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Original Research Article.

A Comparative Study of Intrathecal Hyperbaric Levobupivacaine and Hyperbaric Bupivacaine with Fentanyl in Elective Caesarean Section

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ABSTRACT

Background: Spinal anaesthesia is a common and safe technique for parturients undergoing elective caesarean section. Levobupivacaine and bupivacaine are widely used local anaesthetics with distinct profiles in spinal anaesthesia. This study was undertaken to compare their efficacy and safety in spinal anaesthesia.

Objective: To evaluate and compare the efficacy, safety, and side effect profiles of levobupivacaine and bupivacaine in patients undergoing elective caesarean section.

Method: A randomized controlled trial was conducted with 100 patients undergoing elective caesarean section. Patients were assigned to receive either hyperbaric levobupivacaine (0.5%) plus fentanyl or hyperbaric bupivacaine (0.5%) plus fentanyl for spinal anaesthesia. Efficacy was assessed based on the onset and duration of sensory and motor blocks, while safety was evaluated through monitoring of hemodynamic parameters and recording any adverse effects. Data were analysed using appropriate statistical methods.

Results: Both levobupivacaine and bupivacaine provided adequate anaesthesia without any differences in mean onset of sensory block, time taken for sensory block to achieve T6 level and maximum level of sensory block. The mean duration of analgesia was significantly higher in levobupivacaine. The mean time to onset of motor block and mean time to achieve maximum motor block was significantly reduced but having significantly higher duration of motor block in bupivacaine group. Incidence of side effects like hypotension and bradycardia were higher in bupivacaine receiving patients.

Conclusion: Levobupivacaine and bupivacaine are both effective for spinal anesthesia in elective caesarean section. While their efficacy is similar, levobupivacaine may offer a slight advantage in terms of safety, with fewer side effects. Further studies could provide additional insights into the benefits of levobupivacaine over bupivacaine.

Keywords: Levobupivacaine; Bupivacaine; Spinal Anaesthesia; Caesarean section; Efficacy; Safety; Side Effects.

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INTRODUCTION

Spinal anaesthesia is safer for both neonates and mother than general anaesthesia and is the ideal anaesthesia and method of choice during elective caesarean section.[1] Among the various local anaesthetics used in this modality, hyperbaric bupivacaine has been a long-standing choice due to its reliable anaesthetic properties and extended duration of action.[2] However, advancements in anaesthetic techniques and the introduction of new agents have prompted a re-evaluation of existing practices.[3] Levobupivacaine, a newer local anaesthetic, is a more selective S-enantiomer of bupivacaine has recently been introduced for spinal and epidural anaesthesia.[4-5] It has been suggested to offer a safer profile with potentially reduced cardiovascular and central nervous system toxicity while maintaining effective analgesic and motor block qualities.[6] Hyperbaric levobupivacaine for caesarean section has been found to be 38% less potent than hyperbaric bupivacaine in some studies.[7] Levobupivacaine produces less motor block than bupivacaine when given intrathecally.[8] The addition of opioids, such as fentanyl, to intrathecal local anaesthetics can enhance analgesia by providing synergistic effects that improve pain control and reduce the required dose of local anaesthetics, potentially minimizing side effects.[9]

This study aims to compare the efficacy and safety of intrathecal hyperbaric levobupivacaine and hyperbaric bupivacaine, both combined with fentanyl, in elective caesarean sections. By evaluating these anaesthetic regimens, we seek to determine their comparative impact on onset and duration of sensory and motor block, analgesic efficacy, and the incidence of adverse effects. Understanding these differences will contribute to optimizing anaesthetic practices for elective caesarean sections, ultimately improving patient outcomes and safety.

METHODOLOGY

The present study is a prospective, randomized, double-blind comparison conducted on 100 pregnant patients undergoing elective caesarean section under spinal anaesthesia at Rajindra Hospital, Government Medical College, Patiala. After obtaining Institutional Ethics Committee approval and Clinical Trial Registry of India (CTRI/2023/06/053561), 50 patients were assigned to each of the two study groups using a simple random technique with a closed envelope method. Group A received 0.5% hyperbaric levobupivacaine 10 mg with fentanyl 20 mcg intrathecally, while Group B received 0.5% hyperbaric bupivacaine 10 mg with fentanyl 20 mcg intrathecally. The medications were administered by an anaesthesiologist not involved in patient care or data collection, ensuring a double-blind design. Parturients aged between 18-40 years, ASA physical status I and II, height 135-165 cm, and with gestation over 37 weeks were included. Patients were excluded if they had contraindications such as refusal for consent, coagulopathy, spine disorders, or allergies to the study drugs. Routine pre-anesthetic evaluations and baseline assessments, including vital signs and lab investigations, were performed. On the day of surgery, patients were shifted to pre-anaesthetic room. A suitable peripheral vein was cannulated with 18 G cannula and preloading done with 10ml/kg of ringer's lactate fluid. All routine monitors were applied. The baseline values of heart rate, SpO_2, mean blood pressure, respiratory rate, ecg were recorded in supine position.

After placing the patient in left lateral position, under aseptic and antiseptic precautions and after infiltration of local anaesthetic, a 25/26-gauge quincke point needle was introduced in L3-L4 interspace. Dura was punctured for administration of local anaesthetic solution. Patients were made to lie in supine position immediately. A wedge was put under the right buttock to avoid aorto-caval compression. All patients were supplemented with 3-4 liters of oxygen via nasal canula throughout surgery. Surgery was allowed to start once T6, or above level of sensory block was achieved. Sensory and motor assessment was performed immediately after positioning the patients supine. Time zero (T0) was taken as corresponding to the time of completion of intrathecal injection of study drug. The sensory level was measured by pin prick method bilaterally in the anterior axillary line with 25 G bevelled needle every minute until no pain to pin prick sensation felt at T6 level. Onset of sensory block was defined as the time from T0 to the time when the patient did not feel the pin prick at T10 level. Thereafter the level was assessed every 2 minutes, till the attainment of maximum level of sensory block. Surgical incision commenced when sensory level was at or above T6 level. Time taken to achieve level of T6 was also recorded.

Maximum level of sensory blockade attained and time to achieve maximum level also recorded. Time taken for maximum sensory level blockade was defined as the time taken from T0 to the time at which maximum level of sensory blockade is achieved. Duration of analgesia was given by the time from the onset of sensory block to the time when the patient required first dose of rescue analgesic, i.e, paracetamol 1 g i.v for post operative pain of VAS score>3.

Quality of motor blockade in the lower limb was graded using the modified Bromage scale

0 – no motor blockade, able to lift the leg at the hip.

1 – not able to lift the leg at the hip (hip block) but flexion at ankle and knee possible.

2 – able to flex the ankle but unable to flex hip and knee.

3 – unable to move even the foot (hip, knee and ankle blocked)

Time to onset of motor block was recorded. The onset of motor block defined as the time from intrathecal injection until Bromage scale 1 is achieved. Time taken to achieve maximum Bromage scale was recorded. Duration of motor blockade was taken as the time from onset of motor block till the patient attained slight recovery to Bromage scale 2, was recorded.

Haemodynamic parameters were recorded after every 1 minute for 5 consecutive minutes, then after every 5 minutes up to 20 minutes and then after every 15 minutes throughout the surgery period intraoperatively. Hypotension (fall in BP> 20% from baseline or systolic BP<100 mm Hg) was treated with incremental boluses of injection mephentermine 3mg i.v. Bradycardia was defined as HR<50 per min and treated with atropine. Side effects like nausea and vomiting were recorded and treated with 4 mg of ondansetron i.v. Other side effects like shivering and pruritis were also recorded and treated with injection tramadol 25 mg i.v and injection avil 25 mg i.v respectively.

Table 1: Demographic profile

Variable	Group A (Levobupivacaine)	Group B (Bupivacaine)	p-value
Age (Years)	24.32 ± 3.53	24.90 ± 3.40	0.404 (NS)
Height (cm)	154.38 ± 9.50	153.60 ± 8.95	0.674 (NS)
Weight (kg)	69.10 ± 4.39	68.90 ± 3.41	0.800 (NS)
Body Mass Index (kg/m²)	25.83 ± 2.16	25.97 ± 2.21	0.757 (NS)
ASA Physical Status (I/II)	31/19	30/20	0.838 (NS)
Gestation Age (weeks)	37.43 ± 0.90	38.67 ± 0.88	0.181 (NS)

Table 2: Characteristics of sensory and motor block.

Variable	Group A (Levobupivacaine)	Group B (Bupivacaine)	Mean ± SD	p-value
Time to Onset of Sensory Block (minutes)	2.15 ± 0.57	2.24 ± 0.64	2.15 ± 0.57	>0.05(NS)
Time to Maximum Sensory Block Level (minutes)	8.63 ± 1.43	8.64 ± 1.40	8.63 ± 1.43	>0.05(NS)
Time to Achieve T6 Dermatome Level (minutes)	4.29 ± 1.03	3.95 ± 0.78	4.29 ± 0.15	>0.05(NS)
Mean Duration of Analgesia (minutes)	308.38 ± 13.17	250.80 ± 24.08	308.38 ± 13.17	<0.001
Percentage Achieving T2 Dermatome Level	35 patients (70%)	29 patients (58%)		<0.05
Time to Onset of Motor Block (minutes)	7.55 ± 17.10	2.27 ± 0.64	2.27 ± 0.64	<0.05
Time to Maximum Motor Block (minutes)	8.84 ± 1.30	3.58 ± 0.83	8.84 ± 1.30	<0.001
Mean Duration of Motor Block (minutes)	111.48 ± 12.82	144.32 ± 18.31	111.48 ± 12.82	<0.001

Table 3: Side effect

Side Effect	Group A (Levobupivacaine)	Group B (Bupivacaine)	p-value
Hypotension	9 (18%)	16 (32%)	0.023
Bradycardia	8 (16%)	15 (30%)	0.043
Nausea	4 (8%)	9 (18%)	0.329
Vomiting	4 (8%)	7 (14%)	0.400
Pruritus	1 (2%)	3 (6%)	0.799
Shivering	4 (8%)	8 (16%)	0.609

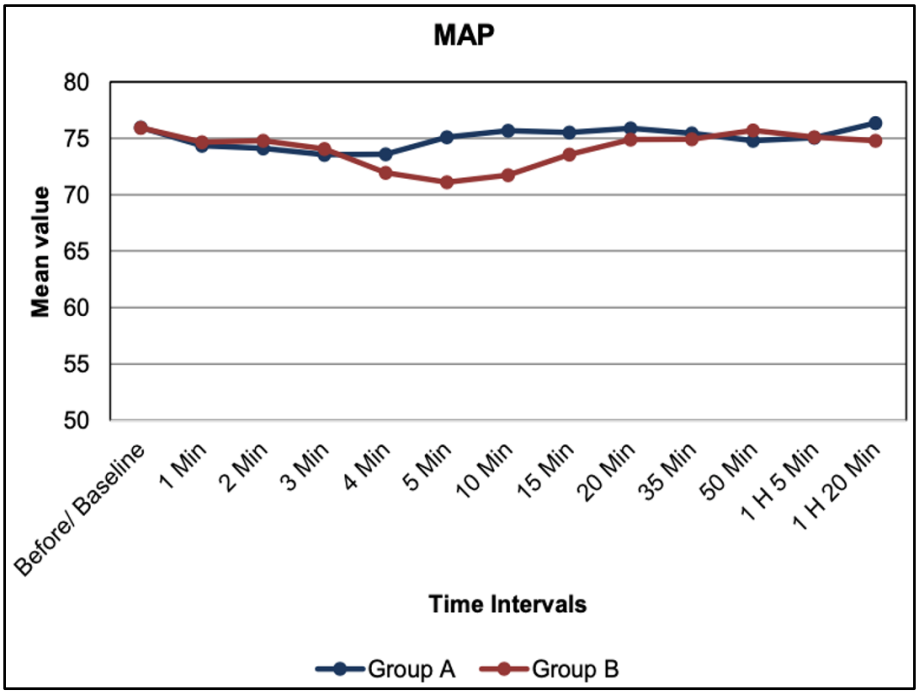

Figure 1: Trend of Mean Arterial blood pressure over different time interval

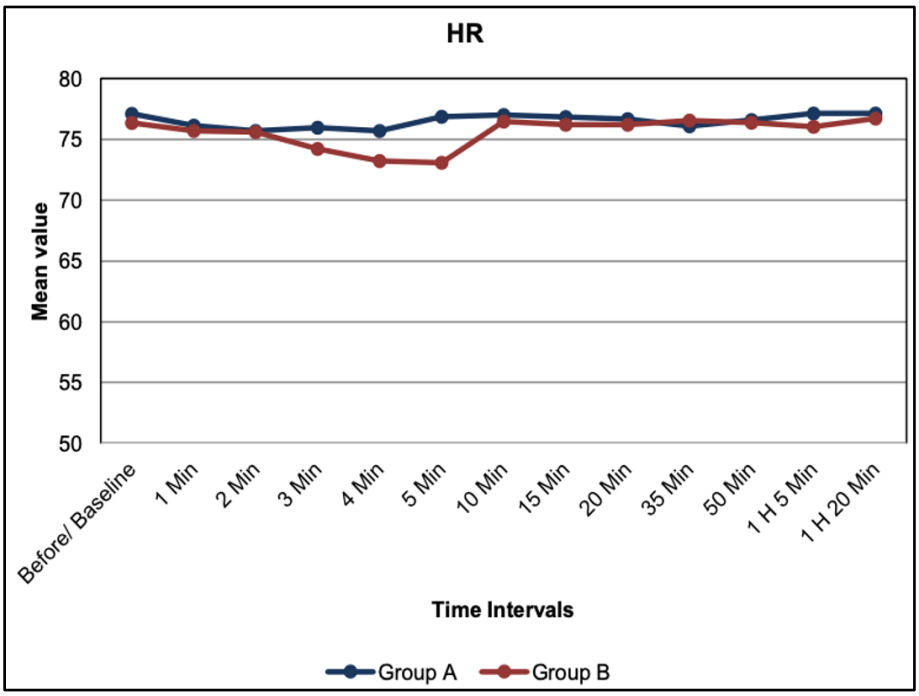

Figure 2: Trend of Mean Heart Rate over different time interval

RESULTS

The results of the study were presented across five key tables, each highlighting different aspects of the comparative analysis between the Levobupivacaine (Group A) and Bupivacaine (Group B) groups. Variables like Age, Height, Body mass index, ASA Physical status I/II and Gestational age were comparable between two groups. Table 2 compares the sensory and motor block characteristics between Group A, which received intrathecal hyperbaric levobupivacaine plus fentanyl and Group B, which received hyperbaric bupivacaine plus fentanyl for elective caesarean sections.

The mean time to onset of sensory block was similar between the two groups, with Group A at 2.15 ± 0.57 minutes and Group B at 2.24 ± 0.64 minutes, showing no significant difference ($p > 0.05$). The time required to reach the maximum sensory block level was almost identical in both groups, with Group A at 8.63 ± 1.43 minutes and Group B at 8.64 ± 1.40 minutes, indicating a non-significant difference ($p > 0.05$). Additionally, the time to achieve the T6 dermatome level was comparable, with Group A achieving it in 4.29 ± 0.15 minutes and Group B in 3.95 ± 0.78 minutes, with no significant difference ($p > 0.05$).

However, there was a significant difference in the mean duration of analgesia between the groups. Group A had a mean duration of 308.38 ± 13.17 minutes, significantly longer compared to 250.80 ± 24.08 minutes in Group B ($p < 0.001$). Furthermore, a higher percentage of patients in Group A (70%) achieved the T2 dermatome level compared to Group B (58%), with this difference being statistically significant ($p < 0.05$).

For motor block characteristics, Group A had a significantly longer mean time to onset of motor block (7.55 ± 17.10 minutes) compared to Group B (2.27 ± 0.64 minutes) ($p < 0.05$). Conversely, the mean time to achieve maximum motor block was significantly longer in Group A (8.84 ± 1.30 minutes) compared to Group B (3.58 ± 0.83 minutes) ($p < 0.001$). The mean duration of motor block was also significantly shorter in Group A (111.48 ± 12.82 minutes) compared to Group B (144.32 ± 18.31 minutes) ($p < 0.001$).

Mean ± SD of MAP (mmHg) at 5 min and 10 minutes in group A was 75.10±7.21 and 75.68±4.92 respectively which was significantly higher as compared to group B 71.12±10.19 (p value=0.026), and 71.74±8.18 (p value=0.004) respectively.

Mean ± SD of Heart Rate (beats/min) at 5 minutes in group A was 76.86±6.77, which was significantly higher as compared to group B 73.08±9.89. (p value=0.028).

Table 3 illustrates the distribution of side effects among patients in the two groups, Group A (Levobupivacaine) and Group B (Bupivacaine). The occurrence of hypotension was significantly higher in Group B (32%) compared to Group A (18%), with a chi-square value of 5.165 and a p-value of 0.023, indicating statistical significance.

Similarly, bradycardia was more prevalent in Group B (30%) than in Group A (16%), with a significant chi-square value of 4.082 and a p-value of 0.043. Other side effects, including nausea, vomiting, pruritus, and shivering, were observed with varying frequencies but did not show significant differences between the groups. Specifically, nausea was experienced by 18% of patients in Group B and 8% in Group A (p=0.329), while vomiting occurred in 14% of Group B and 8% of Group A (p=0.400). Pruritus and shivering were slightly more common in Group B, but these differences were not statistically significant, with p-values of 0.799 and 0.609, respectively.

Overall, these tables highlight that while some characteristics such as the time to onset of sensory and motor blocks were similar between the two groups, the duration of analgesia and motor block was significantly longer in the Levobupivacaine group, suggesting its potential advantages in clinical practice. Result indicates that while some side effects like hypotension and bradycardia were significantly more common in patients receiving Bupivacaine, other side effects were similarly distributed across both groups.

DISCUSSION

This prospective double-blind comparative clinical study was conducted on 100 pregnant females scheduled for elective caesarean sections at Government Medical College and Rajindra Hospital, Patiala. The patients were randomly divided into two groups of 50 each (n=50). Group A received 2ml (10mg) of 0.5% hyperbaric levobupivacaine plus 20mcg (0.4ml) fentanyl intrathecally, while Group B received 2ml (10mg) of 0.5% hyperbaric bupivacaine plus 20mcg (0.4ml) fentanyl intrathecally. The groups were comparable in terms of age, height, weight, ASA physical status, and gestational age.

The time to onset of sensory block and the time to reach the maximum sensory block were key parameters. Onset of sensory block was defined as the time from the completion of intrathecal injection (T0) to when the patient no longer felt a pinprick at the T10 level. The mean time to onset of sensory block was 2.15±0.57 minutes in Group A and 2.24±0.64 minutes in Group B, with no statistically significant difference between the groups ($p > 0.05$). The time to reach the maximum sensory block was also comparable between the groups: 8.63±1.43 minutes in Group A and 8.64±1.40 minutes in Group B ($p > 0.05$).

These findings are consistent with studies by Goyal et al.[10], Duggal et al.[11], and Erbay et al.[12], which reported similar non-significant differences in the onset and time to maximum sensory block between levobupivacaine and bupivacaine groups. However, our results contradict the study by Thakore et al.[13], which found a statistically significant delay in sensory block onset and time to maximum sensory level in the levobupivacaine group compared to the bupivacaine group.

The duration of analgesia was defined as the time from the onset of the sensory block to the first request for rescue analgesia (paracetamol 1g intravenously) when the Visual Analogue Scale (VAS) score exceeded 3. The mean duration of analgesia was significantly prolonged in the levobupivacaine group (308.38±13.17 minutes) compared to the bupivacaine group (250.80±24.08 minutes), with a highly significant p-value (<0.001). This finding may be attributed to the vasoconstrictive properties of levobupivacaine at lower doses compared to bupivacaine. Similar results were observed in studies by Thakore et al.[13] and Erbay et al.[12], which found significantly longer durations of analgesia in the levobupivacaine groups. However, our results differ from those of Duggal et al.[11] and Goyal et al.[10], where the bupivacaine group had a longer duration of analgesia, possibly due to the isobaric formulation of levobupivacaine used in those studies.

In our study, 70% of patients in Group A (levobupivacaine) achieved the T2 sensory level, compared to 58% in Group B (bupivacaine), with the difference being statistically significant ($p < 0.05$). This higher level of sensory block in the levobupivacaine group may also be linked to its vasoconstrictive properties.

Our findings align with the study by Subasi et al.[14], which reported a significant difference in the maximum sensory block level between levobupivacaine and bupivacaine groups. However, our results are contrary to those of Guler et al.[15] and Shukla et al.[16], who found that the maximum sensory block level was lower in the levobupivacaine group or statistically non-significant between the groups.

Motor Block Characteristics

The mean time to onset of motor block was significantly longer in Group A (7.55±17.10 minutes) compared to Group B (2.27±0.64

minutes), with a statistically significant difference ($p < 0.05$). This delay in motor block onset in the levobupivacaine group is consistent with studies by Goyal et al.[10], Thakore et al.[13], and Guler et al.[14], which also found a delayed onset of motor block in levobupivacaine compared to bupivacaine. However, our results differ from those of Shukla et al.[15], who reported no significant difference in the onset of motor block between the two groups.

Overall, the findings from this study suggest that while both levobupivacaine and bupivacaine are effective in providing sensory and motor block for caesarean sections, levobupivacaine offers a prolonged duration of analgesia with a slightly higher maximum sensory level, albeit with a delayed onset of motor block compared to bupivacaine. These characteristics should be considered when choosing the anaesthetic agent based on the clinical scenario and patient needs.

Side effect

In our study, the most common side effect observed was hypotension, occurring in 32% of patients in the bupivacaine group and 18% in the levobupivacaine group, with statistically significant difference between the two groups. This aligns with previous research, such as studies by Goyal A et al.[10] and Guler et al.[14], which also reported hypotension as a frequent side effect with significant differences between the anaesthetics. However, our findings differ from Dar FA et al.[17], who noted similar incidences of hypotension with levobupivacaine also. Overall, both anaesthetics demonstrated similar safety profiles regarding side effects. Bradycardia incidences were found to be 30% in bupivacaine as compared to 16% in levobupivacaine with statistically significant difference between the two groups. The study findings were similar to that of Goyal A et al.[11] and Guler et al.[14], but was on dissimilar ground with the findings F Fattorini et al.[18] who did not find significant difference in the incidences of bradycardia between the two groups.

CONCLUSION

In conclusion, levobupivacaine and bupivacaine both provide fast and effective induction of surgical anaesthesia in elective caesarean section. Levobupivacaine in addition provides prolonged duration of analgesia, lesser duration of motor block with better hemodynamic stability. So we suggest that 0.5% hyperbaric levobupivacaine with fentanyl may be preferred over 0.5% hyperbaric bupivacaine with fentanyl in elective caesarean section under spinal anaesthesia.

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