



Comparative Study of Isobaric Levobupivacaine and Hyperbaric Bupivacaine for Lower Segment Caesarean Section Under Spinal Anaesthesia in Northern India

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Abstract

Background and Objectives: Central neuraxial blocks are the preferred technique for anesthesia for lower segment caesarean section. Local anesthesia drugs have been routinely used for spinal anesthesia to compare various block characteristics and hemodynamic changes in patients undergoing lower segment caesarean section using hyperbaric bupivacaine and isobaric levobupivacaine.

Methods: After Institutional ethical committee approval, 100 patients scheduled for elective lower segment caesarean section were randomized into Group L and Group B. Group L (N=50) received 2.5 mL (12.5 mg) 0.5% isobaric levo-bupivacaine and Group B (N=50) received 2.5 mL (12.5 mg) 0.5% hyperbaric bupivacaine as intra-thecal drugs for spinal anesthesia. The present study was conducted in Operation theaters and the Post-operative ward of LLRM medical college, Meerut. Difference in characteristics of onset of block, regression of block, hemodynamic profile, and side effects were recorded between groups.

Results: Group L, in comparison to Group B, showed prolonged duration of sensory block ($P = 0.01$) with lesser duration of motor block ($P = 0.0002$). Hemodynamically hypotension was statistically significant in the bupivacaine group ($P = 0.016$).

Conclusions: The current study validates that both isobaric levo-bupivacaine and hyperbaric bupivacaine in spinal anesthesia provide effective surgical anesthesia for lower segment caesarean section. Levo-bupivacaine can be a better alternative to bupivacaine in terms of reduced motor block time and a longer sensory block time with lesser incidence of hypotension and better hemodynamic stability.

Keywords: Caesarean Section, Spinal Anesthesia, Bupivacaine, Levo-Bupivacaine, Neuraxial Anesthesia, Subarachnoid Block

1. Background

Neuraxial anesthesia is one of the most common anesthesia techniques used for lower segment cesarean section performed these days. Reducing the risk of airway manipulation and negating the placental transfer of general anesthesia drugs to the fetus, neuraxial anesthesia continues to be the preferred choice of anesthesia. Of all available techniques of neuraxial block, spinal anesthesia is the most simple to perform with early onset and predictable block height. The effect of the block depends on the volume, concentration, and dose of the drug used (1, 2). The ratio of the density of local anesthetics (LAs) and cerebrospinal fluid (CSF), which is known as LA baricity, is one key determinant of LA distribution within the subarachnoid space (3). Bradycardia and hypotension may occur following

mobilization when hyperbaric solutions are used and isobaric solutions are favored due to less sensitivity to position change properties (4).

Levo-bupivacaine use in clinical practice is due to its reduced toxic effects on the heart and central nervous system (5), as compared to bupivacaine.

Studies comparing levo-bupivacaine and bupivacaine have been done in lower abdominal surgeries (6), however, there are few studies in pregnant patients for caesarean section.

Therefore we did a randomized, double blinded, comparative prospective study to compare isobaric Levobupivacaine and hyperbaric Bupivacaine for surgical anaesthesia and post-operative analgesia in patients undergoing elective lower segment caesarean section.

2. Methods

After approval from the Institutional Ethical Committee, the present study was done in operation theaters and the post-operative ward of Lala Lajpat Rai Memorial Medical College, Meerut, India. A total of 100 women in the age group of 18 years to 35 years scheduled for elective lower segment cesarean section, of more than 35 weeks gestation, American Society of Anesthesiologists physical status class I or II, were enrolled in the study.

Patient refusal for regional anesthesia, history of uncontrolled diabetes, hypertension, coagulation abnormalities or any other severe systemic illness like severe respiratory, cardiovascular, and neurological disorders, history of low back surgery, any patient receiving tocolytics, hormonal preparations, and anti-hypertensive medications was excluded from the study. Any contraindication to spinal anesthesia was also considered as the exclusion criteria.

Informed written consent was taken from patients and the procedure was explained thoroughly to all at the time of the pre-anesthesia checkup. All necessary routine investigations were done according to institutional protocol; body weight, height, and vitals were all recorded. No anxiolytics were advised.

Based on a departmental pilot study, considering 95% confidence interval and 80% power of study sample size of 50 patients in each group was found to be appropriate.

Patients in the study were divided equally and randomly using a computer generated random table into 2 groups:

- Group L - 0.5% Isobaric Levo-bupivacaine group of 50 patients.
- Group B - 0.5% Hyperbaric Bupivacaine group of 50 patients.

On the surgical day, the patients were nursed into operation theaters in the left lateral position and the procedure was explained to the patient once again. Once comfortable with the surroundings, on the operation table, multipara monitor (Drager, Infinity Vista XL) was attached and reading of all vitals, including pulse-rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressures (MAP), and peripheral oxygen saturation (SPO₂) were recorded and marked as baseline values. A total of 20 G of intra-venous (I.V) cannulation on the dorsal aspect of non-dominant forearm was done observing all sterile precautions and preloading started with ringer lactate at 10 mL/kg body weight over 10 minutes. After

preloading, the patient was made to sit on the OT table with an adequate footrest. The assistant was asked to maintain the patient in a position such that both the iliac crest are at same horizontal level and both the shoulders are at the same horizontal level. The intervertebral space was identified and under strict aseptic precautions, lumbar puncture was performed in the midline using 26 G quincke spinal needle at L2-L3 or L3-L4 space. A total of 2.5 mL of the drug was injected at 0.2 mL/seconds without barbotage, once free flow of CSF was obtained. Group L patients received Inj Levobupivacaine [Levo-anawin, Neon pharmaceuticals Ltd] 0.5% isobaric 2.5 cc (12.5 mg) intrathecally. Group B patients received Inj Bupivacaine [Anawin heavy, Neon pharmaceuticals Ltd] 0.5% hyperbaric 2.5 cc (12.5 mg) intrathecally. All the patients were comfortable with the above technique and no discomfort was noted from patients.

The study medication was prepared and administered by an anesthesiologist not involved in the present study. Another anesthetist blind to the identity of study medication monitored and managed the patients as well as collected data.

After successful completion of subarachnoid drug placement, patients were made supine. Prior to the start of the surgery, the anesthesiologist checked the sensory and motor block level. The level of sensory block was assessed using the pinprick test using a 25 G blunt needle in the mid clavicular line. The level of motor block was assessed using the modified Bromage scale (0 = no motor block, able to flex hips, knees and ankles; 1 = just able to flex knees, unable to extend legs; 2 = able to move ankles, unable to flex knees; 3 = unable to flex ankles, knees or hips, complete motor block). Oxygen at 4 L/min was administered using a face-mask.

No premedication and sedatives were administered during the course of the surgery.

The characteristics of block were noted at every 2 minutes intervals up to 10 minutes, at 15 minutes then every 15 minutes until 90 minutes. After 90 minutes, the above parameters were noted every 30 minutes up to 240 minutes. The time of intra-theal drug placement was considered as 0, and then various block characteristics in terms of time to onset of sensory block until T₆, the time to onset of motor block, the time taken to reach maximum sensory block level, the time taken to reach maximum motor block, the time to regression of two dermatomes of the sensory block, the duration of the regression of the sensory block level to T₁₂ from the maximum level, and the duration of return of full motor power was recorded.

Time to complete the motor block was recorded when

modified Bromage score of 3 was attained. Complete motor block recovery was defined when modified Bromage score of 0 was achieved. The patient's hemodynamic parameters were recorded at 2 minutes intervals up to 10 minutes and then at 5 minutes interval until 60 minutes then at 75 minutes, 90 minutes, and then every 30 minutes until complete regression of motor and sensory block features.

The surgeon was asked to proceed once T4 or T6 level was achieved. The block was considered a failure if complete sensory and motor block was not achieved even after 15 minutes. Failed blocks were converted to GA and were excluded from study.

Hypotension, defined as a systolic blood pressure less than 100 mmHg or a decrease of more than 25% from baseline, was treated with incremental doses of Injection Mephentermine 6 mg IV. Bradycardia, defined as a heart rate < 50 beats per minute, was treated with Injection atropine 0.5 mg IV.

2.1. Statistical Analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The Qualitative data are represented in Number (%) and mean \pm SD. Quantitative data, presented as the proportion or number, were evaluated by χ^2 test. P value of < 0.05 was accepted as statistically significant.

3. Results

Table 1 shows the anthropometric variables and hemoglobin values between Group L and Group B. Both the groups were similar in terms of anthropometric variables and were clinically and statistically insignificant ($P > 0.05$).

Table 2 shows the various block characteristics in terms of sensory and motor variables.

A total of 62% of patients in the Levobupivacaine group reached highest dermatome above T4 level as compared to only 18% in bupivacaine group.

Tables 3 and 4 show the intergroup comparison of heart rate and mean arterial pressure, respectively.

Table 5 shows the comparison of side effects between two groups.

4. Discussion

In the current study we compared the effect of isobaric levo-bupivacaine and hyperbaric bupivacaine in spinal anesthesia for lower segment caesarean section in 100

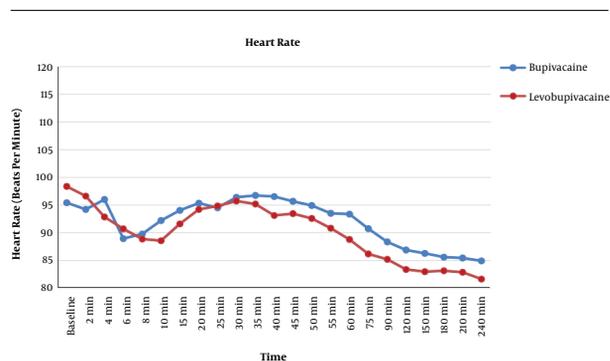


Figure 1. Heart rate comparison between the groups.

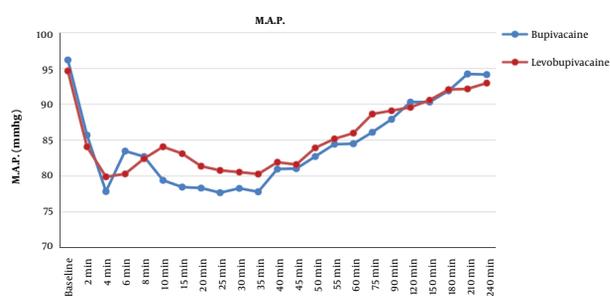


Figure 2. Comparison of MAP between the groups.

patients in northern India without any adjuvant. Block characteristics, hemodynamic parameters, and side effects were compared amongst the groups.

In our study, both the groups were comparable in terms of anthropometric and demographic variables like age, weight, height, BMI, and hemoglobin values, and were statistically insignificant.

In our study, sensory block level required for caesarean section was achieved adequately in both groups. The time to reach T6 sensory height, motor onset time, time to reach maximal sensory blockade, and time to reach full motor blockade were similar in both the groups and were not statistically significant ($P > 0.05$). Vanna et al. reported the similar block characteristics in a RCT done for endoscopic urethral surgery (6).

The 2-segment regression time in minutes was significantly less for the Levobupivacaine group (81.3 ± 18.45) as compared to Bupivacaine group (93 ± 24.05) with $P = 0.007$.

The total duration of sensory blockade was 188.4 ± 22.71 in the Bupivacaine group and 199.8 ± 20.65 Levobupivacaine group. The difference is statistically significant ($P = 0.01$).

The total duration of motor blockade was 201.6 ± 20.14 in

Table 1. Demographic Profile^{a, b}

	Group B (N = 50)	Group I (N = 50)	t Value	P Value
Age (years)	25.78 ± 3.80	25.56 ± 2.84	0.33	0.74
Weight (kg)	52.66 ± 9.49	53.02 ± 9.48	-0.19	0.85
Height (cm)	153.5 ± 5.17	152.84 ± 5.09	0.64	0.52
BMI (kg/m ²)	22.38 ± 3.99	22.59 ± 3.09	-0.29	0.77
Hemoglobin (gm %)	9.49 ± 1.39	9.58 ± 1.155	-0.35	0.725

^aData are presented as mean ± SD.^bP > 0.05 = No significant difference.**Table 2.** Various Block Characteristics in Terms of Sensory and Motor Variables^{a, b}

Minutes	Group B (N = 50)	Group I (N = 50)	t Value	P Value
Time to reach T6 sensory height	4.28 ± 1.93	4.04 ± 1.78	0.64	0.52
Motor onset time	2.44 ± 0.93	2.4 ± 1.07	0.2	0.84
Time to reach maximal sensory blockade	6.7 ± 2.37	6.92 ± 1.57	-0.54	0.58
Time to reach full motor blockade	6.88 ± 1.90	7.72 ± 3.8	-1.39	0.17
2 segment regression time	93 ± 24.05	81.3 ± 18.45	2.73 ^c	0.007 ^c
Total duration of sensory blockade	188.4 ± 22.71	199.8 ± 20.65	-2.63 ^c	0.01 ^c
Total duration of motor blockade	201.6 ± 20.14	182.4 ± 29.59	3.79 ^c	0.0002 ^c
Highest Dermatome reached T2 - T3 - T4 - T5 - T6 (No. of Patients)	1-8-23-7-11	14-17-11-3-5		
Highest Dermatome reached above T4 No. of patient (%)	9 (18%)	31 (62%)		

^aData are presented as mean ± SD.^bP > 0.05 = No significant difference.^cSignificant difference.**Table 3.** Distribution of Mean Heart Rate Between Two Study Groups

Heart Rate	Group B (Mean ± SD)	Group I (Mean ± SD)	t Value	P Value
Base line	95.44 ± 14.47	98.36 ± 14.45	-1.01	0.31
2 minutes	94.2 ± 14.49	96.64 ± 14.73	-0.83	0.40
4 minutes	96 ± 20.47	92.86 ± 15.78	0.86	0.39
6 minutes	88.96 ± 15.89	90.7 ± 14.58	-0.57	0.57
8 minutes	89.8 ± 16.26	88.88 ± 15.03	0.29	0.77
10 minutes	92.2 ± 16.02	88.58 ± 14.54	1.18	0.24
15 minutes	94.06 ± 15.61	91.62 ± 14.07	0.82	0.41
20 minutes	95.36 ± 15.86	94.2 ± 12.63	0.40	0.68
25 minutes	94.5 ± 14.86	94.84 ± 11.79	-0.13	0.9
30 minutes	96.42 ± 14.38	95.72 ± 10.70	0.28	0.78
35 minutes	96.74 ± 15.3	95.18 ± 9.29	0.62	0.54
40 minutes	96.56 ± 13.92	93.14 ± 9.94	1.41	0.16
45 minutes	95.68 ± 13.66	93.44 ± 10.67	0.91	0.36
60 minutes	93.38 ± 16.02	88.78 ± 11.34	1.66	0.10
75 minutes	90.74 ± 16.07	86.18 ± 10.12	1.69	0.09
90 minutes	88.34 ± 11.63	85.2 ± 9.65	1.47	0.14
120 minutes	86.88 ± 12.25	83.4 ± 8.99	1.62	0.11
150 minutes	86.3 ± 10.40	82.98 ± 7.49	1.83	0.07

the Bupivacaine group and 182.4 ± 29.59 in the Levobupivacaine group. The difference is statistically significant (P = 0.0002). Gautier et al. (7) and Gulen Guler et al. (8), dur-

ing spinal anaesthesia for caesarean delivery, also reported that duration of motor block was shorter in the Levobupivacaine group than in the Bupivacaine group similar to

Table 4. Distribution of Mean MAP (Mean Arterial Pressures) Between Two Study Groups

M.A.P.	Group B (Mean \pm SD)	Group I (Mean \pm SD)	t Value	P Value
Base line	96.2 \pm 8.68	94.64 \pm 8.08	0.93	0.35
2 minutes	85.7 \pm 12.69	84.08 \pm 9.32	0.73	0.47
4 minutes	77.84 \pm 10.88	79.9 \pm 10.32	-0.97	0.33
6 minutes	83.5 \pm 10.99	80.3 \pm 10.05	1.52	0.13
8 minutes	82.7 \pm 9.58	82.44 \pm 11.59	0.12	0.90
10 minutes	79.42 \pm 8.32	84.08 \pm 9.48	-2.61 ^a	0.01 ^a
15 minutes	78.46 \pm 10.62	83.14 \pm 9.66	-2.30 ^a	0.02 ^a
20 minutes	78.34 \pm 9.59	81.38 \pm 9.60	-1.58	0.12
25 minutes	77.68 \pm 9.35	80.78 \pm 10.63	-1.55	0.12
30 minutes	78.3 \pm 10.65	80.56 \pm 9.77	-1.10	0.27
35 minutes	77.8 \pm 10.91	80.28 \pm 10.21	-1.17	0.24
40 minutes	80.98 \pm 12.09	81.92 \pm 9.38	-0.43	0.66
45 minutes	81.04 \pm 9.85	81.6 \pm 14.35	-0.23	0.82
60 minutes	84.5 \pm 8.10	85.98 \pm 8.03	-0.92	0.36
75 minutes	86.12 \pm 8.12	88.64 \pm 8.21	-1.54	0.12
90 minutes	87.9 \pm 6.22	89.12 \pm 6.47	-0.96	0.34
120 minutes	90.32 \pm 7.02	89.58 \pm 5.75	0.58	0.56
150 minutes	90.32 \pm 6.27	90.6 \pm 5.78	-0.23	0.82

^aSignificant difference in MAP.

Table 5. Comparison of Side Effects Between Two Groups

Complications	Group B (No. of Patients)	Group I (No. of Patients)	χ^2 Value	P Value
Bradycardia	3	1	1.04	0.31
Hypotension	31	20	5.77 ^a	0.016 ^a
Nausea	5	1	2.83	0.09
Vomiting	2	1	0.34	0.56

^aSignificant difference.

findings in our study. Lower affinity of Levobupivacaine to A- α fibers (somatic motor fibers) than that of Bupivacaine may have resulted in a lesser motor block.

Patients in the Levobupivacaine group achieved statistically higher block height than patients in the Bupivacaine group, which may be due to its isobaric nature. This finding was similar to the study of Vanna et al. (6) and Dilek Subasi et al. (9).

Incidence of hypotension as side effects was seen more in the bupivacaine group as compared to the levobupivacaine group and was clinically significant $P = 0.016$. Other side effects like bradycardia, nausea, and vomiting were also more in the Bupivacaine group than the Levobupivacaine, however, this was statistically insignificant $P > 0.05$. It has been shown that the sympathetic nervous system - related side effects of levobupivacaine are less frequent than those associated with the use of bupivacaine and the mean convulsive dose for levobupivacaine is higher than that of

bupivacaine (10).

Hemodynamic parameters such as heart rate and Mean arterial pressure were similar in both groups and statistically insignificant except at 10 and 15 minutes after spinal, when mean arterial pressure showed a significant difference between the two groups ($P < 0.05$). Good hemodynamic stability, with a reduced prevalence of side effects, has been shown for intrathecal levobupivacaine in elderly patients also in studies by Cuvass et al. and Erdil et al. (11, 12).

4.1. Conclusion

In conclusion, this study shows that spinal anaesthesia performed with both local anaesthetic drugs provides fast and effective induction of surgical anaesthesia for caesarean section. Since motor block time is shorter, sensory block time longer, better hemodynamic stability and lesser patients with hypotension, the Levobupivacaine can be a better alternative in caesarean sections.

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