

**COMPARISON OF TWO DRUG COMBINATIONS FOR LABOUR ANALGESIA, AND ITS EFFECT ON PATIENT SATISFACTION, DURATION OF LABOUR AND FETAL OUTCOME**Jaideep Singh<sup>1</sup>, Pallavi Singh<sup>2</sup>**HOW TO CITE THIS ARTICLE:**

Jaideep Singh, Pallavi Singh. "Comparison of two Drug Combinations for Labour Analgesia, and its Effect on Patient Satisfaction, Duration of Labour and Fetal Outcome". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 41, September 04; Page: 10229-10238, DOI: 10.14260/jemds/2014/3330

**ABSTRACT: BACKGROUND:** Epidural is now established and accepted method to relief labour pain. This study intended to comparison of two drug combinations in labour analgesia and its effect on duration of labour, maternal satisfaction and fetal outcome. Combined epidural infusion of bupivacaine + fentanyl would result in analgesia superior to that provided by a continuous epidural infusion of a similar concentration of Bupivacaine alone. **AIMS AND OBJECTIVE:** To compare the efficacy of two drug combinations for labour analgesia, and its effect on patient satisfaction, duration of labour and fetal outcome. **MATERIALS AND METHODS:** Study design – comparative randomized controlled study. Sample size: For this study 50 pregnant women were randomly selected and divided into two groups. **GROUP I:** Control Group (Continuous epidural infusion of Bupivacaine CEI): 25 parturient who were given a bolus of 0.1% Bupivacaine + 20mcg Fentanyl followed by infusion of 0.0625% Bupivacaine epidurally. **GROUP II:** Study Group (Continuous epidural infusion of Bupivacaine with Fentanyl CEIF): 25 parturients who were given a bolus of 0.1% Bupivacaine + 20mcg Fentanyl followed by infusion of 0.0625% Bupivacaine + 0.0001% Fentanyl epidurally. Duration of labour, Analgesia, maternal satisfaction, fetal outcome was assessed by different scales like bromage scale, visual analogue scale, APGAR score and pin prick method are used. Side effects and complications, if present were recorded. Tests used for statistical analysis were STUDENT'S t-TEST, CHI SQUARE TEST AND FISHERS EXACT TEST **RESULTS:** 1) The drugs in the concentrations used for this study were safe for both the mother and the foetus as there were no significant alterations seen in the vital parameters of the mother (pulse and blood pressure) or the foetal heart rate and neonatal Apgar scores. 2) Parturients in study group (Fentanyl infusion) had consistently lower VAS scores (a difference not statistically significant, however) and needed less number of rescue doses as compared to control group (which was also not statistically significant). 3) Incidence of Caesarean section was equal in both the groups and incidence of instrumental deliveries was also comparable to previous studies, proving the safety of this infusion regimen. 4) The mean duration for the second stage was 36.40 +/- 13.60 for the control group and 48.20 +/- 10.75 for the study group. This difference was statistically significant since p value was 0.001. Thus we conclude that 0.0625% Bupivacaine +0.0001% Fentanyl provides better labour analgesia and maternal satisfaction with good fetal outcome.

**KEYWORDS:** labour analgesia, epidural, bupivacaine, fentanyl, walking epidural.

**INTRODUCTION:** Since ancient times, the understanding and relief of pain during labour has concerned humankind. Attempts to alleviate pain during labour have ranged from psychological, pharmacological, physical or a combination of these techniques. Epidural is now established and accepted method to relief labour pain. This study intended to compare two drug combinations in labour analgesia and its effect on duration of labour, maternal satisfaction and foetal outcome.

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Combined bupivacaine + fentanyl epidural infusion would result in analgesia superior to that provided by a continuous epidural infusion of a similar concentration of Bupivacaine alone.

**AIMS AND OBJECTIVES:** To study the safety and analgesic efficacy of two continuous epidural infusion regimens in patients during labour, following the bolus dose of Fentanyl 20mcg + 0.1% Bupivacaine.

The following will be noted:

1. Duration of first stage of labour- from 3cm to full dilatation of cervix.
2. Duration of second stage of labour—full dilatation to baby delivery.
3. Analgesic efficacy.
4. No. of distressing events requiring rescue analgesia.
5. Adverse events if any.
6. Incidence of instrumental delivery/ Caesarean section.
7. Neonatal outcome (Apgar score).
8. Maternal acceptance of procedure.

**MATERIALS AND METHODS:** The present study “COMPARISION OF TWO DRUG COMBINATIONS FOR LABOUR ANALGESIA, AND ITS EFFECT ON MATERNAL AND FETAL OUTCOME” was carried out in the department of Anaesthesiology and Gynaecology, in Choithram Hospital and Research Center, Indore.

**OBJECTIVE OF THE STUDY:** To compare the analgesic efficacy and safety of the continuous infusion of 0.0625% Bupivacaine and 0.0001% Fentanyl versus 0.0625% Bupivacaine alone, following the bolus dose of Fentanyl 20mcg + 0.1% Bupivacaine for epidural analgesia in labour, maternal satisfaction, duration of labour and fetal outcome.

For this study 50 pregnant women were randomly selected and divided into two groups.

**Control Group** (Continuous epidural infusion of Bupivacaine CEI): 25 parturients who were given a bolus of 0.1% Bupivacaine + 20mcg Fentanyl followed by infusion of 0.0625% Bupivacaine epidurally.

**Study Group** (Continuous epidural infusion of Bupivacaine with Fentanyl CEIF): 25 parturients who were given a bolus of 0.1% Bupivacaine + 20mcg Fentanyl followed by infusion of 0.0625% Bupivacaine + 0.0001% Fentanyl epidurally.

### INCLUSION CRITERIA:

- Parturient (primipara and second gravida) of ASA Physical Status I, ASA Physical Status II in established labour (at least one painful contraction in 5 minutes) at term giving written, informed consent
- Gestational Age of 36-40 weeks.
- Singleton foetus with cephalic presentation.
- Foetus having normal heart rate pattern before induction of epidural analgesia.
- Cervical dilatation of 3 - 5 cm.

**EXCLUSION CRITERIA:**

- Cervical Dilatation more than 5 centimetres.
- Weight of Parturient more than 90 kilograms.
- Age more than 35 years.
- Previous Administration of Sedatives in last four hours.
- Anatomical deformity of Spine or any local infection.
- Bleeding disorders.
- Presence of Obstetric complications.
  - a) Pre-eclampsia/Eclampsia.
  - b) Multiple Pregnancies.
  - c) Pre term Cases.
  - d) Past History of Abdominal delivery.
  - e) Abnormal Lie of the Foetus.
  - f) Foetal Distress prior to induction.
  - g) Placenta Praevia, Hydramnios.

**METHODOLOGY:**

- Pre-procedure investigations- Hemoglobin & Urine –routine and microscopy
- Intravenous Access with 18 G Angiocath was secured and preloading was done with Ringer lactate solution 10 ml/kg.

With patient in sitting position the back was painted and draped under all aseptic precautions.

2 ml of 2% lignocaine was injected into the skin and subcutaneous tissue in the L3-L4 space, up to the interspinous ligament. The 16G Tuohy's needle was advanced up to the supraspinous ligament. The stylet of the Tuohy's needle was removed and a 10 cc LOR syringe was attached to the needle at the hub tightly with 4cc of air in it.

The epidural space was confirmed by loss of resistance technique. After confirming negative aspiration of blood, CSF No.16 Portex catheter with filter was passed through needle in cephalad direction and 5 cm. of the catheter was retained in the epidural space. Following this the needle was removed and the catheter was fixed with catheter clamp, and micropore.

Care was taken during this whole procedure that the Tuohy's needle or epidural catheter was not advanced while the patient is getting a contraction, as the chances of piercing the dura or a blood vessel are extremely high. After fixing the catheter the patient was asked to lie down with the distal end of the catheter being covered in a sterile towel.

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The further drug administration was as follows:

Time	Group 1 (25 Parturients)	Group 2 (25 Parturients)
0 mins.	Test Dose: 3 ml. 2.0 % Lidocaine with 15mcg Epinephrine	Test Dose: 3 ml. 2.0 % Lidocaine with 15mcg Epinephrine
3 mins	Bolus Dose: 4 ml. of 0.1 % Bupivacaine + 20mcg Fentanyl and additional boluses of 2cc of 0.1 % Bupivacaine given until T10 level was achieved.	Bolus Dose: 4 ml. of 0.1 % Bupivacaine + 20mcg Fentanyl and additional boluses of 2cc of 0.1 % Bupivacaine given until T10 level was achieved.
18 Mins	Infusion: 6 ml./ hour of 0.0625 % Bupivacaine.	Infusion: 6 ml/ hour of 0.0625% Bupivacaine + 0.0001 % Fentanyl. (1 mcg/ml)

Throughout the infusion the patient was asked to alternate between either right lateral or left lateral every thirty minutes The cephalad dermatomal level of anaesthesia was assessed by the pin – prick method.

The infusion was continued till delivery of baby.

- Following delivery the epidural catheter was removed and a tincture benzoin seal was given. The tip of the catheter was checked.

**ASSESSMENT AND MONITORING:** The following parameters were assessed:

- 1) MATERNAL HEART RATE AND BLOOD PRESSURE. (MANUAL SPHYGMOMANOMETER)
- 2) SENSORY LEVEL (USING PIN PRICK METHOD)
  - 1) PAIN SCORE USING VISUAL ANALOGUE SCALE (VAS):  
This was assessed at 20 and 30, minutes from bolus dose and every 30 minutes thereafter on a scale of 0-100 where:  
0 stood for no pain at all and 100 stood for worst possible pain.
  - 2) MOTOR BLOCKADE. (USING BROMAGE SCALE)  
The scale assesses the degree of motor block in the following manner.  
Nil – 0 – Free movements of legs and feet.  
Partial – 1 – Just able to flex knees but free movement of feet.  
Almost Complete – 2 – Unable to flex knees but free movement of feet.  
Complete – 3 – Unable to move legs and feet.
- 3) FOETAL HEART RATE. (USING NON STRESS TEST MACHINE)
- 4) NEONATAL APGAR SCORE: At 0, 5 and 10 minutes using the parameters of heart rate, respiratory rate, and muscle tone, skin color and grimace response to stimulus the baby is graded.
- 5) OCCURRENCE OF ADVERSE EVENTS like hypotension pruritus, bradycardia nausea, emesis and urinary retention.

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- 6) MATERNAL SATISFACTION FOLLOWING DELIVERY- This was done by asking the parturient to rate the pain relief in both the first and second stages as Excellent/ Good/ Fair/ Poor.
- 7) Incidence of instrumental delivery and caesarean section was also noted in this study.
- 8) STATISTICAL ANALYSIS (STUDENT'S t-TEST, CHI SQUARE TEST)

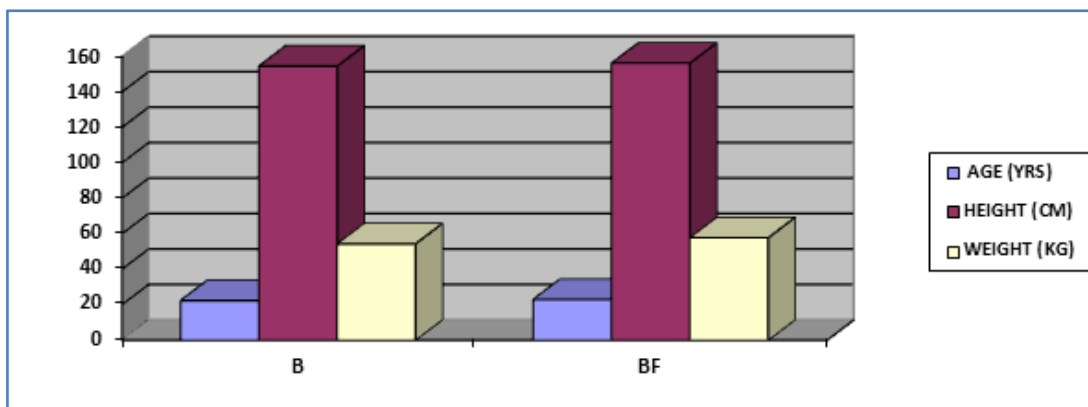
Maternal satisfaction was statistically analyzed using Fisher's Exact Test.

For other parameters like maternal pulse rate, blood pressure and foetal heart rate Students t-Test and Chi-Square test were applied.

A p-value less than 0.05 was considered significant.

### RESULTS:

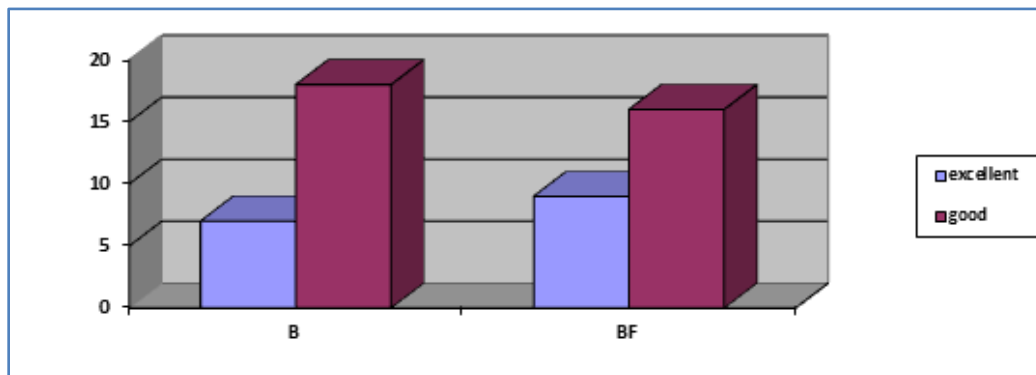
TABLE NO. 1: COMPARISON OF ANTHROPOMETRIC VARIABLES AND AGE OF PARTURIENTS BETWEEN TWO GROUP.



**Table No. 1**

The control and study groups were comparable with respect to mean age, mean heights and mean weight respected p-values by unpaired t-test are 0.310, 0.130 and 0.068 all was not statistically significant.

TABLE NO. 2: GROUPWISE COMPARISON OF MATERNAL SATISFACTION.

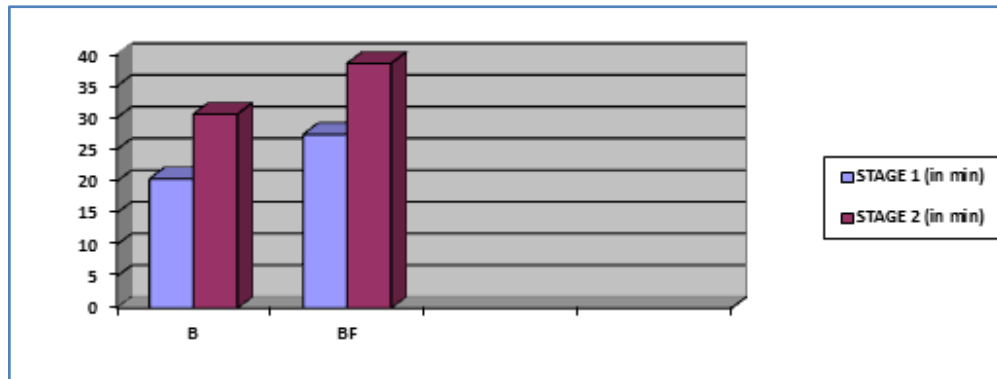


**Table No. 2**

Fisher's Exact Test (p value 0.374) not significant.

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TABLE NO. 3: COMPARISON OF VARIOUS 'DURATIONS' BETWEEN THE TWO GROUPS.

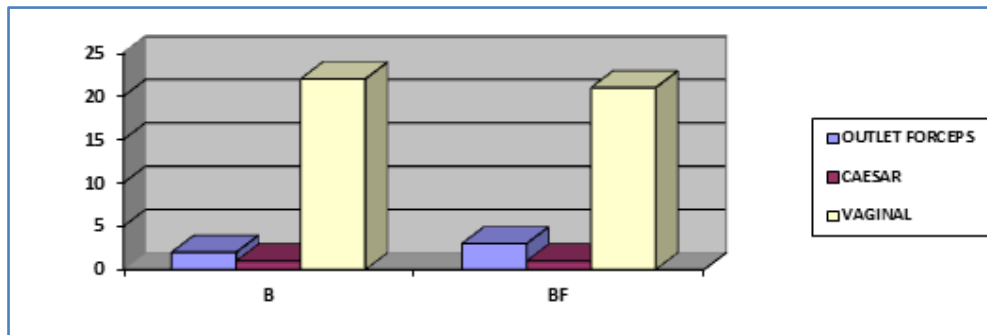


**Table No. 3**

The mean duration for the second stage was 36.40 +/- 13.60 for the control group and 48.20 +/- 10.75 for the study group. This difference was statistically significant since p value was 0.001.

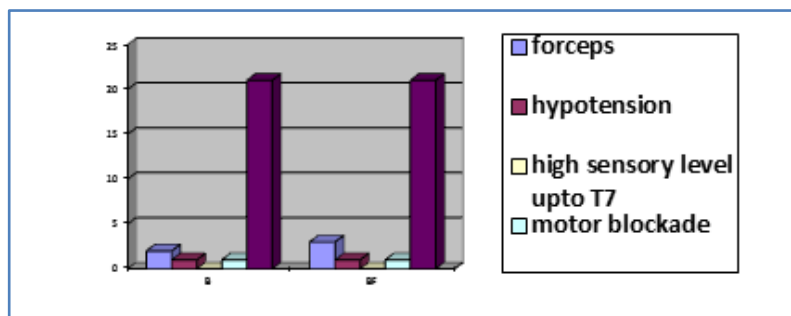
TABLE NO 4: MODE OF DELIVERY IN TWO GROUPS.

Overall epidurals 'per se' are associated with an increased incidence of instrumental deliveries but progressively more dilute concentrations of local anaesthetics reduce this number<sup>51</sup>. The dose sparing effects of opioids on local anaesthetics too adds up.<sup>63</sup>



**Table No. 4**

TABLE NO. 5: GROUPWISE COMPARISON OF ADVERSE EFFECTS.



**Table No. 5**

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TABLE NO. 6: COMPARISON OF VISUAL ANALOG SCALE SCORE AT VARIOUS INTERVALS BETWEEN THE TWO GROUPS.

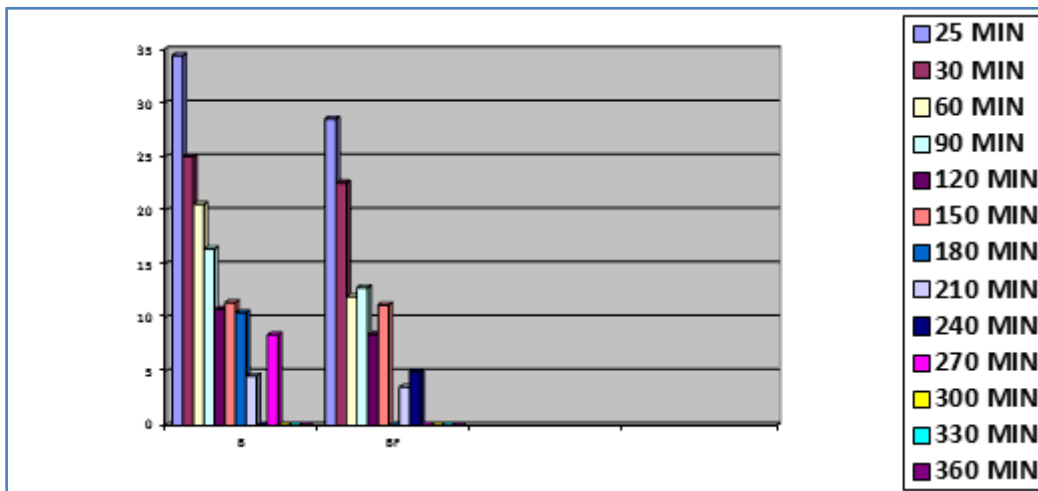


Table No. 6

TABLE NO. 7: GROUP WISE COMPARISON OF RESCUE ANALGESIA.

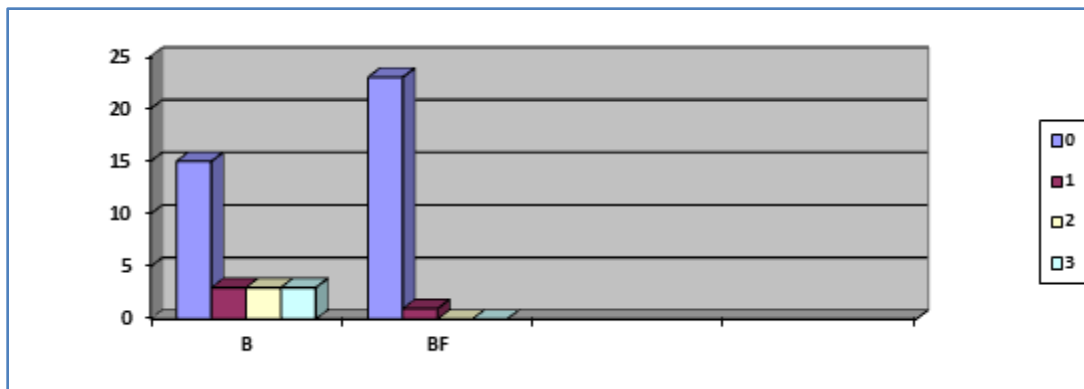


Table No. 7

**DISCUSSION:** The present study evaluated the clinical efficacy and maternal, foetal, and neonatal effects of continuous epidural infusion using Bupivacaine and Bupivacaine- Fentanyl mixture. Drug concentrations and infusion rates were selected and modified with respect to previously published studies, to suit the Indian parturient.

Epidural opioids do not interrupt or 'block' nerve transmission. The injection of opioid into the epidural space provides analgesia by acting on receptors in lamina II, IV and V of substantia gelatinosa. Most uterine pain is conducted by A  $\delta$  fibres, some of which bypass opiate receptors in the substantia gelatinosa.

Combination of an opioid with a local anaesthetic reduces the local anaesthetic requirements and side effects including systemic toxicity, hypotension and motor blockade. Fentanyl was chosen because of its high lipid solubility and high receptor affinity.

## SUMMARY AND CONCLUSION:

1. The drugs used in infusion regimens with their respective concentrations provided comparable pain relief as indicated by VAS scores and maternal satisfaction following delivery.
2. The drugs in the concentrations used for this study were safe for both the mother and the foetus as there were no significant alterations seen in the vital parameters of the mother (pulse and blood pressure) or the foetal heart rate and neonatal Apgar scores.
3. Addition of Fentanyl provided better hemodynamics with lower pulse rates in later stages of labour.
4. Parturients in study group (Fentanyl infusion) had consistently lower VAS scores (a difference not statistically significant, however) and needed less number of rescue doses as compared to control group (which was also not statistically significant).
5. Incidence of Caesarean section was equal in both the groups and incidence of instrumental deliveries was also comparable to previous studies, proving the safety of this infusion regimen.

Thus we conclude that 0.0625% Bupivacaine +0.0001% Fentanyl provides better labour analgesia and maternal satisfaction without any foetal and newborn complications.

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