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Original Research Article

COMPARISON OF HEMODYNAMIC PARAMETERS BETWEEN LEVOBUPIVACAINE 0.5% HEAVY AND BUPIVACAINE 0.5% HEAVY DURING SPINAL ANAESTHESIA IN CAESAREAN SECTION SURGERY: A RANDOMISED CONTROLLED TRIAL FROM INDIA

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ABSTRACT

Background: A more recent local anaesthetic that has been licensed for intrathecal injection is levobupivacaine. Bupivacaine's pure S (-) enantiomer is known as levobupivacaine. With the benefit of a more controlled distribution, plain levobupivacaine is isobaric to cerebral spinal fluid. Levobupivacaine is quite potent, acting slowly at first and for a prolonged period of time. It has a higher rate of dissociation than bupivacaine and reversibly binds sodium ion channels, inhibiting a voltage-dependent rise in sodium ion conductance. It also has a lesser propensity to block inactivated cardiac sodium and potassium channels. **Objective:** To compare hemodynamic stability of Levobupivacaine 0.5% heavy and Bupivacaine 0.5% heavy during spinal anaesthesia in caesarean section surgery.

Materials and Methods: This was a randomised, single blinded clinical trial conducted in aged 18-45 years which will be posted for caesarean section surgery in tertiary care hospital PDMMC Amaravati from July 2022 to June 2024. Patients were randomly divided into 2 groups: **Group L** -10mg of Levobupivacaine 0.5 % heavy (2.2ml) with inj. Bupregesic 60 mcg(0.3ml). **Group B** -10mg of Bupivacaine 0.5% heavy (2.2ml) with inj. Bupregesic 60 mcg (0.3ml) a total of 2.3 cc, administered intrathecally within 10 seconds.

Results: Mean age of the patients in group L was 26.3 + 3 years vs 26.5 + 3.6 years. Two groups were comparable with respect to age ($p>0.05$). Mean pulse rate at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B ($p>0.05$). Mean systolic blood pressure at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B ($p>0.05$). Mean diastolic blood pressure at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B ($p>0.05$).

Conclusion: In the present study, the two groups with ASA II grade, Levobupivacaine 0.5% heavy (Group L) and Bupivacaine 0.5% heavy (Group B) were comparable with respect to age and these two groups did not differ for hemodynamic parameters during caesarean section surgery. So, the two treatments were comparable for hemodynamic changes mean Spo2 at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B ($p>0.05$).

Key words: Hemodynamic stability, Levobupivacaine, Bupivacaine, spinal anaesthesia in caesarean section surgery.

INTRODUCTION

Since general anaesthesia increases the risk of aspiration in pregnant patients following lower segment Caesarean section, spinal anaesthesia is currently the most frequently utilized anaesthetic technique due to a variety of physiological changes influencing the airway.[1,2] As opposed to general anaesthesia, regional anaesthesia is a somewhat safe, simple, dependable, and affordable method for Caesarean section. Airway manipulation is decreased, and there is less placental transfer of anaesthetic medications to the fetus.[2,3]

For spinal anaesthesia, bupivacaine is a frequently used local anaesthetic (LA). Bupivacaine that is plain or glucose-free is commonly referred to as "isobaric" in the literature. However, Blomqvist and Nilsson4 showed that it was hypobaric. In contrast to human cerebrospinal fluid, ordinary bupivacaine is actually hypobaric, according to numerous investigations, including some Randomized Control Trials.[4-6] Clinically, when the spinal block has not spread high enough for surgery, it is sometimes linked to block failure and has an uncertain median sensory block height with a wide inter-individual spread because of its hypobaricity.[7-9]

On the other hand, the use of hyperbaric bupivacaine results in side effects such as bradycardia, hypotension, nausea, and vomiting because it prolongs the sympathetic block. Accidental intravenous injection can be fatally harmful to the heart and central nervous system.[10,11]

A more recent local anaesthetic that has been licensed for intrathecal injection is levobupivacaine. Bupivacaine's pure S (-) enantiomer is known as levobupivacaine.[12] With the benefit of a more controlled distribution, plain levobupivacaine is isobaric to cerebral spinal fluid.[13,14] Levobupivacaine is quite potent, acting slowly at first and for a prolonged period of time. It has a higher rate of dissociation than bupivacaine and reversibly binds sodium ion channels, inhibiting a voltage-dependent rise in sodium ion conductance. It also has a lesser propensity to block inactivated cardiac sodium and potassium channels.[15,16]

Research has indicated that the use of bupivacaine for spinal anaesthesia during caesarean sections is associated with a higher incidence of numerous side effects, such as bradycardia, hypotension, nausea, and vomiting. We have started the present Randomized Control Trial to compare the effects of 0.5% heavy Bupivacaine and 0.5% heavy Levobupivacaine on haemodynamics stability during caesarean section surgery in order to assess all these factors.[17]

Objective

To compare hemodynamic stability of Levobupivacaine 0.5% heavy and Bupivacaine 0.5% heavy during spinal anaesthesia in caesarean section surgery.

MATERIALS AND METHODS

This was a randomised, single blinded clinical trial conducted in aged 18-45 years which will be posted for caesarean section surgery in tertiary care hospital Dr. Panjabrao Deshmukh Memorial Medical College and Hospital, Amravati from July 2022 to June 2024.

The protocol of this study was approved by the Institutional Ethical committee of the medical college. Written informed consent was taken from all study subjects before collection of data and they were informed about complete right to withdraw from the study at any time without disadvantage. In case any patient who was not literate, verbal consent was obtained after reading out the consent form to him and his verbal agreement was recorded by the interviewer in front of a witness. All patients fulfilling inclusion criteria and exclusion criteria were included in the study.

Inclusion Criteria

1. Age 18 to 45 yr.
2. ASA 2 physical status (Normal Pregnancy is considered as ASA 2)
3. Undergoing elective and emergency caesarean section.
4. Giving valid informed consent.

Exclusion criteria

1. Patients with ASA grade 3 and ASA grade 4.
2. Patient refusal to participate in the study.
3. Patient with coagulopathy or on anticoagulants.
4. Patients with known hypersensitivity to study drugs.
5. Patients with uncontrolled neurologic, cardiovascular, renal, hepatic diseases or diabetes mellitus, respiratory problem.

Methods of data collection

After approval of institutional ethics committee and written informed consent of patients, randomized single blind trial will be carried out in a tertiary care hospital at PDMMC Amaravati during the study period from July 2022 to June 2024.

The patients scheduled for elective Caesarean delivery, at more than 37 weeks gestation, ASA physical status ASA II (American society of anesthesiologist) were randomly divided into two groups by odd and even method according to their number while inclusion in the study. Following application of routine monitors (non-invasive Blood Pressure measurement, electrocardiography, and pulse oximetry) and insertion of a peripheral 20 G iv cannula, a rapid infusion of lactated Ringer's solution 10 ml/kg was administered. Baseline systolic BP and heart rate were calculated as the mean of the three recordings. Patients were placed in the sitting position. After disinfecting the skin and infiltrating with 2% lidocaine, lumbar puncture was performed at the L3-L4 interspace using a 25-gauge Quincke point needle.

Patients were randomly divided into 2 groups:

Group L -10mg of Levobupivacaine 0.5 % heavy (2.2ml) with inj. Bupregesic 60 mcg(0.3ml)
Group B -10mg of Bupivacaine 0.5% heavy (2.2ml) with inj. Bupregesic 60 mcg (0.3ml) a total of 2.3 cc, administered intrathecally within 10 seconds.
Subsequently, patients were turned to a 15˚ - 20˚ left lateral supine position. Oxygen at 4 L/min was administered via a Hudson face mask. The sensory level of spinal anesthesia was assessed bilaterally in the anterior axillary line by pinprick, using a short beveled 25 G needle, and was recorded at baseline prior to spinal injection, then every minute for the first 15 min after injection, and every five minutes for the next 30 min, and at 45 min. Blood pressure, heart rate, and the extent of motor block were recorded at the same measurement intervals.
Permission to perform operation was given once a T4-T6 level had been achieved. Considering the time of intrathecal injection as time zero, time to onset of sensory block, time taken to reach maximum sensory block level, time to regression of two dermatomes of the sensory block, duration of the regression of the sensory block level to T6-T8 from the maximum level were recorded. The level of motor block was assessed with Modified Bromage scale. Time to onset of motor block, time to reach Bromage 3 and the time of complete disappearance were recorded.

RESULTS

Table 1: Comparison of two groups according to age groups

Age group in years	Group L		Group B		p
	No.	(%)	No.	(%)	
21-25	25	43.1	25	43.1	0.7
26-30	28	48.28	27	46.55	
31-35	5	8.62	4	6.9	
36-40	0	0	2	3.45	
Total	58	100	58	100	
Mean ± S.D.	26.3 ± 3 years.		26.5 ± 3.6 years.		0.7

In the present randomized, single blinded clinical trial, we have planned to include total 116 cases; 58 in each group, posted for caesarean section to compare Levobupivacaine 0.5% heavy (Group L) and Bupivacaine 0.5% heavy (Group B) for hemodynamic stability during caesarean section surgery.

In the present study, majority, (48.28% in group L vs 46.55% in group B) of cases in both the groups were from the age group of 26-30 years followed by the age group of 21-25 years. Mean age of the patients in group L was 26.3 + 3 years vs 26.5 + 3.6 years. Two groups were comparable with respect to age (p>0.05).

Table 2: Comparison of pulse rate between Levobupivacaine and Bupivacaine

Pulse rate	Group L	Group B	p
	Mean ± SD	Mean ± SD	
Preinduction	104.6 ± 14.9	105.7 ± 13.5	0.6
Induction	101.2 ± 14.9	101.7 ± 14.0	0.8
Postinduction	96.8 ± 13.9	98.0 ± 13.7	0.6
5 min.	96.4 ± 12.2	97.3 ± 10.5	0.6
10 min.	95.2 ± 11.4	95.3 ± 10.7	0.9
15 min.	96.3 ± 11.2	95.4 ± 10.5	0.6
20 min.	91.0 ± 10.1	91.7 ± 10.4	0.7
25 min.	92.1 ± 11.3	91.2 ± 11.9	0.6
30 min.	91.4 ± 9.7	89.4 ± 8.8	0.2
45 min.	88.1 ± 9.8	87.2 ± 7.0	0.6
60 min.	88.1 ± 8.4	86.8 ± 6.6	0.3
75 min.	88.3 ± 7.4	86.5 ± 6.5	0.1

In the present study, mean pulse rate at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05).

Table 3: Comparison of SBP between Levobupivacaine and Bupivacaine

SBP	Group L	Group B	p
	Mean ± SD	Mean ± SD	
Preinduction	124.3 ± 10.3	121.6 ± 10.8	0.1
Induction	117.5 ± 11.9	115.2 ± 11.9	0.3
Postinduction	104.9 ± 10.9	102.6 ± 10.0	0.2
5 min.	102.5 ± 6.8	102.7 ± 9.1	0.8
10 min.	108.9 ± 11.0	107.9 ± 11.4	0.6
15 min.	111.3 ± 10.2	110.7 ± 10.4	0.7
20 min.	112.2 ± 9.0	111.2 ± 8.2	0.5
25 min.	112.8 ± 7.6	111.2 ± 8.9	0.3
30 min.	114.0 ± 6.4	113.1 ± 7.1	0.4

45 min.	115.7 ± 7.3	114.9 ± 8.8	0.5
60 min.	116.9 ± 7.0	116.8 ± 8.4	0.9
75 min.	118.6 ± 7.2	118.9 ± 8.4	0.8

In the present study, mean systolic blood pressure at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05).

Table 4: Comparison of DBP between Levobupivacaine and Bupivacaine

DBP	Group L	Group B	p
	Mean ± SD	Mean ± SD	
Preinduction	76.1 ± 7.7	79.1 ± 8.8	0.05
Induction	65.2 ± 13.8	68.2 ± 15.4	0.2
Postinduction	61.6 ± 7.1	64.3 ± 8.3	0.06
5 min.	61.2 ± 8.4	63.5 ± 9.3	0.1
10 min.	59.5 ± 8.8	60.7 ± 8.2	0.4
15 min.	71.4 ± 10.4	68.3 ± 9.2	0.09
20 min.	73.4 ± 6.0	71.5 ± 6.0	0.09
25 min.	76.1 ± 12.3	74.7 ± 12.7	0.5
30 min.	71.1 ± 7.8	70.3 ± 8.7	0.6
45 min.	71.5 ± 7.9	71.5 ± 9.0	0.9
60 min.	68.9 ± 12.1	68.3 ± 13.8	0.8
75 min.	75.4 ± 5.1	74.3 ± 5.7	0.2

In the present study, mean diastolic blood pressure at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05).

Table 5: Comparison of SPO2 between Levobupivacaine and Bupivacaine

SPO2	Group L	Group B	p
	Mean ± SD	Mean ± SD	
Preinduction	98.4 ± 0.7	98.4 ± 0.6	0.9
Induction	98.9 ± 0.5	98.9 ± 0.5	0.9
Postinduction	99.2 ± 0.4	99.1 ± 0.4	0.1
5 min.	99.3 ± 0.4	99.2 ± 0.4	0.1
10 min.	99.0 ± 0.7	98.9 ± 0.7	0.4
15 min.	98.9 ± 0.6	98.9 ± 0.6	0.9
20 min.	99.0 ± 0.0	99.0 ± 0.3	0.9
25 min.	99.1 ± 0.3	99.0 ± 0.3	0.07
30 min.	99.1 ± 0.3	99.1 ± 0.3	0.9
45 min.	99.1 ± 0.3	99.1 ± 0.3	0.9
60 min.	99.1 ± 0.3	99.1 ± 0.3	0.9
75 min.	99.1 ± 0.3	99.1 ± 0.3	0.9

In the present study, mean Spo2 at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05).

DISCUSSION

In the present study, majority, (48.28% in group L vs 46.55% in group B) of cases in both the groups were from the age group of 26-30 years followed by the age group of 21-25 years. Mean age of the patients in group L was 26.3 + 3 years vs 26.5 + 3.6 years. Two groups were comparable with respect to age (p>0.05). (Table 1)

This is in line with Sethi D. et al,[18] Kiranpreet Kaur et al19 and Dilek Subaşı et al,[20]

In the present study, mean pulse rate at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05). (Table 2). In the present study, mean systolic blood pressure at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05). (Table 3). In the present study, mean diastolic blood pressure at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05). (Table 4). In the present study, mean Spo2 at preinduction, induction, postinduction, 5, 10, 15, 20, 25, 30, 45, 60 & 75 minutes did not differ between group L and group B (p>0.05). (Table 5)

Similarly, Priyank Samar et al,[21] observed more stable haemodynamic parameters with levobupivacaine, Sethi D. et al,[18] also did not find statistically significant differences in haemodynamic parameters, Demet Gulec et al,[22] reported that levobupivacaine did not cause any significant changes in haemodynamic parameters, including systolic blood pressure, and showed a similar sensory block onset time compared with bupivacaine, but it had a significantly longer motor block onset time compared with bupivacaine & Demet Gulec et al,[22] found that intrathecal hyperbaric levobupivacaine-fentanyl combination is good alternative to bupivacaine-fentanyl combination in caesarean surgery as it is less

effective in motor block, it maintains hemodynamic stability at higher sensorial block levels.

CONCLUSION

In the present study, the two groups with ASA II grade, Levobupivacaine 0.5% heavy (Group L) and Bupivacaine 0.5% heavy (Group B) were comparable with respect to age and these two groups did not differ for hemodynamic parameters during caesarean section surgery. So, the two treatments were comparable for hemodynamic changes.

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