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Research Article

A Comparative Study between Efficacy of Hyperbaric Bupivacaine and Hyperbaric Levobupivacaine in the Subarachnoid Block for Cesarean Section

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ABSTRACT

Background: Spinal anaesthesia is one of the most commonly employed regional anaesthetic techniques for cesarean section. The prolonged period and reliability of the sensory blockade have made it possible to recognize bupivacaine as the gold standard of the local anaesthetic to be employed in spinal anaesthesia. However, the cardiotoxicity and neurotoxicity issues associated with bupivacaine triggered the desire to have less toxic analogy such as levobupivacaine that is the pure S-enantiomer of bupivacaine. This study aims to compare the efficacy, safety, and haemodynamic effects of bupivacaine and levobupivacaine when used for spinal anaesthesia in cesarean section.

Materials and Methods: This prospective, randomized, double-blinded study included 112 ASA II parturients scheduled for elective cesarean section. Group B received 2 ml of (10 mg) 0.5% hyperbaric Bupivacaine and Group L received 2 ml of (10 mg) 0.5% hyperbaric Levobupivacaine intrathecally. Sensory and motor block characteristics, duration of effective analgesia, neonatal outcome, and incidence of side effects were compared.

Results: Both drugs achieved effective spinal anaesthesia. The onset of sensory block was comparable between Groups B and L (2.39±0.30, 2.60±0.71 mins, p=0.29). The onset of motor block was fastest in Group B (p<0.001). The duration of sensory block (153.96±12.37, 142.06±11.64 mins), motor block (146.48±12.24, 138.23±11.26 mins, p=0.012), and analgesia (137.21±5.16, 130.16±8.06 mins, p=0.037) were longer in Groups B compared to Group L. Levobupivacaine was associated with significantly greater hemodynamic stability and a lower incidence of side effects such as hypotension, and nausea/vomiting.

Conclusion: Levobupivacaine is a safer and clinically effective alternative to Bupivacaine for spinal anaesthesia in cesarean sections, offering enhanced hemodynamic stability and quicker recovery without compromising anaesthetic efficacy.

Keywords: Obstetric Anaesthesia, Caesarean Section, Levobupivacaine, Bupivacaine, Spinal Anaesthesia, Local Anaesthetics.

INTRODUCTION

Caesarean section is one of the most frequently performed surgical procedures in modern obstetric practice, with a steadily increasing global incidence. Ensuring maternal and fetal safety during this procedure is of paramount importance, and the choice of anaesthetic technique plays a critical role in achieving this goal. Spinal anesthesia is the gold standard for modality for both elective and emergency cesarean section compared to general and epidural anesthesia due to its rapid onset, reliable sensory and motor blockade, and favorable safety profile. In addition to reducing anaesthesia-related maternal mortality, it allows the mother to

remain conscious during delivery, preserves airway reflexes, minimizes fetal drug exposure, and provides effective postoperative analgesia [1,2]. Hyperbaric bupivacaine 0.5% is a racemic mixture made of dextro and levo isomers is commonly used for spinal anesthesia in cesarean section because of its consistent and dense block characteristics. However, bupivacaine is cardiotoxic and also produces motor blockade of prolonged duration [3]. Levobupivacaine, the S-enantiomer of racemic Bupivacaine, is pharmacologically similar in terms of its anaesthetic properties but exhibits reduced affinity for cardiac sodium channels, rendering it less cardiotoxic [4,5]. This makes it a promising agent for regional anaesthesia in obstetric patients, where maternal and fetal safety are of paramount concern.

Hyperbaric formulations are widely used in current clinical practice because they provide more predictable spread within the cerebrospinal fluid (CSF), enhancing consistency of block height and duration in the subarachnoid space compared to isobaric solutions [6]. Many previous studies have used isobaric solutions limiting direct comparability [7,8,9]. There is a relative paucity of literature directly comparing hyperbaric levobupivacaine, and bupivacaine in caesarean section.

Our objective was to comparethe efficacy and safety of hyperbaric levobupivacaine to hyperbaric bupivacainewith respect to intraoperative quality of anesthesia and the postoperative recovery profile in an attempt to use them as an alternativein spinal anesthesia for cesarean section.

MATERIALS AND METHODS:

Study Design, Setting and Sample Size

This prospective, randomized, comparative, double-blind study was conducted in the Department of Anaesthesia at VIMSAR, Burla, a tertiary care teaching hospital at Samblpur, Odisha after obtaining approval from the Institutional Ethical Committee.

The sample size was calculated based on a previous study by Thakore et al. [10], considering the time to duration of analgesia for pain as the primary outcome variable. To detect a clinically significant difference in analgesic requirement with a projected effect size of an alpha error of 0.05, and a power of 80%, a sample size of 56 patients per group was determined.

Participants

The study included 112 parturients of ASA physical status II, aged between 18 and 40 years, gestational age >37 weeks, singletone, scheduled for elective lower segment cesarean section under spinal anaesthesia. Exclusion criteria included parturients with contraindications to spinal anaesthesia, known allergy to local anaesthetics, emergency cesarean sections, spinal deformities, objection to spinal technique, weight less than 50 kg and more than 80 kgs and height less than 150 cm or more than 170 cm.

Randomization and Group Allocation:

The parturients were randomly allocated into two groups of 56 each using a computer-generated randomization table. Allocation concealment was ensured using sealed opaque envelopes, which were opened only after the patient was shifted to the operating theatre.

- **Group B (n=56):** received 2 mL (10 mg) of 0.5% hyperbaric Bupivacaine intrathecally.
- **Group L (n=56):** received 2 mL (10 mg) of 0.5% hyperbaric Levobupivacaine intrathecally.

The details of the recruitment of the subjects are shown in a CONSORT diagram [Figure 1]. The study drug was prepared by an independent anaesthesiologist in a double-blind fashion who did not participate in observation or collection of data. Both the patient and the anaesthesiologist were blinded to the patient's group assignment and all recordings were performed by an anaesthesiologist, who was blinded to the randomization schedule.

Anaesthetic protocol and intervention

All patients underwent a thorough preoperative evaluation including detailed history, general and systemic examination, airway assessment, and spine assessment. Routine investigations included complete blood count (CBC), renal function tests (RFT), liver function tests (LFT), and serum electrolytes. Patients were instructed to score the intensity of the pain on Verbal Numerical Rating Scale VNRS (0 – 10) [No pain: 0, Mild pain: 1,2,3, Moderate pain: 4,5,6, Severe pain: 7,8,9, Worst Imaginable Pain: 10]. The procedure of subarachnoid block was explained. They were made familiar to the methodology for sensory and motor block assessment during the preanesthetic checkup. Patients were instructed to maintain fasting for six hours

prior to surgery and were premedicated with tablet ranitidine 150 mg PO the night before surgery along with 10 mg of intravenous Metaclopromide 1 hour prior to surgery.

On the day of surgery, intravenous access was secured in all patients, and standard monitors including non-invasive blood pressure, electrocardiogram, and pulse oximeter were attached. Baseline parameters were recorded. Intravenous Ringer lactate was infused at 10 mL/kg. and Inj. Ondansetron 4 mg IV administered slowly. The patients were then positioned in the left lateral posture. Under strict aseptic precautions, subarachnoid block was performed at the L3–L4 interspace using a 25G Quincke spinal needle. After confirming free flow of cerebrospinal fluid, the study drug was injected over a period of 10 seconds. Following injection, patients were positioned supine with left uterine displacement and supplemental oxygen at 4 L/min was provided via face mask till the delivery of neonate. After giving spinal anaesthesia vital parameters were noted after spinal anaesthesia (0min), 3 mins, 5 mins and then in every 5 minutes interval till end of surgery. Sensory block was assessed with help of blunt needle every 1 min. Motor block was assessed according to modified Bromage scale (0-able to lift extended leg, 1-just able to flex knee, 2-no knee movement and some movement at ankle, 3-complete lower limb paralysis). Surgery was started once loss of sensation of T6 level and Bromage scale 2 was established. Adverse events such as hypotension, bradycardia, chest discomfort, nausea, vomiting etc were recorded and managed. Intraoperative hypotension episodes (systolic blood pressure <100 mmHg or 20% decrease from baseline) were treated with intravenous fluids and/or ephedrine. Bradycardia (heart rate <50/min) was treated with 0.6 mg atropine given intravenously. Respiratory depression (respiratory rate <8/min or SpO2 <94%) was treated with oxygen supplementation or ventilatory support as needed. Following delivery, intravenous oxytocin 20 units diluted in 500 mL of normal saline was administered. Neonatal outcome was evaluated by the neonatologist at 1 min and 5 min using the APGAR scoring system. APGAR score of ≤7 at 5 min was taken as poor neonatal outcome. The need for neonatal resuscitation and intensive care unit (ICU) admission was considered. Surgeon's subjective evaluation of quality of anesthesia (numerical rating scale (NRS) 1–10 [>8 – excellent, 6–7 – good, 4–5 – fair, <3 – poor, 0 – unequivocal]) was obtained.

Post-operatively all parturients were monitored in PACU for 6 hours as per hospital protocol and then shifted to the ward when they meet the discharge criteria of transfer from PACU. Sedation, nausea, vomiting, and pruritus were noted up to 6 h postoperatively. Sedation was scored by Ramsay sedation score (Score 1: Patient is awake, anxious, agitated, or restless, Score 2: Patient is awake, cooperative, oriented, and tranquil (often considered ideal),Score 3: Patient is awake but responds only to commands, Score 4: Patient is asleep with a brisk response to a light glabellar tap or loud sound, Score 5: Patient is asleep with a sluggish response to a light glabellar tap or loud sound, Score 6: Patient is asleep with no response to stimuli). Postoperatively sensory block was tested every 10 minutes until it regresses up to L1 dermatome and motor block was tested every 20 minutes until full recovery (Bromage scale-0). Combination of Paracetamol 1000mg and tramadol 50 mg was given intravenously as rescue analgesic once they complain of mild but tolerable pain (VNRS ≥3). A subjective score of patient satisfaction for analgesia was recorded on a 10-point scale (numerical rating scale (NRS) 1–10 [>8 – excellent, 6–7 – good, 4–5 – fair, <3 – poor, 0 – unequivocal]).

Parameters studied

For sensory blockade evaluation, parameters assessed included Onset time of sensory block **(**Time from intrathecal injection to loss of pinprick sensation at the T10 dermatome), highest sensory level attained, time to achieve T6 sensory level, time to two-dermatome regression, duration of sensory block (time to regression to the L1 dermatome), and duration of analgesia (time from intrathecal drug administration to first requirement of analgesic when VNRS ≥3). For the evaluation of the motor blockade, parameters assessed included the onset of motor block (time to achieve Bromage grade 2), onset of complete motor block (time to achieve Bromage score 3), and duration of motor block (time from complete motor block to full recovery i,e Bromage score 0). Evaluation of hemodynamic parameters, neonatal outcome, surgeon's satisfaction, maternal satisfactions and adverse effects was also conducted. Urinary retention could not be assessed as our patients were catheterized till 12 h postoperatively.

Statistical Analysis

The statistical analysis was done using Statistical Package for Social Science evaluation (SPSS) version 23. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi-square test or Fisher's exact test as appropriate, $p<0.05$ was considered statistically significant.

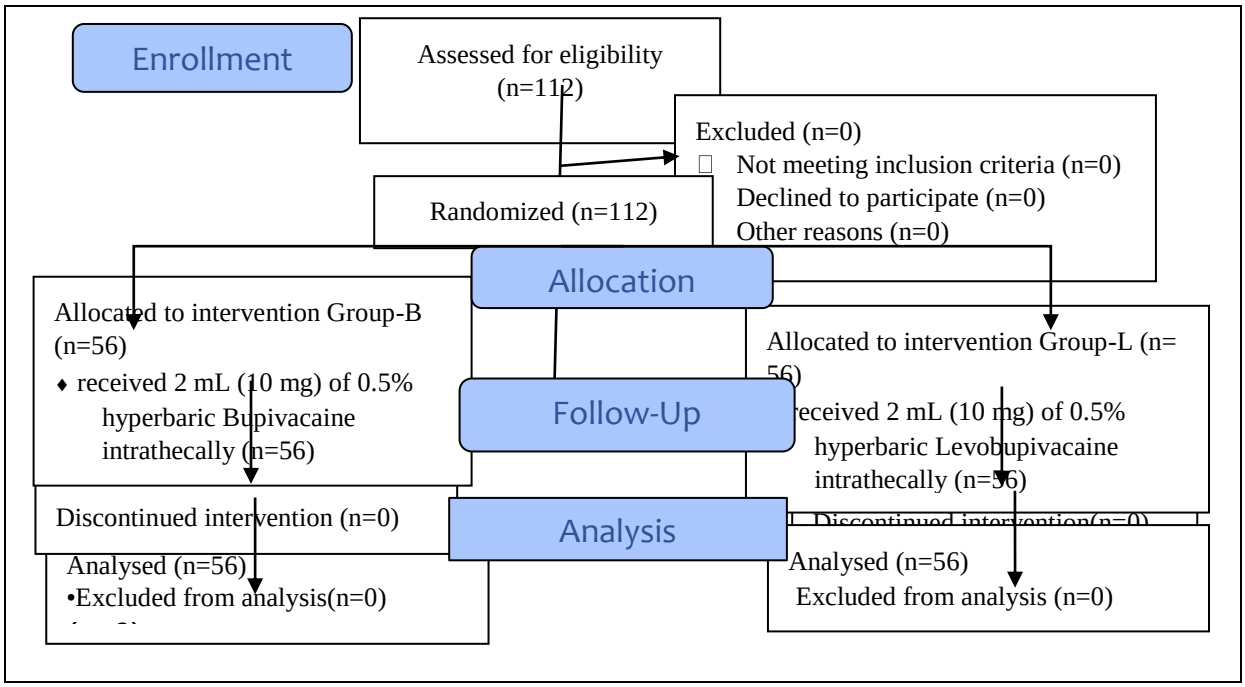

Fig. 1. Consort Diagram Showing the Flow of Participants through Each Stage of the Trial

RESULTS

A total of 112 parturients were recruited for the study and all were completed the study without any dropout [Figure 1]. The two study groups were comparable with respect to baseline demographic, anthropometric, and obstetric characteristics. There were no statistically significant differences among the groups in terms of age, weight, height, body mass index, or gestational age ($p > 0.05$). This ensures that baseline characteristics were evenly distributed, and the groups were homogenous for analysis. [Table 1].

Table 1: Demographic and Baseline Parameters

Parameters	Group B(n=56)	Group L(n=56)	p-value
Age, years	25.57 ± 3.82	25.63 ± 3.65	0.94
Height, cm	156.20 ± 7.14	157.08 ± 6.47	0.92
Weight, kg	67.37 ± 9.47	68.04 ± 10.00	0.73
BMI (Kg/m2)	23.26 ± 2.31	23.91 ± 2.69	0.93
Gestational age (weeks)	38.50 ± 1.12	38.15 ± 1.48	0.43
Duration Of surgery(mins)	50.83 ± 14.3	52.57 ± 13.7	0.68

The mean time of onset of sensory block to T10 in Group B was 2.39±0.30 minutes, in Group L was 2.60±0.71 minutes which is statistically not significant ($p= 0.29$). Mean time to achieve sensory blockade till T6 Level was also comparable in both the groups (group B-3.46±0.52 mins vs group L-3.98±0.81 mins $p=0.18$,). Time of regression of sensory block till L1 Level was faster in group L (group B-153.96±12.37 mins vs group L-142.06±11.64 mins, $p=0.001$). Maximum height of sensory blockade achieved in both the groups was T6-T4. In group B, 44 parturients and in group L, 39 parturients achieved maximum height of T4 ($p=0.21$). (Table 2).

The significant difference ($p<0.05$) was found in time to achieve motor blockade till Bromagen score 3 [group B (5.42±1.01 mins) vs group L (7.01±1.38 mins)] and time to full

recovery of motor blockade [group B (138.23±11.26 mins)] (Table 3). (146.48±12.24 mins) vs group L

Table 2. Sensory Block and Analgesia Characteristics among the Study Groups

Parameters	Group B(n=56)	Group L(n=56)	p-value
Onset of sensory blockade (loss of sensation at T10 level) (mins)	2.39±0.30	2.60±0.71	0.29
Time to reach T6 sensory level (mins)	3.46±0.52	3.98±0.81	0.18
Maximum height of sensory level (T4/T6)	44/12	39/17	0.21
Time to two-dermatome regression	86.46±2.86	80.38±3.06	0.034*
Duration of sensory block (regression to L1 level) (mins)	153.96±12.37	142.06±11.64	0.001*
Time to 1st Rescue analgesia (mins)	137.21±5.16	130.16±8.06	0.037*

Table 3. Motor Block Characteristics among the Study Groups

Parameters	Group B(n=56)	Group L(n=56)	p-value
Onset of motor blockade time to achieve Bromage grade 2) (mins)	3.24±0.62	4.70±0.65	<0.001*
onset of complete motor block (time to achieve Bromage score 3) (mins)	5.42±1.01	7.01±1.38	<0.001*
Duration of motor block (full recovery i,e Bromage score 0) (min)	146.48±12.24	138.23±11.26	0.012*

The incidence of hypotension (group B-55.35%, vs group L-33.92%, P=0.002), nausea and vomiting (group B-14.28%, vs group L-3.57%, P=0.012), were significant less in group L in compared to group B. The neonatal outcome was comparable in both the group. (Table 4).

Mean HR (p = 0.67) and mean arterial pressure (MAP) (p = 0.49) was comparable among the two groups at baseline However, statistically significant differences were observed at almost all intraoperative time intervals from 5 minutes onwards until the end of surgery (p < 0.05). [Figure 2, 3].

Table 4: Neonatal Outcome and Maternal Effects among the Study Groups

Parameters		Group B (n=56)	Group L(n=56)	p-value
Neonatal outcome				
APGAR Score	0 min	8.1±0.30	8.14±0.34	0.69
	5 mins	8.97±0.18	9.0±0.0	0.78
Maternal effects				
Hypotension		31(55.35%)	19(33.92%)	0.002*
Bradycardia		0	0	---
Tachycardia		10(17.85%)	2(3.57%)	0.001*
SpO2 fall		0	0	---
Nausea and vomiting		8(14.28%)	2(3.57%)	0.012*
Ramsay sedation score - 2		56 (100%)	56 (100%)	---

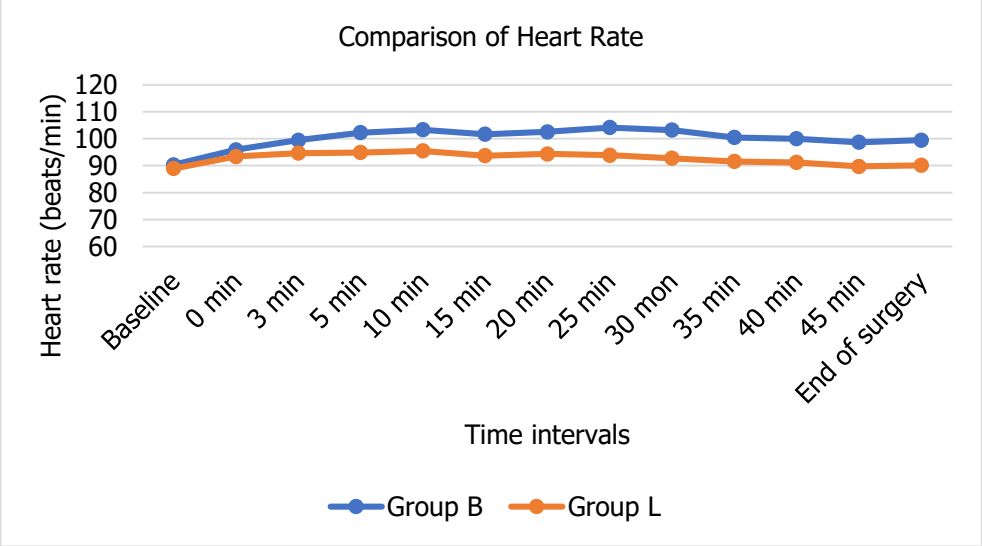

Figure 2: Comparison of Intraoperative Mean Heart Rate between Study Groups

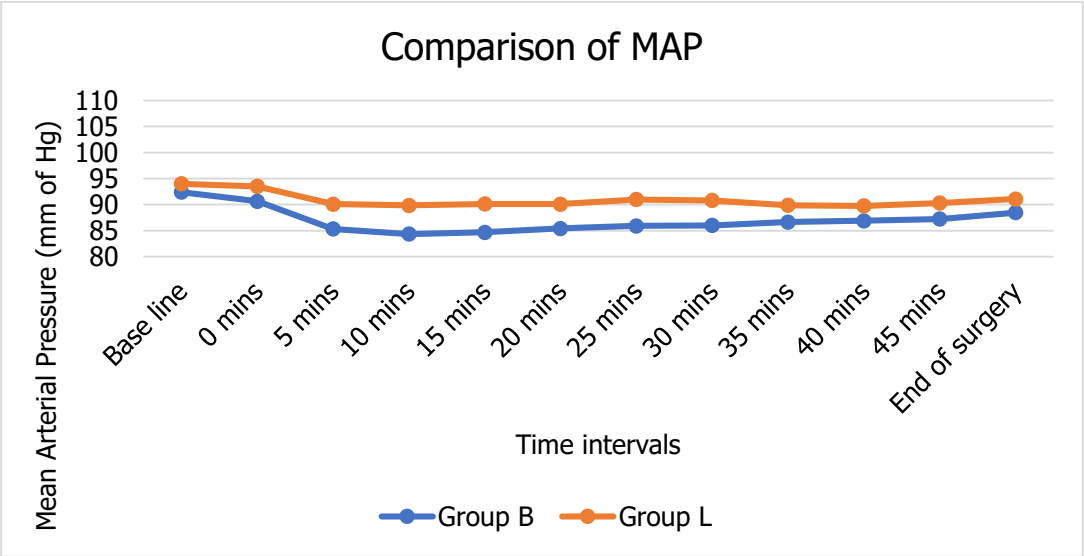

Figure 3: Comparison of Intraoperative Mean Arterial Pressure between Study Groups

DISCUSSION

For cesarean section, adequate sensory and motor blockade and better hemodynamic stability with minimum adverse effect is necessary. Hypotension and bradycardia are the most common complications of sub arachnoid block and are even more serious in caesarean section because of aorta-caval compression by the gravid uterus. [2,11] Early mobilization following caesarean section promotes emotional bonding with the child, adequate breast feeding, reducing the risk of developing deep vein thrombosis and pulmonary thromboembolism [12] Levobupivacaine being enantiomer of bupivacaine with high potency has been approved for intrathecal use. At low concentration, levobupivacaine is favourable for ambulatory surgery as it produces a differential neuraxial block with preservation of motor function [4]

In this study, both the groups were comparable in terms of demographic variables like age, weight, height, and were statistically non-significant. In present study, sensory block level required for CS was achieved adequately in both groups. The time to onset of sensory blockade was slightly less in group B as compared to group L (group B-2.39±0.30 mins vs group L-2.60±0.71 mins,) indicating early onset with bupivacaine but statistically not significant (p-0.29). This finding is similar to those of previous studies [13,14,15,16]. Contrary to our results Babu et al, Duggal et al, and Madanmohan et al, recorded onset time of bupivacaine faster than levobupivacaine [17,18,19]. However, all the studies concluded that characteristic of

sensory block in both bupivacaine and levobupivacaine are nearly comparable. The time to reach T6 sensory height, was also less in group B (group B-3.46±0.52 mins vs group L-3.98±0.81 mins,) but statistically not significant (p-0.18). Maximum height of sensory blockade in the present study was T4 in the majority of the cases in both the groups (T4/T6: group B-44/12 vs group L-39/17, p-0.21) which was similar to that observed by previous studies [13-15]. Babu et al, Duggal et al, and Madanmohan et al, reported this height to be T6 with levobupivacaine and T4 with bupivacaine [17-19] In the present study, time to regression to L1 dermatome was less with levobupivacaine (142.06±11.64 mins) as compared to bupivacaine (153.96±12.37 mins) (p-<0.001). Though variation in duration was observed, but majority studies observed shorter regression time with Levobupivacaine than bupivacaine [8,9,10,13,14]. In contrast, Kumar et al, Ayesha Goel et al., observed longer time to regression with Levobupivacaine [20,21].

Studies comparing the duration of effective analgesia with levobupivacaine and bupivacaine have yielded conflicting results. Guler et al. [22] and Gautier et al. [16] reported that the duration of effective analgesia is shorter with levobupivacaine compared with bupivacaine. On the other hand, Hakan Erbay et al. [23] reported a longer duration of analgesia with levobupivacaine. Fattorni et al. [24] found no difference between the two. Our results showed the duration of effective analgesia is significantly shorter with levobupivacaine compared with bupivacaine (group B-137.21±5.16 mins vs group L-130.16±8.06 mins, p-0.037). This wide variability in results may be attributed to the difference in the dose or baricity of the drugs used, and the position of the parturient during drug administration.

Time to onset of motor blockade were significantly lesser in group B in compared to Group L. Sa Guler et al., [22](same 6) Similarly, in our study, the duration of motor block was significantly shorter with levobupivacaine than with bupivacaine. (group B-146.48±12.24 mins vs group L-138.23±11.26 mins, p=0.012), resulted in quicker motor recovery, and time to walk unaided. This finding corroborates those of Guler et al., Thakore et al., and Şahin et al. [22,10,25]. Bupivacaine exhibited a significantly faster onset of motor block, possibly due to its higher lipid solubility and affinity for neural sodium channels [3]. Pharmacokinetics of levobupivacaine shows that, it is metabolised by CYP2A2 in liver and has higher clearance rate (28-37 mgkg-1min-1) [9] Difference in potency ratio of levobupivacaine/ bupivacaine as reported by various authors range from 0.75 to 0.87. ED95 dose of levobupivacaine for CS in SA is reported to be 12.56 mg [19]. We administered 10 mg of levobupivacaine which was less than ED95 for CS. Levobupivacaine is known to have lower affinity towards Aα fibers (somatic motor fibers) than bupivacaine, which may result in lesser motor block [20]. All these factors can result in short duration of motor block as well as sensory block in patients receiving levobupivacaine.

The study compared the mean arterial pressures (MAP) and mean HR (Heart Rate), among study members in groups B and L at various time points, highlighting significant differences in MAP and HR between the two groups from 5 mins of spinal anaesthesia (P-<0.05). Levobupivacaine demonstrated better hemodynamic stability during surgery. The mean arterial pressures (MAP) were significantly higher and more stable in Group L compared to Group B. This is in line with the findings of recent trials suggesting that Levobupivacaine causes less sympathetic blockade and hence fewer hemodynamic fluctuations.[4,5] Stable maternal hemodynamics are particularly important in cesarean sections to ensure consistent uteroplacental perfusion and fetal oxygenation.

Moreover, the adverse effect profile was clearly more favorable in the Levobupivacaine group. The Bupivacaine group exhibited higher incidences of hypotension, and nausea/vomiting. In our study, the incidence of hypotension was significantly less with the use of levobupivacaine than with bupivacaine (55% vs. 33%). This finding is similar to that of previous studies who found a incidence of hypotension with levobupivacaine significantly less than bupivacaine [7,8,10,13]. These findings are consistent with previous literature that associates Bupivacaine with more pronounced autonomic blockade and related side effects. Bupivacaine, being a more potent local anesthetic than levobupivacaine [16], may cause greater sympathetic blockade, resulting in a greater incidence of hypotension. Respiratory parameters remained within normal limits in all patients. All the patients were tranquil and cooperative as

assessed by Ramsay sedation score. Levobupivacaine's reduced cardiotoxicity and neurotoxicity make it a safer alternative, especially in high-risk obstetric patients.[4,5]

In our study we noted that the mean APGAR score at 0 min and 5 min were about 9 in both the groups and it showed that study drug had no adverse effect in neonate. The results of our study were in consonance with the study by Kamaliya et al., he found in his study that intrathecal bupivacaine, levobupivacaine and fentanyl used for LSCS had no adverse effect as evaluated by APGAR and the pH of arteries in umbilical cord [8].

Surgeons and patients rated the quality of anesthesia as "excellent" for those who received hyperbaric bupivacaine. There was a subtle difference in patient satisfaction and surgeons' rating in the levobupivacaine as compared to hyperbaric bupivacaine group. However, all had rated anesthesia as either excellent or good.

Limitations of the study

The study was concluded with administration of the first dose of rescue analgesic in the post-operative period, hence the total analgesic consumption in the post-operative period could not be studied in both the groups. Unable to objectively quantify and evaluate postoperative pain which being a subjective experience can be a major limiting factor in comparing and estimating the effectiveness of various modalities of treatment.

CONCLUSION

This study compared spinal anesthesia with hyperbaric bupivacaine and hyperbaric levobupivacaine in cesarean sections. While both medications provided effective anesthesia, levobupivacaine emerged as a favorable alternative due to its safety profile. Bupivacaine produced a longer duration of anaesthesia. While this prolonged effect may be beneficial in some surgical contexts, it can delay early ambulation and increase the risk of urinary retention which is less desirable in obstetric patients aiming for early maternal-infant bonding and mobility. The shorter motor block duration seen with Levobupivacaine may help in early ambulation, supports faster postoperative recovery. This facilitates early breastfeeding and bonding with the newborn, aligning with modern obstetric goals for enhanced maternal satisfaction and reduced hospital stays. This makes levobupivacaine as a first option, especially for patients at higher risk of cardiovascular complications. Overall, the study suggests that hyperbaric levobupivacaine offers comparable efficacy with a potentially better hemodynamic profile compared to hyperbaric bupivacaine for spinal anesthesia in Cesarean section.

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