Comparison of Mean Onset of Motor and Sensory Block of Isobaric Ropivacaine and Hyperbaric Bupivacaine for Elective Caesarean Sections at Tertiary Care Hospital, Karachi.

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Abstract

Objective: To compare the mean onset time of motor and sensory block of Isobaric Ropivacaine and Hyperbaric Bupivacaine for elective caesarean sections at Tertiary Care Hospital, Karachi.

Methods: A double blinded Randomized control trial study carried out over the period of six months, from August 2016 to January 2017 using non probability consecutive sampling technique. A total of 128 pregnant women planned for LSCS under spinal anesthesia were enrolled in this study. Patients were randomly divided into two groups (Group B and Group R) receiving equipotent doses of spinal anaesthetic drugs. In group B, spinal anaesthesia were given to 64 patients with intrathecal injection of 3ml of 0.5% (5mg/ml) Hyperbaric Bupivacaine and in group R, 64 patients received spinal anaesthesia using 3ml of 0.5% (5mg/ml) Isobaric Ropivacaine. Motor block was evaluated by using Modified Bromage scale score and a score of >2 is consider as optimal motor nerve block. Sensory block was evaluated by using 25G needle pinprick method along the mid clavicular line bilaterally and sensory block (loss of sensation to pain) at T6 level is consider as optimal sensory nerve block. At 10 minutes, Final outcome for each group B and R will be labelled in term of mean time of achievement of motor and sensory block and two dermatomal sensory segment regression.

Results: Out of 128 patients, 64 patients receiving spinal anaesthesia using Hyperbaric Bupivacaine the mean duration to achieve sensory nerve block at T6 Level is found to be faster as compare to Isobaric Ropivacaine while the mean onset time of motor nerve block was also considerably significant in between the two groups (p=0.049). The Regression time of maximum sensory block from two dermatomal skin level is also found to be earlier in Isobaric Ropivacaine as compare to patients receiving spinal anaesthesia with Hyperbaric Bupivacaine (130.34 \pm 15.26 vs 146.41 \pm 12.81; p-value=0.0005). These regional anaesthetic properties of Isobaric Ropivacaine makes it a safer regional anaesthetic agent as Hyperbaric Bupivacaine.

Conclusion: Spinal anaesthesia using intrathecal Ropivacaine for elective caesarean sections is an effective and optimal drug of choice. Two Dermatomal Sensory Regression was also found to be earlier in Isobaric Ropivacaine thus ropivacaine provides surgically effective anaesthesia of shorter duration and early sensory onset without compromising neonatal outcome and maternal hemodynamics.

Keywords: Isobaric Ropivacaine, Hyperbaric Bupivacaine, Motor and sensory block, Caesarean sections. **IRB:** Approved by College of Physicians and Surgeons Pakistan. Dated: 14th November 2017. Ref No: CPSP/REU/ANS-2013-174-1349.

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Introduction

Anesthesiologists always choose the method that is believed to be safest and most effective for the mothers as well as least depressant to the neonates and provides the optimal surgical environment for the obstetrician during the caesarean section. Spinal anesthesia fulfils all these criteria. In En-

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gland, for example, regional anesthesia was used for cesarian section in about 40% of cases in 2008/2009 compared to 5% using general anesthesia¹. Various preparations of bupivacaine with or without glucose are being extensively used in clinical practice which produces an adequate sensory and motor blockade². Baricity of local anaesthetic used is one of the important intrathecal drug distribution factor that determine the dispersion of anaesthetic in subarachnoid space and thus the level of block³. Newer local anaesthetics (ropivacaine, levobupivacaine) were introduced in Pakistan for clinical use with better drug toxicity profile and denser effect on sensory nerves in comparison to motor nerve fibres⁴.

Hyperbaric bupivacaine is the most popular local anaesthetic drug for providing spinal anaesthesia for caesarean sections as well as in majority of other gynaecological procedures. Ropivacaine is another local anaesthetic of aminoamide class with structural similarity to bupivacaine⁵⁻⁶. It has a safe cardiac toxicity index and has shorter duration of motor block as compare to Bupivacaine. The motor block, however, is of slower onset and recovery time is also significantly reduced⁷. Although cardiac active fibers blockade is not often observed after spinal anaesthesia as it involves very small drug doses, and block characteristics specifically of shorter duration of motor nerve block and haemodynamic stability, these characteristics are of valuable importance in obstetric practice8. Several studies show variable achievement of motor and sensory block. The peak motor time was also significantly delayed in the Ropivacaine group (8.92 ± 2.41 min) as compared to the Bupivacaine group $(4.82 \pm 1.22 \text{ min})$, p<0.001. The two dermatomal sensory segment regression was also founded longer in isobaric Ropivacaine group (117.2 ± 12.5 min) as compared to Bupivacaine (108.5 ± 10.61 min), p<0.0019. Another study showed that the mean onset time of sensory block of Ropivacaine was 3.2 ± 1.5 minutes as compared to Bupivacaine 2.5 ± 1.3 minutes¹⁰. The purpose of presently conducted study at tertiary care hospital is to determine the effectiveness and intrathecal safety of Isobaric Ropivacaine during elective cesarean sections in Obstetric population of Pakistan in order to establish the local perspective as there is paucity of local data.

Patients and Methods

The study is conducted at Department of Anaesthesia Abbasi Shaheed hospital as a double blinded Randomized control trial over the period of six months, from August 2016 to January 2017. For the objective of our study the sample size was calculated by Open epi sample size calculator using non-probability consecutive sampling technique. Mean durations for sensory blocks were Bupivacaine $(2.5 \pm 1.3 \text{ min})$, Ropivacaine $(3.2 \pm 1.5 \text{ min})$, power of the study= 80%, yype I error = 5%. The total sample size computed was 128 (64 patients in each group).

The inclusion criteria were parturient planned for elective caesarean section under spinal anaesthesia between the age 20-40 years; women with singleton pregnancy confirmed on antenatal ultrasound; and ASA I and II. The exclusion criteria were obstetric parturient having pre-eclampsia or eclampsia; known case of diabetes mellitus; non-consenting, gestational age < 36 weeks; patients with pre-existing medical history of CVA; renal impairment and chronic obstructive pulmonary disease; chronic liver disease and CCF was excluded; congenital anomalies diagnosed on antenatal ultrasound; patient with known case of hypo or hyperthyroidism.

After preoperative assessment of patients fulfilling the inclusion criteria patients were randomized in two groups using sealed opaque envelop bearing R=Ropivacaine and B=Bupivacaine. The study was conducted after Informed written consent from all the patients enrolled in both the groups and after being approved from the institutional ethical committee.

Group R = Patients will received 3ml i.e. (15mg) of 0.5% (5mg/ml) of Isobaric Ropivacaine.

Group B = Patients received 3ml i.e.(15mg) of 0.5%(5mg/ml) of Hyperbaric Bupivacaine.

The patients were explained about the procedure of spinal anaesthesia and assessment of motor and sensory block prior to giving intrathecal drug. Patient underwent spinal anaesthesia for Caesarean section were applied standard monitoring of non-invasive Blood pressure (NIBP), ECG, pulse oximetry and baseline vitals will be recorded. Two large bore (16G) intravenous line were maintained and ringer lactate solution is administered to the patient in the dose of 15ml/kg prior to intrathecal administration of the drug. Under aseptic measures dural puncture at L3-L4 or L4-L5 level was performed with a 25-gauge spinal needle. The timing of finishing the injection was considered "time zero". The patient was placed supine with 15 degree left lateral tilt and covered with cotton sheet, supplement oxygen was given by oxygen mask. Non-invasive B.P (NIBP) and heart rate were monitored intermittently after drug administration and when B.P decreased more than 20% of baseline intravenous 6mg of ephedrine was given and if heart rate decreased to less than 60/min intravenous atropine 0.5 mg was given. Motor block was evaluated using Modified Bromage scale and ascore of >2 will be taken as adequate motor block. Sensory block was checked by pinprick using a 25G needle along the mid clavicular line bilaterally every 2 minutes and sensory block (loss of sensation to pain) at T6 level will be considered as adequate sensory block. Assessment of onset of motor and sensory block will be done by senior anaesthetist double blinded to the study objective from time of delivery of drug after every 2 minutes till 10 minutes. At 10 minutes, final study outcomes for both groups were mean duration of achievement of motor and sensory nerve block and two dermatomal sensory level regression.

Results

Total 128 pregnant patients for elective LSCS under spinal anesthesia were included in this study. Patients were randomly divided in two groups (group B and group R). In group B, 64 patients were given spinal anaesthesia with 3ml

(15mg) of 0.5% (5mg/ml) of hyperbaric Bupivacaine and in group R, 64 patients were given spinal anaesthesia with 3ml (15mg) of 0.5% (5mg/ml) of Isobaric Ropivacaine. Descriptive stratification analysis that is age of patients enrolled, patient weight, height, gestational age, systolic BP, diastolic BP, MAP and heart rate according to both groups were shown in table 5. Parity distribution of patients were also shown in figure 1. Out of 128 patients, 85.2% were graded as ASA-I and 14.8% were in ASA-II as shown in figure 2.

In table 1, comparative analysis of both anaesthetic drugs block characteristics were presented. The mean onset time of sensory nerve block at T6 Level is faster in the Hyperbaric Bupivacaine in comparison to Isobaric Ropivacaine (3.20 ± 0.74min vs. 4.22 ± 1.12min; p=0.0005) while the mean onof motor nerve block (time to achieve a Bromage score of >2) was also significant between both groups $(4.75 \pm 1.13 \text{min vs. } 5.13 \pm 1.02 \text{min})$ p=0.049). Time to regress two dermatomal sensory level were evaluated to be earlier in Ropivacaine than Bupivacaine (130.34 ± 15.26 vs. 146.41 ± 12.81; p=0.0005). According to stratification analysis, comparative outcome of mean onset time of motor and sensory block between Isobaric Ropivacaine and Hyperbaric Bupivacaine were not dependent on patient Age, Weight and Parity as well as ASA status also have no effect on both the onset of motor and sensory block outcomes as well as two dermatomal regression for both Isobaric Ropivaciane and Hyperbaric Bupivacaine. Both the Bupivacaine as well as Isobaric Ropivacaine also have no significant effect on neonatal outcome (APGAR SCORE)

Discussion

Cesarean sections were preferably conducted under spinal anesthesia. General Anaesthesia is preserved unless spinal anaesthesia is an absolute contraindication. Propofol is a good induction agent as well as its antiemetic properties make it as a choice of induction agent for patients at increased risk of PONV¹¹. However, Ketamine is an induction agent of choice in patient with hemodynamic insta-

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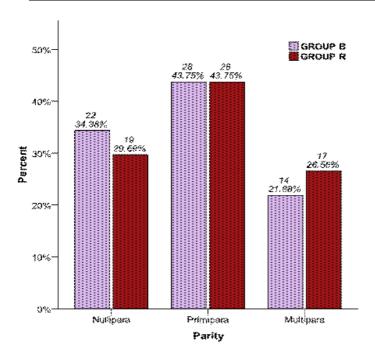


Fig 1. Parity Distribution with Respect to Groups of The Patients

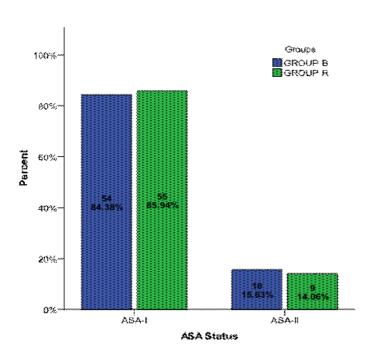


Fig 2. As a status with respect to both groups(n= 128)

Table 1. Stratification Analysis with respect to both groups n= 128

| Variables | GROUP n=64 | В | GROUP R | ? |
|---------------------------|---------------|-----------------------|---------|-----------------------|
| | Mean | Standard Deviation | Mean | Standard Deviation |
| Age in years | 27.05 | 4.45 | 26.05 | 4.22 |
| Height (cms) | 156.17 | 8.121 | 150.73 | 5.74 |
| Weight (kg) | 71.00 | 7.51 | 65.64 | 5.46 |
| Gestational Age (Weeks) | 37.97 | 1.38 | 38.67 | 1.05 |
| Systolic BP (mmHg) | 127.11 | 11.56 | 143.30 | 151.16 |
| Diastolic BP (mmHg) | 78.58 | 9.22 | 78.33 | 8.36 |
| MAP (mmHg) | 91.81 | 7.75 | 90.68 | 9.61 |
| Heart Rate (beats/minute) | 90.94 | 7.67 | 92.16 | 9.47 |

Table 2. Comparitive analysis of mean onset time ofmotor and sensory nerve block between isobaric ropivacaine and hyperbaric bupivacaine for elective cesarean sections Independent sample t-test applied

| Outcomes | GROUP B n=64 | | GROUP R n=64 | | 1p-Values | |
|------------------------------------------------------------------------------------|-----------------|-----------------------|-----------------|-----------------------|-----------|--|
| | Mean | Standard Deviation | Mean | Standard Deviation | • | |
| Mean onset to achieve motor block >=2 on Modified Bromage Scale (Minutes) | 4.75 | 1.13 | 5.13 | 1.02 | 0.049 | |
| Mean onset to achieve sensory block at T6 Level (Minutes) | 3.20 | 0.74 | 4.22 | 1.12 | 0.0005 | |
| Two Dermatomal Sensory level Regression (Minutes) | 146.41 | 12.81 | 130.34 | 15.26 | 0.0005 | |

bility¹² as it has cardiovascular stimulant properties. Maintenance of general anaesthesia is achieved with volatile anaesthetics with or without nitrous oxide. Nitrous oxide has quick and reliable recovery and perspective regarding perioperative Cardiovascular instability and surgical site infections have not been proven in a large randomized study trial¹³. In cesarean deliveries hyperbaric bupivacaine is the preferredlocal anaesthetic of choice while Isobaric Ropivacaine,is more selected to sensory nerve fibers blockade in comparision to motor fibers, and there so gaining popularity due to its re-

duced cardiac toxicity and hemodynamic stability. Recent studies shows surgeries proceeded under spinal anaesthesia with intrathecal ropivacaine have comparatively low cardiovascular as well as neurotoxic effects, as well as better drug tolerability and improved efficacy¹⁴.

Bupivacaine is long acting local anaesthetic drug of amide group that is used for most locoregional procedures¹⁵. It has both hyperbaric and isobaric formulations¹⁶. Baricity of local anaesthetic drugs is the most important predictor that determines level of sensory and motor block. Too high regional block is unsafe and can compromise the patient's hemodynamic status¹⁶. However,these risks can be minimized by perioperative risk stratification using (ACC/AHA) guidelines for noncardiac surgery¹⁷, as well as maintenance of pre requisites for spinal anaesthesia. Hemodynamic effect of spinal anaesthesia on the cardiovascular system occur indirectly through blockade of sympathetic nervous system and it includes a reflex response to the primary cardiovascular effects. Sympathetic blockage due to spinal anesthesia leads to vasodilation and the hemodynamic response monitored were reduction in blood pressure and heart rate¹⁸.

Numerous previously conducted studies have evaluated the drug efficacy and tolerability of spinal anesthesia with Ropivacaine for cesarean section¹⁹.

In present study the mean onset time to achieve sensory block up to T6 Level is found to be faster in the Bupivacaine group in comparison to Ropivacaine (p-value=0.0005). These results were also the outcomes in Amjad et al comparative study²⁰. In some studies it has founded that adding an adjunct to hyperbaric bupivacaine in spinal anaesthesia shortens the time to achieve the highest sensory block level²¹. In Singh S10 reported that mean duration of sensory block was shorter in the ropivacaine group than bupivacaine group (p-value <0.05).

The mean onset of motor block (time to achieve a Bromage score of >2) was also significant between both the groups (p-value=0.049) in

this study. Two dermatomal sensory regression was also found to be earlier in isobaric Ropivacaine than Bupivacaine thus provide early immobilization to patients receiving spinal anaesthesia with ropivacaine. Luck et al⁹. also observed less degree and duration of motor blockade, lower incidence of bromage score of grades III in 63% with hyperbaric 0.5% ropivacaine as compared to 90% with 0.5% bupivacaine, with the similar dose of 3 ml with 30 mg/ml of glucose.

In a study conducted by Bhat SN et al²² comparing drug efficacy and safety of Ropivacaine in comparison to bupivacaine for spinal anaesthesia for lower abdominal and lower limb surgeries it has been founded that the mean duration of sensory blockade in ropivacaine group was 153.57 ± 15.65 minutes and in bupivacaine group was 211 ± 11.29 minutes²². Validating the similar statistics concluded in present study. Girich KJ²³ compared 0.5% isobaric ropivacaine and 0.5% isobaric bupivacaine in spinal anaesthesia for endoscopic urological surgeries mean duration of motor blockade in ropivacaine group was 106.71 ± 10.85 minutes and in bupivacaine group was 168.82 ± 17.90 minutes²³. All the above study results were consistent with the present conducted study findings thus proving isobaric Ropivacane an effective spinal anaesthetic agent of choice. In Chari VRR²⁴ and Marret et al²⁵ study similar results were observed ropivacaine.

Conclusion

Hyperbaric Bupivacaine is the preferred drug for spinal anaesthesia in obstetrics and gynecological procedures. The present conducted study results show that spinal anesthesia with Isobaric Ropivacaine is an effective and safer choice as Bupivacaine. Time for two dermatomal sensory regression was also found to be of shorter duration in intrathecal Isobaric Ropivacaine group patients, thus Ropivacaine provides effective surgical anesthesia of shorter duration without compromising neonatal outcome and Maternal Hemodynamics as well as it

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provides optimal postoperative Analgesia in Obstetric patients.

Conflict of Interest

The authors of the study do not have any conflict of interest with findings of authors of previous studies.

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Answer of Picture Quiz:

Right Testicular torsion leading to gangrene.