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## Dr. M Sangeereni

Associate Professor, Department of  
Obstetrics and Gynaecology, Rajah  
Muthiah Medical College,  
Annamalai University,  
Chidambaram, India

## Dr. Malliga

Professor and Head, Department  
of Obstetrics and Gynaecology,  
Rajah Muthiah Medical College,  
Annamalai University,  
Chidambaram, India

## Dr. Aswathi VS

Final Year Post Graduate,  
Department of Obstetrics and  
Gynaecology, Rajah Muthiah  
Medical College, Annamalai  
University, Chidambaram, India

## Corresponding Author:

### Dr. M Sangeereni

Associate Professor, Department of  
Obstetrics and Gynaecology, Rajah  
Muthiah Medical College,  
Annamalai University,  
Chidambaram, India

## A comparative study of low concentration of levobupivacaine versus bupivacaine with fentanyl for epidural analgesia in labour

Dr. M Sangeereni, Dr. Malliga and Dr. Aswathi VS

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### Abstract

**Introduction:** Labour analgesia technique is the most widely practiced procedures of pain management performed by an anaesthesiologist and are requested by the obstetrician colleagues as well as the parturient mothers. It has been associated with maternal adverse effects like higher incidence of instrumental assisted vaginal delivery (AVD) and motor block leading to decreased ambulation. This study was designed to evaluate the efficacy of low concentrations of local anaesthetics (0.1% bupivacaine and 0.1% levobupivacaine) with 2µg/ml fentanyl as epidural analgesia.

**Materials and Methods:** In this prospective study, 60 labouring parturients were randomly allocated into two groups to receive either 0.1% bupivacaine with 2 µg/ml fentanyl or 0.1% levobupivacaine with 2µg/ml fentanyl as epidural bolus after 10 ml loading dose of the respective solutions. The incidence of instrumental AVD demographic data, maternal and foetal vital parameters, maternal VAS scores, degree of motor blockade and total epidural drug consumption were studied.

**Results:** The incidence of instrumental AVD was found to be equal in the levobupivacaine group and bupivacaine group. This difference was not statistically significant. Both groups were comparable in terms of demographic data, maternal VAS scores, total epidural drug consumption and foetal APGAR scores.

**Conclusion:** The use of newer local anaesthetics (levobupivacaine and bupivacaine) in low concentrations with opioids (fentanyl) as epidural labour analgesia may offer high maternal satisfaction in terms of quality of pain relief with fewer adverse events like instrumental AVD and adverse foetal outcomes.

**Keywords:** Labour analgesia, low-dose local anaesthetics, bupivacaine, levobupivacaine

### Introduction

Labour pain brings in a spectrum of adverse physical implications to the mother as well to the foetus. Apart from special situations, pain can complicate the delivery process to an otherwise healthy mother with normal foetus. Over the ages many techniques to relieve labour pain have been tried like physical, psychological and pharmacological means but none has been so efficacious and successful than the present day's technique. Neuraxial techniques have been considered as the gold standard modality for labour analgesia [4]. In spite of the analgesia and improved safety of epidural labour analgesia, it has been associated with maternal and foetal adverse effects, including prolongation of labour, higher incidence of instrumental assisted vaginal delivery (AVD), decreased ambulation mainly due to varying degrees of motor block especially with the use of higher concentrations of local anaesthetics. Long acting local anaesthetics like levobupivacaine and bupivacaine have been increasingly used along with adjuvants such as opioids to provide safe, effective and adequate pain relief during labour. Lee *et al.* [1] found no significant differences in the mode of delivery, duration of labour and foetal outcomes in the study comparing low concentration of bupivacaine (0.1%) and levobupivacaine (0.1%) with fentanyl (2mcg/ml) for labour epidural analgesia. Further improvement in safety of epidural labour analgesia was achieved following the introduction of the concept of patient controlled epidural analgesia (PCEA) by Gambling *et al.* in 1988 [5, 6].

Studies by various researchers comparing low dose levobupivacaine versus bupivacaine with and without fentanyl have observed varying results regarding the analgesic efficacy, drug consumption, motor and sensory blockade, and mode of delivery.

### Materials and Methods

This study was conducted after approval by Hospital Ethics Committee on a total of 60 parturients (ASA-PS I, II) requesting labour analgesia. A written informed consent was obtained from every parturient.

Parturients with history of anaphylaxis to local anaesthetics and allergy to the drugs used as well as those with any contraindication to epidural catheter placement were excluded.

### Subjects were allocated in two groups

- **Group L:** Comprising 30 parturients who received 0.1% levobupivacaine with 2 µg/ml fentanyl
- **Group B:** Comprising 30 parturients who received 0.1% bupivacaine with 2 µg/ml fentanyl

### Preparation of Drug

Among the sixty coded envelopes containing details of the drug combinations to be used, any one envelope was randomly opened for each parturient by an anaesthetist who was not a part of study any further. The respective drug combinations were prepared and marked with a coded label by the anaesthesiologist who was not a part of study and it was handed over to the anaesthesiologist performing the epidural block in a blinded manner. Neither the principal investigator/observer nor the parturient were aware of the nature of study solution. In group L and group B respectively, 10 ml of 0.1% levobupivacaine and 10 ml of 0.1% bupivacaine was added to 2ml of 0.005% fentanyl.

Baseline monitoring of vitals including maternal heart rate, non-invasive arterial pressure and foetal heart rate were instituted and recorded. After establishing IV access, lumbar epidural insertion was done in L3-L4 interspace under all aseptic precautions using loss of resistance technique.

Participants were randomized using sealed envelope allocation technique to receive a loading dose of 10 ml of 0.1% levobupivacaine with 2mcg/ml fentanyl (group L) or 0.1% bupivacaine with 2mcg/ml fentanyl (group B). This initial loading dose served as the test dose, which was given gradually under monitoring for any signs of inadvertent intrathecal or intravascular placement.

Subjects in group B received epidural drugs (0.1% Bupivacaine with Fentanyl 2mcg/ml) as 10ml bolus in 5ml top-ups. Subjects in group L received epidural drugs (0.1% Levobupivacaine with Fentanyl 2mcg/ml) as 10ml bolus with 5ml top-ups. In both groups at the start of the second stage of labour, a top-up of 5ml was given. If VAS >4 after 15 min of epidural top-ups further study solution was given in aliquots of 5 ml every 5 min till VAS <4. If VAS remains  $\geq 4$  after 30 min or after 30 ml of epidural drug, rescue analgesia with 10ml of study drugs at concentration of 0.25% was given over 5min. If VAS remains  $\geq 4$  in spite of rescue analgesia, then labour analgesia was considered as inadequate and other modes of analgesia to be considered and such parturients were excluded from the study. Total number of top ups required and total amount of drug required were noted. Visual analogue scale score was recorded every 5 min for first 30 min, then at every 30 min till the end of labor. VAS at the end of the first stage and second stage were noted. Randomization was decoded at the end of study and subjected to statistical analysis.

### Outcomes observed

Pain intensity was evaluated during contractions with a 10 mm VAS where 0 represents no pain and 10 represents worst pain imaginable. Assessment of pain was undertaken before epidural catheterization and at 30 minutes interval following loading dose completion. Reduction in pain score to less than equal to 4 was considered to represent the onset of analgesia.

Maternal pulse rate (PR), non-invasive arterial pressure (NIBP), oxygen saturation (SpO<sub>2</sub>) was measured at an interval of 5 minutes for 60 minutes and at 30 minutes interval thereafter.

Hypotension was defined as decrease of 20% below baseline. When hypotension occurred, parturient was administered 100 ml boluses of intravenous fluids along with IV ephedrine in boluses of 6 mg and repeated if required. Foetal heart rate and uterine activity were monitored continuously throughout labour by cardiotocography and recorded at 10 minutes in the Performa.

Motor block and maternal adverse effects including pruritis, hypotension, nausea and vomiting were assessed at 30 minutes interval. Motor blockade was measured using 0 to 3 Modified Bromage scale.

The extent of sensory block was assessed by cold alcohol swab in the mid clavicular line from upper thoracic to lumbar dermatomes at 30 minutes interval.

The study was completed when spontaneous delivery occurred or when AVD or lower segment caesarean section (LSCS) was required. The duration of first, second and third stages of labour, total duration of labour, mode of delivery, 1 and 5 minutes APGAR score was recorded.

### Total epidural drug consumption

The number of top up boluses and number of rescue boluses of study solution were documented. Hourly and total drug consumptions were measured at delivery. Total duration of epidural analgesia was observed.

### Statistical Analysis

Quantitative parametric data such as age, weight, pulse rate (PR), foetal heart rate (FHR), systolic and diastolic blood pressure (SBP, DBP), number of demand boluses, time of first requirement of manual rescue bolus was compared between the two study groups using student's *t*-test. Quantitative non-parametric data such as height, cervical dilatation, period of gestation, oxygen saturation (SpO<sub>2</sub>), visual analogue scale (VAS), total duration of epidural analgesia, onset of analgesia, drug consumption, level of sensory block, duration of labour, total oxytocin consumption, number of uterine contractions, maternal satisfaction and APGAR score was compared between the study groups using Mann-Whitney U test. For comparing categorical data (parity, induced labour, number of manual rescue boluses, incidence of motor block, incidences of various modes of delivery, indications of instrumental AVD and caesarean delivery, maternal adverse effects), Chi square test and Fisher's exact test was performed. All tests were evaluated for 95% confidence interval. A probability value (p value)  $\leq 0.05$  was considered statistically significant. All statistical calculations were done using Statistical Package of Social Sciences (SPSS) 26 version statistical program for Microsoft Windows.

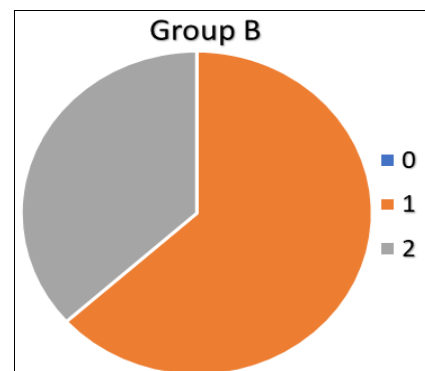


Fig 1: No of top up needed in Bupivacaine Group

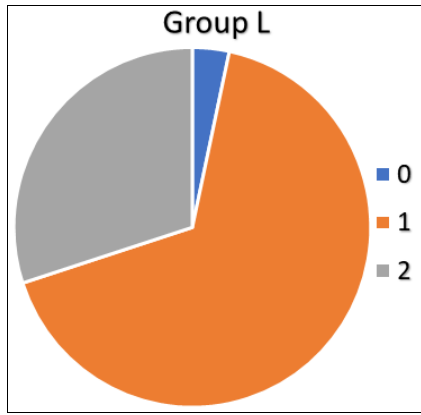


Fig 2: No of top up needed in Levobupivacaine Group

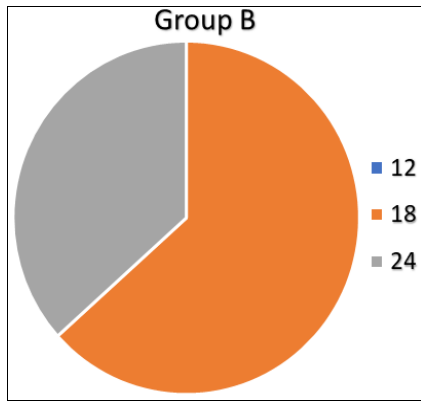


Fig 3: Total dose needed in Bupivacaine Group

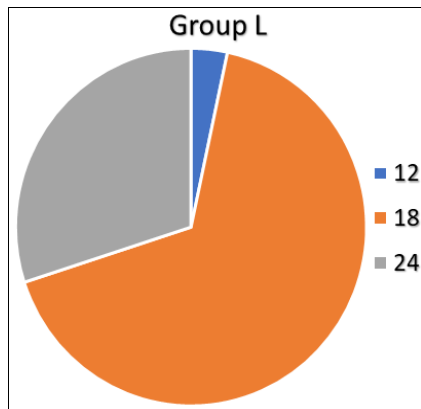


Fig 4: Total dose needed in Levobupivacaine Group

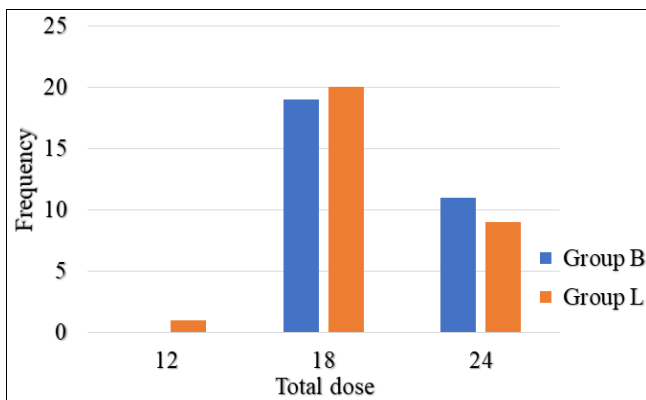


Fig 5: Bar diagram of Total dose needed in Both Groups

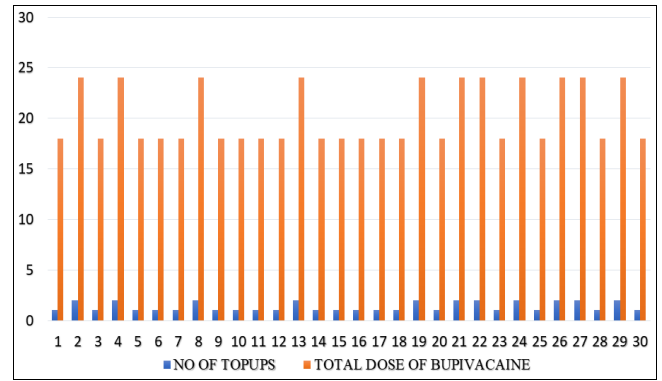


Fig 6: Number of topups and Total dose of Bupivacaine

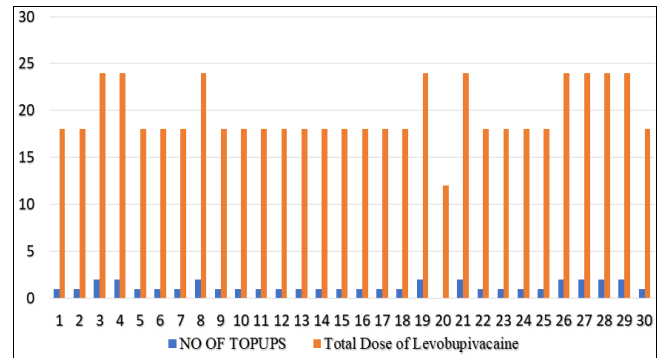


Fig 7: Number of topups and Total dose of Levobupivacaine

**Results**

Demographic parameters, i.e., age, weight, height, cervical dilatation, period of gestation and parity were statistically comparable among both the groups.

No statistically differences were found in terms of pre-epidural parameters (PR, SBP, DBP and SpO<sub>2</sub>) between both the groups.

Median onset of analgesia was 10 (10-15) minutes and 11 (10-15) minutes in groups B and L respectively (P=0.629).

Mean of total duration of epidural analgesia was 169±39.74 minutes in group B and 170.37±34.93 minutes in group L. This was not statistically significant.

Mean number of top ups were statistically insignificant among both groups.

Mean drug consumption (mg) was 20.2±2.51 and 19.6±6.31 in groups B and L respectively. Mean total drug consumption in milligrams (calculated by including loading dose, bolus and rescue boluses) was found to be 58.71±32.02 mg and 65.27±41.34 mg in groups B and L respectively. There were no observed statistically significant differences in hourly and total drug consumption among both the drugs.

**Discussion**

Labour analgesia techniques at the present time are some of the most widely practiced procedures performed by an anaesthesiologist and are requested by the obstetrician colleagues as well as the parturient mothers from the labour room. The newer methods of pain relief have not only brought joy and pleasure to the mother but also bring in a host of advantages and safety to her as well as to her offspring. The most popular among the drug groups used now a days for the purpose of labour analgesia are the potent lipophilic narcotics like Fentanyl / Sufentanyl and long acting long anaesthetics like Bupivacaine / Levobupivacaine.<sup>7</sup> Both these group of drugs are known to produce rapid onset of analgesic action. But their inherent side effects are the matter of concern. This study is

done to compare the onset, quality and duration of analgesic action between the epidural analgesia of Bupivacaine + Fentanyl and Levobupivacaine + Fentanyl labour analgesia. It also compares the incidence of unwanted effect.

Newer drugs (levobupivacaine and bupivacaine) have high differential sensory-motor block ratio, less potential for cardio and neurotoxicity thereby offering better safety profile as compared to bupivacaine.<sup>[9]</sup> Epidural labour analgesia improves maternal analgesia and enhances parturient satisfaction with the use of lowest possible effective doses of local anaesthetics, thereby reducing the total drug consumption. This leads to minimal motor block and probable favorable effect on mode of delivery.

None of the parturients were excluded from the study as all the parturients achieved onset of analgesia within 30 minutes of administration of initial loading dose of study solutions. A uniform analgesia initiation and maintenance technique was used in all the subjects.

The confounding factors which can affect the progress and outcome of labour such as duration of all stages of labour, total duration of epidural analgesia, oxytocin consumption throughout labour, onset of analgesia, the highest level of sensory block and total local anaesthetic drug consumption among both groups varies insignificantly thus making the two groups comparably similar.

Grade I and II motor block was observed only in 6.7% parturients in both the study groups. No statistically significant differences in motor block characteristics were elicited among both groups, which was comparably similar to the observed motor block incidence in studies by Purdie *et al.*<sup>[1]</sup> and Beilin *et al.*<sup>[3]</sup>

A reduced total local anaesthetic consumption was seen in both groups, which was comparable to the observed results of studies. Reduced total local anaesthetic consumption in both the groups explains the negligible motor block observed here.

Apart from motor block, density of neuraxial analgesia also influences the outcome of second stage of labour. In an editorial, Chestnut<sup>[2]</sup> stated that effective second stage analgesia increases the risk for instrumental AVD. The quality of analgesia in our study was adequate with VAS of  $\leq 4$  at most of the time intervals during first and second stage of labour in both the groups. Median VAS at various time intervals of first and second stage of labour was statistically comparable among the groups.

### Limitations of our study

Studies focusing to relate epidural analgesia with mode of delivery are fraught with limitations due to numerous like the time of amniotomy, maternal fever, neonatal birth weight, which can influence the mode of delivery. The major limitation was the small sample size which was primarily chosen based on our institutional data and secondary to a trend towards lower uptake of epidurals by parturients in our settings.

### Conclusion

Hence, we conclude that epidural drug solutions of 0.1% levobupivacaine and 0.1% Bupivacaine with fentanyl 2 mcg/ml using epidural analgesia were equally efficacious in providing adequate analgesia for all stages of labour, exhibiting comparable reduced hourly and total local anaesthetic drug consumption with consequent negligible motor block, high maternal satisfaction and clinically insignificant adverse maternal or foetal effects. This regimen of epidural labour analgesia resulted in statistically insignificant differences in the mode of delivery, with comparable incidence of instrumental

AVD among both the groups.

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**Conflicts of interest:** There are no conflicts of interest.

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