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Original Research Article

COMPARATIVE STUDY OF INTRATHECAL HYPERBARIC(0.75%) ROPIVACAINE WITH HYPERBARIC (0.5%) BUPIVACAINE FOR ELECTIVE CAESAREAN SECTION UNDER SPINAL ANESTHESIA

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ABSTRACT

Background: The aim is to compare the clinical efficacy and safety of equal volume (2ml) of 0.75% Hyperbaric Ropivacaine with 0.5 % hyperbaric Bupivacaine for elective lower segment caesarean section under spinal anaeasthesia.

Materials and Methods: It was a prospective randomized control study. The purpose of this study was to evaluate the clinical efficacy and safety of spinal anesthetic for elective cesarean delivery using 0.75% hyperbaric Ropivacaine and 0.5% hyperbaric Bupivacaine. Thirty patients from each group, Group R (Ropivacaine) and Group B (Bupivacaine), underwent elective LSCS under spinal anesthesia.

Results: The present study revealed that with hyperbaric 0.75% Ropivacaine, there is a quicker start and a shorter duration to peak sensory block. Both groups experienced a comparable degree of sensory block. Compared to Bupivacaine, Ropivacaine caused a substantially shorter duration of sensory block. Time to complete motor block is slower with Hyperbaric Ropivacaine Hyperbaric Ropivacaine produced a shorter-lasting motor blockage than Bupivacaine. Significant differences in hemodynamic parameters were not seen between the two groups. Complications were less common in the group using Ropivacaine. The APGAR score at 5 minutes was more than 7 in both groups, indicating that the research medicines had no detrimental effect in neonates. While the duration of anesthesia and analgesia in the Ropivacaine group was not as long as in the Bupivacaine group, it was still enough for procedures like Caesarean sections. The early recovery from motor blockade with Ropivacaine aids in early ambulation of patient.

Conclusion: Our findings suggest that patients receiving 0.75% hyperbaric Ropivacaine had faster onset of sensory block and shorter duration of sensory and motor block duration than those receiving 0.5% hyperbaric bupivacaine.. The incidence of complications was lower in the Ropivacaine group. In terms of block quality, hyperbaric 0.75% Ropivacaine is comparable to hyperbaric 0.5% bupivacaine, but has a faster recovery time which helps in early ambulation of the patient. APGAR score at 5 minutes was more than 7 in both the groups and it showed that study drugs had no adverse effect in neonates. Thus; we recommend routine use of 0.75% Ropivacaine for Caesarean Section.

Keywords: Hyperbaric Ropivacaine, Bupivacaine, APGAR, Hemodynamic parameters, Caesearn section.

INTRODUCTION

Cesarean delivery is the most common major surgical procedure performed worldwide, with an estimated 23 million procedures performed each year.[1] Spinal anaesthesia has been a widely utilized technique in the field of anaesthesia since 1898, when August Bier of Griefswald, Germany administered the first true spinal anaesthesia on humans.[1-3]

Central neuraxial blockade is regarded as the gold standard approach for obstetric anesthesia and analgesia. Spinal anaesthesia is frequently used for caesarean section due to its rapid onset, dense neural block, lower maternal morbidity and mortality, which is largely due to a reduction in the incidence of pulmonary aspiration and failed intubation, avoids neonatal exposure to depressant anaesthetic drugs, and allows the mother to remain awake during delivery. It is an alternative to general anesthesia for almost all but the most emergent of cesarean deliveries.[2]

Hyperbaric 0.5% bupivacaine is the most commonly used local anesthetic agent for caesarean section. Three decades ago, several patients who received Bupivacaine suffered life-threatening arrhythmias that resisted treatment. Following notification of Bupivacaine's life-threatening cardiotoxicity, the search for better, safer local anesthetic agents began. One noteworthy component of this cardiotoxicity is that it is related to the stereospecificity of Bupivacaine, with the 'S' isomer having far lower cardiotoxic potential than the 'R' form.

The major concern about bupivacaine's cardiotoxicity prompted the invention of ropivacaine, a novel long-acting amide. Ropivacaine was introduced into therapeutic practice in 1996. It is part of the homologous series, which also contains bupivacaine and mepivacaine. It has an isopropyl group attached to piperdine nitrogen instead of mepivacaine's methyl group and bupivacaine's butyl group. It is manufactured as pure s-enantiomer 3 rather than a racemic mixture.

The L form is less cardiotoxic and has a shorter duration of action than bupivacaine. Its limited lipid solubility reduced the risk of negative inotropism and had a lower affinity for cardiac sodium channels than bupivacaine. Thus, it has abetter safety profile than bupivacaine. It has been found to produce effective, well- tolerated surgical anesthesia via the epidural route, for major and small nerve blocks and field blocks, as well as high-quality postoperative analgesia.

Ropivacaine was approved through the intrathecal route, in the European Union in February 2004. Intrathecal Ropivacaine was found to be safe, having shorter duration of action than bupivacaine and lesser incidence of transient neurological symptoms (TNS) as compared with intrathecal Lignocaine.[4,5] It is approximately 40% less potent than bupivacaine6 after spinal injection in nonpregnant individuals. Given the low doses, there is minimal, if any, reduction in risk for local anesthetic systemic toxicity. Further, it is not clear whether ropivacaine produces spinal anesthesia of similar quality to that provided by bupivacaine.[6-8]

Intrathecal use of hyperbaric local anaesthetic agents have become more popular as they produce more predictable block characteristics and reliable Spinal Anaesthesia.

In this prospective randomized control study, we will be comparing the clinical efficacy and safety of commercially available hyperbaric 0.75% Ropivacaine with hyperbaric 0.5% Bupivacaine and assess the suitability of Hyperbaric Ropivacaine as an alternative to Hyperbaric Bupivacaine for elective caesarean section under Spinal Anaesthesia.

Aim of the study

To compare the clinical efficacy and safety of equal volume (2ml) of 0.75% Hyperbaric Ropivacaine with 0.5 % Hyperbaric Bupivacaine for elective lower segment caesarean section under Spinal Anaeasthesia.

Objectives of the study

To determine the,

1. Time to onset of Sensory block.
2. Time to peak Sensory block.
3. Duration of Sensory block.
4. Time to Complete Motor block.
5. Duration of Motor block.
6. Intraoperative Haemodynamics.
7. Complications. (If any)

MATERIALS AND METHODS

Study Centre: Government General Hospital, Nandyala, Andhra Pradesh

Duration of study: 3 Months

Study Design: Prospective randomized control study

Patient Selection: Ethical committee approval and informed written consent from patients involved in this study are obtained before starting this study.

60 patients with below mentioned inclusion and exclusion criteria were enrolled.

Randomization: Patients were randomly allocated into two groups by slips in a box technique.

Inclusion Criteria

- American Society of Anaesthesiologists II
- Elective Caesarean Section
- Age 18-35 years
- Singleton Parturient
- Weight 40-80kg

Patients who has given valid informed written consent

Exclusion Criteria

- Patient refusal
- Age below 18 years or above 35 years
- Infection
- Coagulopathy
- Spinal deformity
- American Society of Anaesthesiologists III and IV
- Allergic to local anaesthetic drugs
- H/o seizures and neurological deficits

- Complicated Pregnancy
- Intrauterine fetal compromise
- Antepartum hemorrhage
- Lack of informed written consent

Sample size Calculation: The sample size was calculated based on the similar previous studies. Considering the power of the study as 80%, type – I error rate (alpha) as 5 % and a superiority margin between the two groups as 25 %, the sample size of this study was calculated to be 60 patients. Patients involved in the study were divided into two groups of 30 each

Group B – Patients in this group received intrathecal 0.5% Hyperbaric Bupivacaine.

Group R – Patients in this group received intrathecal 0.75%Hyperbaric Ropivacaine.

Materials

Drugs

- Inj. 0.5% hyperbaric Bupivacaine
- Inj. 0.75% hyperbaric Ropivacaine
- Inj. 2% Lignocaine
- Emergency drugs

Equipment's

- 25G Quincke Babcock spinal needle
- Sterile drapes and sterile bowl
- Sterile gauze pieces
- Sponge holding forceps
- Sterile 2ml and 5ml syringes

Monitors

- PR
- SpO2
- NIBP
- ECG

Methodology

Pre anaesthetic Evaluation: Patients included in this study underwent preanaesthetic evaluation which included.

- **History:** Presenting complaints, History of any comorbid conditions like diabetes, hypertension, thyroid disorders, Bronchial asthma, renal failure, congenital heart disease, valvular heart disease, seizures; previous surgery/ anaesthesiaexposure; allergy to drugs were noted.
- **Physical examinations:** General examination, head to toe examination, vital signs, systemic examination, local examination of spine and assessment of airway was done.
- **Investigations**
  - Complete Haemogram (Hb%, RBC count, WBC count, Differential count, Platelet count).
  - Random blood sugar
  - Blood urea and Serum creatinine
  - Serum electrolytes
  - Bleeding time, Clotting time
  - Urine albumin and sugar
  - ECG
  - Echocardiogram (if necessary).

Patients who satisfied the inclusion criteria were explained about the nature of study and anesthetic technique and informed written consent was obtained

Pre anaesthetic preparation

1. Anaesthetic machine is checked before starting the procedure.
2. Check the availability of working laryngoscope and endotracheal tubes of various sizes.
3. Ensure that the essential emergency drugs are available.
4. Make sure that the operating table tilts are corrected.
5. Obtain a proper intravenous access (18 G cannula) and preload with 500 ml of crystalloid (Normal saline).
6. Connect monitors to the patient. (ECG, PR, NIBP, SPO2, RR) and baseline vitals are observed.

Technique: Under strict aseptic precaution, patient in left lateral position, lumbar region is painted and draped. L3-L4 intervertebral space is identified by using Tuffier's line. Then skin is infiltrated with 2 ml of 2% lignocaine. By midline approach 25 G Quincke's needle is inserted into subarachnoid space. After confirming free flow of clear CSF, 2 ml of 0.5% Hyperbaric Bupivacaine (10mg) / Ropivacaine (15mg) is administered.

RESULTS

Observation

Vital Signs: Patient's Pulse rate, Systolic Blood pressure, Diastolic blood pressure, Mean arterial pressure, saturation and respiratory rate are observed at 1,3,5,10,15,30,45,60mins after subarachnoid blockade. Common side effects which is observed after sub arachnoid block are hypotension and bradycardia.

Sensory Block

1. Time of onset (Time taken to attain T10 dermatome level).
2. Time to Peak Sensory block. (Time taken to attain T6 dermatome level).
3. Duration of block. (Time of regression upto L1 dermatomal level)

Motor Block

1. Time to complete motor block. (Time taken to achieve Bromage score 3) Degree of motor block is assessed by modified Bromage scale at 5 mins interval.

0 =able to raise straight leg against resistance i.e. no detectable motor block.

1=unable to raise straight leg but able to flex knee.

2=unable to flex knee but able to flex ankles. 3= unable to move hip, knee or ankle.

2. Duration of motor block. (Time of regression to Bromage score 0)

RESULTS

A total of 60 participants were included in the final analysis

Statistical Analysis: The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0. (Armonk, NY: IBM Corp). To describe about the data descriptive statistics frequency

analysis, percentage analysis were used for categorical variables and the mean & Standard Deviation were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Unpaired sample t -test and Mann Whitney U test were used. In both the above statistical tools the probability value .05 is considered as significant level

Table 1: Comparison of mean time of onset of sensory block between the study groups.

Parameter	Groups		Independent t test p-value
	Bupivacaine (n=30)	Ropivacaine (n=30)	
Time of onset of sensory block (in seconds)	197.7 ± 101.2	121.8 ± 68.8	0.001

Table 2: Comparison of median time to peak sensory block between the study groups

Parameter	Groups		Mann-Whitney U test p-value
	Bupivacaine (n=30)	Ropivacaine (n=30)	
Time to peak sensory block	7 (3.3)	6 (2.0)	0.051

Table 3: Comparison of mean duration of sensory block between the study groups.

Parameter	Groups		Independent t test p-value
	Ropivacaine (n=30)	Bupivacaine (n=30)	
Duration of sensory block (in minutes)	151.7 ± 10.9	185.6 ± 15.3	<0.001

Table 4: Comparison of mean time to complete motor block between the study groups.

Parameter	Groups		Independent t test p-value
	Ropivacaine (n=30)	Bupivacaine (n=30)	
Time to complete motor block	12.6 ± 2.4	10.7 ± 3.5	0.019

Table 5: Comparison of mean duration of motor block between the study groups.

Parameter	Groups		Independent t test p-value
	Ropivacaine (n=30)	Bupivacaine (n=30)	
Duration of motor block	125.1 ± 10.5	181.1 ± 17.9	<0.001

Table 6: Comparison of mean pulse rate between the study groups.

Pulse rate	Groups		Independent t test p-value
	Bupivacaine (n=30)	Ropivacaine (n=30)	
Preoperative	105.8 ± 15.5	107.6 ± 14.1	0.645
1 minute	103.9 ± 18.5	98.1 ± 24.8	0.309
3 minutes	99.7 ± 30.1	91.8 ± 28.7	0.302
5 minutes	95.9 ± 25.0	96.9 ± 20.6	0.861
10 minutes	95.6 ± 17.5	95.7 ± 15.9	0.975
15 minutes	92.7 ± 17.3	94.7 ± 15.2	0.630
30 minutes	91.5 ± 16.8	92.2 ± 15.7	0.862
45 minutes	90.5 ± 16.0	90.8 ± 14.2	0.939
60 minutes	90.0 ± 15.1	88.4 ± 17.5	0.706

Table 7: Comparison of mean SBP between the study groups.

SBP	Groups		Independent t test p-value
	Bupivacaine (n=30)	Ropivacaine (n=30)	
Preoperative	117.0 ± 12.8	123.8 ± 13.7	0.053
1 minute	111.7 ± 11.3	114.9 ± 11.0	0.281
3 minutes	100.5 ± 14.2	106.8 ± 12.6	0.072
5 minutes	106.9 ± 13.1	109.3 ± 14.6	0.493
10 minutes	111.4 ± 12.0	110.1 ± 11.9	0.675
15 minutes	112.5 ± 12.8	110.4 ± 12.5	0.509
30 minutes	110.5 ± 13.4	110.5 ± 10.7	1.0
45 minutes	113.7 ± 11.6	112.7 ± 10.8	0.731
60 minutes	116.5 ± 13.4	113.5 ± 10.6	0.353

Table 8: Comparison of mean DBP between the study groups.

DBP	Groups		Independent t test p-value
	Bupivacaine (n=30)	Ropivacaine (n=30)	
Preoperative	75.5 ± 9.4	75.8 ± 9.4	0.913
1 minute	73.9 ± 9.3	75.1 ± 8.7	0.609
3 minutes	68.5 ± 11.1	71.4 ± 12.5	0.347
5 minutes	71.6 ± 8.9	69.4 ± 13.1	0.451
10 minutes	76.8 ± 8.2	70.7 ± 10.5	0.015
15 minutes	74.7 ± 6.7	71.9 ± 9.5	0.191
30 minutes	74.0 ± 5.8	70.9 ± 10.4	0.163

45 minutes	73.3 ± 5.5	71.8 ± 8.7	0.439
60 minutes	74.7 ± 6.7	72.7 ± 7.7	0.301

Table 9: Comparison of mean MAP between the study groups.

MAP	Groups		Independent t test p-value
	Bupivacaine (n=30)	Ropivacaine (n=30)	
Preoperative	89.4 ± 9.8	91.8 ± 10.2	0.349
1 minute	86.5 ± 8.6	88.3 ± 8.7	0.412
3 minutes	79.2 ± 11.6	83.2 ± 11.6	0.182
5 minutes	83.4 ± 9.0	82.7 ± 12.8	0.822
10 minutes	88.3 ± 8.1	83.8 ± 9.7	0.056
15 minutes	87.3 ± 7.1	84.7 ± 9.7	0.242
30 minutes	86.2 ± 6.9	84.1 ± 9.2	0.334
45 minutes	86.7 ± 6.0	85.4 ± 8.1	0.478
60 minutes	88.6 ± 7.4	86.3 ± 7.8	0.252

Table 10: Distribution of adverse effects reported by study participants.

Adverse effects	Bupivacaine	Ropivacaine	Total
Bradycardia	3	5	8
Hypotension	6	3	9
Nausea	6	2	8
Vomiting	3	2	5
Shivering	3	2	5

DISCUSSION

Ropivacaine, a newer local anesthetic agent, has improved cardiovascular safety compared to Bupivacaine. Ropivacaine provides stronger sensory and less motor block than Bupivacaine, allowing for earlier ambulation and recovery.

Fettes et al,[9] compared hyperbaric and normal Ropivacaine for perineal surgery. He concluded that the hyperbaric preparation resulted in a more consistent block with faster start and recovery, while the isobaric solution of ropivacaine resulted in a less favorable block pattern and a higher failure rate.

Gautier et al,[10] compared several doses of Ropivacaine (8, 10, 12, 14 mg) to 8 mg Bupivacaine and determined that Ropivacaine 12 mg had the same effect as 8 mg Bupivacaine. The potency ratio of Bupivacaine: Ropivacaine was 1:1.5. Equipotent dosages of bupivacaine (10mg) and Ropivacaine (15mg) were utilized in this study.

In this study, we compared the commercially available preparation of Hyperbaric 0.75% Ropivacaine (ROPIN- HEAVY) to Hyperbaric 0.5% Bupivacaine, which is commonly used for Caesarean section. We evaluated equivalent doses of Hyperbaric Ropivacaine and Hyperbaric Bupivacaine (15 mg Ropivacaine versus 10 mg Bupivacaine).

In our study, we noticed that ropivacaine substantially caused faster onset and shorter time to peak sensory block (121.8 ± 68.8 sec, 6 ± 2.0 min) than bupivacaine (197.7 ± 101.2 sec, 7 ± 3.3 min) which is statistically significant when compared. This is in contrast to the study conducted by Nazima Menon et al,[11] who showed a somewhat longer onset of effect with Ropivacaine.

However, the level of sensory block obtained was similar, but the duration was much shorter with ropivacaine (151.7 ± 10.9min) compared to bupivacaine (185.6 ± 15.3min). Although the duration of anesthesia and analgesia was less in the Ropivacaine group than the Bupivacaine group, it was sufficient for surgery such as a Caesarean section.

The time to complete motor blockade was 12.6 ± 2.4min in Group R and 10.7 ±3.5min in Group B which is statistically significant and duration of motor blockade was greater in Group B (181.1 ± 17.9min) than in Group R (125.1 ± 10.5min) with a statistically significant p-value of < 0.001.

Our study's findings agree with those conducted by U Shrivastava et al,[12] and Somjit Chatterjee et al.[13] 11 mg of hyperbaric bupivacaine and 15 mg of hyperbaric ropivacaine were studied by U Shrivastava et al. According to the study, 15 mg of hyperbaric ropivacaine produced surgical a local anesthesia that was more effective than 11 mg of hyperbaric bupivacaine in terms of anesthesia's duration, and quality.

In the study conducted by Somjit Chatterjee et al 13 100 patients undergoing elective lower limb orthopedic surgery were given a comparison between 22.5 mg of hyperbaric Ropivacaine and 15 mg of hyperbaric Bupivacaine. 0.75% Hyperbaric Ropivacaine, he noted in the study, produced sufficient and efficient spinal anesthesia with a shorter duration of sensory and motor block. The hemodynamic parameters such as Pulse rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean arterial pressure, SpO2 were monitored at the following time interval – preoperative, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min, 45 min, 60 min.

Hypotension was considered as reading 20% less than preoperative level or systolic blood pressure less than 90mm Hg. Hypotension was treated with IV fluids and Vasopressors Inj. Mephentermine IV in increments of 6mg as necessary.

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.

Independent t-test was used to compare the hemodynamic parameters between the groups and it is statistically insignificant. Patients' heart rates from Group B and Group R were contrasted. Intravenous atropine 0.6 mg was used to treat bradycardia in 5 patients in Group R and 3 patients in Group B.

Inj Mephentermine IV and intravenous fluid were used to treat the hypotension of 6 patients in Group B and 3 patients in Group R, according to a comparison of their mean arterial pressures. The results of our study support the study conducted by Dar et al that the intrathecal ropivacaine can be used to provide good quality anaesthesia with lesser hypotension Patients in both groups experienced only minor, readily treated problems rather than any significant ones.

During the trial, 6 patients in Group B and 2 individuals in Group R experienced nausea. Three patients in Group B and two in Group R both had vomiting.

Three patients from Group B and two from Group R developed intraoperative shivering. Thus we infer that the incidence of adverse outcomes such as hypotension, nausea, vomiting, shivering are less in Group R compared to Group B. The findings in hemodynamic parameters and adverse effects between both groups in our study are similar to that studies conducted by Nizama Memon et al,[11] At five minutes, every neonate had an APGAR score of more than seven. It was determined that the local anesthetics, Ropivacaine and Bupivacaine, had no negative effects on newborns.

CONCLUSION

Ropivacaine is a longer-acting local anesthetic that produces similar effects when given in Equipotent doses. Ropivacaine has a wider margin of safety (a greater therapeutic ratio) due to a lower incidence of cardiovascular and central nervous system damage. Our findings suggest that patients receiving 0.75% hyperbaric Ropivacaine had faster onset of sensory block and shorter duration of sensory and motor block duration than those receiving 0.5% hyperbaric bupivacaine. The incidence of complications was lower in the Ropivacaine group. In terms of block quality, hyperbaric 0.75% Ropivacaine is comparable to hyperbaric 0.5% Bupivacaine, but has a faster recovery time which helps in early ambulation of the patient. Thus, we recommend routine use of 0.75% Ropivacaine for caesarean Section.

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