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Original Article

Effectiveness of Hyperbaric Ropivacaine over Hyperbaric Bupivacainein Spinal Anaesthesia

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ABSTRACT:

Introduction: Spinal anesthesia is widely recognized as an alternative to general anesthesia for the surgery in lower extremities, perineum or lower body wall. The aim of the study was to compare the effectiveness and safety of hyperbaric Bupivacaine over hyperbaric Ropivacaine.

Materials and Methods: We enrolled 60 patients of either sex, ASA grade I &II who were randomly allocated in two groups. Group-B received 3 ml of 0.5% hyperbaric Bupivacaine with glucose 8% and Group-R received 3ml of 0.5% hyperbaric Ropivacaine glucose 8.33%. The various parameters of the subarachnoid block, hemodynamic variables, recovery from sensory and motor blockade and side effects were studied.

Results: The time to onset of maximum sensory block level was faster in Bupivacaine (9.10±3.90min) than in Ropivacaine (10.87±5.37min) and statistically not significant. The time to 5 segments regression was faster in Ropivacaine (116.00±29.72min) than Bupivacaine (143.50±18.76min) and the time to S2 level regression of sensory block was faster in Ropivacaine (154.00±27.84min) than Bupivacaine (186.00±18.73min). The time to onset of the maximum motor was faster with Bupivacaine (8.70±3.19min) as compared to Ropivacaine (13.10±4.40min) The time to regression of motor block by 1 grade was faster with Ropivacaine (97.00±26.64min) than Bupivacaine (146.50±23.53min) and the time to complete regression of motor block was faster with Ropivacaine (149.00±30.75min) than Bupivacaine (183.50±19.96min).

Conclusion: The hyperbaric Ropivacaine (3ml, 0.5%) provides a reliable subarachnoid block of shorter duration than hyperbaric Bupivacaine (3ml, 0.5%) with stable hemodynamic parameters.

Keywords: Hyperbaric Ropivacaine, Hyperbaric Bupivacaine, Motor and Sensory Block, ASA

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INTRODUCTION

Spinal anaesthesia, also called spinal analgesia or sub-arachnoid block (SAB), is a form of regional anaesthesia involving injection of a local anaesthetic into the cerebrospinal fluid (CSF) through a fine needle[1]. Anaesthesia is obtained by blocking the spinal nerves in the subarachnoid space that act on the spinal nerve roots.

Anesthetic drugs as pure S-enantiomers, Ropivacaine and Levobupivacaine have been introduced and used in clinical practice since last few years due to their lower toxic effects in the Heart and central nervous system. [2]It is safe and satisfactory if given with the knowledge of its physiological effects. Spinal anaesthesia continues to dominate the field of anaesthesiology because of its simplicity and economy. Ropivacainerefered as recemate and is marketed as S-(-)-enantiomer belongs to long acting amino amide group of local anesthetics drugs which is less lipophilic than Bupivacaine. Moreover, Ropivacaine and Bupivacaine are structurally related.[3]

This property is associated with a decreased potential for CNS toxicity and cardiotoxicity. This drug, which is currently under clinical investigation, appears to be an effective local anaesthetic with a long duration of action when given epidurally.[3] Similarity is observed in the sensory block characteristic of Ropivacaine 0.5% and Bupivacaine 0.5% after an epidural administration.[4]

However, Ropivacaine 0.5% is less potent than Bupivacaine 0.5% in terms of producing motor block. In recent years, Bupivacaine has been used successfully for spinal anaesthesia in either a glucose-free or a hyperbaric solution.[4]The information concerning the profile of Ropivacaine as a spinal local anaesthetic in humans has been lacking. However, in vivostudies in dogs and mice have indicated that, at equal drug concentrations, Ropivacaine was less potent and had a shorter duration of motor block than Bupivacaine after spinal administration. [5]The aim of the present study was to compare the safety and efficacy of hyperbaric Ropivacaine 15 mg and hyperbaric Bupivacaine 15 mg in patients undergoing lower abdominal, perianal and lower limbs surgery under spinal anaesthesia.

MATERIALS AND METHODS

This prospective, randomized, double blind study was conducted in a post graduate private Medical College with 752 bedded multispecialty hospital located at Birgunj Metropolitan of Parsa district of Nepal. After Institutional Review Committee (IRC) approval and informed consent 60 ASA Grade I and II patients of either sex, aged between 20-60 years undergoing elective lower abdominal, perianal and lower limb surgeries in the period of March 2016 - November 2016 were included in the study. Exclusion criteria includes patient refusal, acute cardiovascular or respiratory disease, spinal deformity, bleeding disorder, caesarean section, history of allergy, sensitivity to local anesthetics of amide group and psychiatry history or any other concomitant disease which may lead to unreliability in clinical assessment. The patients were divided into two groups on the basis of type of solution used for subarachnoid injection.

Table 1: Study group

Groups	Intrathecal hyperbaric LA drug used
Group B	Patients received 3 ml of 0.5% hyperbaric Bupivacaine (n = 30)
Group R	Patients received 3 ml of 0.5% hyperbaric Ropivacaine (n = 30)

Patients were randomly divided into two groups of 30 each, which was computer generated. 30 Patients received intrathecal 3 ml of hyperbaric 0.5% Ropivacaine (80 mg/ml dextrose). Hyperbaric Ropivacaine solution was prepared aseptically just before injection with 2 ml of 0.75% Ropivacaine and 1 ml of 25% dextrose. Ampoules of 25%, 10 ml dextrose were used for each patient to maintain sterility for mixing with commercially available isobaric Ropivacaine. Another 30 patients received intrathecal 3 ml of commercial hyperbaric 0.5% Bupivacaine (80mg/ml dextrose).

Once the patient were shifted to operation theatre, venous access with an 20 G Cannula was secured and all patients were preloaded with 500 ml of isotonic saline or Ringer lactate solution. The patients were monitored with ECG, pulse oximeter and non-invasive blood pressure monitor. Patients were positioned either in the supine or lateral position.

Under strict aseptic conditions subarachnoid space was identified and with 25G Quincke spinal needle after confirming free flow of CSF, subarachnoid injection of the drug was given at the level of second or third lumbar interspace depending on the group which was determined by the random number table generated for 60 patients. Once the injection was done, the patients were positioned in supine position. Patients were monitored for heart rate, blood pressure the level of sensory and motor block. The sensory block was

assessed by loss of pain sensation to pin prick. Motor block was assessed by Modified Bromage scale6 (0= no motor block 1 = inability to raise extended leg; able to move knees and feet, 2= inability to raise extended legs and move knees; able to move feet 3= complete block of motor limb).

Sensory and motor block level was monitored every three minutes for 20 minutes and every 15 minutes thereafter till the complete wear off of the block. Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR) were noted at Zero minute, 5 minute, 10 minute and every 10 minute till 60 minutes. From the data recorded the time of onset of sensory block to the maximum level, time to maximum motor block, time to regression of sensory block by 5 segments, regression of sensory block to S2 segment, time to regression of motor block by 1 grade and time to complete regression of motor block were noted.

Episodes of hypotension (defined as SBP <90 mm Hg), the time of its occurrence, the use of Mephentermine and its total dosage were noted. Similarly bradycardia (defined as HR <60 /min), the time of its occurrence and use of Atropine were noted. All patients were administered oxygen 4 litres/ min via face mask throughout surgery.

Statistical analysis has been carried out in the present study which was analyzed by descriptive statistics (frequency, percentage, mean) and inferential statistics using specific test (independent t test, Chi Square test). SPSS version 16 and Microsoft Excel software were used for data analysis.The levels of significance were set at 0.05 with 95% confidence interval.

RESULTS

Our study reveals the physical characteristics of the patients of both groups. There was no statistical differences in between the patients of both group in accordance with the parameters at the level of p value (>0.05) (table 2).

Table 2: Physical Characteristics of patients

Parameters	Group B	Group R	p-value
Age in years			
20-30	4(13.3%)	3(10%)	
31-40	8(26.7%)	8(26.7%)	0.458
41-50	7(23.3%)	3(10%)	
51-60	11(36.7%)	16(53.3%)	
Gender (M:F)	23:7	22:8	0.766
ASA classification (I:II)	19:11	15:15	0.297
Mean weight	68.77 ±9.44	68.40 ±13.09	0.901
Mean height	165.73 ±4.79	164.43 ±6.26	0.370

This study reveals the various parameters observed among the patients of both groups which were not statistically significant (table 3).

Table 3: Comparison of anesthesia parameters

Parameters	Group B	Group R	p
Time to Max sensory block level(min)	9.10±3.90	10.87±5.37	<0.05
Time to regression of sensory block by 5 segment (min)	143.50±18.76	116.00±29.72	<0.05
Time to regression of sensory block to S2 level (min)	186.00±18.73	154.00±27.84	<0.05
Time to Max motor block(min)	8.70±3.19	13.10±4.40	<0.05
Time to regression of motor block by 1 grade (min)	146.50±23.53	97.00±26.64	<0.05
Time to complete regression of motor block(min)	183.50±19.96	149.00±30.75	<0.05

Table 4: Incidence of Hypotension and Bradycardia at set time

Complication	Group B	Group R	P value
Hypotension(yes: no)	1:29	2:28	1.000
Bradycardia (yes: no)	4:26	6:24	0.488

Table 4 reveals the incidence of hypotension and bradycardia at set time which were not statisticall significant at the level of p-value (>0.05).

DISCUSSION

Spinal anaesthesia has become popular because of the simplicity of the procedure, profound sensory analgesia, adequate muscle relaxation, less operative blood loss and minimal pre-operative preparation. It is safe and satisfactory if performed with the knowledge of its physiological effects.

The study was conducted to compare the efficacy and safety of Bupivacaine and Ropivacaine as a sole anaesthetic agent in patients undergoing lower abdominal, perianal and lower limb surgery under spinal anaesthesia. There was no difference between two groups with regard to age, sex, weight, height, ASA physical status and incidence of hypotension and bradycardia. Study showed that the intrathecal administration of either 15 mg Ropivacaine or 15 mg Bupivacaine was well tolerated and an adequate block for lower abdominal surgery, perianal and lower limb surgery was achieved in all patients in each group. Ropivacaine presented a shorter duration of motor block, as well as a faster resolution of sensory block compared with Bupivacaine. The cephalic spread of sensory block was similar in both the groups.

Onset of Sensory block

The finding of present study revealed that onset time to sensory block was 9.10±3.90 for Bupivacaine and 10.87±5.37 for Ropivacaine. The onset time was faster in Bupivacaine group. This finding is in contrast with finding of another similar study[6] but congruent with the finding of similar study.[6-7]In a similar study the onset time of analgesia was found to be 5.4±1.6 for Bupivacaine and 3.5±2.0 for Ropivacaine.[8]

This finding is in contrast with the finding of present study that onset time to sensory block was longer in both the groups. The difference in onset time may be because of the dermatome level considered to determine the onset of analgesia, in their study analgesia at L1 dermatome was considered to determine the onset of sensory block. The maximum sensory level attained was T8±3 in both the groups and there was no significant difference between two groups in regards to onset of sensory block and maximum cephalic spread of sensory block, which better correlates with another similar study.[9]

Duration of action

In some study the time to regression of sensory block was faster in Ropivacainegroup than in Bupivacaine group.[6-7] In our study we found the similar findings for regression of sensory block to 5 segments and S2 level. In the study the duration of action of Bupivacaine was 237±88 minutes and that of Ropivacaine was 220±30 minutes.[6] In our study time to regression of sensory block to S2 segment was shorter in both the groups, differences in the results could be attributed to differences in the population studied. In another study[7] time to regression of sensory block to S2 level was faster 155min in Ropivacaine than 190.5min in Bupivacaine.

In a similar study time to regression of sensory block was 152.2±64.5 min for Bupivacaine and 116±31.0 min for Ropivacaine.[8] In our study time to regression of sensory block to S2 segment with Bupivacaine was 186.00±18.73 min and with Ropivacaine was 154.00±27.84 min. The mean time to regression of sensory block was longer in our study, this may be because we considered S2 segment regression whereas offset of sensory block was observed at L2 level in another study.[8]

Motor block

Intrathecal injection of Bupivacaine provides faster onset of motor block than Ropivacaine. In our study the onset of motor block in Bupivacaine (Group B) was 8.70±3.19 min and 13.10±4.40 in Ropivacaine (Group-R). This correlates with the findings of another similar study[6], the study showed the time to onset of motor block was faster with Bupivacaine group 8±5min. compared with 12±5min. in the Ropivacaine group. In other study[7] patients in the Ropivacaine had significantly more rapid recovery from motor blockade (Ropivacaine 120 min; Bupivacaine 190min) which was similar finding as our study. In our study complete

regression of motor block was at 149.00±30.75min for Ropivacaine and 183.50±19.96min for Bupivacaine. This also correlates the findings study[9] which showed complete regression of motor block was faster in Ropivacaine 166 ± 42 min than in Bupivacaine 190 ± 51min. Incidence of hypotension and bradycardia was higher in Bupivacaine than Ropivacaine group in previous studies.[7,10] But the results of our study are in contrast with the previous studies. In our study Ropivacaine group has higher incidence of hypotension and bradycardia though statistically not significant (p=1.000). The difference in the incidence of hypotension and bradycardia may be due to difference in monitoring time and population group. In our study Symptoms like sweating, dizziness, nausea, vomiting, were observed in some patients in other time than that was set in the monitor. For which we manually recorded blood pressure and heart rate and hypotension and bradycardia were noted .We have mentioned those events in result as incidence of hypotension and bradycardia at other timing.

In the present study one patient had hypotensive episode in Bupivacaine group and 2 patients with hypotensive episode in Ropivacaine group in set time but we had 6 more patients with hypotensive episode in Bupivacaine group that occurred at different timing than set timing i.e. 3, 4, 6 and 8min. Similarly we had 3 more patients withhypotensive episode in Ropivacaine group at different timing i.e.4, 7 and 15 minutes. Altogether there were 7 patients with hypotensive episode in Bupivacaine but only 5 patients with hypotensive episode in Ropivacaine group.

In the same way, patients with bradycardia episode in Bupivacaine group in set time was 4, and there were no episode of bradycardia in different timing whereas in Ropivacaine group the episode of bradycardia in set time was 6, and there was 1 episode of bradycardia at different timing. Thus altogether there were 7 patients with bradycardia in Ropivacaine group which is greater than that of Bupivacaine group.

Difference in findings of episode of hypotension and bradycardia is due to lack of adequate monitoring timing. It is possible that there might be many patients who had hypotension at other points than our regular monitoring, which were missed because our monitoring interval was little longer. Better results could have been obtained if the monitoring of blood pressure and heart rate were more frequent. Result revealed no evidence of any late sequelae such as backache or other transient symptoms in this study of either drugs similar finding as previous study.[10,11]

Intrathecal administration of either 15 mg Bupivacaine or 15mg Ropivacaine provided similar, effective anesthesia for lower abdominal, perianal and lower limb surgery.[12] In an equal milligram dose, Ropivacaine produced a shorter duration of motor and sensory block than Bupivacaine. It is safe to use either of the drugs alone . So intrathecalRopivacaine[13,14] may prove to be useful when surgical anesthesia of a similar quality but of a shorter duration than that of Bupivacaine is desired.

CONCLUSION

In equal dose, onsets of sensory block were similar in both the groups but onset of motor block was faster with Bupivacaine. Ropivacaine produced shorter duration of sensory and motor block than Bupivacaine. Ropivacaine 15 mg is safe and adequate for spinal anaesthesia of short shorter duration. Intrathecal administration of either 15 mg Bupivacaine or 15 mg Ropivacaine provides effective anaesthesia for lower abdominal, perianal and lower limb surgery. Monitoring of the patients should be of more frequent interval in order to get better results because it was noticed many patients had frequent episode of hypotension at other timings than set timing.

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