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A PROSPECTIVE RANDOMISED DOUBLE BLINDED CONTROLLED STUDY OF COMPARISON OF INTRATHECAL 0.75% HYPERBARIC ROPIVACAINE WITH 0.5% HYPERBARIC BUPIVACAINE IN PREGNANT FEMALES POSTED FOR CESAREAN SURGERY

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ABSTRACT **BACKGROUND AND AIM :** To compare the onset of action, intensity and duration of sensory , motor block of 0.5% hyperbaric bupivacaine with 0.75% hyperbaric ropivacaine in pregnant females posted for Cesarean surgeries. **MATERIALS AND METHODS** 60 pregnant females posted for cesarean delivery under spinal anesthesia were divided randomly allocated into two groups, Group B, (bupivacaine 5 mg/ml with glucose 80 mg/ml;2 ml)and Group R, (ropivacaine 7.5 mg/ml with glucose 80 mg/ml; 2 ml). **RESULTS:** The results were analyzed and compared using Chi-square test, student 's t-test and Fisher's exact tests. The onset of sensory block was more rapid with bupivacaine ($p<0.05$). The maximum cephalad spread was similar in both groups. However, the time required to maximum extent of cephalic spread was less in Group B ($p<0.05$). Motor block 3 according to modified bromage scale was obtained in both groups and the time to achieve the same was not significant. The duration of motor blockade i.e., time to complete regression of motor block was significantly greater with Group B than with Group R (0.0001). We found that there was no significant difference in the time taken to achieve grade 3 motor block but ropivacaine gave a lesser degree of motor block which regressed faster than bupivacaine (113 min versus 156 min; $p<0.0001$). There was no significant difference in hemodynamic parameters except that diastolic and mean pressures remained on lower side in group B ($p<0.05$). **CONCLUSION:** We conclude that 0.75% hyperbaric ropivacaine provides a sensory block of similar onset and extent, shorter duration of action and less frequency of hypotension as compared to 0.5% hyperbaric bupivacaine.

KEYWORDS : : Prospective, Randomized, Hyperbaric, Intrathecal

INTRODUCTION

Cesarean section is a common method of termination of pregnancy, spinal anesthesia is considered as a reasonable choice for cesarean section since it facilitates many advantages including reducing the risk of aspiration, avoiding debilitating factors of analgesics and ability to stay awake.

0.5% hyperbaric Bupivacaine has been extensively used for spinal anesthesia. It provides a longer duration for sensory and motor block. Its longer duration of action makes it unsuitable for ambulatory anesthesia

This led to quest for newer local anesthetic agent which could be used for spinal anesthesia day care cases and could sidetrack the cardio toxic potential of Bupivacaine.

Hyperbaric solutions give more predictable block with greater spread in direction of gravity. It helps to achieve block height as per the requirement of the surgery.

AIM OF THE STUDY

To compare the onset, intensity and duration of sensory and motor block of 0.5% hyperbaric Bupivacaine with 0.75% hyperbaric Ropivacaine in pregnant females posted for elective cesarean section

MATERIALS AND METHODS

This is a prospective randomized double blinded study, conducted in Rangaraya Medical College in patients posted for elective cesarean section from April 2022 to July 2022, after taking ethical committee approval and written and informed consent from patients.

Inclusion criteria :

- Age between 25 to 35 years
- Height between 150-165 cm
- Weight between 65-75kgs
- Gestation weeks: >36weeks

Exclusion criteria :

- Unwilling patient
- Hypersensitivity to any of the study drugs
- Patient with spine deformity, coagulation disorders
- Emergency surgeries

PROCEDURE

- 60 pregnant women undergoing elective cesarean section were randomly allocated into two groups by closed envelope method.
- Group B 0.5% hyperbaric Bupivacaine (5mg/ml with glucose 80mg/ml, 2ml)
- Group R 0.75% hyperbaric Ropivacaine (7.5mg/ml with glucose 80mg/ml, 2ml)
- All patients were evaluated thoroughly during pre anesthetic checkup and relevant investigations were done before surgery
- After shifting to the OR, iv access obtained with 18G IV cannula and IV infusion started with Ringer lactate. The spinal anaesthesia was performed on l3-l4 or l4-l5 space using quincke spinal needle

Parameters observed:

- Onset of sensory block (min)
- Onset of motor block (min)
- Regression sensory block (min)
- Regression of motor block(min)
- Duration of analgesia (min)
- Hemodynamic parameters

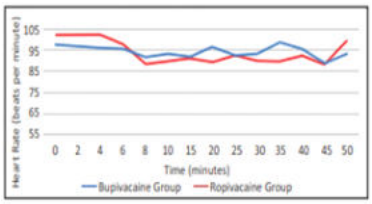
- The systolic and diastolic blood pressure and base line heart rate were recorded before injection
- The sensory and motor block levels assessment was performed at 1, 2min and recorded every 2min until surgical anaesthesia achieved. The segmental level of sensory block to pin prick was assessed
- The motor block of both legs was evaluated using modified bromage scale
- The residual sensory blockade was examined every 15min and wearing of time is noted. (when patient sensation to pin prick regressed to T10)
- Residual motor blockade was examined every 15min, when patient start to lift leg against gravity.
- The patient blood pressure was measured, after the injection at 5 min in first 30min, and after that, was recorded every 15min in post operative period

RESULTS

- The statistical analysis was done by SPSS (version 22) using independent t test for numerical data.
- P value <0.05 was considered to be statistically significant

- The two groups were comparable in terms of age, weight and height in cm

Heart rate trends in two groups



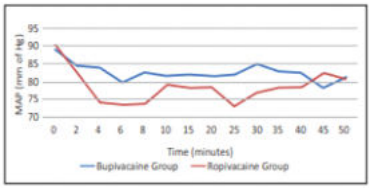
- There was no significant change in heart rate following sub arachnoid block in both groups
- The heart rate was comparable in both groups without any clinical or statistical significance

HR(bpm)	Group-B (n=30)	Group-R (n=30)
Basal	93.2+12.41	99.32+15.78
5 min	94.58 +14.69	100.3+18.67
10 min	95.02+ 15.19	97.94+13.21
15 min	92.26 +15.33	92.92+1.15
20 min	95.06+14.60	92.98+14.48
25 min	95.46+15.07	95.74+13.34
30 min	96.44+15.74	99.02+13.23
35 min	96.8+14.32	99.36+14.96
40 min	94.88+14.24	97.34+14.53
45 min	94.38+13.84	94.58+14.82
50 min	92.78+14.88	96.30+14.55
55min	92.36+13.36	94.68+13.73
60min	91.98+13.73	95.1+11.06

Comparison of MAP between two groups

- Hypotension was noted in 15 patients in group B and 16 patients in group R. It is managed with inj. Mephenterimine 6mg boluses
- Bradycardia was noted in two patients of Bupivacaine group and one patient in group R
- Nausea and vomiting was observed in 1 patient in group B 1 patient in group R
- There is no clinical and statistical significance in incidence of side effects in both groups
- The median fall in MAP was 24 (1-49) mm of Hg in group B and 31(4-50)mm of Hg in group R
- This was clinically and statistically not significant

Comparison of demographic profile between two groups			
	Bupivacaine group (n=30)	Ropivacaine group (n=30)	P-value
Age (years)	24.2+3.99	26.07+4.56	0.097
Weight (Kg)	66.7+6.23	66.03+7.77	0.715
Height (in cm)	157.60+3.84	156.80+3.06	0.722



Side effects	Bupivacaine Group (n=30)	Ropivacaine Group (n=30)
Hypotension	15	16
Bradycardia	2	0
Shivering	3	1
Vomiting	1	1

DISCUSSION

- Ropivacaine is a relatively new amino amide local anesthetic which came into market in 1996
- It has an advantage of separated sensory and motor block with less toxicity to cardio vascular system and central nervous system
- Cesarean section is of shorter duration (>3 hours) for which intense motor block and urinary retention caused by commonly used intrathecal Bupivacaine is not necessary
- The equipotent ratio between Ropivacaine and Bupivacaine is considered to be 3:2 or 2:1 (Mc donald etal , gautier et al)
- In a dose finding study of Ropivacaine for cesarean section, khaw and colleagues noted that ED 50 of isobaric Ropivacaine for cesarean section was 16.7mg (14.1-18.8)
- Hyperbaric Bupivacaine 10mg is commonly used dose in our institution
- Hence equipotent dose of 15mg Ropivacaine was used in the study

Hemodynamic parameters:

- Hypotension occurred in 15 patients in group R, comparable to 16 group B
- Bradycardia is observed in 1 patient of Bupivacaine group and 1 patient in Ropivacaine group
- Fall in MAP is 24mm of Hg with Ropivacaine compared to 31mm Hg in Bupivacaine
- All babies delivered in either group were healthy
- None of the babies had APGAR less than 7
- This augers well with Ogun and others, also observed comparable hemodynamics in their study
- The onset of sensory block with Ropivacaine is similar to Bupivacaine
- The onset of motor block was faster in Bupivacaine group
- The regression of sensory and motor block was faster in Ropivacaine group
- The duration of analgesia lasted slightly long in Bupivacaine group.
- There is delayed onset of motor block and shorter duration of motor for Ropivacaine when compared to Bupivacaine .

MAP(mm of Hg)	Group-B (n=30)	Group-R (n=30)
Basal	90.70+10.18	90.58 +10.60
5 min	84.06+ 12.01	78.70+10.86
10 min	78.80+ 9.77	74.70+11.57
15 min	76.12+10.33	76.49+11.80
20 min	75.96+9.54	74.92+11.17
25 min	75.36+7.74	76.73+12.15
30 min	77.52+9.29	75.22+11.52
35 min	76.62+10.67	73.06+10.06
40 min	76.02+10.5	72.27+9.43
45 min	78.32+9.93	74.18+8.18
50 min	79.18+10.03	75.63+7.46
55min	80.80+10.19	77.67+8.42
60min	81.52+9.34	74.67+6.81

CONCLUSION

- Our study reveals that 15mg hyperbaric Ropivacaine (2ml of 0.75%) when administered intrathecally provides adequate analgesia for cesarean section
- There is delayed motor block and shorter duration of motor block with Ropivacaine compared to Bupivacaine
- Hence Ropivacaine can be used successfully for cesarean section where early recovery expected

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