



Efficacy of Levobupivacaine Vs. Levobupivacaine with Fentanyl for Cesarean Section: An Interventional Study

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ABSTRACT

Background

Spinal anaesthesia is a commonest technique used for lower abdominal surgeries, especially cesarean section. Levobupivacaine is a pure S (–) enantiomer of bupivacaine and a long-acting local anaesthetic that belongs to amide group, which produces a differential neuraxial block. Fentanyl is an opioid with rapid onset of action. It has a strong plasma protein binding capacity and potentiates afferent sensory blockade, thereby reducing dose of local anaesthetics.

Aim

To evaluate the safety and efficacy of plain levobupivacaine with levobupivacaine and fentanyl.

Methods

This randomized study was done at a tertiary care centre among 100 patients scheduled for elective lower-segment cesarean section (LSCS). They were

randomized into two groups of 50 patients each. Group A patients were given only levobupivacaine. Group B patients were given Levobupivacaine with fentanyl. Onset and duration of sensory and motor blocks, adverse effects were compared between two groups.

Results

Most of the patients were 26- 30 years old. Onset of sensory and motor blocks were quick in group B patients. Duration of sensory and motor blocks was more in group B patients. Postoperative analgesia was more significant in group B patients. 64% of patients don't have any adverse effects.

Conclusion

We found that both regimens are effective in providing surgical anaesthesia but combination of

levobupivacaine and fentanyl provided an advantage of rapid onset of blocks and prolonged duration of sensory block and postoperative analgesia

Keywords

Cesarean section, Fentanyl, Intrathecal, Levobupivacaine, Spinal anaesthesia.

INTRODUCTION

Spinal anaesthesia is a commonest technique for used for lower abdominal surgeries, especially cesarean section. Advantages include low cost, effective analgesia, muscle relaxation, unmatched reliability, and improved postoperative analgesia. An ideal anaesthetic agent used for surgeries under spinal anaesthesia shown to reduce the incidence of anaesthesia-related complications and allow for early patient discharge.¹ Levobupivacaine is a pure S(-) enantiomer of bupivacaine and long-acting local anaesthetic that belongs to amide group, which produces differential neuraxial block. It has early onset of action and prolonged duration of sensory block with lower cardiac toxicity compared to bupivacaine.² One study reported extended duration of analgesia of levobupivacaine when given intrathecally.³ It was commonly used in various surgeries after the development of low dose spinal anaesthesia technique.^{4,5} Adding adjuvants improve the characteristics of block. Intrathecal opioids improve sensory block without enhancing motor and sympathetic blocks.^{6,7} Fentanyl is an opioid with rapid onset of action. It has strong plasma protein binding capacity and potentiates afferent sensory blockade, thereby reducing dose of local anaesthetics.^{8,9} It was shown to increase the duration of post-operative analgesia when administered with bupivacaine intrathecally for cesarean section.¹⁰ Many

previous studies compared plain levobupivacaine with fentanyl as an adjuvant given intrathecally.¹¹⁻¹³ But the conclusions are insufficient. Hence the current study was taken up.

AIM

To evaluate the safety and efficacy of plain levobupivacaine with levobupivacaine and fentanyl.

OBJECTIVES

Objectives are to compare onset and duration of sensory and motor blocks, postoperative analgesia, hemodynamic parameters and adverse effects.

MATERIALS AND METHODS

Study site: Tertiary care center named NRI Institute of Medical Sciences, Chinakakani, Andhra Pradesh, India

Type of study and duration: This interventional, randomized study was conducted for 6 months from March 2022 to August 2022 in the department of Anaesthesia on 100 patients scheduled for lower segment cesarean section (LSCS).

INCLUSION CRITERIA

- Pregnant women aged 20-35 years scheduled for elective LSCS.
- Patients who belonged to ASA status II.
- Patients who provided informed consent

EXCLUSION CRITERIA

- Patients with coagulation disorders
- Patients with septicaemia
- Patients with previous spinal surgeries.
- Patients with morbid obesity
- Patients with neurological disorders.
- Patients undergoing emergency cesarean section
- Patients with bad obstetric history

METHODOLOGY

Group A patients received 0.5% isobaric

levobupivacaine(2ml) in the dose of 10 mg along with 0.5 ml of normal saline and group B patients received 2 ml of 0.5% isobaric levobupivacaine in the dose of 10 mg with 0.5 ml of fentanyl that contains 25 µg intrathecally. Total volume of medications was 2.5ml in each group.

Pre anaesthetic check-up was done before surgery. On the day of surgery, patients were shifted to the operation theatre after giving glycopyrrolate 1 hour before surgery. Multipara monitor was attached and continuous monitoring was started. Spinal anaesthesia was given in L3 and L4 space by midline approach in lateral decubitus position under aseptic conditions. On free flow of cerebrospinal fluid, study drug was injected intrathecally. Study drug was prepared in similar syringes and volume was kept constant. The study is single blinded in which the patient doesn't know which drug they are receiving or which group they belong to. Sensory block was measured by the

loss of sensation to pin prick in midline every 2 min for 1st 10 min and then at an interval of 5 min.

Motor block was assessed by using modified Bromage scale¹⁴ every 2 min up to 20 min and then at an interval of 10 min till the completion of surgery.

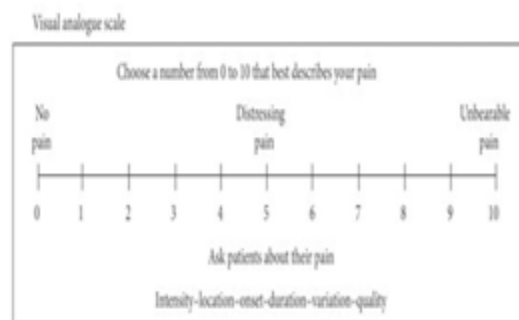
PARAMETERS ASSESSED

- Mean age
- Onset of sensory block
- Onset of motor block
- Duration of sensory block
- Duration of motor block
- Visual analogue scale for assessing post operative pain
- Adverse effects

The minimum VAS score was 0 and the maximum was 10. A score of 10 denotes unbearable pain.

VAS score was assessed as per the following:

Image 1 shows VAS score¹⁵



STATISTICAL ANALYSIS

Students T test was used to compare numerical parameters between two groups. Chi square test was used to compare categorical parameters between two groups. P value < 0.05 was considered significant. Epi info software used for data analysis.

ETHICAL CONSIDERATIONS

Informed consent form was taken from every patient who participated in the study. Institutional committee approval was taken before starting the study.

RESULTS

There is no significant difference in the baseline characteristics in two groups of patients. Hence the comparison is justifiable.

BASELINE variables	Group A	Group B	P value
Mean age	26.2±2.3 years	25.4±3.1 years	0.14
Duration of surgery	55.2±4.1 min	56.1±4.9 min	0.32

Table 1: Baseline characteristics of study patients in both groups

Characteristics of Sensory Block

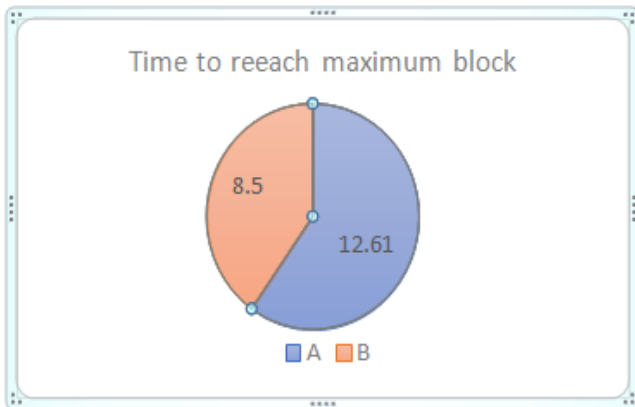
Onset of sensory block was quick in group B patients compared to group A patients. Total duration of sensory block is also more significantly in group B patients.

Parameters	Group A	Group B	P value
Onset of block(min)	7.4±1.3	4.9±3.1	0.001
Duration of block	192±12.4 min	271±13.2 min	0.001
Maximum sensory level	T8 dermatome	T6 dermatome	-

Table 2: Shows characteristics of sensory block

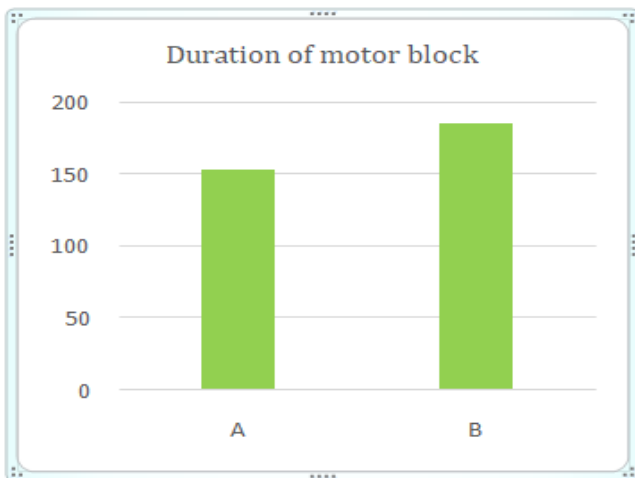
Motor block

Time to reach maximum motor block is more in group A compared to group B significantly(p=0.000).



Graph 1: Time to reach maximum motor block

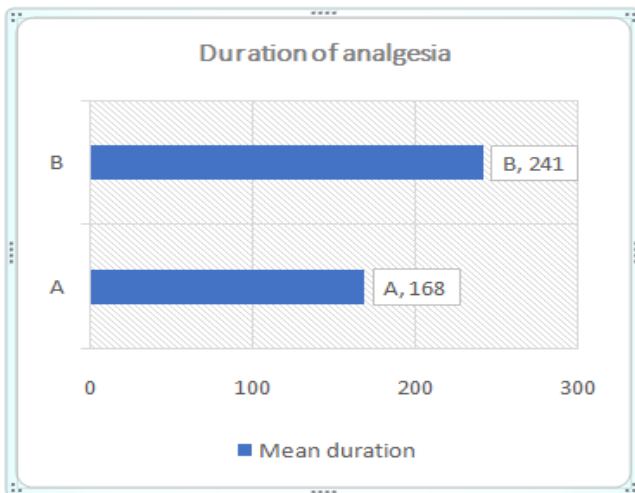
Duration of motor block: It was significantly more in group A compared to group B (P=0.000),



Graph 2: Duration of motor block in each group

Duration of Analgesia

Duration of analgesia was significantly more in group A compared to group B (p=0.000).



Graph 3: Duration of analgesia in both groups

VAS score: There is a significant difference in VAS score at 120 min. It was less in group B patients.

VAS score	Group A	Group B	P value
Baseline	6.5±2.3	6.4±3.1	0.85
60 min after surgery	4.2±2.3	3.8±1.2	0.0001
120 min after surgery	3.2±2.0	2.5±0.9	0.0001

Table 3: shows VAS score in both groups

Adverse Effects

64% of the patients do not have any adverse effects. The most common adverse effect seen was nausea/vomiting in both groups of patients, followed by headache.

Adverse effects	Group A	Group B
Nausea and vomiting	14%	10%
Hypotension	4%	10%
Sedation	6%	8%
Headache	8%	12%
Total	32%	40%

Table 4: Adverse effects in both groups

DISCUSSION

The study included 100 patients scheduled for elective cesarean section. Group A patients received levobupivacaine alone and group B patients received levobupivacaine with fentanyl.

There is no significant difference in the mean age, ASA grade and duration of surgery between two groups. Onset of sensory and motor blocks were quick in Group B. Duration of sensory and motor blocks and duration of analgesia were more in group B patients.

VAS score was less in group B patients significantly. Most common adverse effect is nausea and vomiting.

Girgin et al.,¹⁶ used plain levobupivacaine vs plain levobupivacaine with fentanyl and found that maximum sensory level was T7 and T6 dermatomes respectively. It was T8 and T6 in our study.

Cuvas et al.¹⁷ did a study on fentanyl added to levobupivacaine and compared it with plain levobupivacaine. There is no significant difference in

the time to onset of sensory and motor blocks in both groups, in contrast to our study. Duration of motor block was less in combination group, in contrast to current study findings. present study.

Akan et al.¹⁸ did a study on 10mg of plain levobupivacaine and compared it with 7.5 mg levobupivacaine along with fentanyl and levobupivacaine with sufentanil given intrathecally in patients scheduled for transurethral resection of the prostate and reported that combination provides quick onset of sensory block, along with prolonged analgesia, similar to our study, But duration of motor block was less in combination group, in contrast to our study.

Ozyilkan et al.¹⁹ did a study on comparison on compared 2.2 ml of levobupivacaine with fentanyl or sufentanil as adjuvant for spinal anaesthesia for patients scheduled for LSCS. Onset of sensory and motor block was achieved quick in fentanyl and sufentanil groups of patients. Duration of sensory and motor block was more in combination group patients, compared to plain group patients, similar to our study.

Lee et al²⁰ found that there is no significant difference in heart rate and blood pressure between plain levobupivacaine and its combination,

The strength of this study was we provided effective anaesthetic option to patients scheduled for LSCS. The main limitation is the small sample size.

CONCLUSION

We tested the efficacy of levobupivacaine alone with levobupivacaine and fentanyl in patients scheduled for elective LSCS. We found that both regimens are effective in providing surgical anaesthesia but combination of levobupivacaine and fentanyl provided

an advantage of rapid onset of blocks and prolonged duration of sensory block and postoperative analgesia

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