Original Article

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Comparative Study of Hyperbaric Ropivcaine and Hyperbaric Bupivacaine for Spinal Anaesthesia

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Abstract

Background: Ropivacaine is a newly introduced amide local anaesthetic. Hyperbaric Ropivacaine solutions are known to produce reliable spinal anaesthesia, having good motor sensory dissociation. Ropivacaine is 40 % less potent than Bupivacaine and less cardiotoxic. AIM: To evaluate and compare the clinical efficacy of 0.5% Hyperbaric solution of Ropivacaine versus Bupivacaine in terms of characteristic of spinal blockade, hemodynamic stability, intraoperative and postoperative side effects and recovery profile. **Subjects and Methods:** The study enrolled 100 patients of either sex, ASA grade I and II randomly allocated into two groups Group B (Bupivacaine) and Group R (Ropivacaine). Group B received 3 ml of 0.5 % Hyperbaric Bupivacaine and Group R received 3 ml of 0.5 % Hyperbaric Ropivacaine. Onset and duration of sensory blockade assessed by pin prick method. Onset and duration of motor blockade assessed by modified Bromage scale. Various parameters of subarachnoid blockade, hemodynamic variables, recovery, quality of anaesthesia, recovery and side effects were assessed. **Results:** Hyperbaric Ropivacaine group had late onset of sensory, motor blockade and lesser degree of motor blockade, shorter total duration of motor and sensory blockade with early regression. It had good hemodynamic profile. Patients in this group passed urine sooner. Patients had early mobilization in Ropivacaine group. **Conclusion:** Ropivacaine provided a reliable spinal anaesthesia with early recovery profile and lesser side effects compared to Bupivacaine and hence Ropivacaine may be a better option for day care setting.

Keywords: Spinal anaesthesia, Hyperbaric, Ropivacaine, Bupivacaine.

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Introduction

Spinal anaesthesia is the most efficient and easy technique that provides a deep and fast surgical anaesthetic block through a very small dose of the local anaesthetic solution in the subarachnoid space. It is considered as a simple technique that provides definitive advantage of profound nerve block. It is adequately safe and severe complications are seen rarely. To render adequate pain relief, good performance of surgical procedure without stress and discomfort is the ultimate goal of anaesthesia. Neuraxial blockade has a wide range of clinical applications for surgery, obstetrics, chronic pain relief and acute pain management.

Bupivacaine causes prolonged inhibition of normal conduction as it strongly binds to cardiac sodium channels. It is the most extensively used drug and it produces an adequate sensory and motor blockade.[1] However bupivacaine was attributed to side effects like urinary retension, central nervous system, motor weakness, cardiovascular toxicity. Cardiotoxicity of Bupivacaine is much higher than lignocaine. It has been found in various studies that the R isomers causes cardiotoxic effect of Bupivacaine more as compared S isomers forms of Bupivacaine.

Ropivacaine is considered less lipophilic than Bupivacaine and it is found to penetrate the large myelinated motor fibres less likely, resulting in a relatively reduced motor blockade compared to Bupivacaine. Higher level of motor sensory distinction is found with Ropivacaine which could be advantageous in cases where motor blockage isn't desired.

Ropivacaine is found to be 30 - 40 % less potent than Bupivacaine and its effects are short lived as compared to

Bupivacaine. The motor blockade of Ropivacaine is found to be less profound than that of Bupivacaine, allowing for a better separation between sensory and motor blockade when the local anaesthesia is given epidurally.[1] Ropivacaine is found to produce greater degree of differential blockade at a lower concentration and has a property of producing frequency dependent blockade that offers considerable clinical advantage in providing adequate analgesia with minimum motor blockade with early recovery profile.[2]

Use of intrathecal hyperbaric LAs agents have become popular and produces a reliable spinal blockade and predictable block characteristics.[3] Hyperbaric Ropivacaine appeared to be less potent than Bupivacaine because the onset of sensory and motor blockade was slower and maximum extent and the period of motor and sensory blockade was found to be lesser with Ropivacaine than with Bupivacaine.[3,4]

Subjects and Methods

After obtaining institutional ethical committee approval and patients written informed consent, this randomized double-blind study (sealed envelope technique) was conducted with 100 patients between the age group 20-60 years of either sex, ASA grade I and II posted for different surgical procedures Patients who had history of allergy to local anesthetics, local skin site infection, refused to give consent. ASA grade III, IV, V bleeding disorder, patients on antihypertensive and beta blockers, neurological disease, bleeding disorder, severe back deformities, raised intracranial tension, gross spine abnormalities were not included in the study.

The study enrolled 100 patients (age 20-60 years) of either sex, ASA grade I & II was randomly allocated into two different groups. In group R (ropivacaine group)50 patients received 3 ml intrathecal injection of Hyperbaric Ropivacaine (0.5%) & group B (bupivacaine group) 50 patients
received 3 ml intrathecal injection of Hyperbaric Bupivacaine solution (0.5%).

Pre-Anaesthetic Evaluation

Pre-anaesthetic workup was done at least 24 h before surgery. Tablet alprazolam 0.25 mg to 0.5 mg night before surgery was given to the patients who were posted. Patients were kept nil per oral from midnight. On the day of surgery, 18 -20 G intravenous cannula was secured on the nondominant hand and preloaded using 20 ml of crystalloid/kg of body weight in all patients. The standard multi-channel monitoring was attached and baseline hemodynamic parameters like $Sp0_2$, pulse rate, blood pressure (Systolic, Diastolic and Mean), Electrocardiography (lead II, V5) was recorded.

Preparation of ropivacaine:

The Ropivacaine solution was prepared aseptically immediately before injection (by adding 2 ml of Ropivacaine 0.75% plus 1 ml of 25% Dextrose. The Final glucose concentration of 8.3% (83mg) in Hyperbaric Ropivacaine with specific gravity of (1.02450) at ambient room temperature was prepared. The Hyperbaric Bupivacaine solutions are commercially available.

While performing a spinal anaesthesia, appropriate monitors were placed and airway and resuscitation equipment were kept ready. All equipment for the spinal blockade were ready for use and all necessary medications were drawn up prior to positioning of the patient for spinal anaesthesia. Aseptic precautions were emphasized, 25G Quincke spinal needle was used and subarachnoid block was performed with patient placed in sitting position at L3-L4 intervertebral space.

After the subarachnoid block, vitals were monitored 1 min interval up to 15 min and then, every 5 min interval up to completion of surgery. Vitals of every 15 min was used for our study. Oxygen 5 L/min was administered through Hudson face mask throughout the procedure.

The following readings were noted for assessment of sensory blockade:

1) Time of onset of sensory block
2) Maximum cephalic spread
3) Time to maximum cephalic spread
4) Two segment regression time
5) Total duration of sensory block

The characteristic of motor block was assessed by the Bromage Scale.

Sedation level was assessed using Modified Ramsay Sedation Score.

The quality of intraoperative anaesthesia was assessed using ―four-grade scale'' defined as:

- **Excellent -** No supplementary analgesia or sedative required.
- **Good -** Only sedation required.
- **Fair -** Both sedation and analgesia required.
- **Poor -** General anaesthesia is required

After adequate level of anaesthesia was achieved, surgeons were allowed to operate. The time of beginning of surgery was noted.

a) Any hypotension (>30% fall from basal blood pressure) was treated with injection mephentermine 6 mg I.V. and with loading Ringer lactate solution.
b) Bradycardia (pulse rate below 60 beat / minute) was treated with IV injection of atropine 0.6 mg I.V.

Postanesthesia Care Unit

In recovery room pulse rate, blood pressure, respiratory rate and SPO_2 was monitored at arrival, 15, 30, 45, and 60 minutes with help of multipara monitor. Time taken for regression below L1 and duration of motor block (Bromage scale up to 0) was noted. The total duration of sensory block and motor block defined as interval from intrathecal administration to point of complete regression of sensory block or where Bromage score comes to zero. The patients were shifted to ward with written instruction to withhold any analgesic or sedative in the postoperative period, unless the patients complained of moderate pain and first time of micturition was noted. Patients were watched for side effects like nausea, vomiting, pruritus, hypotension, bradycardia, drowsiness, respiratory depression (respiratory rate < 10 breaths/minute).

Statistical Analysis

The data was analysed by using SPSS version 21 by following statistical test.

Mean & SD for continuous measurement,t -test for significance of mean of two groups, Chi square test for significance of categorical scale between two groups. P value - Value less than 0.05 was considered significant, value more than 0.05 was considered not significant.

Results

Demographic Data

Table 1: Mean age, weight, gender distribution of both the groups

	Group B		Group R		t	p-value
	Mean	SD	Mean	SD		
Age	36.14	11.53	36.4	11.92	-0.111	0.912
Weight	67.1	9.78	66.66	9.02	0.234	0.816
		Group		Total	Chi-square value	p-value
		B	R			
Sex	F	15	12	27	0.457	0.499
	M	35	38	73		
Total		50	50	100		

The demographic profile of the patients was comparable between both the groups.

Table 2: Characteristic of Subarachnoid Blockade. Mean distribution of Onset and Peak time of Sensory Blockade and Onset time to Complete Motor Blockade between Group B vs Group R

	Group B		Group R		t	p-value
	Mean	SD	Mean	SD		
Sensory Block Onset Time (mins)	3.03	0.48	4.44	1.05	-8.598	0.000
Sensory Block Peak Time (mins)	13.62	3. 59	15.38	3.45	2.501	0.014
Time to complete Motor Blockade (mins)	11.46	2.98	14.72	2.68	-5.754	0.000

The sensory block onset time and time to peak sensory blockade was delayed in Ropivacaine group compared with Bupivacaine group as evident from the table II. And the difference found between two groups was statistically highly significant. P < 0.05. And the time to complete motor blockade was delayed in ropivacaine group.

The degree of motor blockade bromage grade - III was efficiently larger in Group B than in Group R patients. (p < 0.05). In Group B and Group R, grade II bromage was detected in 3 and 9 individuals, respectively. (p 0.05, p value = 0.06). This difference found was statistically not significant. But none of these patients required GA as the surgery duration was shorter. Grade 1 Bromage scale was seen in 1 patient of Ropivacaine group. But the difference found was statistically not significant between both the groups. This major difference is due to the Ropivacaine's lower lipid solubility; thus, this drug penetrates myelinated large A fibres more slowly than Bupivacaine, which is more lipid soluble

Two segment regression was found to be early in Ropivacaine group compared to bupivavaine group. The intraoperative quality of anesthesia was excellent in 48 and 41 patients in Group B and R respectively. This difference found in both the group were statistically highly significant. p < 0.05. Only 2 patients had good quality of anesthesia in Bupivacaine group as the average duration of surgery was prolonged. Thus, these patients were supplemented with i.v midazolam. The quality of anesthesia was found to be fair in 4 patients in Group R. p value = 0.117.

The quality of anesthesia was found to be good in 5 patients in Group R and thus these patients were supplemented with I.V midazolam as the surgery duration was less than 1 hour. And those patients who had fair quality of anesthesia in Ropivacaine group were supplemented with I.V. fentanyl 1 mcg/kg as the surgery duration was found to be less than 1 hour. According to modified Ramsay sedation scoring system the patients who had good quality of anesthesia had a score of 2 and the fair groups had a score of 3. In neither group any one of the patients had poor quality of anesthesia nor required general anesthesia.

Table 3: Intraoperative Side Effects in Group B vs Group R

Intraoperative		Group		Total	Chi-square value	p-value
		B	R			
Hypotension	No	38	42	80	1	0.317
	Yes	12	8	20		
Bradycardia	No	47	43	90	1.778	0.182
	Yes	7	3	10		
Sedation	No	48	41	89	5.005	0.025
	Yes	2	9	11		
Total		50	50	100		

Hypotension was observed in 12 and 8 patients of Group B and R respectively.

The fall in BP was not > 30 % from pre-baseline value. This difference found was statistically not significant.

Bradycardia was seen in 7 and 3 patients of Group B and Group R respectively. The fall of PR was not > 30 % from pre-baseline value. Hence no treatment was required. This difference found was statistically not significant.

2 and 9 patients in Bupivacaine and Ropivacaine Group required sedation respectively.

Inj. Midazolam in dose of 1.5- 2 mg I.V was required for these patients. The difference found was statistically highly significant. Sedation level was assessed using modified Ramsay sedation score.

Table 4: Mean total duration of sensory and motor blockade distribution in both the groups

	Group B		Group R		t	p-value
	Mean	SD	Mean	SD		
Total Duration Sensory (mins)	180.30	18.80	153.60	14.36	7.981	0.000
Total Duration Motor (mins)	146.56	33.19	119.10	24.13	8.177	0.000

Total duration of sensory and motor blockade was prolonged in Group B compared with Group R.

Post-operative Side Effects were comparable between both the groups. 4 patients in Group B and 3 patients in Group R had nausea. Patients who had nausea were treated with Inj.ondansetron 4 mg iv. 3 patients in Group B and 2 patients in Group R had headache were treated with analgesics, fluids and bed rest.

The total duration of rescue analgesia was 2.20 hrs and 1.50 hrs in Group B and Group R respectively. Bupivacaine Group had a longer duration of analgesia compared to Ropivacaine. In the Ropivacaine group patients were able to pass urine sooner than those in the Bupivacaine group ($P < 0.05$).

Quality of Anaesthesia

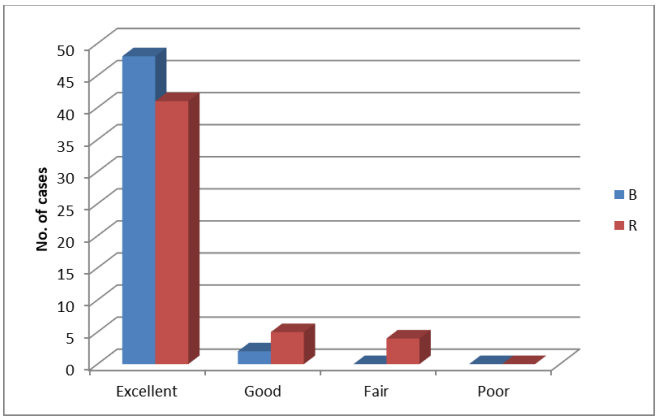

Figure 1: Quality of Anaesthesia in Group B vs Group R

Discussion

Bupivacaine is a long-acting amino amide compound, found to be a very effective local anaesthetic agent of choice for lower limb and lower abdominal surgeries. Bupivacaine though it produces an adequate sensory and motor blockade has been found that it strongly binds to cardiac sodium channels leading to its cardiotoxicity due to prolonged inhibition of normal conduction.

This led to the introduction of Ropivacaine. It is one of the groups of local anaesthetic drugs, the pipecoloxylidides. It is a pure S Enantiomer. Hyperbaric Ropivacaine produces more predictable and reliable spinal anaesthesia for a variety of short duration surgical procedures.

We conducted a randomized double blinded study with 100 patients of ASA I & ASA ll divided into 50 each in Group R (Ropivacaine) and Group B (Bupivacaine) respectively. The clinical efficacy and safety of spinal anaesthesia with 0.5% Hyperbaric Ropivacaine compared with 0.5% Hyperbaric Bupivacaine for elective procedures under spinal anaesthesia was studied effectively. Various parameters were observed throughout the study, vitals were monitored from the beginning till the end of surgery, characteristic of subarachnoid blockade and frequency of adverse effects, quality of anaesthesia, intraoperative and postoperative side effects were noted and the first time of micturition.

In our study the onset time to sensory blockade, time to peak sensory blockade and the time to complete motor blockade was delayed in Ropivacaine group compared to Bupivacaine group. Grade 3 motor blockade was achieved well in Bupivacaine Group compared to Ropivacaine Group. In our study the degree of motor blockade was found to be better and was adequate in Group B as compared to Group R. This major difference is due to the Ropivacaine's lower lipid solubility; thus, this drug penetrates myelinated large A fibres more slowly than Bupivacaine, which is more lipid soluble. Ropivacaine has lower lipid solubility than Bupivacaine, which is responsible for its lower penetration into myelinated motor fibres and thus lesser motor blockade with greater sensory-motor differentiation. Therefore, stating that it has an early recovery profile and can be used for short surgical procedures where early ambulation is required.[5]

The study done by Susan et al, E. Gautier et al, Chang-jong et al, J. B Whiteside et al, H Zekiya Bigat et al also concluded that the onset of both motor and sensory blockade and time to peak sensory was delayed in Ropivacaine group as compared to Bupivacaine. It was more evident from the study done by Kulkarni et al and Luck JF et al that Grade 3 motor blockade was achieved well in Bupivacaine Group compared to Ropivacaine Group.[6,7]

The two-segment regression was earlier in Ropivacaine group and the total duration of sensory and motor blockade was significantly shorter in Ropivacaine group as compared with Bupivacaine group. This is due to Ropivacaine good sensorimotor dissociation property that renders its faster recovery of motor function compared to Bupivacaine and its lower lipid solubility.

In various studies as well as the study done by us showed that, Bupivacaine is found to have a longer duration of sensory and motor blockade, the reason being Bupivacaine's slightly higher protein binding and higher lipid solubility compared to Ropivacaine. The intraoperative quality of anesthesia was found to be excellent in Bupivcaine Group and good quality of anaesthesia was seen in Ropivcaaine Group.

In neither group any one of the patients had poor quality of anesthesia nor required general anesthesia.

Intrathecal Ropivacaine can be utilized to give good anaesthesia with less motor degree blockade and thus producing sensory and motor blockade for a shorter period of time resulting in an early recovery of both sensory and motor function compared to Bupivacaine. Throughout the course of anaesthesia, good hemodynamic stability was maintained in both groups. Patients in Ropivacaine group had an early regression of motor and sensory blockade and hence these patients passed urine earlier compared to Bupivacaine Group. Postoperative side effects were comparable between both the groups.

Conclusion

From this study it was found that Bupivacaine had an early onset of sensory and motor blockade with early peak onset of sensory blockade and the total duration of motor and sensory blockade was found to be prolonged compared to Ropivacaine.

Therefore, Bupivacaine may be considered to have a better

sensory and motor blockade with better quality of anaesthesia and analgesia for longer duration procedures on lower limbs, lower abdomen or genitourinary surgeries. Ropivacaine has a shorter recovery profile compared to Bupivacaine and may be an ideal anaesthetic agent for surgical procedures of short to intermediate duration. Also, due to its early recovery profile and reduced potential for cardiotoxicity, Ropivacaine can be an ideal drug for high-risk patients and those who require early ambulation.

Therefore, we conclude that spinal anaesthesia with Hyperbaric Ropivacaine 15 mg resulted in significantly faster recovery of both motor and sensory block, time to first voluntary micturition was shorter and home-readiness was much earlier in comparison with 15 mg of Hyperbaric Bupivacaine.

References

1. O'Sullivan G. What's new in local anaesthetics for obstetric anaesthesia? Curr Opin Anaesthesiol. 1998;11(3):259-63. doi: 10.1097/00001503-199806000-00003.
2. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian J Anaesth. 2011;55(2):104-10. doi: 10.4103/0019-5049.79875.
3. Rattenberry W, Hertling A, Erskine R. Spinal anaesthesia for ambulatory surgery. BJA Educ. 2019;19(10):321-328. doi: 10.1016/j.bjae.2019.06.001.
4. Fettes PD, Hocking G, Peterson MK, Luck JF, Wildsmith JA. Comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. Br J Anaesth. 2005;94(1):107-11. doi: 10.1093/bja/aei008.
5. Dar FA, Mushtaq MB, Khan UM. Hyperbaric spinal ropivacaine in lower limb and hip surgery: A comparison with hyperbaric bupivacaine. J Anaesthesiol Clin Pharmacol. 2015;31(4):466-70. doi: 10.4103/0970-9185.169064.
6. Luck JF, Fettes PD, Wildsmith JA. Spinal anaesthesia for elective surgery: a comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine, and ropivacaine. Br J Anaesth. 2008;101(5):705-10. doi: 10.1093/bja/aen250.
7. Whiteside JB, Burke D, Wildsmith JA. Comparison of ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery. Br J Anaesth. 2003;90(3):304-8. doi: 10.1093/bja/aeg077.

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