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Original Article

Comparative Evaluation of Hyperbaric Levobupivacaine and Hyperbaric Bupivacaine for Categories 3 and 4 Cesarean Section under Spinal Anesthesia

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Abstract

Introduction: Spinal anesthesia is most widely used for both elective and emergency cesarean section. Hyperbaric bupivacaine (0.5%), an amide-type of local anesthetic, has been the gold standard for intrathecal but has certain side effects including cardiotoxicity. Levobupivacaine is a safer and more equipotent option. This study is done to compare the sensory and motor block characteristics, and hemodynamic changes occurring with 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine when given intrathecally for categories 3 and 4 cesarean section.

Materials and Methods: After Institutional Ethical Committee approval, 100 categories 3 and 4 pregnant females (American Society of Anesthesiologists I-II, aged 18–40 years) and after obtaining written informed consent to receive spinal anesthesia for cesarean section were randomized into two groups. Group A: received intrathecal 12.5 mg hyperbaric bupivacaine Group B: Received intrathecal 12.5 mg hyperbaric levobupivacaine. Sensory and motor block characteristics of the groups were assessed at desired intervals; observed hemodynamic changes and side effects were recorded. Statistical analysis was performed using the Statistical Package for the Social Sciences version 20 software windows. A $P < 0.05$ was considered significant.

Results: There was no statistical difference in all other sensory parameters in both groups. The mean time for the onset of motor block in Group A was faster compared to Group B, with a $P = 0.008$. The mean time to regression in motor characteristics in Group A was longer than Group B and the difference was found to be statistically significant. The hemodynamic parameters did not reveal any significant difference between the groups. The frequency of side effects (hypotension, bradycardia, and nausea) was more in Group A but the difference was not significant.

Conclusion: Hyperbaric bupivacaine is superior in terms of motor block characteristics as compared to levobupivacaine as seen in the study. However, levobupivacaine can be used as a safer alternative to bupivacaine due to its hemodynamic stability, lesser side effects (cardiotoxicity), and satisfactory sensory and motor block characteristics for cesarean section.

Key words: Bupivacaine, Cesarean section, Levobupivacaine, Motor parameters, Sensory parameters, Side effects, Spinal anesthesia

INTRODUCTION

Spinal anesthesia is most widely used for both elective and emergency cesarean section. Neuraxial anesthesia in obstetrics began with the spinal block using cocaine by Oskar Kreis in July 1900.[1]

One of the most important properties of long-acting local anesthetics is to reversibly inhibit the nerve impulse, thus causing a prolonged sensory and motor blockade appropriate for anesthesia in different types of surgeries. The acute pain relief obtained at lower doses in post-operative and labor patients due to sensory blockade is sometimes marred by an accompanying motor blockade, which serves no purpose and is quite undesirable.[2]

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Hyperbaric bupivacaine (0.5%), an amide-type of local anesthetic, has been the gold standard for intrathecal use in spinal anesthesia for many years but also has been associated with hypotension, delayed recovery of motor block, and cardiotoxicity when used in large concentration or when accidentally administered intravascularly.[3] In recent years, hyperbaric levobupivacaine, the pure S enantiomer of bupivacaine, has emerged as a safer alternative for regional anesthesia than its racemic congener.[4] Cesarean section can be classified as following: Category 1: Immediate threat to the life of woman or fetus, Category 2: Maternal or fetal compromise which is not immediately life threatening, Category 3: Needing early delivery but no maternal or fetal compromise, and Category 4: At a time to suit the patient and maternity team.[5]

The purpose of this study is to compare the sensory and motor block characteristics, and hemodynamic changes occurring with 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine when given intrathecally for Categories 3 and 4 cesarean section.

Aims and Objectives

The aim of the study is to compare fixed doses of hyperbaric levobupivacaine (Group A) versus hyperbaric bupivacaine (Group B) for Cat-3/4 cesarean section under spinal anesthesia in terms of sensory and motor block characteristics and hemodynamic parameters.

MATERIALS AND METHODS

Study Design and Participants

It was a randomized double-blind prospective study that included patients of Cat-3/4 cesarean section under spinal anesthesia at the Department of Gynecology, M.L.B. Medical College, Jhansi, Uttar Pradesh, India.

All consecutive patients posted for Categories 3 and 4 cesarean section were selected for the study after taking informed written consent. Approval from the ethical committee was obtained. The study was enrolled in CTRI. CTRI registration number is CTRI/2023/04/051661, dated April 17, 2023. The study was conducted from April 2023 to December 2023. Participants were randomly assigned using an open list of random numbers to either one of the two intervention groups (Group A and Group B) equally.

Study Population

In the current study, a total of 100 patients of categories 3 and 4 cesarean section were randomly assigned to Group A and Group B.

Inclusion Criteria

Inclusion criteria are a pregnant female of gestational age >37 weeks between age group 20 and 40 years posted for categories 3 and 4 cesarean section.

Exclusion Criteria

Exclusion criteria were patient refusal, contraindication to spinal anesthesia, allergy to local anesthetics, fused spine, musculoskeletal abnormalities, and coagulation defects breech presentation.

Intervention and Evaluation

The patients were premedicated with injection ondansetron 8 mg and injection ranitidine 50 mg I/V before the cesarean section. On the day of surgery, the patient's basal vital parameters were recorded. Monitoring was done using a multiparameter monitor having pulse oximetry, electrocardiogram, and non-invasive blood pressure. Intravenous line was obtained with an 18 gauge cannula and co-loading with 15 mL/kg NS was started.

With the patients in the left lateral position under aseptic precautions, a lumbar subarachnoid block was performed with a pillow under the head and table flat or in the sitting position when the patient could not be put in a lateral position.

Lumbar puncture was done in the L3L4 interspace, midline approach, using a 23 or 25-gauge Quincke needle. After obtaining a free and clear flow of CSF, the drug was administered slowly, ensuring of negative aspiration for blood. Patients were made to lie supine immediately after the completion of the injection. During surgery, all the patients were given intravenous fluids, either normal saline or Ringer's lactate solution. Patients were grouped into two groups based on the drug given.

Group A: received intrathecal 12.5 mg hyperbaric bupivacaine

Group B: received intrathecal 12.5 mg hyperbaric levobupivacaine.

The study drug was prepared by an anesthesiologist who was involved with randomization but was not involved further in the study. The anesthesiologist who administered the test drug was also the observer of the parameters. Thus, the observer and the patients were blinded to the study drug.

The Following Parameters Were Studied

Assessment of sensory blockade

Sensory blockade was assessed by pinprick and time was noted for the block to reach different dermatomal levels.

- Time of onset of sensory block
- Time to reach maximum level
- Maximum level reached.
    - Time to regression by 2 dermatomes for sensory block
    - Regression time to T12 for sensory block.

Assessment of onset of motor blockade

- Time of onset of motor block
- Time to reach Bromage ¾
- Time to regression

Hemodynamic parameters

Vital parameters (Blood Pressure[systolic and diastolic]), Pulse Rate, SPO2) were recorded at 5, 10, 15, 30, and 60 min, and then every 15 min till surgery ended, then every hour postoperatively until motility and sensitivity returned to basal condition.

Adverse effects

Patient were also monitored for adverse effects such as hypotension, bradycaradia, nausea, vomiting, etc and noted.

Definitions of the parameters of the study

- Onset of sensory block. This was taken as the time from the deposition of the drug to the evidence of analgesia to pinprick at the T12 level.
- Upper level of sensory block. The highest dermatome of the block was assessed, taken as the interval between the deposition of the drug and the loss of sensation at the highest dermatomal level.
- Onset of motor block was noted. Time taken from onset of paresis to the loss of power, that is, the patient was not able to lift the legs.
- Modified Bromage scale. 0 = no motor blockade, 1 = hip blockade, 2 = hip and knee blockade, 3= hip, knee and foot blockade.
- Duration for 2-segment regression – time taken for recovery of sensory level to 2 dermatomal segments below the highest level.

Statistical Analysis

Data were collected, tabulated, coded then analyzed using the Statistical Package for the Social Sciences® computer software version 29.0. Numerical variables were presented as mean and standard deviation (SD) while the student-*t* test was done. $P < 0.05$ was considered significant.

RESULTS

Participant Flow

Flow diagram [Figure 1].

Baseline Data

In the study, 50 patients were allocated to both groups and all the cases were included in the analysis. The demographic profiles of the patients comparing age, weight, and height show no statistically significant difference and were comparable in both groups of our study. All baseline vital parameters were similar in both groups [Table 1].

Outcome and Estimation

Sensory outcome

The mean time for the onset of sensory block in Group A was observed to be 58.8 s compared to 59.12 s in Group B, with a $P = 0.7$ which was found to be statistically insignificant [Figure 2]. Maximum spread of sensory level was T4 in both groups. There was no statistical difference in all other sensory parameters in both groups [Table 2].

Motor outcome

The mean time for the onset of motor block in Group A was observed to be 172.4 s compared to 214.64 s in Group B, with a $P = 0.008$ which was found to be statistically significant [Figure 2 and Table 3].

The mean time to regression in motor characteristics in Group A was 166.6 min, whereas in Group B, it was found to be 134.64 and the difference was found to be statistically significant.

Hemodynamic Parameters

The hemodynamic parameters did not reveal any significant difference between the groups [Figures 3 and 4].

Side Effects

Both groups showed side effects in the form of hypotension, bradycardia, and nausea. Although the frequency of side effects was higher in Group A, on comparison, the difference was not found to be statistically significant [Table 4].

DISCUSSION

Subarachnoid block is the current widespread popular anesthetic technique available today.

Subarachnoid block has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anesthetic. An ideal anesthetic agent used in the subarachnoid block should have a rapid onset of action, intense analgesia, adequate motor blockade, long duration of action, adequate post-operative analgesia, and minimal cardiovascular change.

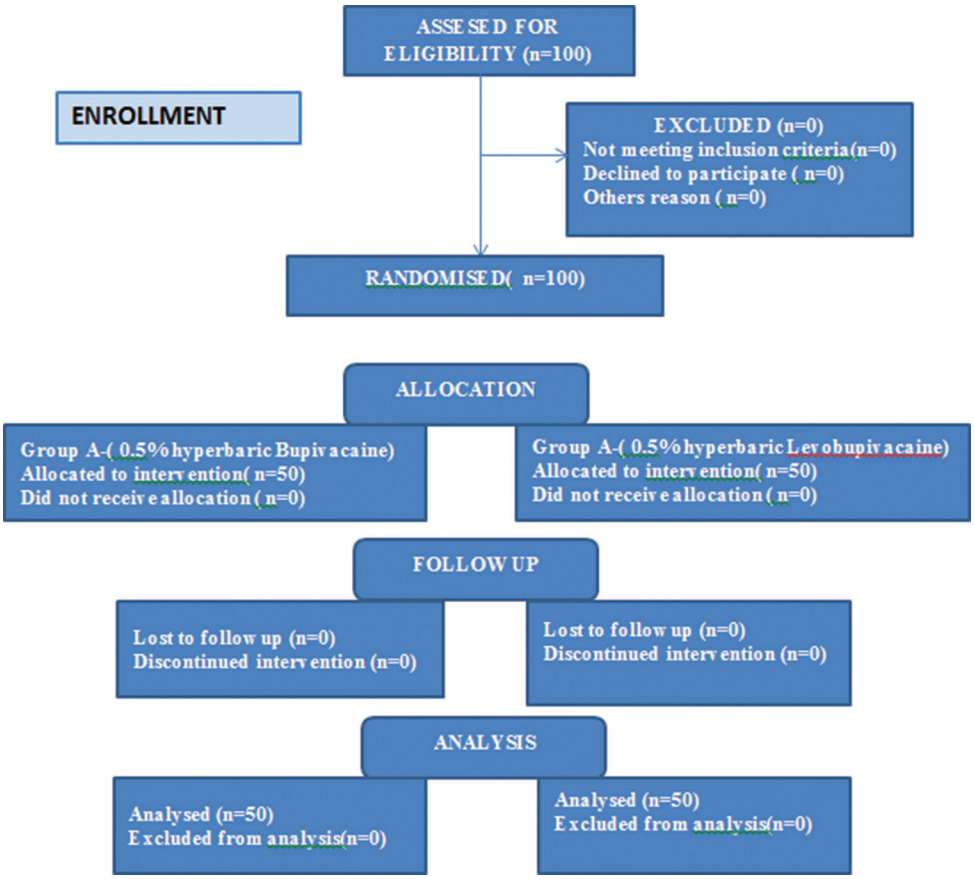

Figure 1: Comparative evaluation of hyperbaric levobupivacaine and hyperbaric bupivacaine for Categories 3 and 4 cesarean sections under spinal anesthesia

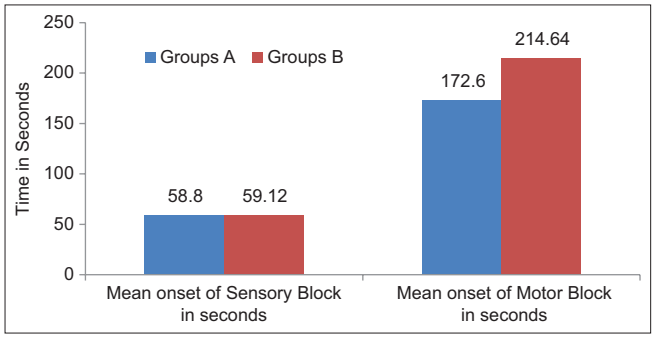

Figure 2: Graphical representation of mean onset of sensory and motor block

Table 1: Demographical data

Parameters	Group A (*n*=50)	Group B (*n*=50)	*P*-value
Age (years)	28.42±6.32	29.62±7.34	0.3832
Weight (kg)	55.56±5.62	56.54±6.66	0.4284
Height (cm)	156±4.45	155±5.54	0.32

Bupivacaine heavy has been the local anesthetic of choice for spinal anesthesia in obstetric cases for a long time. However, it has varied side effects profile which includes hypotension, bradycardia, nausea and vomiting, and cardiotoxicity.[3]

Table 2: Sensory block characteristics

Parameters	Group A	Group B	*P*-value
Time of onset of sensory block (s)	58.80±4.78	59.12±4.82	0.7396
Time to reach T 10 (s)	158.72±6.68	160.74±5.82	0.1131
Time to reach maximum level (s)	312.46±95.9870	301.88±52.157	0.4591
Maximum level reached	T4	T4	
Time to regression by 2 dermatomes for sensory block (min)	98.82±4.824	97.68±4.455	0.22
Regression time to T12 for sensory block (min)	129.84±18.673	127.86±16.644	0.577

Hyperbaric levobupivacaine has emerged as a good alternative to bupivacaine over the years because of its safety profile and similar anesthetic profile to bupivacaine.[4]

In our study, we went with a null hypothesis that isobaric levobupivacaine has similar sensory and motor blocking properties with lesser side effect profiles, and our study also concluded it. In our study, patients in Group A had a mean onset of sensory block faster than Group B, but this was statistically insignificant. The mean time for the onset of sensory block in Group A was observed to be

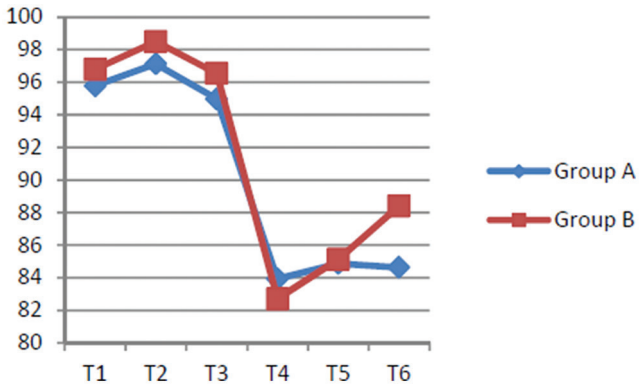

Figure 3: Comparison of heart rate between groups per mins

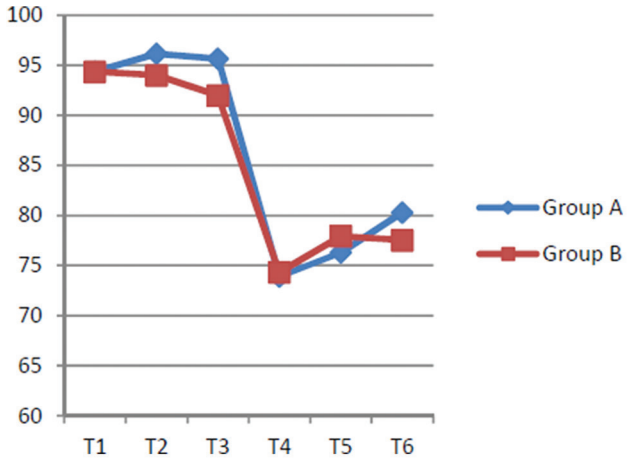

Figure 3: Comparison of Mean Arterial Pressure between groups in mmHg

Table 3: Motor block characteristics

Parameters	Group A	Group B	*P*-value
Time of onset of motor block (s)	172.68±56.64	214.64±64.56	0.0008
Time to reach Bromage ¾ (s)	354.65±54.46	360.88±46.88	0.5413
Time to regression (min)	166.68±66.86	134.64±64.98	0.016

Table 4: Side effects

Complications	Group A	Group B	*P*-value
Hypotension	7	5	0.75
Bradycardia	4	2	0.622
Vomiting	5	4	1.00
Headache	4	3	1.00
Itching	1	1	1.00
Backache	4	3	1.00
Sedation	0	0	
Shivering	8	9	1.00

58.8 s compared to 59.12 s in Group B, with a $P = 0.7$. This finding was comparable to other studies.[6-8]

Maximum level of sensory block achieved is comparable in both groups in our study. In the majority of the cases, the maximum level of sensory block reached was T4 in both groups. Similar finding was present in various studies.[9,10] In our study, the time to reach peak sensory level is also comparable and the difference was statistically insignificant, which correlates with other studies.[7,9]

Time taken for two-segment regression of sensory level in Group A and Group B was comparable and the difference was statistically not significant. This similar finding was present in studies done by Glaser *et al*.[10] and Girish *et al*.[7]

The time of onset of motor block in Group A (172.64 s) is faster than Group B (214.64 s) and the difference is statistically significant. Time to reach a motor block of Bromage ¾ was comparable in both groups and was statistically insignificant. Similarly, the time to regression of motor block in Group A (166.68 s) is much longer than Group B (134.64 s) and the difference is statistically significant. This finding is similar to the studies done by Glaser *et al*.,[10] Girish *et al*.,[7] Luck *et al*.,[6] and Fatorini *et al*.[9]

The hemodynamic parameters of both groups were comparable and were statistically insignificant which was also seen by Girish *et al*.[7] In a study done by Shukla *et al*.,[8] they found systolic blood pressure difference to be statistically significant but all other hemodynamic parameters were comparable. In the current study, authors have excluded breech presentation as published studies have shown a higher risk of hypotension in breech presentation.[11]

We noted that the incidence of hypotension of more in the bupivacaine group 14% (7/50 patients) as compared to levobupivacaine (10%, 5/50 patients) with $P \geq 0.05$ which is statistically non-significant. Similarly, Luck *et al*.,[6] stated: "intra-operative hypotension requiring treatment with i.v ephedrine occurred more often in the bupivacaine group (42.5%) than in levobupivacaine (17.5%)." A Singh *et al*. (2004)[12] also noted that the incidence of hypotension was more common in the bupivacaine group. Similarly, the incidence of bradycardia was more in Group A (4 patients, 8%) compared to Group B (patients, 4%) which was similar to the studies conducted by Luck *et al*.[6] There was no statistically significant difference in the side effects among both groups.

CONCLUSION

Hyperbaric bupivacaine is superior in terms of motor block characteristics as compared to levobupivacaine as seen in the study. However, levobupivacaine can be used as a safer alternative to bupivacaine due to its hemodynamic stability, lesser side effects (cardiotoxicity), and satisfactory sensory and motor block characteristics for cesarean section.

Limitations

Our study is a single-centered study with a small sample size. Inclusion criteria limit cases with only vertex presentation and ASA -1 patients.

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REFERENCES

1. Schneider MC, Holzgreve W. 100 years ago: Oskar Kreis, a pioneer in spinal obstetric analgesia at the University Women's Clinic of Basel. Anaesthesist. 2001;50:525-8.
2. Oraon P, Hembrom B, Kumar M, Ram B, Lakra L. Comparative study between intrathecal 0.5% isobaric levobupivacaine, 0.5% isobaric ropivacaine, and 0.5% hyperbaric bupivacaine in elective lower segment cesarean section: A randomized clinical study. Anesth Essays Res 2022;16:238.
3. Hansen TG. Ropivacaine: A pharmacological review. Expert Rev Neurother 2004;4:781-91.
4. Athar M, Ahmed SM, Ali S, Siddiqi OA. Levobupivacaine: A safer alternative. J Curr Res Sci Med 2016;2:3-9.
5. Lucas DN, Yentis SM, Kinsella SM, Holdcroft A, May AE, Wee M, *et al*. Urgency of caesarean section: A new classification. J R Soc Med 2000;93:346-50.
6. Luck JF, Fettes PD, Wildsmith JA. Spinal anaesthesia for elective surgery: A comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine, and ropivacaine. Br J Anaesth 2008;101:705-10.
7. Girish BK, Srinivas HT, Reddy SM, Archana KN. A comparative study of hyperbaric 0.5% levobupivacaine with bupivacaine 0.5% for spinal anaesthesia in elective surgeries. Indian J Anesth Analg 2018;5:2013-20.
8. Shukla C, Sharma N, Meena H, Goyal G. A Comparative Clinical Study of Effect of Hyperbaric Levobupivacaine and Bupivacaine for Spinal Anaesthesia in Patients Undergoing Elective Lower Abdominal and Limb Surgeries; 2016. Available from: https://www.academia.edu/download/61690190/A180810010920200105-13311-1pu1imi.pdf [Last accessed on 2023 Dec 20].
9. Fattorini F, Ricci Z, Rocco A, Romano R, Pascarella MA, Pinto G. Levobupivacaine versus racemic bupivacaine for spinal anaesthesia in orthopaedic major surgery. Minerva Anestesiol. 2006;72:637-44.
10. Glaser C, Marhofer P, Zimpfer G, Heinz MT, Sitzwohl C, Kapral S, *et al.* Levobupivacaine versus racemic bupivacaine for spinal anesthesia. Anesth Analg 2002;94:194-8.
11. Jain A, Pandey S, Kumar R, Sethi C, Sharma S. A retrospective study to correlate breech presentation and enhanced risk of postspinal hypotension during cesarean delivery. Local Reg Anesth 2015;8:129-34.
12. Singh A, Gupta A, Datta PK, Pandey M. Intrathecal levobupivacaine versus bupivacaine for inguinal hernia surgery: a randomized controlled trial. Korean J Anesthesiol 2018;71:220.

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