COMPARISON OF EFFECTS OF BUPIVACAINE AND ROPIVACAINE IN PATIENTS UNDERGOING ELECTIVE CESAREAN SECTION

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ABSTRACT

Introduction

Spinal anesthesia is considered a reasonable choice for cesarean section. Bupivacaine and ropivacaine have been used as intrathecal drugs alone or in combination with various opioids. Ropivacaine is considered a valid and safe alternative to bupivacaine for spinal anesthesia.

Objective

To compare the efficacy and safety of hyperbaric ropivacaine with hyperbaric bupivacaine in spinal anesthesia for elective cesarean section.

Methodology

Sixty pregnant women undergoing elective cesarean section were allocated into two groups. Group R received 3 ml of 0.5% hyperbaric ropivacaine (2 ml 0.75% plain ropivacaine mixed with 1 ml of 25 % dextrose) and Group B received 2.5 ml of 0.5% hyperbaric bupivacaine. Both the groups were compared in terms of onset of sensory and motor block, regression of sensory and motor block, duration of analgesia and side effects.

Result

The onset of sensory block was comparable in both groups but was statistically insignificant. The onset of motor block in Bupivacaine (7.53 ± 1.72) min was faster when compared to Ropivacaine group (14.33 ± 6.19) min. Regression of sensory and motor block both were faster in Ropivacaine group. Duration of analgesia was longer in Bupivacaine group (131.17 ± 32.95)min than Ropivacaine group (125.33 ± 30.54) min.

Conclusion

Ropivacaine can be used as an alternative to Bupivacaine for spinal anesthesia in cesarean section but has a shorter duration of sensory and motor block.

KEYWORDS

Bupivacaine, cesarean section, pregnancy, ropivacaine, spinal anesthesia

INTRODUCTION

The objective of an anesthesiologist is to make the patient free of pain, during both surgical procedure and postoperative period since the outcome of untreated pain and inadequate anesthesia can be devastating.[1] Adequate analgesia enables early rehabilitation and reduces hospital stay by restoring normal functions like ventilation, coughing and mobility.[2] Several options are available for intraoperative anesthesia as well as postoperative analgesia.[3] Nevertheless, spinal and epidural analgesia, wherever possible using local anesthetics with or without additives are among them. They provide distinct benefits over other modalities like general anesthesia and peripheral nerve blocks.[4]

Bupivacaine is commonly used for spinal anesthesia during cesarean delivery. Ropivacaine is now becoming popular, since sensory nerve fibers are blocked more readily than motor fibers, and has reduced cardiac toxicity with overdose.[5] Ropivacaine and Bupivacaine both belong to amino-amide group of local anesthetic drugs. Though they have same mechanism of action as other local anesthetics, there are some differences in their structural, physiochemical, pharmacokinetic and pharmacodynamic properties.[6-8] Ropivacaine is enantiomerically pure (S-enantiomer), whereas, Bupivacaine is a racemic mixture of two (R and S) enantiomer of same class, structurally related to bupivacaine, but with fewerneurotoxicity and cardiac toxicity .[9]

Bupivacaine is widely used for cesarean section under spinal anesthesia in Nepal. Therefore this study aims to compare the safety and efficacy of bupivacaine and ropivacaine in patients undergoing elective cesarean section under spinal anesthesia. Both the drugs will be compared in terms of onset of both sensory and motor block, duration of analgesia and it's side effects like hypotension, bradycardia, nausea, vomiting and shivering.

METHODOLOGY

This Hospital based, Prospective, Comparative study was conducted in Department of Anesthesiology of Nobel Medical College Teaching Hospital, Biratnagar from May 2018 to December 2018 after taking informed consent from the patients and ethical clearance from institutional review committee.

Sample size calculation was done using the formula, $N = 2SD^2(Z_{/2}+Z_{/2})/d^2$. A power analysis based on data from a study done by Nuray CE and Berrin G, in which the mean duration to reach maximum sensory block was measured with ropivacaine and compared with the previous data for bupivacaine.[10] To detect a 3.5 min difference in mean duration to reach maximum sensory block between the groups for type 1 error of 0.05 and a power of 80% and a standard deviation of 4.1, a group size of 22 patients would be necessary. So we took 30 patients in each group.

A minimum of 60 cases aged 25 to 35 years, height between 150 to 165 cm and Weighing 50-70 kg who were planned for elective cesarean section under spinal anesthesia were included in the study. Exclusion criteria of the study consisted of Patient aged below 25 or above 35 years, patient belonging to ASA(American Society of Anesthesiologist) Physical status Grade III, IV and V, unwilling patient, known hypersensitivity to any of the study drugs, patients taking anticoagulant or antiplatelet therapy or patients with bleeding diathesis or coagulopathy, patients with spinal deformity or puncture site infection, history of any chronic disease like hypertension, diabetes mellitus, respiratory disease, psychiatric or cardiac disease, chronic history of headache and backache, any neurological or neuromuscular disease, patients in whom spinal anesthesia failed and general anesthesia was required during previous surgery, parturients having pre-eclampsia or eclampsia, any obstetric complications or signs of fetal compromise or suspected fetal malformation.

The cases were divided randomly into two equal groups by using computer generated random number list. Group R received 3 ml of 0.5% hyperbaric Ropivacaine (2 ml 0.75% plain ropivacaine mixed with 1 ml of 25 %dextrose) and Group B received 2.5 ml of 0.5% hyperbaric Bupivacaine which is available commercially. Sterility was maintained by mixing autoclaved ampoules of 25 %, 10 ml dextrose with commercially available sterile preservative free isobaric Ropivacaine.The volume of drug in Group R was taken as 3 ml to make Ropivacaine hyperbaric and drug concentration of 0.5 % since we wanted to compare between hyperbaric ropivacaine and bupivacaine. Similar volume of drug has been used in a study done by Singhal et al.[11]

All the patients were assessed and prepared preoperatively as per preoperative protocol of the Department of Anesthesiology of Nobel Medical College Teaching Hospital. Intravenous access was obtained with an 18G cannula through which all participants were pre-loaded with 20 ml/kg of Ringer Lactate over ten minutes before inducing Spinal anesthesia. Patient either received 2.5 ml of 0.5% hyperbaric bupivacaine or 3ml of 0.5% hyperbaric ropivacaine. Under all aseptic precautions the lumbar puncture was done in sitting position at the L3-4 interspace by midline approach using a 25-gauge Quincke spinal needle and study drug was given @ 0.2 ml/sec based on the groups after obtaining free flow of cerebrospinal fluid. Patients were then placed in supine position after intrathecal injection.

Sensory and motor block was assessed after the intrathecal injection at 1 and 2 minutes and the subsequently at 2 minute intervals until surgical anesthesia was achieved by an anesthesiologist who was blinded regarding the study drugs. The segmental level of sensory block to pin prick was assessed by a short beveled 27 gauge needle bilaterally along the midclavicular line. The motor block of both legs was evaluated using the modified Bromage scale (0 = no motor block, 1= inability to raise extended leg; able to move knees and feet, 2= inability to raise extended leg; able to move feet, 3= complete motor block of limb). The induction of anesthesia was considered when at least the T_6 dermatome was anaesthetized. The time of onset of sensory (loss of pin prick sensation) at T_4 dermatome and motor block (complete motor block) was noted. Hemodynamic

parameters like maternal heart rate, electrocardiogram (ECG), blood pressure and oxygen saturation (SpO_2) were monitored. The values were documented before the induction, every 2 minutes during the first 10 minutes after spinal block, then every 5 minutes during the first hour and then every 10 minutes until the patient is transferred to the recovery room. Oxygen at a rate of 4 L/min was given via face mask.

Fall in blood pressure and heart rate below 20 % of the baseline values were defined as hypotension and bradycardia. Intravenous boluses of mephentermine 6 mg initially and which added up to a maximum of 30 mg if required, was given to treat hypotension and intravenous atropine was given to treat bradycardia. Intravenous ondansetron 4 mg was given to treat nausea and vomiting.

Patients who requested to sleep received intravenous Midazolam 2mg after the delivery of the baby. Intravenous Fentanyl 50 µg was administered for pain or discomfort during surgery.

The duration of surgery was noted after the completion of surgery, and the patient shifted to the postoperative ward. Regression of sensory and motor blockade was examined by the researcher. The residual sensory blockade was examined every 15 min and its wearing off time was noted (when sensation to pin prick regressed to T10). Residual motor blockade was examined every 15 min and its wearing off time was noted (when patient start to lift leg against gravity).Pain was assessed using Numerical Rating Scale (NRS). Time for first request for postoperative analgesic (duration of analgesia) was noted and Injection Tramadol 50 mg was given when the NRS score was 5 or more. All patients were assessed for possible adverse effects due to hemodynamic changes and treated accordingly. Data was collected and recorded as per working proforma. Data analysis was done by statistical package for the social sciences(SPSS) version 16 using independent t test for numerical data. A p value 0.05 was considered to be statistically significant.

RESULTS

A total of 60 eligible participants, enrolled in the study were assigned into two study groups. The groups were comparable in terms of age, weight and duration of surgery (Table 1).

Table 1: Comparison of demographic profile between two group

	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
Duration of surgery (min)	31.17 ± 9.44	30.17 ± 12.07	0.722

The characteristics of block between two groups is shown in table 2. The onset of sensory block were comparable in both groups. There was statistically significant difference in onset of motor block in Bupivacaine(7.53±1.72) min and Ropivacaine group (14.33 ± 6.19) min respectively. Regression of sensory and motor block both were faster in Ropivacaine group. Duration of analgesia was longer in Bupivacaine group (131.17 ± 32.95) than Ropivacaine group(125.33 ± 30.54).

Table 2: Comparison of characteristic of block between two groups

	Bupivacaine Group (n=30)	Ropivacaine Group (n=30)	p-value
Onset sensory(min)	4.87 ± 1.46	4.87 ± 1.72	1.000
Onset motor(min)	7.53 ± 1.72	14.33 ± 6.19	0.000
Regression Sensory(min)	140.5 ± 41.03	131.5 ± 38.71	0.386
Regression motor(min)	171.33 ± 38.73	98.5 ± 34.47	0.000
Duration of analgesia(min)	131.17 ± 32.95	125.33 ± 30.54	0.480

The table 3 compares the various side effects and requirement of rescue analgesia between two groups. The incidence of hypotension and bradycardia is similar in both groups but three patients in Bupivacaine group had shivering and two patients require rescue analgesia.

Table 3: Comparison of side effects between two groups

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

The changes in heart rate(HR), oxygen saturation(SPO_2) and mean arterial pressure(MAP) over time is shown in figure 1, figure 2 and figure 3 respectively.

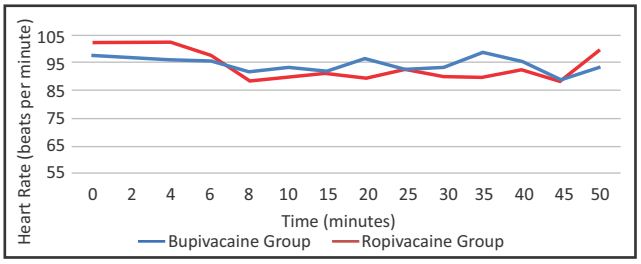

Figure 1: Heart rate trend in two groups.

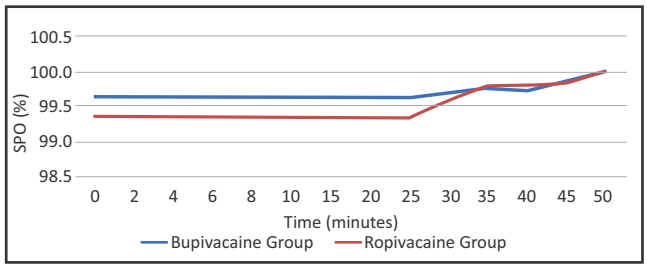

Figure 2: SPO_2 trend in two groups

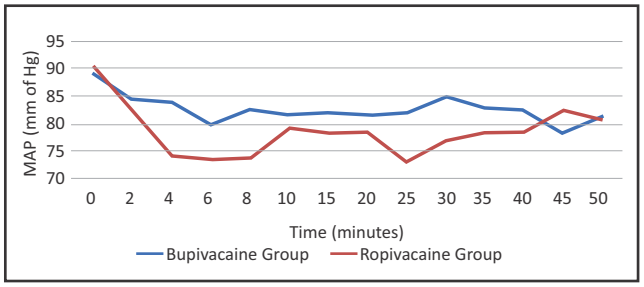

Figure 3: MAP trend in two groups.

DISCUSSION

This study demonstrated that 0.5% hyperbaric ropivacaine can be used as an alternative to 0.5% hyperbaric bupivacaine in spinal anesthesia for elective cesarean delivery but with shorter duration of sensory and motor block.

In our study we found out that there was no statistical difference in onset of sensory block between two groups. The onset of sensory block in both Ropivacaine group and Bupivacaine group was similar (4.87 min) in our study. This finding is in contrary to the finding of the study done by Singh et al where the onset of sensory block is delayed in Ropivacaine group.[12] This may be attributable to the fact that we have used 0.5% hyperbaric Ropivacaine instead of 0.75 % isobaric Ropivacaine used by Singh et al. Addition of glucose would increase the density of drug resulting in a more even distribution of the local anaesthetic, gravity presumably encouraging spread of the bolus of drug 'down' the slopes of the lumbar curve when the patient is placed supine after injection.[13] It is now a well-known fact that, hyperbaric solutions when compared with plain local anaesthetic solutions results not only in a more predictable cephalad spread, but also prolongs the duration of the clinically useful block (given by duration at the T10 dermatome), and leads to a more rapid regression of sensory block and recovery from motor block.[14,15]

The onset of motor block was faster in Bupivacaine group in comparison to Ropivacaine group. The regression of sensory and motor block was faster in Ropivacaine group in comparison to Bupivacaine group. The regression of sensory block was quicker than regression of motor block in Bupivacaine group whereas in Ropivacaine group the motor block regressed faster than sensory block. The duration of analgesia lasted slightly longer in Bupivacaine group. These results confirm that spinal bupivacaine is more potent than ropivacaine in terms of onset of motor block, regression of sensory and motor block and duration of analgesia. This may be attributable to the fact that ropivacaine is less lipid soluble which causes the drug to penetrate the large myelinated A fibers more gradually than the more lipid-soluble bupivacaine.[16] Similar findings were found in studies done by Singh et al[12], Chung et al[17], Danelli et al[18], Eryilmaz et al[10], Bhat al[19], Chari et al[20] and Ingale et al.[21]

The incidence of side effects like hypotension and bradycardia were comparable in both groups. Shivering was observed more in Bupivacaine group and one patient had vomiting in Ropivacaine group. Rescue analgesia was required in Bupivacaine group. Similar findings were also seen in study done by Chung et al[17] and Srivastava et al[22].

Although our study shows that Bupivacaine is more potent than Ropivacaine when used in spinal anesthesia, Ropivacaine may be appropriate for short procedures where a rapid return of ambulatory function is required, and its recovery profile could confer a distinct clinical benefit. Early recovery from anesthesia might as well increase the patient's satisfaction.

CONCLUSION

Ropivacaine can be used as an alternative to Bupivacaine in patients undergoing cesarean section under spinal anesthesia but with shorter duration of sensory and motor block.

RECOMMENDATIONS

This study compared the effect of Ropivacaine and Bupivacaine in patients undergoing elective cesarean section only. Further studies should be done in patients undergoing lower abdominal and lower limb surgeries. The minimum and effective dose of Ropivacaine required for cesarean section has not been explored that much. Therefore such studied can be conducted in future.

LIMITATION OF THE STUDY

This study has been conducted in only one hospital and the study population were pregnant women undergoing cesarean section. Therefore the result may not be representative of general population. The comparison of height of the patients between two groups were not done in this study. The volume of drug in both the groups were different. Both the factors might have impact on the result of the study.

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CONFLICT OF INTEREST

None declared

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