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COMPARISON OF THE EFFECTIVENESS OF HYPERBARIC LEVOBUPIVACAINE (0.5%) AND HYPERBARIC BUPIVACAINE (0.5%) COMBINED WITH FENTANYL IN PATIENTS UNDERGOING CASEREAN SECTION

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ABSTRACT
INTRODUCTION- The most popular local anaesthetic for spinal anaesthesia in patients having an elective caesarean delivery is hyperbaric bupivacaine. Enantiomers could possess the same desired properties but fewer adverse effects. In comparison to bupivacaine, levobupivacaine, the S (-)-enantiomer of bupivacaine, has recently been approved for obstetric spinal and epidural anesthesia. Hence, the study has been formulated to sensory and motor effect with hyperbaric levobupivacaine and bupivacaine with fentanyl in patients undergoing caserean section.
AIM & OBJECTIVE: To compare analgesic and anesthetic effectiveness of hyperbaric 0.5% levobupivacaine and hyperbaric 0.5% bupivacaine in combination with fentanyl in spinal anesthesia in patients undergoing caserean section.
METHOD: Patients with ASA Status I & II were divided into two groups of 27 patients each at randomly. Group LF: 27 patients receiving 0.5% hyperbaric levobupivacaine 2 ml (10 mg) combined with 25 µg fentanyl. Group BF: 27 patients receiving 5 ml (10 mg) Bupivacaine combined with 25 µg fentanyl. During surgery, sensory and motor levels, and hemodynamic monitoring were noted. Postoperatively, the total time of the motor and sensory block and the period of rescue analgesia were noted.
RESULT: Group BF had faster sensory onset time at T10. Group LF had longer sensory block and analgesia, and two segment regression time was also longer in Group LF. Hemodynamic parameters were comparable between two groups.
CONCLUSION: The combination of intravenous levobupivacaine and fentanyl increased the duration of the sensory block and the relief from pain without extending the motor block, which may have aided in the onset of early ambulation.

KEY WORD: hyperbaric levobupivacaine, caserean section, Spinal anaesthesia

INTRODUCTION

Lower segment caesarean sections are among the most common obstetric surgical procedures performed under spinal anaesthesia (LSCS).Spinal anaesthesia is frequently used because it provides effective sensory and motor blockage with a quick onset.

The most popular local anaesthetic for spinal anaesthesia, 0.5 % Hyperbaric bupivacaine, has been reported to cause cardiac toxicity after spinal anaesthesia. It can also cause hypotension or bradycardia. Levobupivacaine is one of these local anaesthetics; it is the pure enantiomer of racemic bupivacaine, fully isobaric with respect to the CSF of pregnant women, and less harmful to the heart and CNS.

Local anaesthetics and opioids were thought to have advantages in spinal anaesthesia, including rapid action, improved efficacy with few toxic side effects, and selective sensory

block. Fentanyl can be combined with local anaesthetics to create spinal anaesthesia; when done so, it prolongs the duration of action and spread of sensory block.

As a result, without altering the outcome for the baby, postoperative analgesia during caesarean delivery can be greatly improved in terms of quality and duration, as well as parturient comfort. Prolonging analgesia is the best method for encouraging patients to walk as soon as possible in the postoperative phase. In order to extend the sensory blockade without intensifying the motor block, several additives, including fentanyl and sufentanil, have been added to local anaesthetic.

Therefore, the aforementioned study was designed to evaluate and compare sensory and motor characteristics after spinal anaesthesia using hyperbaric levobupivacaine (0.5%)and hyperbaric bupivacaine (0.5%) combined with fentanyl in patients undergoing caserean section.

AIM

To assess and compare sensory and motor outcomes following spinal anaesthesia using fentanyl in combination with hyperbaric levobupivacaine (0.5%) and hyperbaric bupivacaine (0.5%) in patients undergoing caserean section.

OBJECTIVE

I. To assess Efficacy of sensory and motor blockade between two groups
II. To compare duration of analgesia and hemodynamic parameters between two groups

METHODOLOGY

The total sample size 54 was calculated in this prospective observational study using Open EPI software (version 3.01) based on a previous study by Thakore s et al by using the onset of motor effect value (Group L mean 3.2±1.3 Group B mean 2.3±1.0). with 80% confidence and a 95% confidence interval.

INCLUSION CRITERIA

- Full term parturient
- ASA grade I & II
- Age 20 to 40 years
- No known history to allergy
- Patient willing to give informed consent

EXCLUSION CRITERIA

- Patient’s refusal
- Allergy to local anaesthetics
- Patient on anticoagulants
- Injection site local infection
- Patient with spine deformities
- Weight less than 50 kg and more than 90 kg

After obtaining permission and written informed consent from the patients this study was conducted in 54 full term parturient, posted for elective lower segment caesarean section have been selected for the study. Randomization and group allocation were done with simple random sampling by concealed numbers in envelope system.

Patients divided into 2 groups comprising of 27 patients in each group.
Group BF received inj. Bupivacaine hyperbaric (0.5%) 2 ml (10mg) + 25 µg fentanyl
Group LF received inj. Levobupivacaine hyperbaric (0.5%) 2 ml (10mg) + 25 µg fentanyl

Preop evaluation

A comprehensive history, vitals, general and systemic examination, and airway assessment were performed. Routine laboratory tests were carried out, including a complete haemogram, random blood sugar, liver function test, renal function test, coagulation profile, and an electrocardiogram.

Patient preparation

Each patient was reassured and the process was explained to them. For at least 6 hours, all patients were kept nil per oral. An 18 G intravenous cannula was placed, and preloading was accomplished with a 10 ml/kg infusion of RINGER LACTATE/NORMAL SALINE.

Following that, the patient was transferred to OT and standard monitors were attached to measure pulse rate, NIBP, ECG, and SpO2. All patients received aspiration prophylaxis consisting of an intravenous injection of metaclopramide (10mg) and ranitidine (50mg) 10 minutes before surgery.

Methods of spinal anaesthesia

Skin over the back was prepped with antiseptic solution and draped with sterile towel under strict aseptic procedures. Spinal anaesthesia was administered in a sitting position using a midline approach and a 25 G quinke's spinal needle at the L3-L4 intervertebral region. The correct insertion of the needle was determined by the free flow of cerebrospinal fluid, and a total of 2.5 ml of drug volume was slowly injected. The patient was then positioned supine. Patients were positioned 15 - 20 degrees left lateral supine. A facial mask was used to deliver 6 L/min of oxygen.

If a patient's systolic blood pressure was less than 90mm/Hg or 20% lower than their baseline, they were given titrated dosages of Injection Ephedrine 6mg I.V.
If the heart rate is less than 50 beats per minute, a 0.2mg glycopyrolate IV injection is administered.
Following the delivery of the infant, 10 IU of oxytocin is administered through drip.

Intraoperative vitals were monitored every 5 minutes until 30 minutes, then every 10 minutes till surgery was completed and every 1 hour until rescue analgesia was administered.

SENSORY AND MOTOR BLOCK EVALUTION

- Onset **of** sensory effect at T10 level
- Time to achieve peak sensory level
- Total duration of sensory block
- Two segment regression time
- Total duration of analgesia
- Onset of motor effect
- Total duration of motor block

- The onset of sensory and motor block was measured every minute after the injection ended until the peak effects occurred.
- Sensory block was tested bilaterally in the anterior axillary line using the pinprick method, with the period from intra-thecal injection to the lack of pin prick feeling at T10 level considered the **onset of sensory block.**
- **Duration of sensory block** is the time it takes from total block to the resumption of paraesthesia.
- The time taken for **maximum sensory blockade** was defined as the time it took from the completion of the research drug injection to the highest sensory blockade obtained.
- **Two segments regression** is the time interval between the injection of the first dose of local anaesthetic and the time when the maximal sensory level has receded by two segments.
- **The duration of analgesia** was measured by the interval from the start of the sensory block and when the patient needs to take their first dose of a rescue analgesic.
- **Onset of motor block** defined as the time from spinal injection until Bromage 1 score was registered.
- **Duration of motor blockade** taken as the time from onset of motor block till the patient attained slight motor recovery to Bromage 3 was noted.

- Modified bromage scale:

1. Complete motor block (unable to move feet or knees)
2. Almost complete motor block (able to move feet only)
3. Partial block (just able to move knees)
4. Detectable weakness of hip flexion
5. No detectable weakness of hip flexion while supine (full flexion of knees)
6. Able to perform partial knee bend

ETHICAL ASPECTS

- I will explain procedure day before surgery to patients and patient's relatives.
- Written informed consent will be taken from all participants.
- No identity of participants will be revealed.
- There will be no identification of the patient by name while the data is being analysed. In the event of any publication resulting from the study, no personally identifiable information will be shared.
- After participation, all participants are free to withdraw or exit the study at any time.
- Patients will be given equal importance even after they choose to stop participation at any time.

STATISTICAL ANALYSIS

For data collection and analysis, a pre-structured proforma is employed. To analyse data in the form of tables, graphs, and tests of significance, Microsoft Excel 2019, openEpi 3.01, and the statistical programme SPSS version (20) were used. For intergroup comparison, we utilised the independent t-test, and for demographic data, we used the Chi square test.

The significance of the P value was indicated as follows: (With a 95% confidence interval)

P value > 0.05 was insignificant, P value 0.05 was significant, P value = 0.000 was extremely significant.

RESULT

[**Table 1**. **demographic profile**]

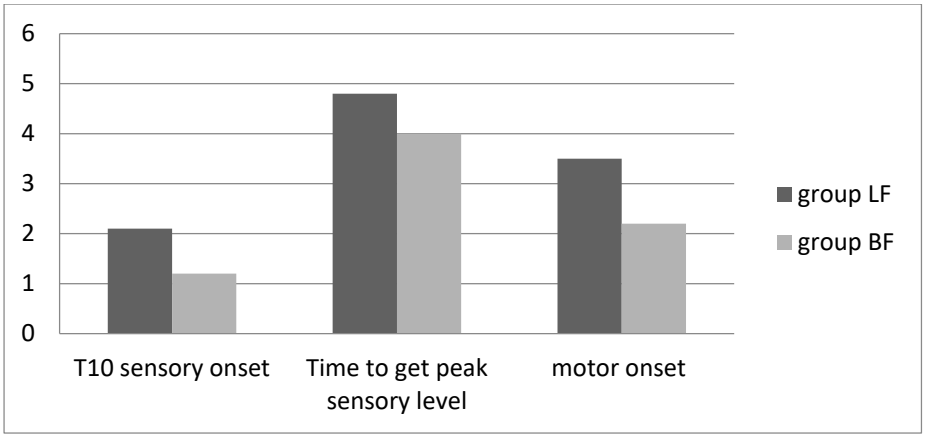
	Group LF	Group BF	P value
Age(year)	26.1 ± 3	25.1 ± 3	0.4546
Height(centimeter)	161.3 ± 5	164 ± 9	0.0194
Weight(kilogram)	67 ± 4	67.2 ± 6	0.9178
Duration of surgery(minutes)	48.6 ± 4	48.1 ± 5	0.6988

In our study there were 54 patients, 27 in each group. Patients' age, weight, height and duration of surgery were comparable and there was no significant difference as shown in Table 1.

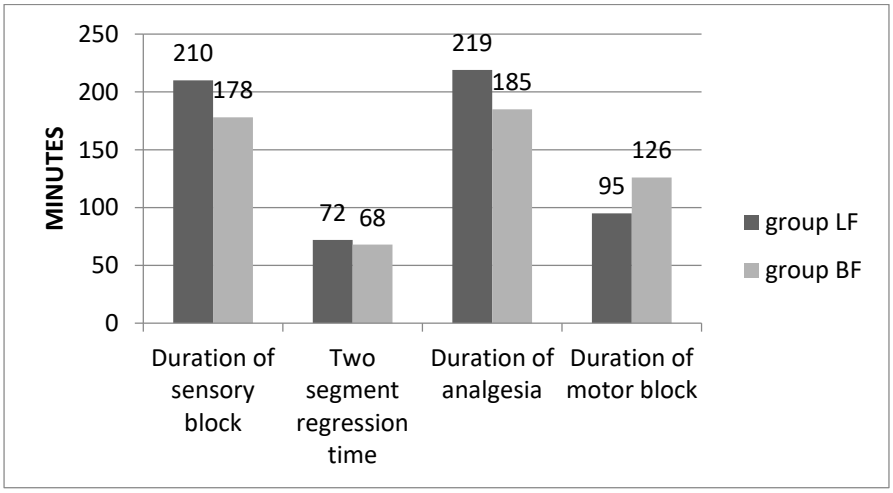
[**Table 2. Sensory and motor blockade characteristics]**

	Group LF	Group BF	P value
T10 sensory onset(minutes)	2.1±0.18	1.2±0.2	0.447
Time to get peak sensory level (minutes)	4.8±1.2	4±0.8	0.499
Duration of sensory block (minutes)	210±5.3	178±4.8	0.000
Two segment regression time (minutes)	72±4.3	68±5.8	0.000
Duration of analgesia (minutes)	219±6.4	185±7	0.000
Motor onset (minutes)	3.5±0.2	2.2±0.1	0.273
Duration of motor block (minutes)	95±5.8	126±6	0.000

[**Chart 1. Sensory and motor blockade characteristics]**



[Chart **2. Sensory and motor blockade characteristics]**



Sensory onset time at T10 level was faster in Group BF (1.2±0.2 minutes) than Group LF (2.1±0.18) and the difference was not significant.
The mean duration of time to achieve maximum sensory level was comparable between two groups. Total time to achieve higher sensory level was longer in Group LF (4.8±1.2 minutes) than Group BF (4±0.8 minutes). The difference was statistically insignificant. (P >0.0)

Group LF had longer sensory block than Group BF and the difference was statistically significant.

When compared to Group BF, Group LF has longer duration of analgesia and that was highly significant with p value 0.000

Two segment regression time was also longer in Group LF

Onset time of motor blockade was comparable between two groups but it was not significant, although total time of motor blockade was longer in Group BF & it was statistically significant.

Patients' hemodynamic parameters were comparable between two groups such as pulse rate, blood pressure, SpO2 at different time interval intra-operatively. There was no significant difference between two groups.

Discussion

Appropriate sensory and motor blockade, as well as increased hemodynamic stability, are needed for caesarean procedures. Spinal anaesthesia is the most often used method in LSCS due to its quick and easy induction, effective sensory and motor blocking, and absence of significant fetal side effects. Opioids are used to increase the duration of anaesthesia without harming the foetus by speeding up the onset of sensory blocking. The greatest strategy to promote early patient ambulation in the postoperative period is to prolong analgesia.

In this study, we discovered that parturients undergoing LSCS who received intrathecally administered levobupivacaine and fentanyl had superior hemodynamic stability, longer duration of analgesia, longer sensory block durations, shorter motor block durations, and less postoperative discomfort. Similarly ***Majunath et al*****,** found that levobupivacaine plus fentanyl provide faster onset of sensory block, longer duration of sensory block and shorter duration of motor block that could help in post-op analgesia and early ambulation.

Similar to our study ***Thakore s et al*** concluded that When compared to hyperbaric bupivacaine at a similar dose,levobupivacaine plus fentanyl offers an appropriate amount of sensory blockade with a much shorter length of motor blockade and a significantly longer duration of analgesia. It is understood by ***bremerich et el*** that an intrathecally given mixture of opioids and local anaesthetics has a synergistic analgesic effect. Early ambulation would be the therapeutic significance of a shorter period of motor block caused by lower doses of levobupivacaine plus fentanyl. ***Kulkarni et el*** found that group LF had a longer duration of analgesia and a longer duration of sensory block. It could be connected to levobupivacaine's vasoconstrictive characteristics. In contrast ***Duggal et el*** discovered a shorter duration of sensory block in the levobupivacaine group, which could be attributed to the fact that they used isobaric levobupivacaine.

Dar et al. similarly discovered that the regression period was considerably shorter in the levobupivacaine group, which is consistent with this findings. Sensory onset time and time to peak sensory level were faster in group LF in our research, which is similar with ***B debbarma et al.***

Gori et al explained that because isobaric levobupivacaine has a specific gravity that is very close to that of the central spinal fluid, it reacts indifferently to gravitational forces both immediately and later. As a result, intrathecal isobaric levobupivacaine does not spread unpredictably high and levels of sensory block are unaffected by changes in patient position.

The duration of the two-segment regression was comparable between the two groups,with no statistically significant difference between the two. ($P>0.05$) similarly In study by ***Erdil at al*** two segment regression time with levobupivacaine and bupivacaine was insignificant.

In contrast to our study the total duration of motor block was higher with bupivacaine in the study by ***P ture et al*** but this difference was not statistically significant.

Demographic parameters such as age, sex, weight and height, duration of surgery have no statistically significant difference between the 2 groups. Our study does have certain limitations. The sample size used was small. Its application to a larger population group will necessitate additional investigation.

Conclusion

Levobupivacaine plus fentanyl provide adequate postoperative analgesia, shorter duration of motor block and better haemodynamics, thus improve postoperative pain and enable early mobilization.

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