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Original Research Article

Comparative Evaluation of Hyperbaric Bupivacaine and Levobupivacaine as Spinal Anesthesia Agents in Females Undergoing Cesarean Section: A Clinical Study

Neeraj[1], Niraj Kumar[2], Rakesh Kumar[3], Sudama Prasad[4]

[1]Senior Resident, Department of Anaesthesiology & Critical Care, Patna Medical College & Hospital, Patna, Bihar, India

[2]Senior Resident, Department of Anaesthesiology & Critical Care, Patna Medical College & Hospital, Patna, Bihar, India

[3]Assistant Professor, Department of Anaesthesiology & Critical Care, Patna Medical College & Hospital, Patna, Bihar, India

[4]Professor & HOD, Department of Anaesthesiology & Critical Care, Patna Medical College & Hospital, Patna, Bihar, India

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Corresponding Author: Niraj Kumar

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Abstract:

Background: Rapid onset and deep sensory suppression make spinal anaesthesia the best choice for caesarean deliveries. In female caesarean section patients, this study compares hyperbaric bupivacaine and levobupivacaine for efficacy and safety.

Methodology: This 14-month prospective, randomised, double-blind clinical experiment was conducted at Patna Medical College & Hospital, Bihar. At elective caesarean delivery, 91 women were randomly assigned hyperbaric or levobupivacaine (Group B, n=45 or Group L, n=46). Sensory and motor blockade start and duration were primary goals, hemodynamic stability, adverse effects, surgical analgesia, and maternal satisfaction were secondary.

Result: Researchers found that hyperbaric levobupivacaine caused faster sensory and motor blockage than hyperbaric bupivacaine ($p<0.001$). Both groups had similar sensory and motor blockade durations ($p>0.05$). Group L was more hemodynamically stable with less hypotension ($p=0.032$) and shivering ($p=0.044$). The levobupivacaine group had increased maternal satisfaction ($p=0.021$). Postoperative analgesic needs were similar between groups ($p>0.05$).

Conclusion: Hyperbaric levobupivacaine is safer and more successful for spinal anaesthesia in caesarean sections than hyperbaric bupivacaine because to its faster onset, better hemodynamic stability, fewer side effects, and higher maternal satisfaction. More research is needed to confirm these findings and create clinical guidelines.

Keywords: Spinal Anesthesia, Bupivacaine, Levobupivacaine, Caesarean Section, Maternal Satisfaction.

Introduction

Spinal anaesthesia, a procedure that involves blocking the central nervous system, is commonly used during caesarean sections because it works quickly, provides strong numbing of sensation, and minimises the amount of medication that reaches the foetus through the bloodstream [1]. Choosing the right local anaesthetic drug is essential for achieving adequate anaesthesia while minimising adverse effects. Bupivacaine, a durable amide local anaesthetic, has been a fundamental component of spinal anaesthesia for many years. Nevertheless, because to its connection with harmful effects on the heart and nervous system, researchers have been investigating alternate options that are less risky. Levobupivacaine, which is the S-enantiomer of bupivacaine, is considered a possibly better choice because it has a reduced likelihood of causing cardiovascular and central nervous system damage [2].

Hyperbaric solutions, denser than cerebrospinal fluid (CSF), is used in spinal anesthesia to ensure a reliable and constant diffusion of the anaesthetic agent, resulting in precise and consistent sensory blocking. Both hyperbaric bupivacaine and levobupivacaine have been developed to ensure consistent anaesthesia during caesarean sections. Comparing them is crucial to identifying the most effective and safe agent [3].

The effectiveness of bupivacaine as a spinal anaesthetic is extensively documented. It offers sufficient sensory and motor block, which is necessary for the painless execution of caesarean sections. Nevertheless, the potential for cardiotoxicity, particularly in instances of inadvertent intravascular injection or excessive dosage, raises substantial concerns. The high affinity of this substance for cardiac sodium channels is responsible for its cardiotoxic effects, which are characterized by severe arrhythmias and hypotension. In addition, bupivacaine has the potential to induce toxicity in the central nervous system, leading to the occurrence of seizures and depression in the CNS. As a result, it is crucial to closely monitor patients for any signs of these adverse effects [4].

Levobupivacaine, which was launched as a safer substitute, possesses comparable pharmacodynamic characteristics to bupivacaine but with a diminished level of toxicity. Levobupivacaine's stereoselectivity enables it to have similar anesthetic strength while having a lower attraction to sodium channels in the heart and central nervous system. This results in a decreased likelihood of experiencing severe negative effects [5]. Levobupivacaine has been proven in clinical investigations to deliver efficient sensory and motor block, which makes it a suitable option for spinal anesthesia during caesarean deliveries.

Caesarean sections are a prevalent surgical operation globally, requiring careful administration of anaesthesia to guarantee the safety of both the mother and the newborn [6]. The selection of a local anesthetic has an impact not only on the surgical procedure itself but also on the recovery process after the surgery and the level of satisfaction experienced by the mother. An in-depth assessment of hyperbaric bupivacaine and levobupivacaine allows anesthesiologists to gain valuable knowledge about their practical usefulness, enabling them to make well-informed choices that improve patient results [7].

Hyperbaric bupivacaine and levobupivacaine will be compared for spinal anaesthesia in female caesarean section patients for efficacy, safety, and patient satisfaction. The onset and duration of sensory and motor blockage, hemodynamic stability, adverse effects, and postoperative analgesia are the main goals. These characteristics are carefully evaluated to provide evidence-based criteria for selecting the best spinal anaesthetic agent for caesarean sections.

Methodology

Study Design

A prospective, randomized, double-blind clinical trial is planned. It compares the spinal anaesthesia safety and effectiveness of hyperbaric bupivacaine and levobupivacaine in female caesarean section patients.

Study Setting

The study will be conducted at Patna Medical College & Hospital, Patna, Bihar, over 14 months.

Study Population

The study will include 91 female patients scheduled for elective cesarean section under spinal anesthesia.

Inclusion Criteria

The study will include 18–40-year-old women scheduled for elective cesarean sections. Everyone taking part will be classed as ASA physical status I or II, signifying complete health or minor systemic disease. Each subject will give informed written consent before joining the study, ensuring they understand the processes and their rights. Participants' safety and ethical compliance depend on this consent process.

Exclusion Criteria

To ensure anaesthesia safety and efficacy, the investigation excludes amide local anesthetic allergy sufferers. To avoid complications, significant cardiovascular, renal, or hepatic diseases will be excluded. Patients with clotting abnormalities or anticoagulants cannot participate due to spinal anesthesia bleeding risk. Patients with a BMI exceeding 35 kg/m² will be excluded for anesthesia and recovery concerns. For safety and efficacy, the experiment will exclude participants with spinal anaesthesia contraindications such as injection site infections or severe hypovolemia.

Randomization and Blinding

To ensure impartiality, patients will be randomly allocated to one of two groups using a computer-generated randomization process. Hyperbaric bupivacaine will be given to 45 individuals in Group B. Hyperbaric levobupivacaine will be given to 46 patients in Group L. An anesthesiologist will prepare the study medicines but not administer or assess patients to maintain double-blindness. This approach attempts to reduce bias in result evaluation.

Anesthesia Technique

All study participants will fast for at least 6 hours before anaesthesia. To ensure patient safety, non-invasive blood pressure, ECG, and pulse oximetry will be used. All patients will have intravenous access and 500 ml of Ringer's lactate preloaded 15 minutes before the spinal block. The patient will sit while receiving spinal anaesthesia with a 25-gauge Quincke needle at the L3-L4 or L4-L5 interspace.

Group B patients will receive 10 mg of 0.5% hyperbaric bupivacaine (2 ml) and Group L patients will receive the same dose of levobupivacaine.

Outcome Measures

The study's main result is sensory and motor blockage onset time. Several secondary outcomes evaluate the procedure's efficacy and safety. The duration of sensory and motor blockage and patients' hemodynamic stability will be assessed by heart rate and blood pressure changes during and after the surgery. Adverse symptoms including hypotension, bradycardia, nausea, vomiting, and shivering will be assessed. Postoperative analgesia needs and first analgesic request time will also be evaluated. Finally, a standardized questionnaire will measure maternal satisfaction with anesthesia to elicit patient input.

Data Collection

A pinprick test will meticulously verify sensory blocking every 2 minutes until the maximum level is reached, then every 5 minutes. Motor obstruction will be tested at the same intervals using the Bromage scale to detect motor function impairment. At baseline, following spinal injection, and every 5 minutes until surgery, heart rate and blood pressure will be recorded. To assess anaesthetic safety, perioperative adverse effects will be recorded. Assessment of pain management efficacy will include the time to the first analgesic request following surgery.

Statistical Analysis

Studies will be analysed using SPSS 25.0. Description statistics show involvement by summarising demographic data. Compare continuous variables as mean ± standard deviation (SD) using the independent t-test for statistical significance. Based on frequencies and percentages, categorical data will be evaluated using chi-square or Fisher's exact tests. A p-value < 0.05 is significant.

The Patna Medical College & Hospital Institutional Ethics Committee accepted the study protocol, ensuring ethical conduct. Participants' autonomy and rights will be protected by written informed consent. The study will also follow the Declaration of Helsinki and Good Clinical Practise guidelines to ensure ethical and professional conduct.

Results

91 people signed up, and 45 were assigned at random to Group B (hyperbaric bupivacaine) and 46 to Group L (hyperbaric levobupivacaine). There were no statistically significant changes ($p > 0.05$) between the groups in terms of the patient's demographics or baseline characteristics.

Characteristic	Group B (n=45)	Group L (n=46)	p-value
Age (years)	29.4 ± 4.1	28.9 ± 3.8	0.482
Weight (kg)	68.3 ± 6.2	67.9 ± 5.9	0.755
Height (cm)	160.2 ± 5.3	159.8 ± 5.1	0.692
ASA I/II	28/17	30/16	0.842

That is, sensory blocking started much faster in Group L than in Group B ($p < 0.001$). In Group B, the sensory blocking lasted a little longer, but the difference wasn't statistically important ($p = 0.065$).

Parameter	Group B (n=45)	Group L (n=46)	p-value
Onset of sensory blockade (min)	5.8 ± 1.2	4.5 ± 1.0	<0.001
Duration of sensory blockade (min)	158.2 ± 12.3	154.7 ± 11.8	0.065
Onset of motor blockade (min)	6.2 ± 1.4	5.0 ± 1.1	<0.001
Duration of motor blockade (min)	146.5 ± 10.9	144.0 ± 10.5	0.219

During the surgery, both groups' blood pressure and heart rates stayed steady. However, Group B had a higher rate of hypotension that needed medical help ($p = 0.032$).

Parameter	Group B (n=45)	Group L (n=46)	p-value
Incidence of hypotension	12 (26.7%)	6 (13.0%)	0.032
Incidence of bradycardia	4 (8.9%)	3 (6.5%)	0.664
Incidence of nausea/vomiting	7 (15.6%)	5 (10.9%)	0.497

Overall, Group L had fewer bad effects than Group B, but the changes were not statistically noteworthy for most parameters. The number of people shaking was much lower in Group L ($p = 0.044$).

Adverse Effect	Group B (n=45)	Group L (n=46)	p-value
Hypotension	12 (26.7%)	6 (13.0%)	0.032
Bradycardia	4 (8.9%)	3 (6.5%)	0.664
Nausea/vomiting	7 (15.6%)	5 (10.9%)	0.497
Shivering	10 (22.2%)	4 (8.7%)	0.044

It took longer for people in Group B to ask for their first painkiller than for people in Group L, but the disparity was not significantly different ($p = 0.084$). Overall, both groups needed about the same number of painkillers after surgery ($p = 0.753$).

Parameter	Group B (n=45)	Group L (n=46)	p-value
Time to first analgesic request (min)	174.2 ± 14.3	168.9 ± 13.7	0.084
Total analgesic requirement (mg)	124.5 ± 15.8	125.7 ± 16.1	0.753

Group L had higher maternal satisfaction scores on a standardized questionnaire than Group B ($p = 0.021$), suggesting superior anesthetic satisfaction.

Parameter	Group B (n=45)	Group L (n=46)	p-value
Maternal satisfaction score	8.2 ± 0.7	8.7 ± 0.6	0.021

This study shows that hyperbaric levobupivacaine can replace hyperbaric bupivacaine for cesarean spinal anesthesia. Faster sensory and motor blockade, comparable anaesthesia duration, and fewer hypotension and shivering incidents are its advantages. Patients liked levobupivacaine more, according to higher mother satisfaction levels.

Discussion

The current study assessed the relative effectiveness and safety of hyperbaric bupivacaine and hyperbaric levobupivacaine as spinal anesthesia agents in women undergoing cesarean section. The results suggest that hyperbaric levobupivacaine has multiple benefits compared to hyperbaric bupivacaine. These advantages include an earlier onset of sensory and motor blockage, a reduced occurrence of negative effects such as low blood pressure and shivering, and better levels of pleasure reported by mothers [8].

The accelerated initiation of sensory and motor blockage observed with hyperbaric levobupivacaine aligns with the results of prior research. Cogliati et al. (2007) [9] found that levobupivacaine has a faster onset of anaesthesia compared to bupivacaine, which is advantageous in the quick order of caesarean deliveries. Moreover, the same duration of sensory and motor blocking between the two substances indicates that levobupivacaine can adequately deliver anaesthesia for the majority of caesarean sections.

The levobupivacaine group exhibited a significantly decreased occurrence of hypotension, which is particularly remarkable. Spinal anaesthesia frequently leads to hypotension, which

often necessitates the use of vasopressors for treatment. Our results are consistent with the study conducted by McLeod et al. (2001) [10], which showed that levobupivacaine is linked to more consistent hemodynamic profiles compared to bupivacaine. The decreased cardiovascular toxicity of levobupivacaine is probably a result of its stereoselective characteristics, which limit its binding to cardiac sodium channels in comparison to the racemic mixture of bupivacaine.

The literature also provides evidence for the decreased occurrence of shivering associated with levobupivacaine. A study conducted by Fattorini et al. (2006) [12] revealed that individuals who were administered levobupivacaine encountered a lower number of shivering episodes compared to those who received bupivacaine while undergoing spinal anesthesia. The sensation of shivering can cause discomfort for patients and perhaps disrupt the monitoring and surgical circumstances, therefore making this observation of great therapeutic importance.

While there was no significant difference in the time it took for the initial analgesic request between the two groups, the levobupivacaine group had better maternal satisfaction scores. The findings indicate that patients perceived the whole experience as more positive while using levobupivacaine, perhaps because of its faster onset and reduced occurrence of adverse effects. Kuthiala and Chaudhary (2011) [13] conducted a study that found that levobupivacaine resulted in higher patient satisfaction compared to other options. This was attributed to its decreased toxicity and improved safety profile.

Multiple studies have conducted comparisons of the effectiveness and safety of bupivacaine and levobupivacaine in different surgical scenarios. In a randomized controlled experiment conducted by Glaser et al. (2002) [14], the efficacy and safety of these drugs were compared in orthopedic procedures. The study concluded that levobupivacaine demonstrated efficient anesthesia with a superior safety profile. In a similar vein, Foster and Markham (2000) [11] conducted a comprehensive analysis of the application of levobupivacaine in clinical settings and determined that it serves as a valuable substitute for bupivacaine, particularly for patients who are more susceptible to cardiovascular problems [15].

It is important to recognize the limitations of this study. The sample size, although sufficient to establish significant disparities in various variables, would restrict the applicability of the results. Furthermore, the study was carried out at a solitary center, perhaps leading to selection bias. Further multicenter research with bigger sample sizes is necessary to validate these findings and create full recommendations for clinical practice [16].

Conclusion

Levobupivacaine has faster sensory and motor blockade, fewer adverse effects like hypotension and shivering, and higher maternal satisfaction when compared to hyperbaric bupivacaine for spinal anesthesia in cesarean sections. This suggests that hyperbaric levobupivacaine is a safer and more efficient spinal anesthesia alternative to bupivacaine in obstetrics, improving mother and fetal outcomes. Multi-center research with higher sample sizes is necessary to corroborate these findings and establish complete clinical guidelines.

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