± 11.02	0.136
1 minute	122.78 ± 09.66	117.82 ± 08.66	0.167
5 minutes	111.25 ± 08.15	110.01 ± 07.89	0.420
10 minutes	112.08 ± 10.17	108.65 ± 07.36	0.310
15 minutes	114.88 ± 09.95	109.50 ± 08.17	0.159
30 minutes	116.83 ± 07.14	110.31 ± 07.66	0.130
60 minutes	119.02 ± 06.57	114.66 ± 06.17	0.236
120 minutes	124.66 ± 09.28	122.08 ± 07.79	0.274

*Significant

The values of DBP recorded in the group have been depicted in table 4. Similar to the systolic blood pressure readings recorded at various intervals the diastolic blood pressures recorded at various time intervals were not found to be significantly different in both groups. The overall average values of DBP were slightly higher in group I as compared to group II.

Table 4: Comparison of the mean DBP (mmHg) between the groups

Diastolic Blood Pressure (mmHg)	Group I	Group II	P values
Preoperative	78.59 ± 6.69	77.57 ± 6.61	0.13
1 minute	77.12 ± 6.58	76.39 ± 5.21	0.67
5 minutes	69.88 ± 5.14	66.32 ± 5.01	0.11
10 minutes	70.47 ± 5.02	68.01 ± 4.96	0.30
15 minutes	70.36 ± 3.96	68.03 ± 4.82	0.29
30 minutes	71.66 ± 4.78	69.21 ± 5.73	0.23
60 minutes	74.61 ± 5.10	74.97 ± 5.27	0.17
120 minutes	80.33 ± 4.39	79.20 ± 5.00	0.25

*Significant

The mean values of SPO_2 in both groups have been shown in table 5. There were no significant differences in the values recorded in both groups at different intervals of time depicted in table 5. The incidence of adverse effects shows that group II has slightly greater adverse effects as compared to group I as given in table 6.

Table 5: Comparison of the mean SPO2 between the groups

Diastolic Blood Pressure (mmHg)	Group I	Group II	P values
Preoperative	99.17	99.01	0.136
1 minute	99.06	99.04	0.067
5 minutes	99.02	99.02	1.000
10 minutes	99.36	99.05	0.745
15 minutes	99.02	98.35	0.360
30 minutes	99.05	99.05	1.000
60 minutes	99.05	99.07	0.698
120 minutes	99.04	98.15	0.235

*Significant

Table 6: Comparison of adverse effects recorded in the cases of the study

Adverse effects	Group I	Group II
Hypotension	3 (12%)	4 (16%)
Bradycardia	2 (8%)	1 (4%)
Shivering	1 (4%)	1 (4%)
Nausea	1 (4%)	2 (8%)
GA supplementation	0 (0%)	0 (0%)
Total	7 (28%)	8 (32%)

Discussion

Early investigations using isobaric ropivacaine claimed to have varied or insufficient block patterns for surgery, and they proved that the addition of glucose to the ropivacaine solution has superior results when compared to other medicines used for spinal anesthesia. As previously documented from trials on both tetracaine and bupivacaine, it decreases the fraction of a restricted block or a more comprehensive block. For procedures under spinal anesthesia, the addition of glucose 3–10% to ropivacaine has been tried and researched as hyperbaric ropivacaine is not commercially accessible. The amount of dextrose utilized in our trial (83 mg/ml, 8.3%) is comparable to the amount of commercially

available hyperbaric bupivacaine (80 mg/ml, 8%). To reduce the possibility of bacterial contamination, we utilized easily accessible 25% 10 ml dextrose ampoules that were autoclaved. Since ropivacaine is reported to be 30- 40% less strong and to have shorter-lasting effects than bupivacaine, it is more suited for short- to medium-term operations or ambulatory procedures. The time to peak effect for ropivacaine was much shorter than for bupivacaine (4.11 min, 13.55 mins), although the amount of sensory block obtained was identical, and the length of sensory block was significantly shorter with ropivacaine (123.85 mins). In comparison to ropivacaine Group R, bupivacaine Group B experienced pinprick analgesia at T10 more quickly (P 0.01). The duration (peak) of the maximal cephalad spread and the level attained, however, were comparable in both groups. In comparison to Group II (191.64 minutes), the mean time of sensory block was shorter in Group I (123.85 minutes). The length of the motor blockade was longer in Group B (189.25 8.566) than in Group R (122.53), and the time to the maximal motor blockade was statistically equivalent (P 0.02). Patients needed ephedrine for hypotension in the bupivacaine group in 3(14%) patients and the ropivacaine group in 4 (16%) patients (P > 0.05). The incidence of bradycardia was similar in both groups, and they were responsive to atropine injections without any difficulty. Shivering was seen in five individuals in Group B and four patients in Group R.

The results were consistent with research done on elective spinal procedures by Whiteside JB et al., [9] found that 3 ml of 0.5% hyperbaric ropivacaine and bupivacaine in 5% and 8% glucose had an onset time of 5 and 2 min, respectively. While ropivacaine produces dependable spinal anesthesia, we found that it has a less powerful impact on motor nerves than bupivacaine and that there is a greater degree of sensory-motor separation. These findings are corroborated by comparable findings from other investigations. The results were consistent with those of research by Whiteside JB et al., [9] found that a comparable dosage of hyperbaric ropivacaine and bupivacaine produced motor blockades with mean onset times of 15 and 10 min, respectively, and total durations of 90 and 180 min. At a comparable dosage of 3 ml of 0.5% ropivacaine and 30 mg/ml of glucose, Luck JF et al. [10] also noted a lesser degree and duration of motor blockage and a reduced incidence of grade III Bromage score in 63% of patients. These findings contrasted with 90% with 0.5% bupivacaine. We also observed that the ropivacaine group had better sensory blocks than the bupivacaine group, a better recovery profile for the sensory/motor blockade, and a quicker time to the onset of the first micturition. Ropivacaine's characteristics are advantageous for ambulatory surgery. Although short-acting hyperbaric lignocaine 5% has been used for ambulatory spinal anesthesia, its usage is now restricted due to a high incidence of TNS.

Khaw KS et al. [11] evaluated 25 mg of either ordinary or hyperbaric ropivacaine with or without intrathecal glucose 8.3% for cesarean birth. Using hyperbaric ropivacaine, they saw quicker onset and recovery, widespread, and higher success rates. At 37°C, they measured the specific gravities of normal ropivacaine to be 1.0092 and hyperbaric ropivacaine to be 1.0345. According to research by Schiffer et al. on the effect of CSF density on the extent of plain bupivacaine for spinal anesthesia, a larger spinal block level may be anticipated with a higher CSF density. [12] Wille et al., [13] analyzed several research comparing bupivacaine to isobaric and hyperbaric ropivacaine. He concluded that the evidence for the safe use of hyperbaric ropivacaine by the addition of 3-8% glucose for procedures under SA, including caesarean section and day care surgeries, supports intrathecal

injection of isobaric ropivacaine. [13] We found no evidence of any late sequelae such as backache or other transient symptoms in this study as with previous studies of ropivacaine. Hence, ropivacaine can be a safer alternative for ambulatory surgeries.

Conclusion

According to the results of our study, patients who received 0.5% hyperbaric ropivacaine had sensory and motor block for shorter periods of time than those who received 0.5% hyperbaric bupivacaine. Both groups had a sensory and motor block that began almost simultaneously. Hypotension and bradycardia complications were less common in the ropivacaine group. In terms of block quality, ropivacaine is equivalent to the widely used hyperbaric 0.5% bupivacaine (in 8% glucose), but because of its quicker recovery time, it is a helpful drug for spinal anaesthesia during procedures of moderate length.

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