Vol. 4 No. 12 (2023): December 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i12.916
Original article

A COMPARATIVE ANALYSIS OF HYPERBARIC BUPIVACAINE AND LEVOBUPIVACAINE FOR SPINAL ANAESTHESIA IN CAESAREAN SECTIONS: A CLINICAL STUDY.

Soubhagya Kumar Das[a], Nagendra Kumar Rajsamant[b], Chittaranjan Thatei[c], Satyajit Jena[d,]*
[a]Assistant Professor, Department of Anaesthesiology, SCB Medical College and Hospital, Cuttack, Odisha, India
[b]Assistant Professor, Department of Surgery, SCB Medical College, Cuttack, Odisha, India,
[c]Assistant Professor, Department of CTVS, SCB Medical College, Cuttack, Odisha, India,
[d]Assistant Professor, Department of Obstetrics and Gynaecology, SCB Medical College, Cuttack, Odisha, India

ABSTRACT

Introduction:

Spinal anesthesia for cesarean sections often involves the use of various local anesthetics. The research aimed to conduct a comparative study on the effects of intrathecal levobupivacaine and hyperbaric bupivacaine concerning sensory and motor blocks, hemodynamics, adverse effects, and recovery profiles.

Methods:

A prospective observational study was conducted on 100 in-patients undergoing elective cesarean sections, excluding those with specific contraindications at SCB Medical College and Hospital in Cuttack, Odisha, India. Parameters including the (analgesic effect) sensory block and the (muscle paralysis) motor block, hemodynamic responses, and adverse effects, were observed and noted. Statistical analysis included descriptive statistics and parametric tests.

Results:

Onset times for sensory and motor blocks were significantly different between the groups ($p < 0.001$). Levobupivacaine exhibited delayed onset compared to hyperbaric bupivacaine. Duration of sensory and motor blocks was significantly shorter with levobupivacaine ($p < 0.001$). Levobupivacaine demonstrated fewer incidences of bradycardia and hypotension compared to hyperbaric bupivacaine. Incidences of other adverse effects were similar between the groups.

Conclusion:

The comparative analysis highlights the distinct characteristics of intrathecal levobupivacaine and hyperbaric bupivacaine in spinal anesthesia for lower-segment cesarean sections. Levobupivacaine demonstrated delayed onset of sensory block, potentially superior hemodynamic stability, and significantly lower occurrences of bradycardia.

Recommendations:

Based on the observed outcomes, it is recommended that further comprehensive studies with larger sample sizes be conducted to validate the present findings. Extensive investigations are required to evaluate the long-term effects and rare adverse events associated with both agents. Additionally, multi-center trials could provide more robust evidence and enhance the generalizability of the results, aiding in the development of evidence-based guidelines for anesthetic choices in obstetric practice.

Keywords: Intrathecal Levobupivacaine, Hyperbaric Bupivacaine, Hemodynamic, Sensory Blocks, Motor Blocks, Bradycardia
Submitted: 2023-12-11 Accepted: 2023-12-11

Corresponding Author: *Satyajit Jena[d,*]Assistant Professor, Department of Obstetrics and Gynaecology, SCB Medical College, Cuttack, Odisha, India,*
Email: drbapi@gmail.com

INTRODUCTION

"Spinal anesthesia" is a type of regional anesthesia that involves the injection of anesthetic medication into the space around the spinal cord. This procedure numbs a larger area of the body, typically from the waist down, providing pain relief during surgical procedures, including cesarean sections [1]. It blocks the transmission of nerve impulses, temporarily preventing sensation in the lower part of the body while allowing the patient to remain conscious during the surgery [1]. This method offers advantages such as effective pain relief, rapid onset of action, reduced risk compared to general anesthesia, better monitoring during surgery, and precise dosage control for optimal pain management and recovery [2]. Contemporary obstetric anesthesia aims to achieve proper pain relief and muscle relaxation, minimizing adverse effects on both the mother and the fetus during Caesarean sections [3].

The utilization of bupivacaine for this purpose has gained popularity in recent times [2]. Currently, the predominant choice for "obstetric anesthesia" is "hyperbaric bupivacaine" 0.5%, which is an amino-based local anesthetic. This drug is frequently administered in an 8% glucose solution. Compared to "human cerebrospinal fluid" (CSF), bupivacaine demonstrates hyperbaric properties [2, 3]. Isobaric solutions demonstrate a lower incidence of cardiac complications compared to hyperbaric solutions, as suggested by studies [4]. Therefore, the differences observed in the sensory block and the motor block between the two groups in the study cannot solely be attributed to the difference in baricity [5].

"Levobupivacaine", an enantiomer of bupivacaine, has emerged as a favorable choice in regional anesthesia due to its extended duration of action and reduced potential for cardiac toxicity [5]. Its enhanced safety profile is notable, particularly in reducing cardiotoxic effects when compared to racemic bupivacaine [6]. This characteristic makes it a preferred option for managing regional anesthesia, contributing to better patient outcomes. With its reduced risk of central nervous system toxicity, Levobupivacaine proves advantageous, especially in spinal anesthesia procedures, where a balanced blockade is desired without undue risk to the CNS [6]. Moreover, the use of Levobupivacaine in "obstetric anesthesia" provides an improved safety margin for both the mother and the fetus due to its minimized cardiac and CNS effects, promoting a safer delivery process. The stable hemodynamic responses observed post-Levobupivacaine administration are crucial, ensuring steadier blood pressure and heart rate, which is beneficial for patients undergoing surgery [5, 6].

This randomized investigation aims to assess the impact of levobupivacaine on block quality and side effects, particularly hypotension, in comparison to hyperbaric bupivacaine during spinal anesthesia for cesarean sections. The study's objective is to evaluate and compare the clinical and medical effects, including sensory and motor block characteristics, cardiovascular reaction responses, and Apgar score in cesarean sections.

MATERIAL AND METHODS

Study Design:

This study employs a prospective observational design to assess the effects of intrathecal levobupivacaine and hyperbaric bupivacaine in spinal anesthesia for lower-segment cesarean sections.

Study Settings:

The study was conducted at SCB Medical College, Cuttack, Odisha, India, specifically focusing on patients scheduled for elective lower-segment cesarean section.

Duration of study:

The study was conducted over one year (July 2021 to March 2022)

Participants:

Participants comprise 100 in-patients from both genders.

Inclusion criteria:

Participants having ASA (American Society of Anesthesiologists) I and II status, participants who were willing to engage in the study, and subjects who were required to have elective LSCS were the inclusion criteria for the research.

Exclusion criteria:

Patients with restrictions to spinal anesthesia, weight over 95 kg, height less than 140 cm or more than 170cm, systemic diseases, and expecting females with fetal abnormalities, "placenta previa" were excluded from the research.

Ethical considerations:

The study design was approved by the ethics committee and written informed consent was received from all the participants before the study.

Bias:

Efforts were made to minimize bias by excluding patients with specific contraindications and ensuring the sample selection criteria are strictly adhered to. Additionally, randomization and blinding techniques will be employed to reduce biases during the allocation of interventions and outcome assessment.

Study Size:

The sample size of 100 participants has been determined based on inclusion and exclusion criteria, aiming to achieve adequate statistical power to detect meaningful differences between the effects of levobupivacaine and "hyperbaric bupivacaine" in spinal anesthesia for cesarean sections.

Statistical Analysis:

Statistical analysis included comparing the medical effects on the body, sensory block and motor block, hemodynamic responses, Apgar score recorded at one and five minutes respectively, and adverse effects between the two groups using appropriate parametric or non-parametric tests. Descriptive statistics will be used to summarize the characteristics of the study population. The threshold for significance will be at p-values less than 0.05.

Methodology:

Patients were prepared for surgery by positioning them in the left lateral position. Baseline parameters, including non-invasive blood pressure, pulse oximetry, and ECG readings, were recorded. 2.5 ml of the investigating drug was administered into the L3-L4 subarachnoid space by a specialist who was not involved in the study. Injection time was recorded at 0 minutes. Patients were positioned supine with a 15˚just below the backbone tail area and initiated the surgery achieving the desired sensory block.

Sensory and motor blocks were evaluated using pin prick tests. Intraoperative analgesia quality was recorded using a modified "Belzarena scale". Hemodynamic changes were recorded every 5 minutes until delivery, followed by monitoring every 10 minutes until the end of surgery. Apgar scores at 1 and 5 minutes were documented by the expert. Patients were monitored postoperatively for "post-dural puncture headache" (PDPH) and follow-ups over 3 to 4 days.

Table 1- Patient Demographic categorization

Categories	**Group A** Levobupivacaine (Mean ± SD)	**Group B** Hyperbaric bupivacaine (Mean ± SD)
Age	25.72 ± 3.99	26.00 ± 11.1
Height	163.03 ± 3.01	162.00 ± 2.4
Weight	60.17 ± 4.01	60.61 ± 2.98
Gestation period	34.20 ± 0.30	39.33 ± 0.61
Surgery Period	47.10 ± 2.80	48.33 ± 3.87

Table 2: Characteristics of Sensory block and Motor block

Characteristics	**Group A**	**Group B**	**P-value**
Onset of Sensory Block (time)	1:45 ± 0:10	1:35 ± 0:13	< 0.001
Two Segment Regression (time)	71.01 ± 5.03	75.11 ± 6.77	< 0.001
Complete Sensory Recovery (time)	157.89 ± 17.50	164.40 ± 11.13	< 0.001
Onset of Motor Block (time)	4:15 ± 0:33	3:18 ± 0:22	< 0.001

Duration of Motor Block	120.39 ± 10.30	140.28 ± 9.26	< 0.001

RESULTS

The patient demographic characteristics of participants mentioned in Table 1 in Group A and Group B were comparable. In Group A, the mean age was 25.72 ± 3.99 years, while in Group B, it was 26.00 ± 11.1 years. Similarly, the mean heights were 163.03 ± 3.01 cm and 162.00 ± 2.4 cm for Groups A and B, respectively. The weight, gestation period, and surgery duration also demonstrated similar trends between the two groups, with Group A having mean values of 60.17 ± 4.01 kg, 34.20 ± 0.30 weeks, and 47.10 ± 2.80 minutes, and Group B having mean values of 60.61 ± 2.98 kg, 39.33 ± 0.61 weeks, and 48.33 ± 3.87 minutes, respectively. These findings indicate a balanced distribution of demographic parameters between the two study groups.

In table 2, Levobupivacaine displayed a slightly delayed onset of sensory and motor blocks with an average onset time of 1:45 ± 0:10 compared to 1:35 ± 0:13 for Hyperbaric Bupivacaine ($p < 0.001$). However, Levobupivacaine exhibited quicker regression and recovery times, with sensory block regression at 71.01 ± 5.03 (vs. 75.11 ± 6.77 for Hyperbaric Bupivacaine, $p < 0.001$) and complete sensory recovery at 157.89 ± 17.50 (vs. 164.40 ± 11.13 for Hyperbaric Bupivacaine, $p < 0.001$). Regarding motor block, Levobupivacaine demonstrated an onset time of 4:15 ± 0:33 (vs. 3:18 ± 0:22 for Hyperbaric Bupivacaine, $p < 0.001$) and a duration of 120.39 ± 10.30 (vs. 140.28 ± 9.26 for Hyperbaric Bupivacaine, $p < 0.001$). These outcomes suggest that while Levobupivacaine shows a delayed onset, it offers faster regression and recovery profiles compared to Hyperbaric Bupivacaine in obstetric anesthesia for caesarean sections.

Table 3- Adverse Effects

Adverse Effects	Group A (%)	Group B (%)	P-value
Bradycardia	0.00	5.78	< 0.05
Headache	3.23	9.00	> 0.05
Nausea	7.70	14.00	> 0.05
Itching	0.00	2.00	> 0.05

The comparison between adverse effects in Group A (treated with levobupivacaine) and Group B (administered hyperbaric bupivacaine) in Table 3 revealed distinct patterns. Group A exhibited significantly lower occurrences of bradycardia compared to Group B, showcasing a noteworthy advantage (0.00% vs. 5.78%, $p < 0.05$). While trends of higher headache and nausea were observed in Group B, these differences did not achieve statistical significance ($p > 0.05$). The incidence of itching was minimal in both groups, with no substantial disparity observed ($p > 0.05$).

DISCUSSION

The findings of this study indicated differences in the onset and duration of sensory and motor blocks between the two groups. Group A, administered with levobupivacaine, exhibited a significantly delayed onset of analgesic block compared to Group B ($p < 0.001$). Moreover, while both groups demonstrated regression of two dermatomal segments, Group A showed a comparatively prolonged period for complete sensory recovery ($p < 0.001$). Regarding motor block characteristics, Group B displayed a significantly quicker onset, but longer duration compared to Group A.

Research by Guler *et al* and Goyal *et al* conducted this analysis, and their results were significant ($p<0.05$) just as observed in the present research [7, 8]. A study also suggested that two-segment regression (time) for Group B was 155±50 and for Group A was 152±48, which is slightly more than the research which could be because of the method they followed [9]. For Motor blocks, studies suggest that results for motor blocks were statistically significant ($p< 0.05$), but the initiation time much more when compared to the study may be because of the difference in the participants that were considered and the difference in methodology [7-9].

In the investigation, the complete motor block was observed universally among patients in both the bupivacaine and levobupivacaine groups. Notably, hypotension was a common occurrence in both groups; however, the bupivacaine group exhibited a more pronounced decrease in blood pressure ($p < 0.05$) and a higher requirement for ephedrine injection ($p < 0.05$), indicating statistically significant differences. Similarly, in a previous

investigation, it was observed that there was a complete motor block reported in all patients who underwent cesarean sections with either bupivacaine or levobupivacaine [10].

Trends of increased hypotension with bupivacaine were noted in these studies. Similarly, in previous studies comparing levobupivacaine and bupivacaine in subarachnoid anesthesia for older patients, higher rates of hypotension in the bupivacaine group were observed, which resonates with our findings [10, 11]. However, some studies showed varying incidences of hypotension between the two drugs without statistically significant differences [11, 12]. The study also revealed a marked discrepancy in bradycardia rates between the groups. Specifically, Group A exhibited no instances of bradycardia, suggesting the potential advantages of levobupivacaine in maintaining superior hemodynamic stability during spinal anesthesia compared to hyperbaric bupivacaine.

The study noted occurrences of headache, nausea, and itching in both study groups without significant differences between them ($p > 0.05$). However, Group A showed a notably lower incidence of bradycardia, implying potential cardiac safety advantages compared to hyperbaric bupivacaine. These findings require cautious interpretation due to limitations such as sample size and the absence of long-term follow-up, potentially impacting result generalization and rare adverse event assessment. In the bupivacaine group, adverse reactions like bradycardia, itching, and nausea were occurring more often, although they were managed without complications. This aligns with similar observations from other studies, highlighting increased incidences of nausea and vomiting with bupivacaine [12, 13]. Some studies found insignificant differences in side effect occurrences between the two drugs, indicating the multifaceted nature of side effects in regional anesthesia for cesarean sections [13, 14].

CONCLUSION

The comparative analysis highlights the distinct characteristics of intrathecal levobupivacaine and hyperbaric bupivacaine in spinal anesthesia for cesarean sections. Levobupivacaine demonstrated delayed onset of sensory block, potentially superior hemodynamic stability, and significantly lower occurrences of bradycardia.

LIMITATIONS

The study, despite yielding insightful results, encountered some limitations that warrant consideration. Firstly, the sample size of 100 participants did not adequately capture rare or delayed adverse events due to its moderate scale. For instance, while it observed some side effects, such as headache or nausea, their occurrence might be higher in a larger and more diverse population.

Additionally, the study's follow-up duration, limited to 3 to 4 days post-surgery, might have overlooked potential long-term effects or delayed complications arising beyond this timeframe. Moreover, the stringent selection criteria, excluding patients based on specific characteristics, might restrict the generalizability of the findings to a broader demographic. While the study provides valuable insights, these limitations highlight the need for larger-scale, multi-center studies with longer follow-up periods to comprehensively evaluate the safety and efficacy of the medications used in spinal anesthesia for cesarean sections.

RECOMMENDATIONS

These findings advocate for the consideration of levobupivacaine as an alternative with potential clinical advantages in specific scenarios, but further research with larger cohorts is necessary to substantiate these observations and ascertain its comprehensive safety profile. Based on the observed outcomes, it is recommended that further comprehensive studies with larger sample sizes be conducted to validate the present findings. Extensive investigations are required to evaluate the long-term effects and rare adverse events associated with both agents. Additionally, multi-center trials could provide more robust evidence and enhance the generalizability of the results, aiding in the development of evidence-based guidelines for anesthetic choices in obstetric practice.

ACKNOWLEDGMENT

We extend our heartfelt thanks to the study participants for their invaluable contribution. Our appreciation also goes to the dedicated healthcare professionals, supportive institutions, and colleagues for their essential roles in this research.

LIST OF ABBREVIATIONS:

CSF- Cerebrospinal Fluid
CNS- Central Nervous System
ASA- American Society of Anesthesiologists
PDPH- Post-Dural Puncture Headache

SOURCE OF FUNDING

None

CONFLICT OF INTEREST

None

REFERENCES

1. Løvstad R, Granhus G, Hetland S. Bradycardia and asystolic cardiac arrest during spinal

anaesthesia: A report of five cases. Acta Anaesthesiologica Scandinavica.
2. Huang Y, Pryor M, Mather L, Veering B. Cardiovascular and Central Nervous System Effects of Intravenous Levobupivacaine and Bupivacaine in Sheep. Anaesthesia and Analgesia. 1998;86:797-804.
3. Vercauteren M, Coppejans H, Hoffmann V, Saldien V, Adriaensen H. Small-Dose Hyperbaric Versus Plain Bupivacaine During Spinal Anesthesia for Caesarean Section. Anesthesia and Analgesia. 1998;86:989-993.
4. Richardson M, Collins H, Wissler R. Intrathecal Hypobaric Versus Hyperbaric Bupivacaine with Morphine for Caesarean Section. Anesthesia and Analgesia. 1998;87:336-340.
5. Sarvela P, Halonen P, Korttila K. Comparison of 9 mg of Intrathecal Plain and Hyperbaric Bupivacaine Both with Fentanyl for Caesarean Delivery. Anaesthesia and Analgesia. 1999;89:1257-1262.
6. Glaser C, Marhofer P, Zimpfer G, Heinz M, Sitzwohl C, Kapral S *et al*. Levobupivacaine Versus Racemic Bupivacaine for Spinal Ana esthesia. Anaesthesia and Analgesia. 2002;94:194-198.
7. Ayesha Goyal, P. Shankaranarayan, and P. Ganapathi. A randomized clinical study comparing spinal anesthesia with isobaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in elective caesarean sections. Anesth Essays Res. 2015; 9:57–62.
8. Guler G, Cakir G, Ulgey A, Ugur F, Bicer C, Gunes I *et al*. A Comparison of Spinal Anesthesia with Levobupivacaine and Hyperbaric Bupivacaine for Caesarean Sections: A Randomized Trial. Open Journal of Anesthesiology. 2012; 02:84-89.
9. Thepakorn Sathitkarnmanee, Cattleya Thongrong,Sirirat Tribuddharat, Maneerat Thananun, Khochakorn Palachewa, Radda Kamhom "A Comparison of Spinal Isobaric Levobupivacaine and Racemic Bupivacaine for Lower Abdominal and Lower Extremity Surgery" J Med Assoc Thai. 2011;94:716-20.
10. Mantouvalou M, Ralli S, Arnaoutoglou H, Tziris G, Papadopoulos G. Spinal anaesthesia: Comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. Acta Anaesth. Belg. 2008;59:65-71.
11. Herrera R, De Andrés J, Estañ L, Olivas F, Martínez Mir I, Steinfeldt T. Hemodynamic impact of isobaric levobupivacaine versus hyperbaric bupivacaine for subarachnoid anaesthesia in patients aged 65 and older undergoing hip surgery. BMC Anesthesiology. 2014;14:97.
12. Dar F, Mir I, Bhat H. Comparison of intrathecal hyperbaric bupivacaine and levobupivacaine for Caesarean section. Ain-Shams Journal of Anesthesiology. 2015; 8:89.
13. F. Fattorini, Z. Ricci, A. Rocco, R. Romano, M. A. Pascarella, G. Pinto. Levobupivacaine versus racemic bupivacaine for spinal anesthesia in orthopedic major surgery. Minerva Anesthesiologic. 2006; 72:637-44.
14. Deepa Ravindra Shriyan, Bhaskar Murlidhar Patil, Pinakin Gujjar, Nikhil Kamble. A Prospective Randomized Study to Compare Pro Seal LMA and Laryngeal Tube with Suction in Patients Posted for Short Duration Surgeries Under General Anesthesia with Controlled Ventilation. International Journal of Contemporary Medical Research. 2016; 3:1235-1238.

Vol. 4 No. 12 (2023): December 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i12.916
Original article

PUBLISHER DETAILS

Publishing Journal: Student's Journal of Health Research Africa.
Email: studentsjournal2020@gmail.com or admin@sjhresearchafrica.org

(ISSN: 2709-9997)

Publisher: SJC Publisher Company Ltd
Category: Non-Government & Non-profit Organisation
Contact: +256775434261(WhatsApp)
Email: admin@sjpublisher.org
Website: https://sjpublisher.org
Location: Wisdom Centre Annex, P.O. BOX. 113407 Wakiso, Uganda, East Africa.