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Comparison of Spinal Anaesthesia with Hyperbaric Bupivacaine, Levobupivacaine and Ropivacaine for Caesarean Section: A Prospective, Randomized, Double Blind Study

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Abstract: ***Introduction: Spinal anaesthesia with hyperbaric bupivacaine is widely used for caesarean sections but often causes hypotension. Ropivacaine and levobupivacaine, newer alternatives, offer better hemodynamic stability and reduced motor block. This study aims to evaluate and compare the quality of anaesthesia and hemodynamic characteristics of bupivacaine, ropivacaine, and levobupivacaine in caesarean section patients. Objective: The objectives of this study are to assess the time of onset and offset of sensory and motor block, evaluate the success rate of the block, determine the incidence of side effects such as hypotension, bradycardia, nausea, and vomiting, assess the quality of surgical anaesthesia, and gauge patient satisfaction regarding the anaesthesia experience. Material and methods: This prospective, randomized, double - blind study will include parturients aged over 18 years with singleton full - term pregnancies undergoing lower segment caesarean sections. Patients will be randomly assigned to receive spinal anaesthesia with either hyperbaric bupivacaine, ropivacaine, or levobupivacaine, all combined with fentanyl. Hemodynamic parameters, sensory and motor block characteristics, incidence of side effects, and patient satisfaction will be monitored and recorded throughout surgery and postoperatively. Results: A total of 180 patients were randomly allocated into three groups receiving bupivacaine, ropivacaine, or levobupivacaine for spinal anaesthesia. Sensory block onset was significantly delayed, and motor block duration was shorter in the ropivacaine group. Bupivacaine exhibited the longest two - segment regression and motor block duration. The incidence of hypotension was higher in the bupivacaine and levobupivacaine groups, while patient satisfaction and muscle relaxation were comparable across all groups. Conclusion: The study concluded that while bupivacaine provided a quicker onset and longer duration of sensory and motor block, ropivacaine exhibited faster recovery and fewer side effects, such as hypotension and bradycardia. Levobupivacaine offered similar characteristics to bupivacaine with better hemodynamic stability. Ropivacaine and levobupivacaine are safe and effective alternatives to bupivacaine for cesarean sections, especially when quicker recovery is desired.***

Keywords: Analgesia, Bupivacaine, Caesarean Section, Hemodynamic Stability, Levobupivacaine, Ropivacaine.

1. Introduction

Spinal anaesthesia is accepted as a safe technique for caesarean section worldwide. Hyperbaric bupivacaine with or without narcotics is the established drug of choice for caesarean section (Burns et al 2001). Commonly used dose of 10 mg of bupivacaine for spinal anaesthesia is associated with high incidence of hypotension with possible deleterious effect on mother and baby (Lee et al 2002). In yester years, ropivacaine has been introduced in clinical practice for spinal anaesthesia. It is a long- acting amide local anaesthesia being alike to bupivacaine. It has lesser motor block and more hemodynamic stability, thanbupivacaine and it is used for caesarean section (Auzola et al, 2012).

Levobupivacaine is S (-) /3 isomer of the racemate bupivacaine, it is a long-acting amide type local anaesthetic, similar to bupivacaine and has been used in caesarean section, for better hemodynamic stability (Turkmen et al 2010, Bellin et al 2010, Nakamura et al 2009) A number of researchers have used ropivacaine and levobupivacaine for caesarean section (Gautier et al 2003, Rao et al 2020). However, there is no conclusive data yet, whether these are superior or inferior to bupivacaine.

Therefore, this study is planned to evaluate quality of anesthesia and hemodynamics characteristics in patients requiring caesarean section with intrathecalbupivacaine, ropivacaine or levobupivacine.

2. Review of Literature

There has been an increasing trend for caesarean section in last two decades and most of the surgeries are done under regional anaesthesia. Single shot spinal anaesthesia is the most common method for anaesthesia for both emergency and elective surgery. Till recently bupivacaine was the local anaesthesia of choice for these surgeries due to safe profile (Gautier et al 2003). Cardiac toxicity is one of the reasons to choose other options.

Two new long amide local anaesthetics levobupivacaine and ropivacaine have been developed, which have shown promising results for spinal anaesthesia during caesarean section (Bader et al1999, Malinovsky etal 2000, Perpaglioni et al 2006). Duggal et al (2015), used bupivacaine, ropivacaine and levobupivacaine in caesarean section. Levobupivacaine is the pure S (-) enantiomer of racemic bupivacaine and has been recently introduced for obstetric use (Bader et al 1999). It has lower risk of cardiovascular and CNS toxicity. Ropivacaine is another enantiomer which has been used intrathecally (Chung et al 2016) for caesarean section. Chung et al showed that 18mg of 0.5% hyperbaric ropivacaine provided similar and effective spinal anaesthesia with shorter duration of sensory and motor block, as compared with 0.5% hyperbaric bupivacaine for caesarean section.

Ropivacaine is pure enantiomeric form of bupivacaine though structurally similar to bupivacaine, has reduced potential for cardiovascular and neurtoxicity with lesser motor block (Bellin et al 2010, Nukamura et al 2009). Ropivacaine has advantage of hemodynamic stability than bupivacaine, so was suggested to have a beneficial effect and Levobupivacaine shows reduced hypotension than bupivacaine.

Thus, ropivacaine and levobupivacaine will be more beneficial than bupivacaine. Burns et al (2001) conducted a study on prevention and management of hypotension during spinal anaesthesia for caesarean section. They included bupivacaine alone or in combination with narcotics.10mg bupivacaine showed deep and prolonged sensory block for lower segment cesarean section. Minimal effective dose of intrathecal levobupivacaine and ropivacaine for cesarean delivery was investigated by Parpaglioni et al (2006). They demonstrated that minimal local anaesthetic dose for levobupivacaine was 10.58 mg (95% CI 10.08 - 11.09) whereas that of ropivacaine was 14.22mg (CI 13.67 - 14.77).

3. Material and Methods

After getting approval from Institutional Ethics committee, written and informed consent, were taken from parturient aged more than 18 years with singleton full term pregnancy, undergoing lower segment caesarean section, were recruited in this prospective randomized double- blind study.

Inclusion Criteria
Patients aged more than 18 years, Single live foetus, Gestational age>36 weeks

Exclusion Criteria
Age <18 year, Patient having any absolute contraindication for spinal anaesthesia, Patient with complicated pregnancy eg. Eclampsia

All the patients will undergo thorough pre operative assessment before lower segment cesarean section and will receive metoclopramide 10mg and pantaprazole intravenously 30min before surgery. In the operation theatre IV line will be secured with 18 or 20 guage cannula and all patients will be preloaded with 500ml ringer lactate 15 mins before spinal anaesthesia. Monitoring will be done using multiparameter monitor having pulse oximeter, electrocardiograph and non invasive blood pressure.

The eligible patients will be randomly allocated into 3 groups according to local anaesthetic used for spinal anaesthesia: GROUP B - will receive 2ml of 0.5% hyperbaric bupivacaine with 25mcg fentanyl GROUP R - will receive 2ml of 0.75% hyperbaric ropivacaine, with25mcg fentanyl GROUP L - will receive 2ml of 0.5% hyperbaric levobupivacaine with 25 mcg fentanyl

To facilitate blinding, study drug will be prepared by person who will not be part of anaesthetic team. The person recording the observation of the patient will be unaware of the local anaesthetic solution used for spinal anaesthesia. Under aseptic precautions spinal block will be performed at the level of L2 - L3 or L3 - L4 interspa ce through a midline approach using 25 gauge Quincke spinal needle. The patient will be turned supine after spinal injection with a pillow under right hip. All patients will receive 4liters of oxygen by mask till delivery. Surgery will be allowed when upper dermatome level (T6) to loss of pinprick will be attainted (onset time of sensory block). For inadequate anaesthesia 50%oxygen and N2O will be given. If patient still has discomfort, anaesthesia will be supplemented by IV ketamine. Hemodynamic monitoring will be done, during the block every 5 min for first 15min and every 10 min for next 30 min and every 15 min till the end of surgery and postoperatively every hour. During surgery intraoperative hypotension (fall >20% from the baseline) will be treated by i. v fluids, ephedrine (6mg) and O2 by mask. Bradycardia will be treated by i. v atropine. Nausea / vomiting by injection ondansetron.

During surgery the surgeon will evaluate muscle relaxation according to four point scale (excellent, good, fair or poor). Immediately after surgery the patient will be inquired about quality of anaesthesia as satisfactory / non satisfactory. After surgery the patient will be shifted to post anaesthesia care unit for observation.

The following data of each patient will be noted:

Demographic data, gestatonal age, indication of caesarean section, Systolic, diastolic and mean blood pressure, on arrival in operation theatre, before spinal anaesthesia, just after spinal anesthesia and every 5 min for 20min then every 10min till the end of surgery, Onset and time to achieve highest level of sensory blockade. Sensory block will be recorded bilaterally along mid - clavicular line using pinprick method with a blunt tipped 27G needle at every two minute for first 20 mins and every 10 mins till recovery to T10 level Motor block will be tested 10, 15 and 20 minutes after spinal injection and as soon as after surgery by modified Bromage scale: a) The patient is able to move the hip, knee and ankle, score= 0 b) The patient is unable to move the hip but is able to move the knee and ankle, score= 1 c) The patient is unable to move the hip and the knee but able to move the ankle, score =2 d) The patient is unable to move the hip, knee, or ankle, score=3 Time elapsed between spinal injection and time of skin incision Time between incision and delivery of baby Uterine incision and delivery time APGAR score of baby at 1 and 5 mins Time of first demand for analgesia in

postoperative period 10. Incidence of hypotension, bradycardia, nausea vomiting etc

Statistical Analysis

Statistical analysis was performed using suitable statistical analysis software. The values were represented in number (%), mean and SD Sample size was calculated based on previous study (Chung et al 2001 Gautier et al 2003). Minimum 32 patients per group were required with type 1 error of 0.01 and a power of 90%.

4. Results

The mean age in Group, Group L and Group R was 26.63 ±3.84 years, 26.30 ±4.16 years and 27.47 ±3.50 respectively with no significant difference among groups (p value = 0.222). Regarding gestational age we found the mean gestational age in Group B, L and R was39.1 ±1.23, 38.8 ± 1.29 and 39.2 ±1.32 weeks respectively with no statistical significant difference (p value = 0.240).

The comparison of mean levels of anthropometric variables among three groups. We found all three groups were comparable in terms of mean levels of height, weight and BMI (p value = 0.111, 0.858 and 0.091 respectively.

The distribution of the study subjects according to ASA status. Majority of the study subjects had ASA status II (86.7%) and 24 (13.3%) had ASA status III. All three groups were comparable in terms of ASA status (p value = 0.865).

Most common indication was fetal distress involving (69.4%) cases followed by meconium-stained fluid (12.8%), mal - presentation (10.6%), and others (7.2%).

The mean duration of surgery in Group B, L and R was 52.73 ±5.10, 51.55 ±6.30 and 50.91 ±6.07 minutes respectively with no statistically significant difference.

Onset of sensory blockade was significantly longer in Group R (3.22 ±1.18 minutes) in comparison to Group B and Group L (2.42 ±1.03 and 2.47 ±1.08 minutes respectively) (p value = 0.0001 and 0.0004 respectively. However, the onset of sensory blockade was comparable between Group B and Group L (p value = 0.0796).

Time for the sensory block to reach T10 was significantly longer in Group R (5.63 ±1.43 minutes) in comparison to Group B and Group L (4.40 ±1.58 and 4.37 ±1.45 minutes respectively) (p value = 0.0001 and 0.0001 respectively). However, the time for the sensory block to reach T10 was comparable between Group B and Group L (p value = 0.904)

Two segment regression time from highest block was significantly longer in Group B (106.80 ±10.65 minutes in comparison to Group L (97.67 ± 11.08 minutes) and Group R (90.22 ± 6.34 minutes) (p value = <0.0001).

While comparing the time of regression to L1 we found it was significantly shorter in Group R (105.52 ±6.15 minutes) in comparison to Group B (161.13 ±32.51 minutes) and Group L (153.70 ±.02) minutes (p value = <0.0001). However, the difference in Group B and Group L was comparable (p value = 0.096)

Time to complete motor block was significantly shorter in Group B (7.07 ±1.18 minutes) in comparison to Group L (7.58 ±1.50 minutes) and Group R (10.93 ±0.92 minutes) (p value= 0.038 and <0.0001 respectively).

While comparing the total duration of motor block we found it was significantly shorter in Group R (115.18 ±6.25 minutes) in comparison to Group B (146.10 ±10.73 minutes) and Group L (141.52 ±.11.91) minutes (p value = <0.0001). However, the difference in Group B and Group L was comparable (p value = 0.208).

Duration of Analgesia was significantly shorter in Group R (126.62 ±9.66 minutes) in comparison to Group B (137.43 ±6.48 minutes) and Group L (136.18 ±.9.30 minutes) (p value = <0.0001). However, the difference in Group B and Group L was comparable (p value = 0.394). Time for first rescue analgesia was significantly longer in Group B (162.17±24.02 minutes) in comparison to Group L (143.75 ±24.026.17 minutes) and Group R (134.62 ±6.66) (p value = <0.0001)

Incidence of hypotension was significantly higher in Group B and Group L in comparison to Group R. Incidence of bradycardia was also significantly higher among patients of Group B in comparison to Group L and Group R. While comparing the incidence of nausea and vomiting it was comparable among three groups.

Regarding the surgical relaxation we found 45 (75%) patients in Group B, 40 (66.7%) in Group L and 38 (63.3%) patients in Group R had excellent muscle relaxation. Good muscle relaxation was seen in 10 (16.7%) patients in Group B, 12 (20%) patients in Group L and 15 (25.0%) in Group R. Regarding muscle relaxation we found all three groups were comparable (p value= 0.779).

Patient's response was satisfactory in 55 (91.7%) patients in Group B, 52 (86.7%) in Group L and 53 (88.3%) in Group R with no statistically significant difference among three groups (p value = 0.674)

5. Discussion

One of the most popular surgical procedures in obstetrics is the cesarean section. A cesarean section may be performed for a variety of reasons, such as older age at delivery, lower delivery rates, more use of electronic birth control, and many more. Local anesthetics make spinal anesthesia—particularly subarachnoid block—easy to administer, safe, and dependable. It enables quick establishment of a sufficient degree of relaxation and analgesia.

Spinal anesthesia has a clear benefit over general anesthetic due to the avoidance of polypharmacy, greater maternal satisfaction, and effective postoperative analgesia that promote early nursing and the development of a mother - child relationship.

Pregnancy is linked to a challenging airway, and the use of general anesthesia increases the likelihood of parturients

experiencing regurgitation and pulmonary aspiration of stomach contents, resulting in acid aspiration syndrome. This syndrome is a significant contributor to illness and death.

Preventing aspiration of stomach contents, avoiding the potentially incapacitating effects of analgesics, and maintaining consciousness are just a few of the numerous benefits of anesthesia during a cesarean section. The fourth thoracic nerve root is the appropriate degree of spinal anesthesia for cesarean sections (T4). Mother's hemodynamic instability and sympathetic paralysis are risks associated with greater levels of anesthetic.

Opioids such morphine, fentanyl, sufentanil, and buprenorphine have been given intrathecally as additional treatments to decrease intraoperative visceral pain felt by parturients during manipulation of the uterus. Shortness of postoperative analgesia, headache, pectoral nerve damage, nausea, urinary retention, backache, cardiac arrest, spinal canal hematoma with or without neurological complications, epidural abscess, and hemodynamic disorders like hypotension and bradycardia are some of the disadvantages of spinal anesthesia (when combined with topical analgesics). The impact of the block is contingent upon the volume, concentration, and dosage of the substance administered.

LA baricity, the ratio between the density of local anesthetics (Las) and cerebrospinal fluid (CSF), plays a crucial role in determining how Las are distributed in the subarachnoid area. Recent research have verified that simple bupivacaine is hypobaric when compared to human cerebrospinal fluid (CSF). From a clinical perspective, this presents as an uncertain level of sensory block in the middle, with a wide variation between individuals. Sometimes, this can result in the failure of the block if the spinal anesthesia has not spread sufficiently for the surgical procedure.

We may infer from the data that the start of sensory block was similar for levobupivacaine and bupivacaine, but it took longer in the ropivacaine group. In comparison to isobaric levobupivacaine and ropivacaine, hyperbaric bupivacaine produced the greatest degree of sensory block and regression of sensory blockade. Compared to the bupivacaine and levobupivacaine groups, the ropivacaine group had a delayed start of motor block, but the length of the block was shorter in this group. While bradycardia and hypotension were seen in all three groups, ropivacaine showed the lowest frequency of these conditions. These findings support the notion that spinal bupivacaine is more effective than ropivacaine in terms of the time it takes for motor block to start, the regression of sensory and motor block, and the length of analgesia; nonetheless, both ropivacaine and levobupivacaine are safe and effective options for caesarean sections.

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