ORIGINAL ARTICLE

Comparison of intrathecal 0.5% isobaric levobupivacaine with fentanyl and 0.5% hyperbaric bupivacaine with fentanyl in LSCS surgeries – A randomized double-blind trial

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Objectives: The objectives of this study were to compare isobaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in spinal anesthesia in patients undergoing cesarean section. **Materials and Methods:** We conducted a prospective randomized double-blind study in 80 patients undergoing cesarean section. All patients were divided into two groups A and B. Group A patients received 5 mg (1 mL) isobaric levobupivacaine and 20 mcg (0.4 mL) fentanyl and Group B patients received 5 mg (1 mL) hyperbaric bupivacaine and 20 mcg (0.4 mL) fentanyl, which was administered intrathecally within 10 s, using a 25-gauge Quinke spinal needle at the L3-4 inter vertebral space. **Results:** The demographic profile was similar in all patients of both groups and is comparable. The onset of sensory and motor blockade was seen earlier with group receiving bupivacaine with fentanyl. The duration of regression blockade was seen more in levobupivacaine with fentanyl. The incidence of side effects such as post-operative pain, shivering, and neonatal status was not seen in group receiving levobupivacaine with fentanyl. **Conclusion:** The duration of sensory and motor blockade was prolonged in levobupivacaine plus fentanyl group with slower regression of block and lesser incidence of side effects and increased mean time for first rescue analgesia in post-operative period which makes it better suited for elective lower section cesarean section.

KEY WORDS: Levobupivacaine, bupivacaine, fentanyl, cesarean section

INTRODUCTION

Neuroaxial anesthesia is the method of choice for lower segment cesarean procedures. Despite the fact that spinal, continuous spinal, and spinal-epidural combined, procedures have all been promoted. Single-shot spinal anesthetic is used to perform the majority of cesarean sections.[1]

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Spinal anesthesia (SA) was performed first by August Bier on August 16, 1898, where he used 3 mL of 0.5% cocaine intrathecal injection into a 34-year-old laborer.[2]

SA, which is a safe, dependable, and reasonably priced technique with the added benefit of providing surgical anesthesia and prolonged post-operative pain relief through the use of various local anesthetic agents, was the first major regional technique that was introduced into clinical practice. SA reduces endocrine, autonomic, and somatic reactions as well as intraoperative discomfort. Moreover, it offers an efficient and quick-acting sensory and motor blockage.[2]

SA using only local anesthetic often provides suboptimal analgesia with greater side effects. Many drugs have been adjusted to local anesthetics to provide optimal analgesia with lesser side effects such as opioids.[3,4]

Pain control after lower-segment cesarean section (LSCS) improves breastfeeding and satisfaction of mother. In addition, light analgesia can lead to elevated plasma catecholamine levels, which results in adverse effect on all organ systems.[5]

In parturients undergoing elective cesarean delivery under SA, the most common local anesthetic used is hyperbaric bupivacaine.[6,7] However, if it is compared to other local anesthetics, it also has considerable side effects on the cardiovascular system and central nervous system.[8] Levobupivacaine, the S(-)-enantiomer of bupivacaine, recently introduced for obstetric spinal and epidural anesthesia.[9,10] Enantiomers seen to have same desired pharmacological properties, but less adverse effects. In comparison to racemic bupivacaine, it has also been observed to provide a more focused neuraxial blockade.[11]

After a cesarean delivery, the quality and duration of postoperative analgesia are significantly improved when intrathecal opioids such as fentanyl or sufentanil are administered. It also provides better parturient comfort without affecting the neonatal outcome.[12]

In this study, we will use lower dose of bupivacaine/ levobupivacaine with higher dose of fentanyl (adjuvant) than those used in earlier studies and observe which group would provide better post-operative analgesia and early ambulation post-LSCS and facilitate breastfeeding and satisfaction of mother with adjusted doses of drugs.

Aims and Objectives

The aims of this study were to compare isobaric levobupivacaine with fentanyl and hyperbaric levobupivacaine with fentanyl in SA in patients undergoing cesarean section.

Primary objective

To compare:
1. Onset of sensory blockade
2. Onset of motor blockade.

Secondary objective

To compare:
1. Hemodynamic changes
2. Post-operative analgesia.

Duration of study

This study was October 2020–November 2021.

MATERIALS AND METHODS

Place of Study

The study was carried out at Rohilkhand Medical College and Hospital Bareilly after obtaining the approval from the Institutional Ethical Committee. Informed and written anesthesia consent was obtained from the patient or next of the kin.

Type of Study

This is a prospective randomized double-blind study which was carried out in 80 patients divided into two groups each comprising of 40 patients.

This study was conducted in the females of reproductive age group admitted in RMCH Bareilly. Patients were divided in two groups-
- Group A: Will receive spinal anesthesia with 5 mg (1 mL) isobaric levobupivacaine and 20 mcg (0.4 mL) fentanyl
- Group B: Will receive spinal anesthesia with 5 mg (1 mL) hyperbaric bupivacaine and 20 mcg (0.4 mL) fentanyl.

Time of Study

This study was 1 year starting from November 1, 2020, to October 31, 2021.

Subjects

This study was patients undergoing LSCS.

Sample Size

Sample size was taken to be 40 in each group as per statistical calculations which are done using the software power and sample size program

(Alfa [α] - type 1 error = 5%, Delta [δ] =7, Sigma [σ] = 12, Power = 0).
- PO- Proportion of outcome in Group 1
- P1- Proportion of outcome in Group 2
- M- Number of cases in control = 1.

Inclusion Criteria

The following criteria were included in the study:
- Undergoing LSCS
- ASA grade I or II
- Age group 18–45 years (reproductive age group).

Exclusion Criteria

The following criteria were excluded from the study:
- Not willing for spinal anesthesia
- Allergic to local anesthetics
- Patients with spine deformities
- With acute fetal distress
- Complicated pregnancy such as pregnancy induced hypertension, placenta previa, and abruption placenta
- Systemic disorders such as diabetes, heart disease, chronic hypertension, and pulmonary disease
- With bleeding or coagulation disorders.

Methodology

Methodology of the study is according to ethical principles for medicine research involving human subjects outlined in the Declaration of Helsinki.

Thorough pre-anesthetic check-up was done 1 day before the surgery and informed and written anesthesia consent was taken for participation in the study.

Patients were advised for nil per oral (NPO), 6 h for solids and 3 h for liquids. Light dinner was allowed before NPO order. Patients were kept on intravenous (IV) 5% dextrose to avoid fetal hypoglycemia.

On arrival at the operating room and after connecting of routine monitors such as non-invasive blood pressure measurement, electrocardiography, pulse oximetry, and insertion of a peripheral 18-gauge IV cannula, patients were preloaded with IV Ringer lactate solution at 10 mL/kg. Antiemetic prophylaxis was given using Injection Ranitidine 1 mg/kg and Injection Metoclopromide 0.2 mg/kg.

Baseline systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR) were recorded. Patients were placed in the left lateral position. Under all aseptic precautions and after disinfecting the skin with savlon, spirit and betadine 5%, and infiltrating with 2% lidocaine, lumbar puncture was performed using a 25-gauge Quinke type spinal needle at the L3-4 inter vertebral space. After confirmation of clear and free flow of cerebrospinal fluid, Group A patients received 5 mg (1 mL) isobaric levobupivacaine and 20 mcg (0.4 mL) fentanyl and Group B patients received 5 mg (1 mL) hyperbaric bupivacaine and 20 mcg (0.4 mL) fentanyl, which was administered intrathecally within 10 s. Patients were then turned to a supine position with a wedge placed under their right hip. A Hudson face mask was used to provide 4 L/min of oxygen.

Continuous measurements were made of the patient's HR, MAP, and respiratory rate. Hypotension is characterized by a more than 20% drop in either the MAP or the systolic pressure from the baseline. Injection Ephedrine 5–10 mg was administered intravenously in a bolus dose along with any necessary IV fluids. Bradycardia was treated with 0.6 mg of IV atropine when the HR was <20% of the baseline value.

Sensory dermatomal level achieved was analyzed by pinprick with 24G hypodermic needle.

When a patient's ability to raise their extended legs was lost, it was said that the patient had experienced the onset of a motor block. The Modified Bromage scale was used to grade the severity of the motor block as follows:

Modified Bromage Scale

Grade	Criteria	Degree of block (%)
O	Free movement of legs and feet	Nil (0)
I	Knee flexion decrease but full flexion of feet and ankle	Partial (33)
II	Unable to flex knees, flexion of ankle, and feet present	Partial (66)
III	Unable to flex knee or ankle or move toes	Complete paralysis (100)

Onset of post-operative pain was considered when patient requests first rescue analgesic.

OBSERVATION AND RESULTS

Mean onset of sensory blockade was 3.11 ± 0.28 in Group A and 1.82 ± 0.14 in Group B, as depicted in Table 2, and Diagram 5 with $P < 0.001$*, which was statistically significant.

Mean onset of motor blockade was 4.74 ± 0.51 in Group A and 3.81 ± 0.35 in Group B, as depicted in Table 3, and Diagram 6, with $P < 0.001$*, which was statistically significant.

Mean value of duration of post-operative analgesia was 8.63 ± 0.72 in Group A and 6.42 ± 0.24 in Group B, as depicted in Table 4, and Diagram 10, with $P < 0.001$*, which was statistically significant.

Hemodynamic Changes

HR, SBP, DBP, and MAP in pre-operative, intraoperative, and post-operative values were statistically insignificant among both groups.

DISCUSSION

Demographic Profile

The pregnant women who underwent cesarean sections for our study were split into two groups, A and B, each with 40

Table 1: Distribution of age (in years), height (in cm), and weight (in kg) among Groups A and B

Objectives	Group A mean±SD *n*=40	Group B mean±SD *n*=40	*P*-value
Age in years	(28.45±5.84)	(30.13±6.32)	0.782#
Height in cm	159.43±4.53	157.68±5.74	0.134#
Weight in kg	58.96 ± 7.52	60.24 ± 8.09	0.328#

#Statistically insignificant

Table 2: Comparison of onset of sensory blockade (in minutes) among Groups A and B

Objectives	Group A mean±SD *n*=40	Group B mean±SD *n*=40	*P*-value
Onset of sensory blockade	3.11±0.28	1.82±0.14	<0.001*

Table 3: Comparison of onset of motor blockade (in minutes) among Groups A and B

Objectives	Group A mean±SD *n*=40	Group B mean±SD *n*=40	*P*-value
Onset of motor blockade	4.74±0.51	3.81±0.35	<0.001*

Table 4: Comparison of duration of post-operative analgesia (in hours) among two groups

Objectives	Group A mean±SD *n*=40	Group B mean±SD *n*=40	*P*-value
Duration of postoperative analgesia (in hours)	8.63±0.72	6.42±0.24	<0.001*

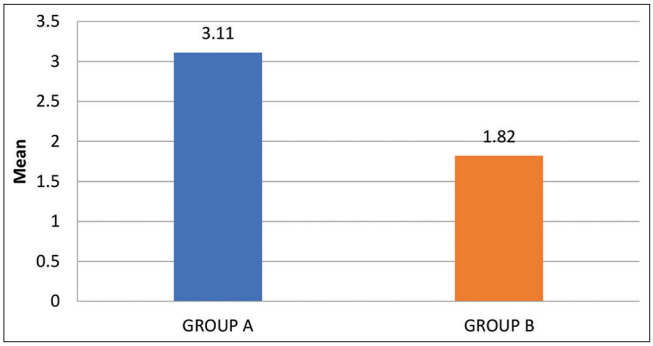

Figure 1: Bar diagram showing comparison of onset of sensory blockade (in minutes) among Groups A and B

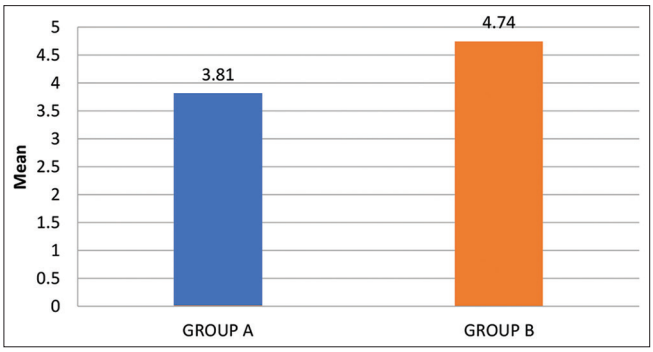

Figure 2: Bar diagram showing comparison of onset of motor blockade (in minutes) among Groups A and B

participants. Patients in Group A were 28.45 ± 5.84 years old, whereas those in Group B were 30.13 ± 6.32 years old [Table 1 and Figure 1], which was comparable ($P > 0.05$). The patient's height was 159.43 ± 4.53 cm and 157.68 ± 5.74 cm [Table 2 and Figure 2], which was similar ($P > 0.05$); similarly, the patient's weight was 58.96 ± 7.52 kg and 60.24 ± 8.09 kg [Table 3 and Figure 3], which was similarly similar ($P > 0.05$). Thus, our groups were similar.

Prabha *et al*., Turkmen *et al*., and Goyal *et al*., also found no significant difference in demographic profile of patients in the groups in their respective studies.[13-15]

Sensory Characteristics

Onset time of sensory blockade

The onset time of sensory blockade is the time from the administration of SA at L2-L3 interspace to the loss of sensation to pin prick at dermatome level T10 (dermatome for surgical readiness).

In our study, we found that the time taken from intrathecal injection to skin incision in Group B were 2 min 15 s and in Group A, it was 3 min 11 s and $P < 0.05$. This shows that Group B has faster onset of sensory than Group A [Table 2 and Graph 5].

In a similar study by Turkmen *et al*. also showed similar results.[14]

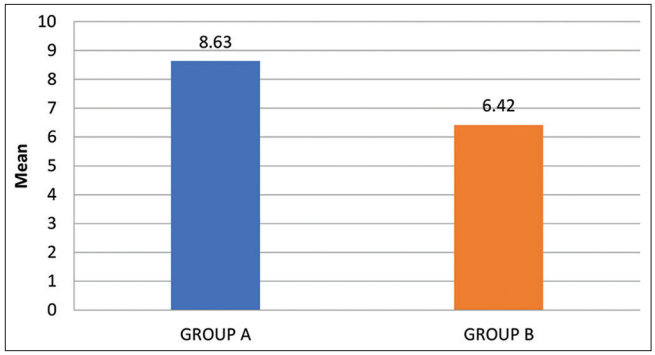

Figure 3: Bar diagram showing distribution of duration of postoperative analgesia (in hours) among two groups

Motor Characteristics

Onset of motor blockade

The onset of motor blockade is the time from administration of SA to the motor blockade with modified Bromage score of 3.

Onset of motor blockade was 3.81 ± 0.35 min in Group A and 4.74 ± 0.51 min in Group B, as shown in Table 3, and Diagram 6, with $P < 0.001$*, which was statistically significant. In a similar study by Turkmen *et al*. showed similar study.[14]

Time for first rescue analgesia

The time for first rescue analgesia was more in Group B as compared to Group A. It was 8.63 ± 0.72 h in Group A and 6.42 ± 0.24 h in Group B.

Turkmen *et al*., also concluded that addition of opioid intrathecally provides enhanced post-operative analgesia and decreases the rescue analgesic requirement.[14]

Hemodynamics changes

In our study intraoperatively, we noted that in Group B, there was a fall in MAP of >20% of the basal value, whereas in Group A, there was no such fall in MAP noted. We also noted that in Group B, the intraoperative arterial pressure was increased 20% more from basal arterial pressure, whereas in Group A, stable arterial pressure was documented intraoperatively. This shows that intrathecal 0.5% isobaric levobupivacaine with fentanyl had better hemodynamic stability than 0.5% hyperbaric bupivacaine with fentanyl in LSCS.

This was similar in a study by Turkmen *et al*., who observed that decrease in arterial pressure and arterial pressure as well as changes in arterial pressure was in acceptable ranges.[14]

CONCLUSION

We conducted a study in patients who underwent elective cesarean section and we concluded that duration of motor and sensory blockade level was more with slower regression time in levobupoivacine with fentanyl group. There was also lesser

incidence of post-operative pain and associated side effects with better neonatal outcome and hemodynamic stability with patient satisfaction.

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