



A COMPARATIVE STUDY BETWEEN EFFECT OF HYPERBARIC LEVOBUPIVACAINE VERSUS HYPERBARIC ROPIVACAINE IN SPINAL ANESTHESIA LOWER CAESAREAN SECTION IN PATIENTS WITH PREGNANCY INDUCED HYPERTENSION

Anaesthesiology

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ABSTRACT

Introduction- Preeclampsia is associated with maternal and fetal mortality globally, where spinal anesthesia has been beneficial for stabilizing maternal hemodynamics. With newer drugs like hyperbaric Levobupivacaine and Ropivacaine, hemodynamic remains stable, also offers early recovery and ambulation, which reduces airway complications and the stress response associated with general anesthesia. In terms of cardiovascular toxicity, Levobupivacaine and Ropivacaine have a better safety profile compared to Bupivacaine, with Ropivacaine offering greater stability than Levobupivacaine. **Materials And Methods:** Our study included 84 patients ASA II and III with pregnancy induced hypertension (PIH) posted for lower segment caesarean section (LSCS). Patients randomly divided into two groups of 42 each. Group L received 2ml of 0.5% hyperbaric Levobupivacaine (10mg) and Group R received 2ml of 0.75% hyperbaric Ropivacaine (15mg). Hemodynamic monitoring with HR, SBP, DBP, MAP was done every 5mins until surgery and every 15 minutes till the effect of block was regressed. The onset of sensory block was seen by Hollmen scale with help of 24gauge hypodermic needle while the motor block was assessed by modified Bromage scale. The APGAR score of new born baby was recorded at 0 mins, 5mins of birth. The side effects like nausea, vomiting, hypotension, bradycardia, total spinal anesthesia, urinary retention, allergic reactions were also noted. **Results:** Ropivacaine takes longer to achieve motor and sensory level as compared to Levobupivacaine with earlier regression of levels. Also, Ropivacaine did not cause significant changes in hemodynamics as observed with Levobupivacaine. **Conclusion:** Ropivacaine is a better choice for spinal anesthesia in PIH patients which causes minimum hemodynamic changes and also aids in early recovery promoting early ambulation.

KEYWORDS

Pregnancy induced hypertension, Spinal Anesthesia, Levobupivacaine, Ropivacaine

INTRODUCTION

The third most typical reason for maternal mortality is preeclampsia, an idiopathic multisystem disorder with onset of hypertension and proteinuria at 20th week of gestation with estimated mortality of 50,000 parturient worldwide. Such individuals are at high risk and general anesthesia for LSCS may result in a heightened cardiovascular response to intubation, which could produce cerebral hemorrhage and oedema, cardiovascular decompensation, and pulmonary oedema. These outcomes would increase morbidity and mortality rates for both the mother and fetus.

Regional anesthesia increases uteroplacental blood flow and newborn outcome in addition to avoiding maternal problems associated with GA, such as difficult intubation and vasopressor response to intubation.^[1] Choice of regional anesthesia over general anesthesia is also beneficial for fetus. The APGAR-score was created to help identify problems early and lower infant mortality and morbidity.^[2]

Levobupivacaine and Ropivacaine both have a clinical profile that is similar to that of racemic Bupivacaine, with slightly different anesthetic potencies, with racemic Bupivacaine > Levobupivacaine > Ropivacaine.^[3] Compared to Levobupivacaine, Ropivacaine is less toxic to the heart and produces a milder neuromotor blockade.^[4]

Because hyperbaric Levobupivacaine and hyperbaric Ropivacaine preparations are relatively new to the market, we decided to study and compare the effects of hyperbaric Levobupivacaine versus hyperbaric Ropivacaine in spinal anesthesia given for lower segment caesarean section in pregnancy induced hypertension.

MATERIALS AND METHODS

After Institutional ethics committee approval, a double blind randomized prospective study was designed with 84 ASA II and III parturient with pregnancy induced hypertension with controlled hypertension, between age of 18-35yrs and BMI <35kg/m² which were posted for lower segment caesarian section. Patients having infection on back, allergy to drugs, having bleeding tendencies, refusing procedure, patient with uncontrolled hypertension or hypotension, cardiovascular disease, hepatic or renal disease, bronchospastic disease, ASA Grade IV or more, patients taking any psychotropic drugs, seizure disorder, coagulopathy, morbid obesity, HELLP

syndrome were excluded from study.

Patients were randomized in 2 groups with 42 patients in each group with computer generated random numbers using a sealed envelope technique. One group was received: 0.5% hyperbaric Levobupivacaine (2ml) and another group was received 0.75% hyperbaric Ropivacaine (2ml) intrathecally.

Baseline pulse rates (PR), systolic, diastolic and mean arterial blood pressures (SBP), (DBP), (MAP) were recorded preoperatively. Group L was received 0.5% hyperbaric Levobupivacaine 10mg (2ml) and Group R was received 0.75% hyperbaric Ropivacaine 15mg (2ml). Patient was monitored for pulse rate, mean arterial pressure, respiratory rate and sedation continuously. Sensory level was determined by pinprick using 24gauge hypodermic needle. Onset of analgesia was defined as time interval from completion of subarachnoid injection to loss of pinprick sensation at T8. Maximum dermatomal level was tested by pinprick in midclavicular line, every minute until level is stabilized for two consecutive tests. After that sensory level was tested every 15 minutes until two segment regression. Time taken to achieve maximum sensory level, two segment regression were noted.

Time of onset of motor blockade was noted. Heart rate, SBP, DBP, MAP indicates the cardiovascular stability and were monitored every 5 mins during surgery and for every 15 mins till effect of blockade regressed in the post operative period and patient was shifted to ward after effect of spinal anesthesia vanished.

Oxygenation saturation was monitored every 5 mins for first 10 mins and for every 15 mins for entire procedure. After delivery of baby APGAR score was assessed at 0 mins and 5 mins of birth. Adverse events such as Hypotension, Bradycardia, Nausea, Vomiting, Headache, backache and tingling or pain in legs, Sedation, retention of urine were reported.

Data Analysis

Data was collected and entered in excel sheet and data cleaning was done with the coding. Data analysis was done by appropriate statistical method with statistical software SPSS Ver. 20. Quantitative data was presented with the help of frequency, percentages, mean and standard

deviation. The Chi-square test of independence was employed to analyze the relationship between two categorical variables between both the groups. The Chi-square test yielded a statistic value, which was then compared to a critical value from the Chi-square distribution or used to determine a p-value. P value less than 0.05 was considered as statistically significant. The paired t-test was utilized to compare the means of the two related groups. By comparing the t-statistic to the critical value from the t-distribution or by using the corresponding p-value, the study assessed whether there was a statistically significant change or effect between the two conditions or time points.

OBSERVATION AND RESULTS

Table No 1- Comparison Of Demographic Profile Between L Group And R Group

Variables	L Group (n=42)	R Group (n=42)	P value
Age (years)	24.1±3.89	23.7±3.31	0.672
Weight (Kg)	65±3.36	63.3±6.7	0.090
Height (m)	156±3.16	160±5.93	<0.001
Body Mass Index (kg/m ²)	26.6±1.51	24.6±2.42	<0.001

For Age and Weight, there are no statistically significant differences between the groups. Whereas for Height and BMI: Significant differences are observed, with the R Group being taller and having a lower BMI compared to the L Group.

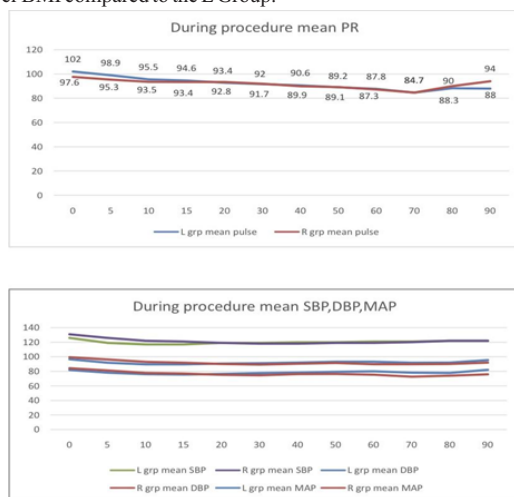


Figure No. 1 shows the Comparison of vitals during procedure between L Group and R Group

L Group experiences a larger initial decrease in pulse rate and more fluctuation in diastolic blood pressure and R Group maintains a higher pulse rate and starts with higher blood pressures but shows more stability in diastolic blood pressure over time which was statistically significant.

Table No. 2 Shows Comparison Of Block Characteristics Between L Group And R Group

Variables	L Group (n=42)	R Group (n=42)	P value
Duration of surgery (mins)	66.7 ± 9.67	54.8 ± 10.4	<0.001
APGAR at 0 mins	8.71 ± 0.97	8.45 ± 0.91	0.182
APGAR at 5 mins	9.95 ± 0.30	10	0.323
Time taken for motor onset (minutes)	2.06 ± 0.39	2.25 ± 0.43	0.087
Time for T8 level (minutes)	2.68 ± 0.618	3.12 ± 0.83	0.007
Time for 2 segment regression (hours)	1.93 ± 0.38	0.820 ± 0.317	<0.001

The time of onset of motor blockade was earlier in Levobupivacaine group than Ropivacaine group. The time of onset of analgesia that is T8 level is earlier in Levobupivacaine group than the Ropivacaine group with statistically significant difference in two groups.

Table No.3 Comparison Of Adverse Effects Between The Group L And Group R.

Adverse effects	L Group	R Group	P value
Hypotension	3(7%)	2(4.7%)	X ² =1.0142
Vomiting	4(9.3%)	2(4.7%)	P value=0.7978

Shivering	6(14%)	6(14%)
NIL	29(67.4%)	32(74.4%)

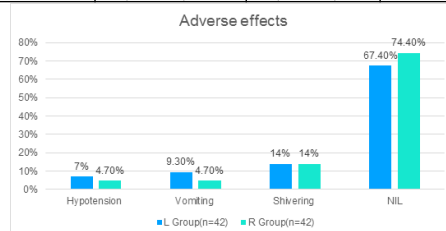


Figure No.2 - Comparison of adverse effects between the Group L and group R.

The incidence of Hypotension and vomiting with the L group which were higher than group R which were not statistically significant. The incidence of shivering was same for both groups. p value was not significant for adverse reactions for the groups stating, both the groups are comparable for adverse effects.

DISCUSSION

For caesarean sections overall, spinal anesthesia is preferred technique because of several benefits, including ease to perform, cost effective, good intraoperative and postoperative analgesia, avoiding complications with general anesthesia, early recovery, lesser chances of DVT, lower stress response, and early mother-child bonding. In PIH patients, central neuraxial blockade is the better option than general anesthesia for elective cesarean delivery. The use of neuraxial anesthesia eliminates the possibility of aspiration, challenging and unsuccessful intubations, and laryngoscopic response associated with general anesthesia.^[5] When compared to normal parturients following LSCS delivery, preeclamptic parturients had a two-fold reduced incidence of spinal induced hypotension and a lower demand for vasopressors and hence it is preferred choice of anesthesia in patients with PIH.^[6] According to a study conducted by Rashad Siddiqi, Syed Asadullah Jafri, majority of patients recorded a high level of satisfaction with spinal anesthesia.^[7] Levobupivacaine and Ropivacaine are two novel, long-acting local anesthetics that have been developed, put into clinical practice as a result. Instead of being made as a racemic combination of the drugs Levo- and dextro-forms, are prepared as a single levorotatory isomer.^[8] In a related investigation on volunteers, the same group likewise compared the identical dosages of Ropivacaine and Bupivacaine and found that Ropivacaine is half as potent as Bupivacaine, utilizing a 1-1.5 dose ratio between Bupivacaine and Ropivacaine generated a spinal block that was similar.^[9] In the study conducted by Manziar Athar, Syed Moied Ahmed showed that even at equipotent doses of 1.5:1(Ropi:Levo), Ropivacaine offer significantly shorter duration of analgesia compared to Levobupivacaine.^[10] The authors reported sensory and motor block characteristics identical to those generated with 8 mg Bupivacaine when the dose of Ropivacaine was increased to 12 mg. This implicitly confirmed an equipotency ratio of 1-1.5 between Bupivacaine and Ropivacaine.^[3] Hence we used 15mg of Ropivacaine in comparison with 10mg of Levobupivacaine. Theoretically, Ropivacaine has a better clinical safety profile than Levobupivacaine since lipophilicity is a significant factor in local anesthetic toxicity.^[8] As we need early onset analgesia and higher level blockade in case of fetal distress so as to decrease time of anesthesia to delivery of baby, use of hyperbaric local anesthetic drug provides advantage over isobaric.^[11] Earlier isobaric solutions of Levobupivacaine and Ropivacaine were available but now as hyperbaric preparations are available, we decided to study and compare their effects on LSCS. When patients were under spinal anesthesia for a Caesarean section and receiving 12-15mg of hyperbaric Bupivacaine, Norris investigated the association between height and sensory diffusion of analgesia. He observed no variation in the analgesic distribution among patients whose heights ranged from 147 to 174 cm. It was also observed that vertebral column length did not appear to be indicative of the spread of sensory analgesia. This runs counter to Hartwell's findings. It has been noted that individuals who are term pregnant, vertebral column length but not height had a significant prognostic value for the spread of spinal anesthesia.^{[12][13]} In a study conducted by QuijuCheng, W Zhang et al, comparing Ropivacaine versus Levobupivacaine, they reported findings of Ropivacaine being more hemodynamically stable than Levobupivacaine which were observed in our study.^[4] Our findings were supported with the findings of Chari et al who found a fewer hemodynamic changes with Ropivacaine when compared with

Bupivacaine.^[14] Ropivacaine provides a noticeably shorter duration of analgesia than Levobupivacaine, even at equipotent dosages of 1.5:1 (Ropi:Levo). This was consistent with earlier research by authors that demonstrated Ropivacaine's early decline in comparison to Levobupivacaine. According to study done by Manziar Athar, Syed Moied Ahmed they concluded that Levobupivacaine produces significantly longer duration of analgesia than Ropivacaine when used in a ratio of 0.6:1. Because of its effectiveness, toxicity, and hemodynamic profile, Ropivacaine is good choice for procedures involving low thresholds for hypotension.^[12] APGAR scores were comparable in both groups, according to Chung et al. Hypotension was the most frequent adverse effect in both groups, according to Chung et al.^[15] According to Danelli et al., there were no differences between the two groups in the intraoperative quality of anesthesia or in the clinical hypotension that required the administration of ephedrine.^[11]

CONCLUSIONS

To conclude from our study we observed a quicker onset of motor and sensory blockade with Levobupivacaine than Ropivacaine with a quicker regression with Ropivacaine. The intraoperative cardiac parameters (HR, SBP, DBP, MAP) remained more stable with Ropivacaine than Levobupivacaine. In our study we conclude our results with Ropivacaine having least effects on hemodynamics. However Levobupivacaine proved to be more potent than Ropivacaine in spinal anesthesia. As there is lower time observed for two segment regression in Ropivacaine group it is beneficial for early recovery and ambulation of mother also helping mother to breast feed her newborn. Hence, Ropivacaine is a good choice for spinal anesthesia in LSCS.

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