Original Research Paper

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"A COMPARATIVE EVALUATION OF INTRATHECAL HYPERBARIC LEVOBUPIVACAINE 0.5% WITH HYPERBARIC BUPIVACAINE 0.5% FOR ELECTIVE CAESAREAN SECTION: A PROSPECTIVE RANDOMIZED STUDY."

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ABSTRACT **Background:** Hyperbaric Bupivacaine is the most commonly used local anaesthetic agent in caesarean section. Levobupivacaine, which is S (-) enantiomer of bupivacaine, may provide more selective sensory blockade compared to racemic bupivacaine and can be used in place of bupivacaine due to its lower cardio toxicity and neurotoxicity. We conducted a study comparing efficacy of hyperbaric Bupivacaine (0.5%) and hyperbaric Levobupivacaine (0.5%) in elective caesarean section. **Materials And Methods:** This prospective randomized double-blind study was undertaken on 70 pregnant females belonging to American society of anaesthesiologists class 1 & 2, between18 to 40 years of age undergoing elective caesarean section. Group L received 2ml (10mg) hyperbaric Levobupivacaine 0.5% whereas Group B received 2ml (10mg) hyperbaric Bupivacaine 0.5%. Characteristics of sensory and motor blockade, hemodynamic parameters, neonatal Apgar score and adverse effects were recorded. Data were analyzed by appropriate statistical tests and a value of $P < 0.05$ was considered significant. **Results:** The onset of sensory & motor block, maximum level of sensory block and neonatal Apgar score in both groups were comparable ($P > 0.05$). The total duration of sensory and motor block was significantly less in Group L compared to Group B ($P < 0.05$). Although incidence of bradycardia was slightly more and that of hypotension was less in group L than in group B; the difference was not statistically significant ($p > 0.05$). **Conclusion:** Intrathecal 0.5% hyperbaric levobupivacaine can be utilized as a suitable alternative to 0.5% hyperbaric bupivacaine in spinal anaesthesia for patients undergoing elective caesarean delivery. This drug is effective enough to produce the sensory and motor blockade with clinically comparable onset time, comparatively prolonged duration and stable hemodynamic profile to that of hyperbaric bupivacaine. In addition, this novel drug hyperbaric levobupivacaine may offer the advantage of decreased cardiovascular and central nervous system toxicity.

KEYWORDS : Bupivacaine, caesarean section, hyperbaric, Levobupivacaine, spinal anaesthesia

INTRODUCTION

Spinal anaesthesia is accepted as a safe technique for caesarean section worldwide [1]. With the increasing number of the caesarean section under spinal anaesthesia various local anaesthetic agents are being studied for their efficacy, hemodynamic stability and other effects. Hyperbaric Bupivacaine is the most commonly used local anaesthetic agent in elective caesarean section. Bupivacaine is a racemic mixture of dextro and levo isomers and provides dense sensory and motor block which may lead to prolonged immobilization and hypotension. Enantiomers of Bupivacaine may have the similar pharmacological properties, but fewer side effects. Levobupivacaine, which is S(-) enantiomer of bupivacaine, provides more selective sensory and motor blockade compared to racemic bupivacaine and can be used in place of bupivacaine due to its lower cardio toxicity and neurotoxicity [2, 3]. The S (−) isomer exhibits weaker potassium channel-blocking potency, reducing the likelihood of QTc interval prolongation. Stereo selective binding to sodium and potassium channels decreases the inhibitory effects, thereby lowering the overall toxicity potential compared to bupivacaine. It also provides extended advantages because of its more pronounced affinity for sensory fibres than motor fibres and provides predictable spread after spinal anaesthesia [4].

While performing spinal anaesthesia, hyperbaric solutions of local anaesthetic agents are preferred because their spread is influenced by gravity. These solutions are denser than cerebrospinal fluid (CSF), allowing their distribution to be controlled by adjusting the patient's position. This facilitates targeted spread to achieve the desired sensory block level. When appropriately positioned, they can provide a higher sensory level and faster onset of anaesthesia due to their predictable spread [5].

Hyperbaric levobupivacaine was commercially not available previously but as of now, hyperbaric solutions are marketed in India.

There are some studies that have compared the efficacy of isobaric levobupivacaine with that of hyperbaric bupivacaine but there is paucity in literature regarding use of hyperbaric levobupivacaine in caesarean section. We conducted a study to compare the efficacy of hyperbaric levobupivacaine with hyperbaric Bupivacaine in caesarean section where the primary outcome was comparison of sensory and motor block characteristics. We hypothesized that both hyperbaric levobupivacaine and hyperbaric Bupivacaine are equally effective for spinal anaesthesia in caesarean section.

MATERIAL AND METHODS

Sample Size Calculation:

Expected mean of group L(X1) = 3.87
Expected mean of group B (X2) = 3.60
Expected standard deviation in group L (SD1) =0.73
Expected standard deviation in group B (SD2) = 0.08
Pooled standard deviation Sp = $[SD^{21} + SD^{22}/2]1/2 = [0.73^2 + 0.08^2 /2]1/2$ =0.51

Difference between two means (d) = X1 - X2 =3.87-3.60=0.27
Set level of confidence (<1.0) =0.9
Set level of power of test (<1.0) =0.8
Z value associated with confidence =1.28
Z value associated with power =0.84

Formula of calculating sample size is:
n = 2[Z(1- +Z (1-]2Sp2/d2

So n = 2 (1.28 + 0.84)2 × 0.512 /0.272
n= 34
For convenience we included 35 patients in each group.

Ethical Consideration:

Ethics committee approval was taken from institutional ethics committee and Scientific Advisory committee of MGM's Medical College and Hospital, Chh. Sambhajinagar, Maharashtra, India.

A Prospective Randomized double blinded clinical study was done in Department of Anesthesiology, at MGM Medical College, Chh. Sambhajinagar over a period of 2 years. Pregnant females between ages 18 to 40 years and belonging to ASA class 1 or 2 were screened for enrolment in the study. Pre-anaesthetic check-up of all patients were done a day prior to surgery which included detail history, thorough physical examination (general & systemic) & basic relevant investigations. Patients undergoing caesarean delivery for foetal distress or hypertensive disorders of pregnancy; patients with liver, renal or cardiac disease or BMI > 30 were excluded from the study. Consent for participation in study was obtained from patients. Before enrolment of first patient in this study; registration for trial was done with CTRI no. – CTRI/2023/10/058567. The study participants were divided randomly by sealed envelope method into two groups. Group L: Hyperbaric levobupivacaine 0.5% 2ml (10 mg) and Group B: Hyperbaric Bupivacaine 0.5% 2ml (10mg)

Patients were kept NBM 6 hours prior to the surgery. On the day of procedure, monitors were attached and baseline readings which included heart rate (HR), Non-invasive mean blood pressure (MAP), Oxygen Saturation (SPO2) and ECG were recorded. IV access was obtained using 20 G intravenous cannula. Co- loading was done by infusion of 500ml Ringer Lactate. Heart rate and blood pressure (mean) was recorded. Spinal anaesthesia was administered in sitting position in L3-L4 intervertebral space using 25G Quincke spinal needle under all aseptic precautions. Drug was given for subarachnoid block as per the allocated groups. The Anaesthesiologist not participating in the study administered spinal anaesthesia. The observer and the patient both were unaware of the drug used thus making the study double blind.

After intrathecal injection of the drug, sensory block was tested by pin prick in midaxillary line after positioning the patient in supine position, every 3 minutes till peak sensory level i.e. two consecutive reading at the same dermatomal level was achieved. Thereafter, sensory block was checked every 20 min till the block regression to L1 level. The time from spinal injection (T-0) to time taken to achieve T10 level was considered as onset of sensory blockade. The time from T-0 to L1 regression was taken as total duration of the sensory block.

Motor block was checked at repeated intervals of 3 minutes using Modified Bromage scale from intrathecal injection till starting of surgery. Motor block onset was taken as the time from T- 0 to obtaining a motor block of grade 2. Thereafter motor block was tested in post-operative period every 20 minutes till complete recovery (grade 0) and motor block duration was taken into consideration as time duration from T0 till complete motor recovery to grade 0.

Surgery was permitted once the sensory block reached up to T10 and grade 2 motor block. Failure to achieve the required block in 20 min was regarded as failure of block and general anaesthesia (GA) given to those patients.

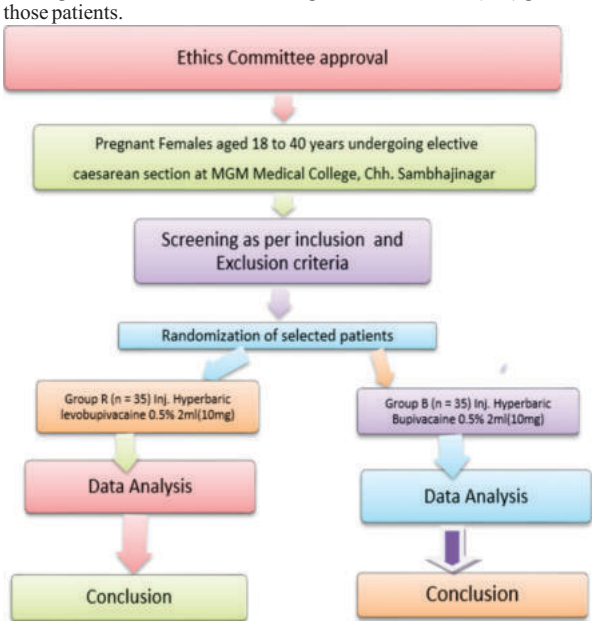


Figure c: Flow Chart Of Schematic Presentation Of Methodology

Intra operatively quality of sensory block was noted on four point scale (5) - 1. Perfect, 2. Some feeling; no discomfort 3. Some discomfort 4. Major discomfort. If the patient had discomfort, rescue analgesic in the form of Ketamine 0.25mg/kg was given and repeated after 10 minutes if necessary. If third dose of Ketamine was needed; GA was given to the patient. Number of patients requiring GA was noted.

After spinal anaesthesia was administered, heart rate and blood pressure (mean) were recorded every 3 minutes for first 20 minutes. Thereafter it was monitored every 10 minutes till regression of sensory block to L1. Decrease in the mean arterial pressure by more than 20% of base line was defined as hypotension and treated with Inj. Mephentermine 3 mg intravenously; repeated if required. Decrease in the heart rate to less than 60 beats/ minute was taken as bradycardia and treated with Inj. Atropine 0.6 mg IV. After delivery of baby; neonatal outcome was checked by the Apgar score at first and fifth minute.

Inj. Ondensetron 4 mg IV was given to treat intra operative nausea/ vomiting. Inj. Tramadol 25mg IV was given to treat intraoperative or postoperative shivering.

Statistical Analysis:

Quantitative data was expressed in form of Mean ± SD. Statistical analysis was performed by using SPSS software. The unpaired t-test was used for comparison of mean between two groups. The paired t-test was used for intra-group comparison. Qualitative data was expressed in form of Frequency and Percentage. The chi-square test was used for qualitative data. P-value <0.05 was regarded as statistically significant, P value <0.001 was taken as highly significant and P value >0.05 was regarded as non-significant.

OBSERVATION AND RESULTS

In present study we enrolled 70 patients allocated into two groups i.e. **Group L:** Hyperbaric levobupivacaine 0.5% 2ml (10 mg) and **Group B:** Hyperbaric Bupivacaine 0.5% 2ml (10mg).

Table 1: Comparison Of Demographic Parameters Between Two Groups.

Parameters	Group L (n = 35)	Group B (n = 35)	P value
Age (in years) *	25.03±3.28	26.83±5.59	*P* = 0.105 NS
Duration of surgery (in minutes) *	49.31±9.58	52.17±11.23	*P* = 0.256 NS

NS = Not significant, * mean ± SD

The mean age in Group L and Group B was comparable (P= 0.105). All 70 patients in the study belonged to ASA class II. The difference in the mean duration of surgery between both the study groups was not statistically significant (*P* = 0.256).

Table 2 – Comparison Of Sensory And Motor Block Parameters Between The Two Groups

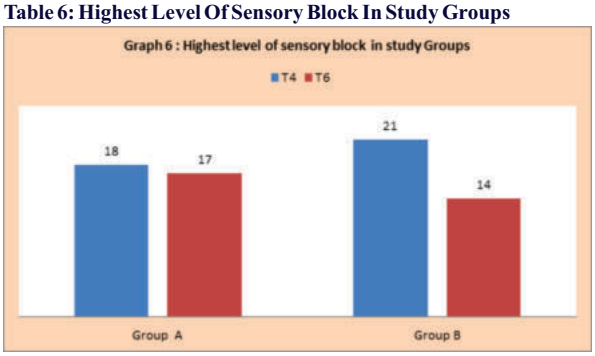
Parameter	Group L (n = 30)	Group B (n = 30)	P value
Onset of sensory block (Minutes) *	3.23 ± 1.08	3.31± 0.68	P = 0.693 NS
Duration of Sensory Blockade (Minutes) *	145.54 ± 19.61	174.74 ± 29.89	P < 0.0001 S
Onset of motor block(minutes) *	3.06 ± 1.13	2.91 ± 0.98	P = 0.575 NS
Duration of motor block (minutes) *	133.80 ± 21.06	163.43 ± 24.05	P < 0.0001 S

NS = Not significant, S = Significant, * mean ± SD

The mean Onset of sensory block [in min] in Group L was 3.23±1.08 min and in Group B was 3.31±0.68 min. The mean Onset time of sensory block between Group L and Group B did not differ significantly (P= 0.693). The mean duration of Sensory Block [in min] in Group L was less 145.54±19.61 min than Group B i.e.174.74±29.89 min. The mean duration of Sensory Block between Group L and Group B had statistically significant difference (P < 0.0001). The mean Onset of Motor block [in min] in Group L was 3.06±1.13 min and in Group B was 2.91±0.98 min. The mean Onset of motor block between Group L and Group B had no statistically significant difference (P= 0.575). The mean duration of Motor Block (Mins) in Group L was lower 133.80±21.06 min than Group B i.e. 163.43±24.05 min. The mean duration of Motor Block between Group L and Group B was

statistically significant (P<0.0001).

Table 6: Highest Level Of Sensory Block In Study Groups



Highest level of Sensory block was T4 in both groups. In Group L, T4 was the maximum i.e. 18(51.4%) height of sensory block attained and T6 was in 17(48.5%) of patients Group B had 21(60.0%) of patients has attained T4 level and 14(40.0%) of patients was attained T6 level. The highest level of sensory block in study Groups had no statistically significant association (p =0.521).

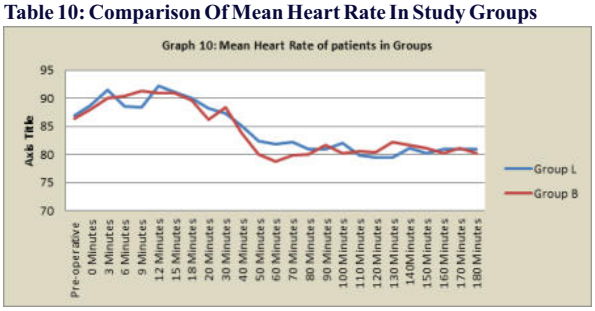
Table 9: Comparison Of Mean Apgar Score At 1 Minute And 5 Minutes Of In Study Groups

Apgar score (Mean ± SD)	Group L	Group B	P-value
at 1 minute	7.14 ± 0.84	7.23±0.54	P = 0.616 NS
at 5 minutes	8.46±0.56	8.54±0.51	P = 0.504 NS

NS = Not Significant

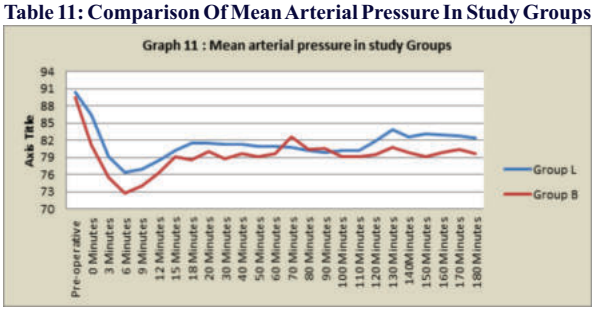
The difference in mean Apgar score at 1 & 5 minutes between Group L and Group B was not statistically significant (P=0.616 & 0.504 respectively).

Table 10: Comparison Of Mean Heart Rate In Study Groups



The difference in the heart rate between the two groups at various time intervals was not statistically significant (p > 0.05).

Table 11: Comparison Of Mean Arterial Pressure In Study Groups



The mean arterial pressure between the two groups at various time intervals was not statistically significant (p > 0.05).

Table 12: Intra Operative Complications In Study Groups

Intra operative	Group L		Group B		p-value
	No	Percentage	No	Percentage	
Hypotension	10	28.6	13	37.1	P=0.445 NS
Bradycardia	02	5.7	00	00	P=0.089 NS
Shivering	04	11.4	03	8.6	P=0.690 NS

NS = Not Significant

Incidence of bradycardia, hypotension and shivering was statistically comparable in both the groups. (p > 0.05).

DISCUSSION:

The study entitled "comparison of the efficacy & safety of intrathecal 0.5% hyperbaric levobupivacaine with 0.5% hyperbaric bupivacaine for spinal anaesthesia in patients undergoing elective caesarean section." was conducted in Department of Aanesthesia MGM's Medical College and Hospital, Chh. Sambhajinagar (Aurangabad) from April 2023 to February 2025 aimed at evaluating the sensory block onset, Maximum height of sensory block, Sensory block duration, motor block onset, Motor block duration, Intra operative haemodynamic parameters and observing any adverse effects between the two groups.

Spinal anaesthesia has been commonly used in lower limb surgeries, caesarean section and bupivacaine (a racemic mixture of dextrobupivacaine and levobupivacaine) being the gold standard for intrathecal use. There were some studies that compared the efficacy of isobaric levobupivacaine with that of hyperbaric bupivacaine. But until recently Levobupivacaine was available only as isobaric solution. As hyperbaric levobupivacaine was currently made available in India, we conducted the study with hyperbaric levobupivacaine for elective caesarean section.

Levobupivacaine is claimed to be equipotent to racemic bupivacaine. Sinchana A S et al [6], Rashmi Duggal et al [7] and T Karthik et al [8] compared subarachnoid block with 0.5% levobupivacaine and 0.5% bupivacaine in patients undergoing elective caesarean section.

The average drug dose Levobupivacaine used in most of the abovementioned studies was 10 mg (2ml) So in our study we decided to compare intrathecal 10mg 0.5% (2ml) hyperbaric levobupivacaine with 10mg 0.5% (2ml) hyperbaric bupivacaine for spinal anaesthesia in patients undergoing elective caesarean section.

The demographic parameters i.e. mean age, ASA class and average duration of surgery were statistically comparable in both the study groups (p > 0.05).

In present study the mean onset of sensory block in Group L was 3.23±1.08 min and in Group B was 3.31±0.68 min. The difference in mean Onset of sensory block between Group L and Group B was not statistically significant (P= 0.693). Similar findings were reported by T Karthik et al [8] that the time of sensory block onset (min) in hyperbaric Levobupivacaine group was 2.03 ± 1.73 compared to 1.83 ± 0:37 for Hyperbaric Bupivacaine; the difference was not statistically significant. Whereas Soubhagya Kumar Das et al [9] reported that Levobupivacaine displayed a slightly delayed onset of sensory block at an average onset time of 1:45 ± 0:10 compared to 1:35 ± 0:13 for Hyperbaric Bupivacaine (p < 0.001). The delayed onset of sensory block observed in the aforementioned study can be attributed to the use of 2.5 ml of intrathecal levobupivacaine, which differs from the drug and dosage used in our study. Madhanmohan C et al [10] found that the Sensory onset was significantly faster with hyperbaric bupivacaine (3.8±0.81 min) as compared to levobupivacaine (4.28±1.04 min), p = 0.011. This faster onset of sensory block in their study could be attributed to the fact that they have used hyperbaric bupivacaine 10 mg and compared it with isobaric levobupivacaine 12.5mg instead of hyperbaric Levobupivacaine 10 mg in our study.

The mean duration of Sensory Block in Group L was less 145.54±19.61 min as compared to Group B i.e.174.74±29.89 min. There was statistical significant difference in mean duration of Sensory Block between Group L and Group B (P<0.0001). Similar findings were reported in the study conducted by Madhanmohan C et al [10] that mean duration of Sensory Block [in min] in levobupivacaine group was 186.0 and in hyperbaric bupivacaine was 210.7. Duration of sensory block was significantly longer in hyperbaric bupivacaine Group as compared to levobupivacaine Group (p=0.0001). Sinchana AS et al [6] also observed that the levobupivacaine group showed a significantly shorter total duration of sensory block compared to the bupivacaine group. The average duration of sensory block was notably shorter in the levobupivacaine group (166.78 minutes) than in the bupivacaine group (194.6 minutes). Our findings correlate with the abovementioned studies.

In our study highest level of Sensory block was T4 in both groups. In Group L, T4 was the maximum i.e. 18(51.4%) height of sensory block

attained and T6 was in 17(48.5%) of patients Group B had 21(60.0%) of patients has attained T4 level and 14(40.0%) of patients was attained T6 level. There was not statistical significant association between highest level of sensory block in study Groups (p =0.521). Madhanmohan C et al [10] also found that the maximum sensory dermatome level reached was same in both groups (T4-6).

The mean Onset of Motor block in Group L was 3.06±1.13 min and in Group B was 2.91±0.98 min. There was not statistically significant difference in mean Onset of motor block between Group L and Group B (P= 0.575).

Kurmanadh Kalepalli [11] found that the onset of motor block in Levobupivacaine group was 6.32 minutes and hyperbaric Bupivacaine group was 4.89 minutes. The delayed onset in the motor block observed in the above mentioned study compared to our study may be attributed to the use of an adjuvant (Inj. Fentanyl) with both drugs in their study, which was not utilized in ours. Rashmi Duggal et al [6] reported that the Motor block onset [in min] in Levobupivacaine group significantly prolonged(3.87 ± 1.22 min)than Hyperbaric Bupivacaine (2.87 ± 0.57 min) (p < 0.001). They compared isobaric levobupivacine 10 mg (2 ml) and hyperbaric bupivacaine 10mg (2 ml) as opposed to our study where we compared both the drugs in hyperbaric form. The difference in observations of both the studies may be attributed to the difference in baricity of the drugs used.

The Motor Block duration in Group L was significantly lower (133.80±21.06 min) than Group B (163.43±24.05 min) (P<0.0001). Kurmanadh Kalepalli [11] also found that the motor block duration was 96.56 minutes in Levobupivacaine group and 152.26 minutes in hyperbaric Bupivacaine group. The difference was statistically significant. Similar findings were reported by T Karthik et al [8] that the Motor Block duration (Mins) in hyperbaric Levobupivacaine was 101.06±9.42 compared to 135.03±4.83 for Hyperbaric Bupivacaine. There was significant difference in mean duration of Motor Block between hyperbaric Levobupivacaine and hyperbaric Bupivacaine. Soubhagya Kumar Das et al [12] reported that the Motor Block duration in Levobupivacaine was 120.39 ± 10.3 min compared to Hyperbaric Bupivacaine i.e. 140.28 ± 9.26 min and this mean difference was statistically significant (p < 0.001). Our findings match all the above mentioned studies.

In present study, majority of patients of Group A i.e. 31(88.6%) & group B i.e. 30 (85.7%) were found to have perfect intra operative quality of sensory block. Four patients (11.4%) in both the groups had some feeling but no discomfort. Only 01 (2.9%) of patients in group B was found to have Some discomfort intra operatively. There was not statistically significant association between intra operative quality of sensory block and groups (p > 0.05).

In the present study, the average Apgar score at 1 minute was 7.14 ± 0.84 in Group L and 7.23 ± 0.54 in Group B. Similarly, the mean Apgar score at 5 minutes was 8.46 ± 0.56 in Group L and 8.54 ± 0.51 in Group B, with no statistically significant difference between the groups (P = 0.616 & 0.504 respectively).

The difference in the heart rate and mean arterial pressure between the two groups at various time intervals was not statistically significant (p > 0.05).

Present study reported 10 (28.6%) patients of hyperbaric Levobupivacaine group and 13 (37.1%) patients in hyperbaric Bupivacaine group who developed hypotension during the surgery. Two (5.7%) patients of hyperbaric Levobupivacaine group and no patients in hyperbaric Bupivacaine group developed Bradycardia. Shivering was found in 04 (11.4%) and 03 (8.6%) of patients of Group L and Group B respectively. The incidence of bradycardia, hypotension and shivering was comparable in the two groups. (p > 0.05).

Kurmanadh Kalepalli[11] reported that 6 patients in Levobupivacaine group and 12 patients in hyperbaric Bupivacaine group developed hypotension during the surgery which was managed with 3-6 mg mephentermine and intravenous fluids. The difference in incidence of hypotension was statistically significant among the two groups. Bradycardia was taken as heart rate below 50 per minute 1 patient in Levobupivacaine group and 7 patients of hyperbaric Bupivacaine group were seen with bradycardia which was managed with single dose of 0.5 mg atropine iv. Madhanmohan C, et al [10] found that the adverse effects observed in this study were hypotension 36% (n=18) in hyperbaric bupivacaine Group and 28% (n=14) in levobupivacaine group. Their incidence of adverse effect was comparably more in hyperbaric bupivacaine Group but could not make a statistically significant difference. Similarly Sinchana A S, et al [6] observed that the occurrence of bradycardia was similar in both groups. Bupivacaine group experienced more shivering (36.1%) compared to levobupivacaine group (13.8).

CONCLUSION:

In this study it can be concluded that, intrathecal 0.5% hyperbaric levobupivacaine can be utilized as a suitable alternative to 0.5% hyperbaric bupivacaine in spinal anaesthesia for patients undergoing elective caesarean delivery. This drug is effective enough to produce the sensory and motor blockade with clinically comparable onset time, comparatively prolonged duration and stable hemodynamic profile. In addition, this novel drug hyperbaric levobupivacaine may offer the advantage of decreased cardiovascular and central nervous system toxicity.

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