

COMPARISON OF 0.1% BUPIVACAINE WITH 2 MCG/ML FENTANYL AND 0.1% ROPIVACAINE WITH 2 MCG/ML FOR LABOUR ANALGESIA

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ABSTRACT

BACKGROUND

Epidural neuraxial blockade is an efficient and an easy method of administering labour analgesia without any adverse effects on the foetus. Labour analgesia thus helps the mother enjoy the delivery of her child without pain or stress enhancing patient satisfaction. Bupivacaine was the routinely used local anaesthetic for labour analgesia. Bupivacaine combined with low dose of opioid was used to reduce the concentration of bupivacaine without compromising on quality of analgesia produced and also reducing the extent of motor blockade. But even with lowering the concentration of bupivacaine used and the addition of opioids, patient had minimal motor blockade which prevented them from being ambulant. Ropivacaine has helped us to provide ambulatory analgesia by overcoming the motor blockade without compromising on the quality of analgesia.

The objective of this study was to compare analgesic efficacy, onset, duration of action, total dose of anaesthetic required, intensity of motor blockade and haemodynamic stability in patients admitted for safe confinement.

MATERIALS AND METHODS

100 ASA physical status I & II parturients, aged 20-40 years, with normal to high BMI scheduled for safe confinement were included in the study. Patients were randomly allocated into two groups Group B (n = 50) & Group R (n = 50). Epidural technique was standardised. Efficacy of 0.1% bupivacaine with 2 mcg/ml fentanyl was compared with 0.1% ropivacaine with 2 mcg/ml fentanyl for labour analgesia.

RESULTS

The onset of analgesia as well as motor blockade was faster with bupivacaine when compared to ropivacaine. The total volume of local anaesthetic required was higher and the level of motor blockade produced was minimal with ropivacaine when compared to bupivacaine. There was no undue prolongation in duration of labour and the incidence of instrumental delivery were comparable between the groups. The patient satisfaction score, APGAR SCORE, demographic and haemodynamic parameters were comparable between the groups.

CONCLUSION

Administration of 0.1% Ropivacaine with 2 mcg/ml fentanyl provides minimal motor blockade when compared to 0.1% bupivacaine with 2 mcg/ml fentanyl.

KEYWORDS

Epidural analgesia, bupivacaine, ropivacaine, fentanyl.

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BACKGROUND

The pain of childbirth is considered as the most painful experience a woman will endure in her lifetime. An array of pharmacological and non-pharmacological techniques have been used for labour analgesia. In our country the awareness of labour analgesia is still lacking. Central neuraxial analgesia is the most versatile method of labour

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analgesia and the gold standard technique for pain control in obstetrics. The satisfaction of birth experience is greater with neuraxial techniques. Epidural blockade is an effective means of providing analgesia during labour. Bupivacaine had been the routinely used local anaesthetic for labour analgesia due its excellent sensory blockade. Bupivacaine combined with low dose of opioid reduced the concentration of bupivacaine and hence reduced motor blockade. But even with low dose of opioids it produced minimal motor blockade which prevented the patient from ambulating. Ropivacaine - pipercoloxylidide derivative has been recently used to provide ambulatory analgesia. In our randomised double blinded controlled study, we compared the analgesic efficacy and degree of motor blockade produced by 0.1% bupivacaine with 2 mcg/ml fentanyl and 0.1% ropivacaine with 2 mcg/ml fentanyl.



MATERIALS AND METHODS

Prior to starting the study, a pilot study was conducted to analyse the feasibility of the study and to estimate the value of 'n' or the number to be assigned for group B and group R using the statistical formula for detecting the sample size of the study population that would be an appropriate representative of the entire population that had been covered by the study. From the pilot study the 'n' was deciphered as 50 for Group A and 50 for Group B. Thus, a group of 100 antenatal women in term pregnancy admitted for safe confinement in a Government tertiary care hospital were randomly divided to two groups to receive the following drugs.

- Group B- Received 0.1% Bupivacaine with 2 mcg/ml Fentanyl (n=50).
- Group R- Received 0.1% Ropivacaine with 2 mcg/ml Fentanyl (n=50).

Inclusion Criteria

- Primi gravida with term gestation
- Singleton pregnancy with vertex presentation
- ASA physical status 2
- Uncomplicated pregnancy with no comorbid conditions like preeclampsia, diabetes mellitus and anemia.
- Normal fetal heart rate
- Height > 150 cm
- Cervical dilatation < 5 cm

Exclusion Criteria

- Multiple gestation
- Preterm
- ASA physical status 3 & above with comorbid conditions
- Contraindications to neuraxial analgesia
- Drug allergy
- Cervical dilatation > 5 cm

Preparation of the Patient

After getting Institutional Ethical committee approval and patients consent, patients were randomized into one of the two groups by lot system wherein odd numbers in one group and even numbers into another group. All patients were assessed prior to the procedure. A brief obstetric history was elicited. General and systemic examinations were carried out. Baseline heart rate, systolic, diastolic, mean blood pressure and fetal heart rate by CTG were recorded. Also, cervical dilation and condition of membranes were recorded by the obstetrician.

Investigations included complete haemogram, random blood sugar, blood urea, serum creatinine and electrocardiogram.

Once inside the operating room, after connecting the routine monitors like Electrocardiography (ECG), Noninvasive Blood Pressure (NIBP) and Pulseoximetry (SPO₂) the baseline parameters were recorded. An Intravenous access was secured with 18 G IV cannula and all parturients were preloaded with 10 ml/kg of Ringer lactate solution. The parturient and the anaesthesiologist,¹ performing the technique, administering the drug and

observing the parameters were blinded to the drug being administered. Under aseptic precautions patient in lateral position epidural space identified with 18 G Touhy needle in L2-L3 space via midline approach with loss of resistance to air technique and 18 G epidural catheter was threaded 5 cm cephalad into the epidural space. After negative aspiration for blood and CSF, test dose of 5 ml of study drug was administered and patient was monitored for change in heart rate of 20 beats per minute from baseline to rule out inadvertent intravascular spread of drug and also for dense motor blockade were observed over a period of 10 minutes to rule out inadvertent intrathecal administration of drug. Parturients with test dose positive were excluded from the study. 10 minutes after administering the test dose, loading dose of 15 ml of the study drug – 0.1% of Bupivacaine (3 ml of 0.5% bupivacaine diluted with 12 ml distilled water) with 2 mcg/ml of fentanyl in Group B or 0.1% Ropivacaine (3 ml of 0.5% bupivacaine diluted with 12 ml distilled water) with 2 mcg/ml of fentanyl in Group R was administered in 5 ml increments at intervals of 5 minutes. Parturients not experiencing adequate analgesia in 20 min were supplemented with additional 5 ml of the study drug. Following the loading dose additional supplements of the drug were administered based on the VAS score upto a maximum of 20 ml/hr, whenever VAS score exceeds 4. The patient monitoring was done in labour ward with Boyle's apparatus, drugs and equipment's ready for resuscitation of the parturient in case of emergency. FHR monitoring was done using CTG. Per vaginal examination for cervical dilation was done by Obstetrician.

The following parameters were recorded:

A. Haemodynamic Parameters-

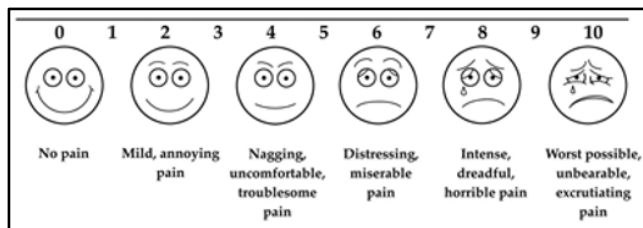
1. Maternal Heart rate.
2. Blood pressure – systolic, diastolic and mean arterial pressures.
3. Oxygen saturation.
4. Foetal heart rate.

All the vitals are monitored and recorded continuously at 5, 10, 20, 30, 45, 60 min. and every 30 min. after that until delivery.

Adverse effects like hypotension, bradycardia and oxygen desaturation were recorded and managed accordingly. Hypotension was defined as fall in systolic blood pressure by 20% from baseline or SBP <90 mm hg. Hypotension was managed with left uterine displacement, IV fluids and bolus Inj. Ephedrine 6 mg top ups as and when required.

B. Non-Haemodynamic Parameters-

5. Cervical dilation – every 2 hours.
6. Pain score – assessed by visual analogue score (VAS) – 0 to 10.
7. Highest level of sensory blockade- assessed by pin prick sensation.
8. Degree of motor blockade is assessed by modified Bromage score.



Modified Bromage Score

- Grade 0- Patient able to move at all the joints (Hip, Knee, and Ankle).
 - Grade 1- Unable to move at hip joint.
 - Grade 2- Unable to move at both hip and knee joint.
 - Grade 3- Unable to move at all the 3-joint hip, knee and ankle.
9. Total dose of the local anaesthetic required.

All these parameters are recorded at 15 min after the loading dose till 1 hour and 30 min thereafter.

After Delivery

Patient’s satisfaction score- assessed as excellent, good, fair or poor.

1. The mode of delivery- spontaneous, vaginal, instrumental vaginal and caesarean section
2. Total dose of local anaesthetic required.

RESULTS

Totally 100 women were included in the study, 50 women receiving 0.1% bupivacaine with fentanyl and the other 50 receiving 0.1% Ropivacaine with fentanyl. The group size was selected by using proportions sample size estimates (power= 80%). The results obtained were analysed with SPSS (Statistical Package for Social Sciences) version 13.0(after obtaining written permission) using t-test and chi square test. P< 0.05 is considered significant.

There were no difference between the groups with respect to demographic and labour characteristics (Table 1).

Characteristics	Bupivacaine (n=50)	Ropivacaine (n=50)
Age (years)	22.80 ± 1.80	23.84 ± 2.09
Weight (kg)	51.20 ± 6.75	50.32 ± 5.77
Height (cm)	154.08 ± 5.08	152.92 ± 3.39
BMI (kg/m ²)	21.52 ± 2.44	21.63 ± 2.22
Cervical dilation before injection(cm)	3 ± 1	3 ± 1
First stage of labour (min)	216.60 ± 30.32	210.52 ± 20.88
Second stage of labour(min)	18.32 ± 5.7	27.72 ± 5.47
Third stage of labour(min)	5.92 ± 1.97	6.72 ± 1.37

Table 1. Demographic and Obstetric Characteristics

The mean time to onset of action of drug in Group B was 13.08 ± 2.01 min and in Group R was 15.96 ± 2.05 min was significant (p=0.00) (Table- 2).

The intensity of motor blockade in group B was 0.92 ± 0.27 and there was no motor blockade in group R which was significant (p=0.00).

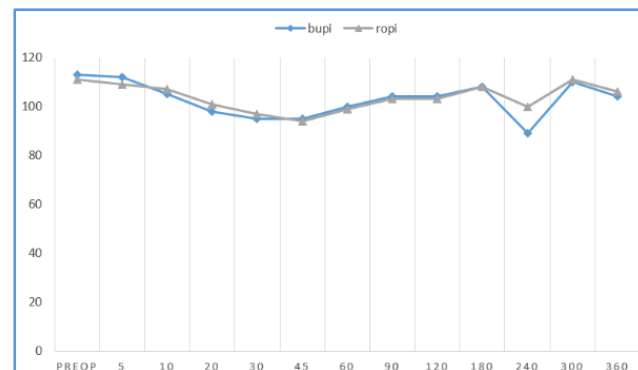
The patient satisfaction score for epidural labour analgesia between the two groups were similar (Table 2).

Characteristics	Bupivacaine	Ropivacaine
Onset of action (min)	13.08 ± 2.01	15.96 ± 2.05
Intensity of motor blockade Bromage score)	0.92 ± 0.27	0
Patient satisfaction score % - Excellent	16% (4)	28% (7)
Good	84% (21)	72%(18)
Total Local anaesthetic required (ml)	67 ± 8.036	75.40 ± 4.311

Table 2. Analgesia and Motor Blockade

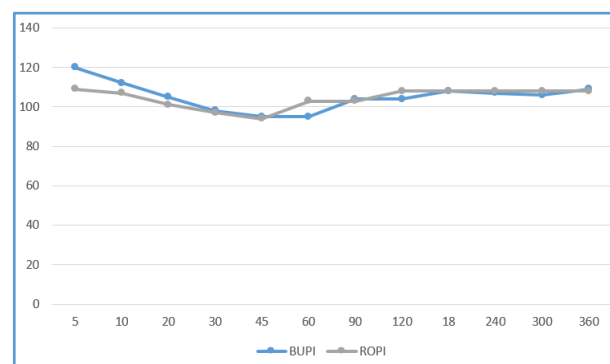
Characteristics	Bupivacaine	Ropivacaine
Apgar score	8.48 ± 0.51	8.52 ± 0.51
Mode of delivery % Spontaneous	92% (23)	88% (22)
Instrumental	8% (2)	12% (3)

Table 3. Mode of Delivery and Effect on Foetus



Graph 1. Mean Heart Rate

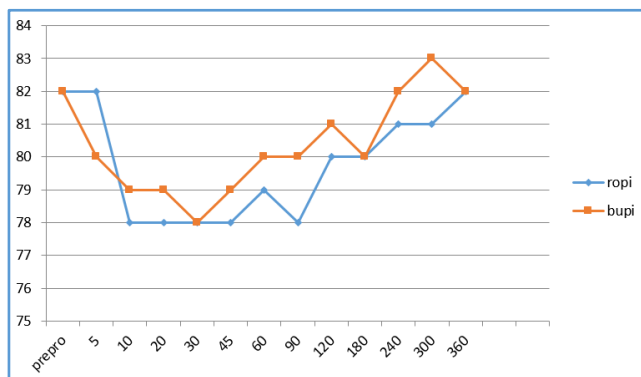
Graph 1 shows the mean heart rate in both the groups. The differences in the mean heart rate between the two groups were found to be statistically insignificant.



Graph 2. Mean Systolic Blood Pressure

Graph 2 shows the mean systolic blood pressure of patients in both the groups.

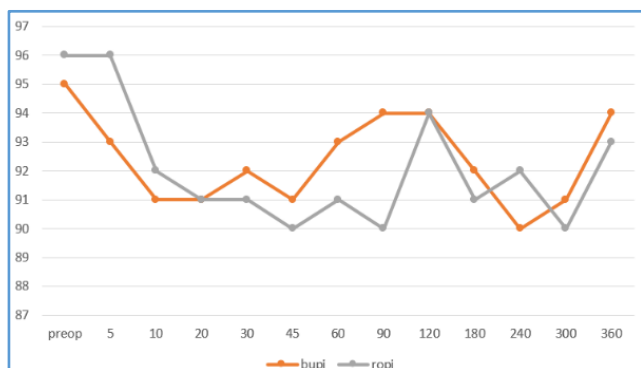
The differences in the mean systolic blood pressure between the two groups were found to be statistically insignificant.



Graph 3. Mean Diastolic Blood Pressure

Graph 3 shows the mean diastolic blood pressure in both the groups.

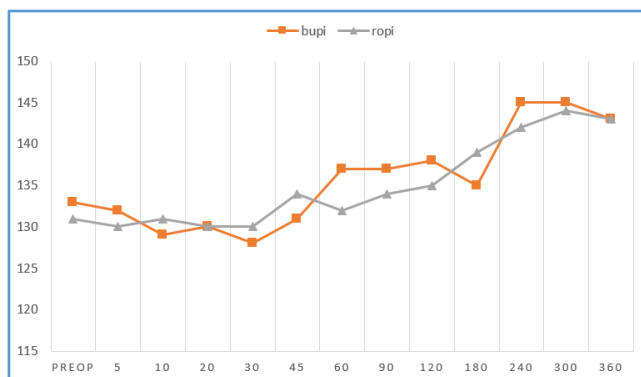
The differences in the mean diastolic blood pressure between the two groups were found to be statistically insignificant.



Graph 4. Mean Arterial Pressure

The graph 4 shows the mean arterial pressure in both the groups.

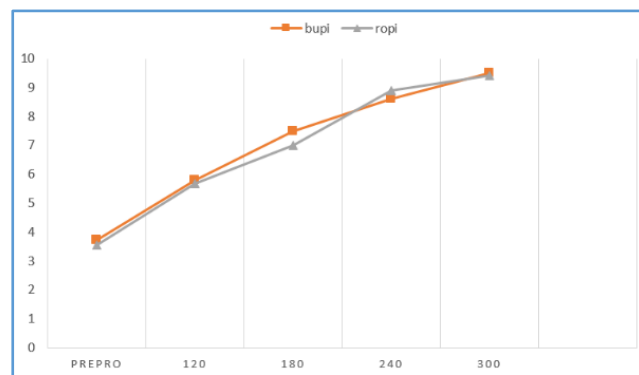
The differences in the mean blood pressure between the two groups were found to be statistically insignificant.



Graph 5. Foetal Heart Rate (bpm)

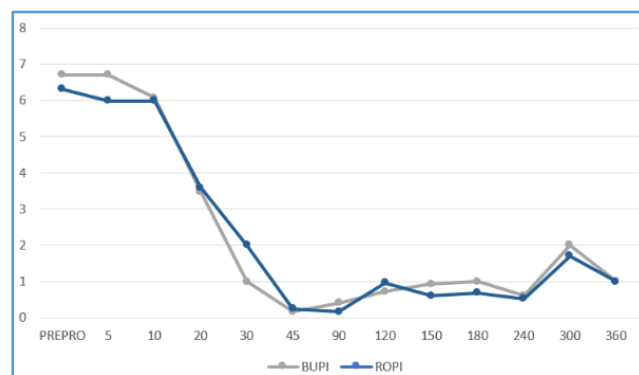
The graph 5 shows the fetal heart rate in both the groups.

The differences in the foetal heart rate between the two groups were found to be statistically insignificant.



Graph 6. Cervical Dilatation

Graph 6 shows the cervical dilatation between groups 1 and 2 was comparable between the two groups ($p = 0.074$).



Graph 7. Visual Analogue Score

The graph 7 shows the visual analogue score between the two groups which was comparable between the groups ($p = 0.174$).

DISCUSSION

In this study, 0.1 % bupivacaine and 2 mcg fentanyl with 0.1 % ropivacaine and 2 mcg/ml fentanyl were compared for labour analgesia with regard to analgesic efficacy, onset of action, total dose of local anaesthetic required, intensity of motor blockade, maternal satisfaction, neonatal outcome and pain score in 100 patients by randomizing them into one of the two groups, the Bupivacaine (B) with Fentanyl and the Ropivacaine (R) group with Fentanyl.

The results obtained were analysed with SPSS (Statistical Package for Social Sciences) version 13 using student t-test and chi square test.

Demographic Parameters

The mean age in Group B was 22.80 ± 1.8 years and in Group R was 23.84 ± 2.09 years. The differences in mean age between the two groups were statistically insignificant ($p=0.066$).

The mean weight of the patients was 51.20 ± 6.75 in Group B and 50.32 ± 5.77 in Group R. The differences were found to be statistically insignificant ($p=0.623$).

The Group B patients had a mean height of 154.08 ± 5.08 cms and in Group R it was 152.92 ± 3.39 cms and the differences were found to be statistically insignificant ($p=0.347$).

The mean BMI of the patients in Group B was 21.52 ± 2.44 kg/m² and in Group R was 21.63 ± 2.22 kg/m² and the differences were found to be statistically insignificant ($p=0.869$).

Thus, both the groups were comparable with respect to age, weight, height and BMI.

Onset of Action

The time of onset of analgesia in Group 1 was 13.08 ± 2.019 min when compared to Group 2 which was 15.96 ± 2.051 min which was statistically significant ($p = 0.00$). This was due to the less lipid solubility of ropivacaine.

This Correlated with the Previous Study by

1. Helene Finegold et al¹ where onset time was 10.62 ± 4.9 min in Group 1 and 11.3 ± 4.7 min in Group 2.
2. Isha Chora and Akhlak Hussain² where onset was 9.40 ± 2.37 min in Group 1 and 13.20 ± 2.53 min in Group 2.

Total Dose of Local Anaesthetic Required

The total volume of local anaesthetic required in Group 1 was 67.0 ± 8.036 ml when compared to Group 2 was 75.40 ± 4.31 ml which was statistically significant ($p = 0.00$). Though equiconcentrations were used the requirement of ropivacaine was higher than bupivacaine because of ropivacaine being less potent than bupivacaine.

This Correlated with the Previous Study by

- (1) Halpern et al,³ where 84.8 ± 61 ml of 0.125% bupivacaine required against 87.7 ± 68 ml of 0.1% ropivacaine.
- (2) Mesiter et al,⁴ where 102.5 ± 82 mg of 0.125% bupivacaine required against 113.0 ± 43.3 mg of 0.125% ropivacaine.

Patient Satisfaction Score

The patient satisfaction score recorded in Group 1 was 84 % with good analgesia and 16 % with excellent analgesia when compared to group 2 wherein it was 78 % with good analgesia and 22 % with excellent analgesia with p value of 0.306.

This Correlated with the Study by

1. Stienstra et al,⁵ with results of Group 1 and 2 recorded with 58% and 64.5% for excellent analgesia respectively, 42% and 35.5% for good analgesia in group 1 and 2 respectively.
2. Jaime Fernandez et al,⁶ with results of Group 1 and 2 recorded with 81.3% and 78.7% for excellent analgesia respectively, 15.7% and 21.3 % for good analgesia in group 1 and 2 respectively.

Mode of Delivery

In group 1, 92% delivery was spontaneous and 8% instrumental when compared to group 2 where it was 88% of spontaneous and 12 % with instrumental delivery ($p = 0.637$). The rate of spontaneous delivery was higher due to the usage of lower concentrations of both the drugs

The spontaneous vaginal delivery rate was lower in Girard et al,⁷ with 33% and 50% in Chen et al.⁸ The rate of spontaneous vaginal delivery in both the groups were lower due to the usage of higher concentrations of bupivacaine (0.125%).

Neonatal Outcome

The APGAR score in Group 1 was 8.48 ± 0.51 when compared to 8.52 ± 0.51 in Group 2 ($p = 0.783$). This was due to less transfer of both the drugs to foetus as their F/M ratio is around 0.33.

This correlated with Robert Gaiser et al⁹ wherein APGAR >7 was 100% in group 1 versus 97% in group 2.

Duration of First Stage of Labour

The mean duration of first stage of labour was 216.60 ± 30.32 min in Group B and 210.52 ± 20.88 min in Group R and the differences were found statistically insignificant ($p = 0.413$).

This correlated with the previous study by Jaime Fernandez et al,⁶ wherein there was no prolongation of first stage of labour between Group B – 401 ± 184 min and Group R – 365 ± 186 min with no statistical significance.

Duration of Second stage of labour

The mean duration of second stage of labour was 18.32 ± 5.70 min in Group B and 27.72 ± 5.47 min in Group R and the differences were found statistically significant ($p=0.00$)

The Results had no Correlation with the Previous Study by

1. Jaime Fernandez et al,⁶ wherein the duration of second stage of labour was 57 ± 47 min in Group B and 47 ± 38 min in Group R which was comparable between groups.
2. Pirbudak et al,¹⁰ wherein the second stage of labour was shorter in Group 2 ($p < 0.01$).

Haemodynamic Parameters

The differences in the mean heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation and fetal heart rate were comparable between both the groups.

The haemodynamic parameters correlated with the previous study by Pirbudak et al,¹⁰ and Jaime Fernandez et al,⁶ were there was no statistical significance in haemodynamic parameters.

CONCLUSION

1. Bupivacaine 0.1% with 2 mcg/ml Fentanyl and Ropivacaine 0.1% with 2 mcg/ml Fentanyl produced equivalent analgesia for labour without compromising foetal outcome and maternal safety.

2. Ropivacaine produced minimal motor blockade when compared to Bupivacaine.
3. The total volume of the local anaesthetic solution required was higher with Ropivacaine when compared to Bupivacaine.

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