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A Comparative Study of Hyperbaric Ropivacaine 0.75% and Hyperbaric Bupivacaine 0.5% in Spinal Anaesthesia for Caesarean Section

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Abstract:

Background: *Ropivacaine is a newly introduced amino-amide local anesthetic agent introduced in1996 (2009 in India). Ropivacaine is gaining popularity as it is less cardiotoxic than conventional bupivacaine. The use of Ropivacaine in Obstetric patients ensures safety and better hemodynamic stability.*

Methods: *Sixty Parturients belonging to ASA grade I and II posted for elective Caesarean Section under spinal anesthesia were divided into two groups: Group R (received 15 mg Hyperbaric Ropivacaine) and Group B (received 10 mg Hyperbaric Bupivacaine). Block parameters like onset of sensory blockade, onset of motor blockade, duration of sensory and motor blockade and time taken from giving spinal anesthesia to skin incision were noted. APGAR score of newborn at 1 min and 5 min was also recorded to study the effect of both drugs on neonatal outcome. Hemodynamic parameters like heart rate and mean arterial pressure were monitored. Also Incidence of complications like hypotension, bradycardia, nausea, vomiting and shivering was noted.*

Results: *The onset of sensory and motor blockade was earlier in Group B (2.28 ± 0.62 and 3.58 ± 0.63) than Group R (3.76 ± 0.53 and 4.03 ± 0.65). The mean duration of sensory and motor blockade was more in Group B (160.60 ± 17.27 and 141.0 ± 19.44) than Group R (132.23 ± 16.47 and 116.73 ± 5.97). However this resulted in early recovery of patients from spinal anesthesia and early ambulation. Moreover, Group R patients were haemodynamically more stable than Group B which resulted in improved outcome of patients.*

Conclusion: *Use of Hyperbaric Ropivacaine has increased margin of safety with less alteration in hemodynamic profile as compared to Hyperbaric Bupivacaine.*

Keywords: *hyperbaric, bupivacaine, ropivacaine, Caesarean section.*

INTRODUCTION

The introduction of Ropivacaine in clinical practice has revolutionized the safety profile of local anesthetic agents. Both Bupivacaine and Ropivacaine belong to Pipecoloxylidide group, Ropivacaine having propyl group and bupivacaine having butyl group. Ropivacaine is the pure S-enantiomer[5] which is associated with decreased cardiotoxicity as compared to Bupivacaine. Bupivacaine is 50:50 racemic mixture of S and R-enantiomer. R isomer has more affinity for voltage gated sodium channels which is responsible for its Cardiotoxicity. The improved safety profile of Ropivacaine is also attributed to its lower lipid solubility[5] resulting in lesser penetration in large myelinated nerve fibers producing less motor blockade than bupivacaine[2].

The present study was conducted to compare equipotent doses of Hyperbaric Ropivacaine 0.75% and Hyperbaric Bupivacaine 0.5% in spinal anesthesia for Caesarean section, in terms of sensory and motor block characteristics, hemodynamic profile and incidence of complications. Ropivacaine is 40% less potent than bupivacaine[8].

MATERIAL AND METHODS

After institutional Ethical Committee approval, a comparative study of Hyperbaric Ropivacaine 0.75% and Hyperbaric Bupivacaine 0.5% in spinal anesthesia for Caesarean section was carried out at tertiary health care centre. Sixty patients of ASA grade I/II posted for elective Caesarean Section were included in this study. A written informed valid consent was obtained from all patients. The patients were divided into 2 groups:

Group R received Hyperbaric Ropivacaine (0.75%).As hyperbaric Ropivacaine is not marketed commercially, Hyperbaric Ropivacaine was prepared by adding 1 ml 25% dextrose (autoclaved ampoules to maintain sterility) to 2ml 0.75% Ropivacaine (Total volume=3 ml)

Group B received Hyperbaric Bupivacaine (0.5%).To keep volume constant, 1 ml normal saline was added to 2 ml 0.5% hyperbaric bupivacaine. (Total volume=3 ml)

The specific gravity of both the mixtures was measured at standard laboratory. The specific gravity of Group R drug was 1.018 and Group B was 1.021 at 37° C.

The study was randomized double blind trial. The study drug was prepared by a person not involved in the study. Randomization was done using sealed envelopes containing code of each drug. Both person conducted study and patient were not aware of the drug administered.

Inclusion criteria

1. Patients undergoing Elective Caesarean section.
2. Age 18-40 years
3. ASA I/II.
4. Height between 145-160 cm
5. Weight between 50-80 kg

Exclusion criteria

1. Patient's refusal
2. Coagulopathy
3. Patients with Severe Pregnancy induced hypertension, pre-eclampsia or eclampsia.
4. Maternal diabetes.

5. Infection at local site.
6. Pre-existing cardiac or neurological disorders.

All patients were evaluated night prior to elective Caesarean section. The patients were kept nil by mouth overnight. All routine investigations were done including complete haemogram, random blood sugar, kidney function tests, liver function tests & urine routine and microscopy. After shifting patient in operation theatre, standard monitoring done including Blood pressure, heart rate, ECG, Respiratory rate and SpO_2. All parturients were premedicated with IV Ranitidine 50mg and IV Metoclopromide 10 mg 30-45 min prior to surgery. Preloading was done with Ringer lactate solution 10ml/kg.

Spinal anesthesia was given by midline approach in sitting position in L3-L4 interspace with 25 G spinal needle. After this the patient was made supine with a wedge placed under the right hip to prevent aortocaval compression. Onset of sensory blockade was evaluated with pinprick sensation with 23G hypodermic needle every 5 min. Onset of motor blockade was evaluated with Modified bromage scale. (0 = Able to move the hip, knee and ankle, 1 = Unable to move the hip, but able to move the knee and ankle, 2 = Unable to move the hip and knee, but is able to move the ankle, 3 = Unable to move hip, knee and ankle). Duration of sensory blockade was taken as time taken from sensory blockade from highest level to regression to S_2 dermatome. Duration of motor blockade was time taken to achieve bromage 3 from bromage 0.

Hemodynamic monitoring was done with measurement of Mean blood pressure using noninvasive automated blood pressure monitoring, heart rate and SpO_2 at 0 , 1, 5, 10, 15, 20, 25, 30, 45, 60, 75 & 90 minutes. Hypotension was considered as reading 30% less than preoperative level or systolic blood pressure less than 90mm Hg. Hypotension was treated with IV fluids and Vasopressors. Bradycardia was considered as Heart rate less than 60 and treated with intravenous atropine.

The incidence of complications like hypotension, bradycardia, nausea, vomiting and shivering were noted.

Also the block parameters like onset of sensory blockade, onset of motor blockade, duration of sensory and motor blockade, time taken from giving spinal anesthesia to skin incision were noted. APGAR score of neonate at 1 min and 5 min was recorded to study the effect of both drugs on neonatal outcome.

Data collected were analyzed by Graphpad Instat software version 3.0. Results were expressed as mean ± standard deviation (SD). For continuous variables, student's t-test was used and discrete variables were analyzed with chi-square test. A $p< 0.005$ was considered statistically significant.

RESULTS: All Values are Mean ± SD

A. Demographic profile (Table 1)

The two groups were comparable with respect to age, weight (Kg), height (cm), ASA status of the patient and Duration of Surgery (minutes)

Table 1: Demographic profile.

	Group R n = 30	Group B n = 30	p value	Significant/ Not significant.
Age (years)	26.93 ± 3.09	25.66 ± 3.59	0.7413	Not significant
Weight (Kg)	63.13 ± 7.23	66.16 ± 8.74	0.1486	Not significant
Height (cm)	154.97 ± 3.06	155.23 ± 3.27	0.7461	Not significant
ASA grading I:II	28: 02	27:03		
Duration of surgery (min)	53.36 ± 11.06	52.66 ± 10.41	0.8017	Not significant

B. Onset of Sensory and Motor Blockade (Table 2)

The onset of Sensory and Motor blockade was earlier in Group B than Group R. But it did not affect the maternal and neonatal outcome.

Table 2: Onset of sensory and motor blockade (minutes)

Onset	Group R n = 30	Group B n = 30	p value	Significant/ Not significant.
Sensory Blockade(minutes)	3.76 ± 0.53	2.28 ± 0.62	P < 0.0001	Significant
Motor Blockade(minutes)	4.03 ± 0.65	3.58 ± 0.63	P = 0.0089	Significant

C. Time taken from drug administration to skin incision (Table 3)

The mean time taken from drug administration in spinal anesthesia to skin incision was prolonged in Group R (9.56 ± 0.56) than Group B (7.43 ± 0.56).However, this delay was not associated with any adverse neonatal outcome since APGAR Score at 1 min & 5 min as seen in Table 4.

Table 3: Mean time from drug administration to skin incision.

Parameter	Group R n = 30	Group B n = 30	p value	Significant/ Not significant.
Time taken from drug administration to skin incision (minutes)	9.56 ± 0.56	7.43 ± 0.56	p < 0.0001	Significant

D. Apgar score The APGAR scores of the newborn babies born to Parturients of both groups were comparable and as far as neonatal outcome was concerrneded no statistically significant differenence was observed between these 2 groups

Table 4: APGAR Score of the newborns at 1 min and 5 min

Apgar Score	Group R n = 30	Group B n = 30	p value	Significant/ Not significant.
1 min.	7.4 ± 0.49	7.36 ± 0.55	0.80	Not significant
5 min.	9.33 ± 0.54	9.43 ± 0.50	0.464	Not significant

E. Duration of Sensory and Motor Blockade (Table 5)

In Fig. 5, The duration of Sensory and motor blockade in Group R was less than Group B leading to early maternal recovery, early ambulation and early establishment of maternal-neonatal bonding.

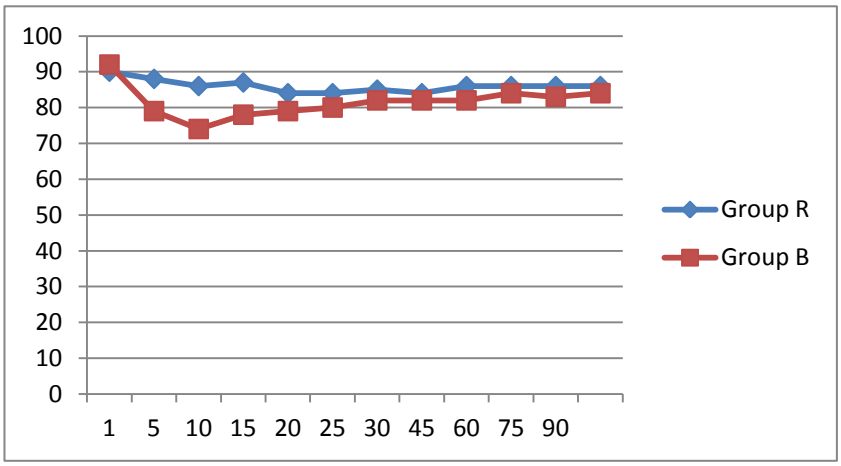
Table 5 : Duration of Sensory and Motor Blockade

Duration	Group R n = 30	Group B n = 30	p value	Significant/ Not significant.
Sensory Blockade (minutes)	132.23 ± 16.47	160.60 ± 17.27	$p < 0.0001$	Significant
Motor Blockade (minutes)	116.73 ± 5.97	141.0 ± 19.44	$p < 0.0001$	Significant

The duration of Sensory and motor blockade in Group R was less than Group B leading to early maternal recovery, early ambulation and early establishment of maternal-neonatal bonding.

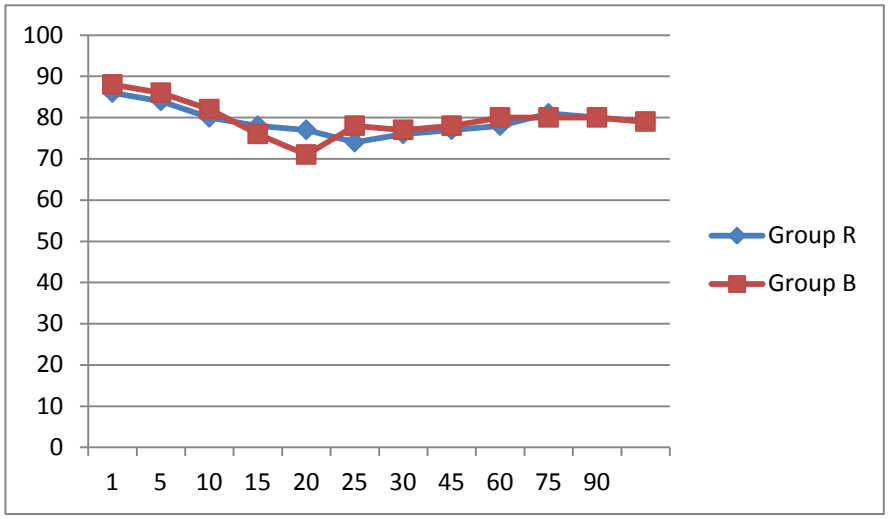
F. Hemodynamic Profile (Fig. 1 & 2)

Fig 1: Heart rate variation in Hyperbaric Ropivacaine group(Group R) and Hyperbaric Bupivacaine group(Group B)



Heart rates of patients in Group B and Group R were compared. 1 Patient in Group R and 5 patients in group B had bradycardia which was treated with intravenous atropine.

Fig 2: Mean Arterial Pressure variation in Hyperbaric Ropivacaine group(Group R) and Hyperbaric Bupivacaine group(Group B)



Comparison of Mean arterial pressure in Group B and Group R showed that 11 Patients in Group B and 6 Patients in group R had hypotension which was treated with intravenous Ephedrine and Intravenous fluids.

G. Quality of intraoperative surgical anesthesia as judged by operating obstetrician:

Table 6: Quality of Anesthesia.

Quality of Anaesthesia	Group R n = 30	Group B n = 30
Excellent	26	27
Good	03	03
Poor	01	00

The majority of patients in both groups had excellent quality of anaesthesia, only one patient in Group R required supplementation in the form of intravenous Midazolam and Intravenous Ketamine.

H. Incidence of Complications: (Table 7)

Table 7: showing Incidence of intraoperative complications

Complications	Group R n = 30	Group B n = 30
Hypotension	6	11
Bradycardia	1	5
Nausea	2	7

Vomiting	1	2
Shivering	4	3

Patients in both groups had no major complications and only minor complications as shown in Table 7 occurred which were easily treatable.

DISCUSSION

Ropivacaine is a newer local anesthetic agent introduced in clinical practice with increased cardiovascular safety when compared with Bupivacaine[6]. Ropivacaine produces differential block with more sensory and less motor block as compared to Bupivacaine, thus leading to early ambulation and early recovery.

Fettes P.D et al[4] compared hyperbaric and plain Ropivacaine for perineal surgeries He concluded that the hyperbaric preparation produced a higher, more consistent block with faster onset and recovery, whereas isobaric solution of ropivacaine was associated with less favorable block pattern and high failure rate.

In the present study, we compared Hyperbaric Ropivacaine with Hyperbaric Bupivacaine which is routinely used for Caesarean section. We compared the equipotent doses of Hyperbaric Ropivacaine with Hyperbaric Bupivacaine (i.e. 15 mg Ropivacaine with 10 mg Bupivacaine).Gautier et al[7] compared different doses of Ropivacaine (8,10,12,14 mg) with 8 mg Bupivacaine and concluded that Ropivacaine 12 mg produced equivalent effect as that of 8 mg Bupivacaine. The potency ratio of bupivacaine:ropivacaine being 1:1.5 equipotent doses of bupivacaine (10mg)and Ropivacaine (15mg) were used in our study.

The onset of effect was slightly prolonged with Ropivacaine but did not result in any adverse neonatal outcome. The duration of anesthesia and analgesia was less in Ropivacaine group than Bupivacaine group, but was sufficient for surgery like Caesarean Section. (The duration of anesthesia and analgesia in Ropivacaine group, though less than Bupivacaine group, was sufficient for surgery like Caesarean Section). For prolonged surgeries, Ropivacaine can be used by addition of adjuvants. Also incidence of complications was less in Ropivacaine group with better hemodynamic stability.

The results of our study are consistent with study done by U Shrivastava et al[14]. U Shrivastava et al[14] compared 11 mg of hyperbaric Bupivacaine with 15 mg Hyperbaric Ropivacaine. The study showed that 15 mg of Hyperbaric Ropivacaine provided effective surgical anesthesia in terms of onset, duration and quality of anesthesia to that provided by 11 mg of hyperbaric Bupivacaine.

Somjit Chatterjee et al[13] compared 22.5mg of hyperbaric Ropivacaine to 15 mg of hyperbaric Bupivacaine in 100 patients undergoing elective lower limb orthopedic surgery He observed in the study that 0.75% Hyperbaric Ropivacaine provided effective and adequate spinal anesthesia with shorter duration of sensory and motor block

compared to hyperbaric Bupivacaine 0.5% for lower limb orthopedic surgery.

Hyperbaric Ropivacaine can be routinely used for patients undergoing Caesarean Section under spinal anaesthesia. Higher cost and maintainance of sterility while preparing hyperbaric Ropivacaine by addition of dextrose were the only important limiting factors while using Ropivacaine.

CONCLUSION

Hyperbaric Ropivacaine (0.75%) has many advantages over Hyperbaric Bupivacaine(0.5%) in Obstetric Anaesthesia especially for Caesarean Section :

1. Ropivacaine is longer acting local anaesthetic agent producing similar effects when used in Equipotent doses. Duration of motor blockade is almost similar.
2. Ropivacaine is less cardiotoxic and less arrhythmogenic than Bupivacaine
3. Ropivacaine has mild vasoconstrictive property so it does not require addition of adrenaline even when used epidurally.
4. Ropivacaine produces sensorimotor differential blockade with early recovery from motor blockade and thus leading to early ambulation of patient. This property also aids in giving labour analgesia with the use of epidural Ropivacaine.
5. Ropivacaine has increased margin of safety (higher therapeutic ratio) due to decrease incidence of Cardiovascular and Central Nervous System toxicity.

Thus, we recommend routine use of 0.75% Ropivacaine for Caesarean Section.

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