Section: Anaesthesiology

Original Research Article

COMPARISON OF HYPERBARIC 0.75% ROPIVACAINE WITH 0.5% BUPIVACAINE FOR ELECTIVE CAESAREAN SECTION UNDER SPINAL ANAESTHESIA: A DOUBLE BLIND RANDOMISED CONTROLLED STUDY

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Abstract

Background: Introduction: Hyperbaric bupivacaine is a commonly used local anaesthetic for caesarean section under spinal anaesthesia. Hyperbaric ropivacaine provides a reasonably safe alternative to bupivacaine due to lower cardiac and neurotoxicity. Increased baricity produces a predictable effect as compared to an isobaric solution. This study was conducted to compare the efficacy and safety of hyperbaric ropivacaine with hyperbaric bupivacaine in spinal anaesthesia for elective caesarean section. **Materials and Methods:** Eighty-six pregnant women undergoing elective caesarean section were allocated into two groups of 43 each. Group R received 2 ml of 0.75% hyperbaric ropivacaine intrathecally, while Group B received 2 ml of 0.5% hyperbaric bupivacaine. Both groups were compared in terms of onset and offset of sensory and motor block, duration of analgesia and side effects if any.R package software was used for statistical analysis. The unpaired student's t-test was used for the analysis of quantitative variables and the chi-square test was used for categorical variables. **Result:** The onset and regression of sensory block were comparable in both groups. The onset of motor block in the Ropivacaine group (11.95 ± 3.78 min) was slower than the bupivacaine group while the regress ion was faster. Duration of analgesia was also comparable in both groups [Group R (130 ± 30.35) vs Group B (135 ± 35.67) (p=0.323)]. **Conclusion:** Hyperbaric ropivacaine produces predictable spinal anaesthesia with a dense sensory block but limited motor block, making it ideal for procedures with short to intermediate duration such as caesarean section.

INTRODUCTION

Spinal anaesthesia is a modality of choice for caesarean section and offers many advantages such as reduced stress response, improved post-operative pain relief and most importantly early mother-child bonding.[1] Intrathecal bupivacaine is a preferred drug for spinal anaesthesia in caesarean section but it produces prolonged dense motor blockade which delays the recovery profile.[2] Ropivacaine presents a distinctive opportunity for faster recovery of motor function when compared with bupivacaine. Due to pure S (-) enantiomeric form, with high pKa and low lipid solubility, it blocks nerve fibres involved in pain transmission (Aδ and C fibres) to a greater degree than those controlling motor function (Aβfibres) and produces distinctively sensorimotor dissociation.[3] Furthermore, it has reduced potential for cardiotoxicity and neurotoxicity. Hyperbaric solutions confer the advantage of producing predictable anaesthesia when given intrathecally in comparison to isobaric or hypobaric solutions.[4] Various studies have been conducted to compare isobaric ropivacaine with comparable local anaesthetics used intrathecally but hyperbaric ropivacaine has been studied to a lesser extent.

This study aims to compare the efficacy of 0.75% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine for spinal anaesthesia in elective caesarean section.

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MATERIALS AND METHODS

This double-blind randomised control study with a design for equivalence was conducted in the tertiary centre after approval from the Institution's ethical committee. After informed written consent, patients were recruited into two groups with equal allocation. Sample size was calculated based on previously conducted study by Subba et al. for randomised clinical trial with parallel design considering difference in onset of sensory block of three minutes.5 With study powered at 80% and alpha error at 5%, the calculated sample size comes out to be 39 in each group. Considering dropout rate of ten percent, the sample size in this study was 43 in each group (Total sample size=86). Randomisation was done using computerized generated random number table. Black opaque envelopes were used for concealment of group allocation. Patient and primary investigator were blinded to group allocation while an independent anaesthesiologist who did not participate in the study prepared the drugs for administration.

Inclusion criteria comprised of age 16-35 years, American society of anaesthesiology (ASA) physical status II and without any craniospinal deformity or lesion. Patients unwilling to participate in the study, age >35 years, ASA physical status >II, patients with altered consciousness, significant neurological, psychiatric, neuromuscular, cardiovascular, pulmonary, renal, hepatic diseases, morbid obesity [Body mass index(BMI)>40 kg/m2], coagulopathy, patients with spine deformity, localized sepsis, raised intracranial pressure and patient with a history of allergy to drugs under study were excluded from the study.

Eighty-six patients were equally divided into two groups of 43 each with patients in group R receiving 2 ml of 0.75% hyperbaric ropivacaine while patients in group B receiving 0.5% hyperbaric bupivacaine. After a thorough evaluation of the patient during the pre-operative period, the patient was shifted to the operation theatre. ASA guidelines were followed for investigations and preoperative fasting, with the patient receiving carbohydrates containing clear fluid for up to two hours. Intraoperative monitoring was attached as per ASA protocol and encompassed continuous monitoring of electrocardiogram(ECG) and pulse oximetry(SpO2) while Non-invasive blood pressure(NIBP) was measured continually at an interval of five minutes. A wide bore cannula was secured and patients were preloaded with 500 ml crystalloid while 500 ml crystalloid was co-loaded during the administration of spinal anaesthesia. Under aseptic conditions, patients were administered spinal anaesthesia at L2-L3 interspace or L3-L4 interspace with 25G/27G quincke's needle in the lateral decubitus position. Before each caesarean section, the black opaque envelope containing group designation was opened and the drug was administered as per group allocation. The patient and anaesthetist administering the spinal anaesthesia were blinded to the group allocation. The drug was prepared by an anaesthesiologist who was not part of the study. After administration of spinal anaesthesia, the patient was turned supine, oxygen was supplied with a poly mask @ 6L/min and observations were recorded. If adequate sensory (T6 dermatome) and motor (Modified Bromage score 3) responses were not achieved till ten minutes, general anaesthesia was administered and the patient was excluded from the analysis.6 On regression of sensory level up to the level of incision or complaint of pain by the patient during surgery, rescue analgesia was given. In case of persistent pain, general anaesthesia was administered and the patient was excluded from the study. Clinically significant hypotension was defined as a decrease in mean arterial pressure (MAP) by >20 % from baseline values or <70 mm Hg. It was treated with Inj. ephedrine 6 mg intravenous(IV) and the total amount of ephedrine required was measured. Clinically significant bradycardia was considered at a heart rate <50 beats per min and was treated with Inj. atropine 0.6 mg.

The primary objectives of the study were to assess the onset of sensory and motor blocks. The secondary objectives of the study included the comparison of regression of sensory and motor blockade, duration of analgesia, intraoperative haemodynamic parameters and side effects. The time for spinal anaesthesia was considered as T0. Sensory block was assessed by loss of cold sensation to spirit swab in the anterior axillary line, at an interval of one minute till achievement of the maximum blockade. The onset of sensory block was defined as the absence of pain sensation at the T6 dermatome. The duration of sensory regression was considered after two segment regressions from the attained maximum level. Motor block in both groups was assessed every minute according to the modified Bromage scale. Total duration of analgesia was considered up to the time of self-reporting of pain by the patient. Haemodynamic parameters (HR and MAP) were measured from the time of administration of spinal anaesthesia up to discharge from PACU. Any side effects/adverse events such as hypotension, bradycardia, dyspnoea, nausea, vomiting and high spinal were documented and managed as per institutional protocol.

The collected data were recorded into an Excel spreadsheet and analysed using R statistical package. Categorical variables were analysed using the chi-square test. For quantitative data, the student's t-test was used for the comparison of means. A P-value <0.05 was considered statistically significant.

RESULTS

None of the patients was lost in follow-up and all patients were analysed for the outcome. Patients in both groups were comparable in their demographic profile including age, weight, height and BMI [Table

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1]. The onset and regression of sensory block were similar in both group R and group B [Table 2]. Similary, duration of analgesia was also comparable between both groups (p=0.323) [Table 2]. The onset of motor block was slower in group R as compared to group B and was found to be statistically significant [Table 2]. Also, the duration of motor block was significantly smaller in group R when compared to group B. Duration of surgery, the requirement of rescue analgesic and the incidence of side effects was also similar in both groups [Table 3,4]. Though the overall requirement of fluid boluses to maintain haemodynamic stability was comparable in both groups but group R required a lesser number of ephedrine shots for the same [Table 3].

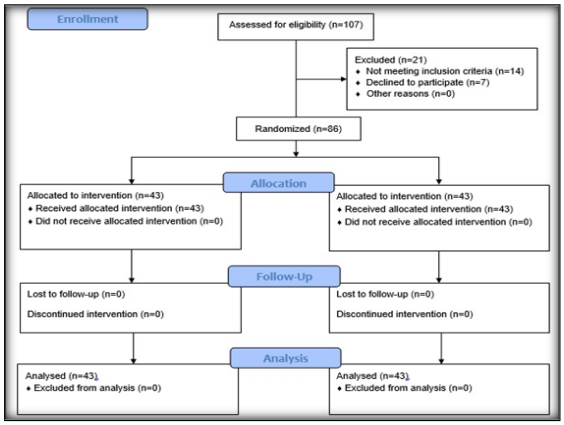

Figure 1: CONSORT diagram of the study

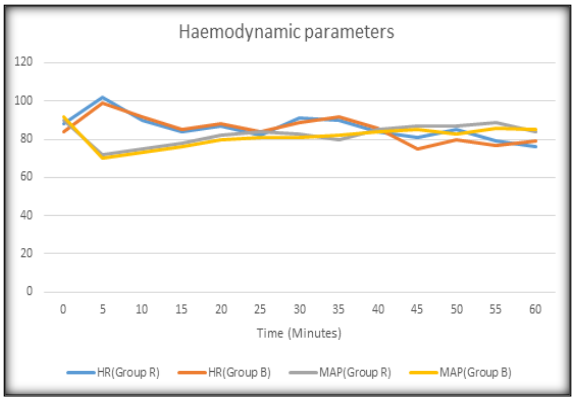

Figure 2: Haemodynamic parameters in both groups

Table 1: Comparison of demographic profile between Group R and Group B

	Group R(n=43)	Group B(n=43)	p value
Age(years)	23.2 ± 4.7	24.7 ± 3.9	0.673
Weight(kg)	67.6 ± 5.7	68.4 ± 4.9	0.548
Height(cm)	145 ± 7.5	149 ± 6.0	0.517
Body mass Index (kg/ m2)	23. 2 ± 3.0	22.1 ± 3.3	0.431

Table 2: Comparison of block characteristic between Group R and Group B

	Group R	Group B	p value
Onset of sensory block(min)	4.27 ± 1.64	4.35 ± 1.51	0.863
Onset of motor block(min)	11.95 ± 3.78	6.83 ± 2.97	<0.005
Regression of sensory block(min)	121.8 ± 37.18	127.5 ± 41.03	0.467
Regression of motor block(min)	105.8 ± 43.37	163.13 ± 39.98	<0.005
Duration of analgesia (min)	130 ± 30.35	135 ± 35.67	0.323

Table 3: Intraoperative vasopressor, fluid and analgesia requirement in group R and group B

	Group R	Group B	p value
Doses of ephedrine	1.5 ± 0.9	2.1 ± 0.7	<0.005
Fluid bolus(200 ml)	2.5 ± 0.9	2.7 ± 0.7	0.563
Rescue Analgesic	3/43	1/43	0.000
Duration of surgery	40.20 ± 9.1	38.70 ±10.5	0.326

Table 4: Comparison of side effects between group R and group B

Side effects	Group R(n=43)	Group B(n=43)
Hypotension	18	23
Bradycardia	1	1
Nausea	15	17
Vomiting	1	1
Shivering	5	7

DISCUSSION

The present study was conducted on 86 patients who were divided into two groups of 43 each with group R receiving Inj Ropivacaine 0.75% while group B received Inj Bupivacaine 0.5%. This study observed that 0.75% heavy ropivacaine has a comparable sensory profile to 0.5 % heavy bupivacaine but the motor duration is significantly shorter. Patients receiving ropivacaine required lower doses of ephedrine for maintenance of haemodynamic stability though overall side effects were comparable in both groups.

In this study, we observed that the onset of sensory block and level of regression were similar in both groups. This result was in contrast to the previously conducted study by Oraon et al who observed that the onset of block in patients receiving ropivacaine was

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delayed.[7] This can be attributed to a higher concentration of ropivacaine (0.75%) used in our study as compared to Oraon et al who used 0.5%. Owing to only two third potency of ropivacaine as compared to bupivacaine, previous doses used by researchers were not equipotent and hence produced the suboptimal result on the comparison.

In our study, the duration of analgesia was similar in both groups. The addition of dextrose to make a hyperbaric solution produces a predictable effect of the intrathecally applied local anaesthetics and prolongs the duration of analgesia as reported by various authors previously.[8-10]

The onset of motor block was slower in Group R and the duration of motor block was also shorter as compared to group B. Despite equipotent analgesic dosage, ropivacaine still falls short in producing an equally effective motor block, due to its pharmacological properties such as lower lipid solubility which results in gradual penetration in the large myelinated A fibres. Previously conducted studies by Chung et al and Danelli et al have made similar observations.[12,13]

The incidence of observed side effects was comparable in both groups but patients in group R needed lesser no. of intermittent vasopressors for the achievement of haemodynamic stability. Chung et al and Srivastava et al reported similar incidences of side effects.[11,14]

Bupivacaine has been the standard treatment for intrathecal administration but its administration is marred with multiple concomitant side effects such as severe hypotension and prolonged motor block. The caesarean section is a procedure of a shorter duration, hence drugs with limited motor effects such as ropivacaine provide a sustainable alternative and can very well replace bupivacaine for such procedures. Early motor recovery from anaesthesia may also improve patient satisfaction but this will need further evaluation.

Our study had a few limitations. This study was conducted in a specified population of pregnant females which makes it difficult to apply the results to the general population. The study was not powered enough to assess the requirement of vasopressors and fluid boluses for the maintenance of haemodynamic stability

CONCLUSION

Our research observes that intrathecal administration of 0.75% hyperbaric ropivacaine provides comparable anaesthesia to 0.5% heavy bupivacaine. Though sensory profiles including duration of analgesia are comparable with both the drugs but ropivacaine provides the added advantage of shorter motor blockade and hence quicker postoperative recovery. Detailed research will be needed in the future to analyse postoperative recovery and quality of anaesthesia.

Conflict of interest None declared.

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