

A Comparative Study of Equi-concentration of Bupivacaine-Fentanyl and Ropivacaine-Fentanyl for Epidural Labor Analgesia

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Abstract

Introduction: Pain relief in labor has always been surrounded with myths and controversies and providing effective and safe analgesia during labor has remained an ongoing challenge. Neuraxial techniques were introduced for pain relief in labor in 1950. Modern neuraxial labor analgesia reflects a shift in obstetrical anesthesia, thinking away from a simple focus on pain relief toward a focus on the overall quality of analgesia.

Aims and Objectives: The present study is carried out to compare equi-concentration of low dose (0.125%) bupivacaine-fentanyl 2 µg/mL and (0.125%) ropivacaine-fentanyl 2 µg/mL in primigravid full-term parturients for epidural labor analgesia.

Materials and Methods: A prospective randomized double-blind controlled study was undertaken after obtaining Ethical Committee approval to compare the effect of equi-concentration of 0.125% bupivacaine with fentanyl 2 µg/mL and 0.125% ropivacaine with fentanyl 2 µg/mL in 60 parturients coming for delivery at Government Maternity Hospital, Hanamkonda.

Results: This study was undertaken to compare equi-concentration of bupivacaine-fentanyl and ropivacaine-fentanyl for epidural labor analgesia in primigravida patients. Providing excellent labor analgesia, statistically significant motor blockade produced by bupivacaine compared to ropivacaine does not change mode of delivery at lower concentrations.

Conclusion: In our study comparing equi-concentration (0.125%), bupivacaine-fentanyl 2 µg/mL and (0.125%) ropivacaine-fentanyl 2 µg/mL for epidural labor analgesia results indicate that both are equally effective clinically by intermittent epidural supplementation in providing excellent labor analgesia with hemodynamic stability, minimal motor blockade, mode of delivery, maternal satisfaction without serious maternal, or fetal side effects.

Key words: Bupivacaine, Epidural labor analgesia, Ropivacaine, Visual analog scores

INTRODUCTION

Pain relief in labor has always been surrounded with myths and controversies and providing effective and safe analgesia during labor has remained an ongoing challenge.

Neuraxial techniques were introduced for pain relief in labor in 1950. Modern neuraxial labor analgesia reflects a shift in

obstetrical anesthesia, thinking away from a simple focus on pain relief toward a focus on the overall quality of analgesia.^[1]

A study shows that, in India, the average incidence and practice of labor analgesia is only 11%. In our country, the awareness of regional analgesia for labor is still lacking and except a few centers that run a comprehensive labor analgesia program, the national awareness or acceptance of pain relieving options for women in labor virtually does not exist. Central neuraxial analgesia is the most versatile method of labor analgesia and the gold standard technique for pain control in obstetrics that is currently available.^[2] The satisfaction of birth experience is greater with neuraxial techniques. Epidural blockade is an effective means of providing analgesia during labor.

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Bupivacaine and ropivacaine are widely used to provide efficient epidural analgesia in labor. The value of bupivacaine is limited by the risks of motor blockade and toxicity. There have been conflicting comparisons of ropivacaine and bupivacaine for labor analgesia.^[3-5] Some studies have suggested that ropivacaine produces less motor block than bupivacaine while others found the drugs to be indistinguishable. Dilute solutions of epidural local anesthetics combined with opioids may be used to minimize unwanted motor block. The amount by which fentanyl reduces local anesthetic dose requirement depends on dose of fentanyl.^[6]

Present day epidural local anesthetic for labor is low concentration, minimal, dose, and volume with opioids. The present study is taken up to provide labor analgesia service to our patients and compare the analgesic requirement, hemodynamic effects, and mode of delivery of fetus with bupivacaine and ropivacaine.

Objectives of the Study

The present study is carried out to compare equi-concentration of low dose (0.125%) bupivacaine-fentanyl 2 µg/mL and (0.125%) ropivacaine-fentanyl 2 µg/mL in primigravid full-term parturients for epidural labor analgesia. The following parameters were compared:

- Analgesic efficacy
- Degree of motor blockade
- Hemodynamic parameters
- Mode of delivery
- Maternal satisfaction
- Total dose of local anesthetic used.

Sample size

Total sample size 60 patients, 30 patients in Group B - received bupivacaine (0.125%) with fentanyl (2 µg/mL) and 30 patients in Group R - received ropivacaine (0.125%) with fentanyl (2 µg/mL).

Expected result

Results expected to achieve in this study, equi-concentration (0.125%) bupivacaine-fentanyl 2 µg/mL and (0.125%) ropivacaine-fentanyl 2 µg/ml for epidural labor analgesia are equally effective in terms of highest sensory blockade, hemodynamics, patient satisfaction, and total dose used. Motor blockade produced by bupivacaine compared to ropivacaine does not change mode of delivery at low concentrations.

MATERIALS AND METHODS

A prospective randomized double-blind controlled study was undertaken after obtaining Ethical Committee approval

to compare the effect of equi-concentration of 0.125% bupivacaine with fentanyl 2 µg/ml and 0.125% ropivacaine with fentanyl 2 µg/ml in 60 parturients coming for delivery at Government Maternity Hospital, Hanamkonda, with the following inclusion and exclusion criteria.

Inclusion Criteria

The following criteria were included in the study:

1. ASA physical status I–II
2. Primigravida women with gestational age ≥ 36 weeks
3. Singleton pregnancy with vertex presentation
4. Uncomplicated pregnancy with normal fetal heart rate (FHR)
5. Cervical dilatation 3–5 cm.

Exclusion Criteria

The following criteria were excluded from the study:

1. ASA physical status III or IV
2. Multiple or preterm gestation
3. Allergy to any study drug
4. Contra indications or patients unwilling for labor analgesia
5. Cervical dilatation > 5 cm.

Method of Study and Collection of Data

After obtaining Ethical Committee approval, a written informed consent was obtained. A detailed examination of the patient was done, and the following parameters were recorded: Demographic data, parity and gestational age, condition of membranes, vital parameters, and FHR.

Patients were randomized into two groups based on a computer-generated randomization table.

- Group B - received 0.125% bupivacaine with 2 µg/mL fentanyl.
- Group R - received 0.125% ropivacaine with 2 µg/mL fentanyl.

Preparation of the Parturient

The parturient was prepared as per the routine preparations done for delivery. In addition, preparation of the back was done for performing the epidural block. The onset of active labor, degree of cervical dilatation and adequacy of the pelvis for vaginal delivery were all assessed by the attending obstetrician before institution of the epidural block.

An intravenous access was secured with an 18G cannula and the parturient was preloaded with 500 mL of Ringer's lactate solution. 3 lead electrocardiogram, pulse oximeter, and non-invasive blood pressure were connected, and baseline vitals were recorded.

All equipment needed for resuscitation of the mother and the fetus was kept ready before the institution of the block.

A disposable epidural set (BRAUN Perifix 18G) was used to perform the block. The parturient and anesthesiologist performing the technique and administering the study drug were blinded to the drug. Study solutions were prepared by an anesthesiologist not directly involved in the patient's care or data collection.

Under aseptic precautions epidural space was identified in sitting position with midline approach using 18 gauge Tuohy needle in L₃₋₄ or L₄₋₅ interspace with loss of resistance to air technique and catheter was threaded cephalad 3–4 cm into epidural space. After negative aspiration for blood and cerebrospinal fluid, a test dose of 3 mL of lignocaine 2% with 1:2,00,000 adrenaline was administered through the catheter. Intravascular spread of the drug was detected by a change in heart rate of > 30 beats per minute from baseline within 20–40 s. Intrathecal spread was detected by appearance of motor blockade within 3 min. Subjects with positive test dose response were excluded from the study. 3 min after administering the test drug, 10–15 ml of study drug of either 0.125% bupivacaine with fentanyl 2 µg/mL or 0.125% ropivacaine with fentanyl 2 µg/mL, depending on the height and weight of the patient, was given in 5 ml increments over 10 min. Patients not experiencing analgesia within 20 min of initial bolus were supplemented with additional 5 mL of the solution. Patients not experiencing analgesia within 20 min of drug administration were excluded.

Analgesia was maintained by intermittent bolus injections of 5 ml every 40–60 min. Patients who experienced inadequate analgesia (visual analog score [VAS] >4) during the process were supplemented with additional 5 mL of solution up to a maximum of 10 mL/h until the delivery of the baby. During the second stage of labor, additional supplementation of 5–10 mL was given in sitting position to maintain VAS <4.

After administration of bolus dose, the following parameters were noted:

1. Level of sensory block - assessed by loss of temperature discrimination to alcohol swab.
2. Degree of motor blockade was assessed using Bromage scale.
 - 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 three joint hip, knee, and ankle.
3. Pain score - assessed using VAS 0–10, where 0- no pain and 10 - worst possible pain.



4. Oxygen saturation
5. Heart rate
6. Non-invasive blood pressure
7. FHR.

The level of sensory block and Bromage scale were assessed at 20 min after the initial bolus and every 30 min thereafter. All other parameters were monitored at 0, 5, 10, 20, 30, 45, and 60 min and every 30 min after that, until delivery.

Adverse effects such as hypotension, bradycardia, and arterial desaturation were noted and managed if necessary.

Hypotension is defined as fall of systolic blood pressure (SBP) >20% of base line or <90 mmHg. Bradycardia is defined as heart rate <60/min and was managed by injection atropine 0.6 mg.

After delivery, the following parameters were noted:

1. Patient's satisfaction - assessed as excellent, good, fair, or poor. Satisfaction was assessed based on a verbal numerical score from 0 to 10. 8–10 was taken as excellent, 5–7 was taken as good, 2–4 was taken as fair, and <2 was taken as poor.

[POOR]	[FAIR]	[GOOD]	[EXCELLENT]							
0	1	2	3	4	5	6	7	8	9	10
2. The mode of delivery - spontaneous, vaginal, instrumental vaginal, and cesarean section.
3. Total dose of local anesthetic used and number of additional supplementation in mL/h was recorded.

RESULTS

A total of 60 primigravida patients who were taken up for the study were randomized into two groups.

- Group B - received 0.125% bupivacaine with 2 µg/mL fentanyl.
- Group R - received 0.125% ropivacaine with 2 µg/mL fentanyl.

They were monitored continuously until the delivery of the baby. The following observations were made during the study:

Age

The mean age in Group B was 22.30 with SD 2.57 and in Group R was 23.33 with SD 1.95 with *P*-value of 0.085 which was statistically not significant.

Age Distribution

The patients were distributed into 3 age groups 19–21 years, 22–25 years, and >25 years. The percentage of patients in Group B was 36.6%, 50%, and 13.4%, and Group R was 13.3%, 76.7%, and 10%.

Height

The mean height in Group B was 153.26 cm with SD 3.609 and in Group R was 154.03 cm with SD 3.285 with *P* = 0.393 which was statistically not significant.

Weight

The mean weight in Group B was 64.86 with SD 5.21 and in Group R was 60.60 with SD 4.810 with *P* = 0.002 which was statistically significant.

Duration of Labor (Min)

The mean duration of labor in minutes was 251 ± 50.74 in Group B and $242 \text{ min} \pm 50.40$ in Group R, *P* value was 0.49 which was not significant.

Level of Sensory Block

In Group B, 23 patients (76.7%) achieved T_8 , 4 patients (13.3%) achieved a level of T_{10} , and 3 patients (10%) achieved a level of T_6 . In Group R, 21 patients (70%) achieved T_8 , 8 patients (26.7%) achieved T_6 , and 1 patient (3.3%) achieved T_{10} with *P* = 0.125 which was not significant.

DISCUSSION

Labor is a physiologic process but associated with the most severe of pains. The goal of labor analgesia is to provide adequate pain relief without causing any maternal and fetal jeopardy. Continuous/intermittent epidural analgesia depending on the situation is the most versatile and most commonly used technique, because it can be used for pain relief during labor and for subsequent vaginal delivery as well as analgesia and anesthesia for cesarean section if necessary.^[7]

Obstetricians and anesthesiologists have always feared that incidence of instrumental deliveries in women receiving epidural analgesia could be higher than in those who do not receive it.

Thus, it is intriguing to the obstetric anesthetist to strike a balance between patient satisfactions by providing good analgesia, reduces motor block thus making the parturient

participate in labor and decrease instrumental deliveries due to prolonged second stage.

Factors contributing to instrumental delivery include as follows:

- Diminished pain and sensation from uterine contraction leading to diminished Ferguson's reflex and of the perception of the need to push at full dilatation
- Reduced motor force due to weakened abdominal musculature and
- Inadequate rotation of the presenting part due to weakened pelvic floor musculature.

All these factors have generated intense interest in epidural analgesia in three forms: Decreased local anesthetic concentration, combining with opioids, and combined spinal epidural technique.

Effective pain relief with minimal motor block is the necessary ingredient of an ideal epidural block for labor analgesia. Bupivacaine is the most commonly used drug for providing reliable epidural analgesia during labor.^[8]

Epidural bupivacaine provides excellent pain relief during labor and delivery and is still the most widely used local anesthetic for obstetric analgesia. However, its potential for motor blockade and cardiac/central nervous system toxicity by accidental intravenous injection is clinically undesirable, especially for obstetric patients.^[9]

Therefore, dilute solutions of epidural bupivacaine (0.25%, 0.125%, and 0.0625%) combined with opioid are used to minimize the unwanted motor blockade. The amount by which fentanyl reduces the local anesthetic dose requirement depends on the dose of fentanyl. The optimal dose of fentanyl varies from 2 to 3 mg/mL. Most workers have used 2 mg/mL of fentanyl.

The new two S-enantiomer drugs, ropivacaine and levobupivacaine have purportedly lesser motor block and toxicity related to bupivacaine. They are theoretically advantageous in obstetric patients and may be good alternatives to bupivacaine for labor analgesia.

Many authors have tried relative analgesic potency of ropivacaine and bupivacaine for epidural labor analgesia. The studies on relative potencies of these local anesthetics are conflicting. A number of clinical labor studies comparing ropivacaine and bupivacaine in 0.2–0.25% have demonstrated differences in the motor block between these drugs. However, some studies suggest that the extent of epidural motor block produced by 0.125% ropivacaine was indistinguishable from 0.125% bupivacaine in laboring patients.

Epidural labor analgesia was initiated when cervical dilatation was 3–5 cm. There was no accidental intravascular/intrathecal injection in all the 60 patients. All patients experienced adequate analgesia within 20 min of the first bolus dose.

Study considered the mean of numerical data such as Bromage score, VAS score, and heart rate over the entire duration, and we have considered mode for the non-numerical data such as level of sensory block and mode of delivery.

Demographic Profile

Age

The age group of all the 60 patients was between 19 and 27 years. The mean age of all the 60 patients was 22.81. The mean age in Group B was 22.30 with SD of 2.57 and in Group R was 23.33 with a SD of 1.95 with $P = 0.085$ which was not statistically significant [Table 1]. Most of our patients (63.3%) were between 22 and 25 years age group. 25% were in the 19–21 years age group and 11.6% were above 25 years. The age distribution of the 2 groups was comparable with $P = 0.86$ which was statistically not significant [Table 2].

Height

The mean height in Group B was 153.26 cm with a SD 3.609 and in Group R was 154.03 cm with a SD of 3.285. Both groups were comparable with $P = 0.393$ [Table 3].

Weight

The mean weight in Group B was 64.86 kg with a SD of 5.21 and in Group R was 60.60 kg with a SD of 4.81. P -value was significant (0.002) [Table 4].

Regarding the demographics both the groups were comparable with respect to age and height, weight was statistically significant in our study which was due to random sampling.

Duration of Labor

The duration of labor is highly variable. We have considered the overall mean time duration in both the groups. In our study, the mean duration of labor was 251 ± 50.742 min in Group B and 242 ± 50.405 min in Group R. Both groups were comparable with P -value of 0.49 which was not significant [Table 5].

In the similar study conducted by Paddalwar *et al.*, duration of Stage I and II of labor and total duration in the ropivacaine with fentanyl and bupivacaine with fentanyl were comparable and showed no statistical significance, P -value was >0.01 . The total duration of labor between the two groups which was 196.07 ± 42.32 min and 186.33 ± 43.67 min in the ropivacaine and bupivacaine groups, respectively ($P = 0.380$).

Table 1: The mean age and SD in both the groups

Group	<i>n</i>	Mean±SD	<i>P</i> value
Bupivacaine	30	22.30±2.57	0.085 ^{NS}
Ropivacaine	30	23.33±1.95	

SD: Standard deviation

Table 2: The distribution of age in both the groups and *P* value

Age (years)	Bupivacaine (%)	Ropivacaine (%)	χ^2 (<i>P</i> -value)
19–21	11 (36.6)	4 (13.3)	0.086 ^{NS}
22–25	15 (50)	23 (76.7)	
More than 25	4 (13.4)	3 (10)	
Total	30 (100)	30 (100)	

Table 3: The mean height in cm and SD in both the groups

Group	<i>n</i>	Mean±SD	<i>P</i> value
Bupivacaine	30	153.26±3.609	0.393
Ropivacaine	30	154.03±3.285	

SD: Standard deviation

Table 4: The mean weight in kg and SD in both the groups

Group	<i>n</i>	Mean±SD	<i>P</i> -value
Bupivacaine	30	64.86±5.210	0.002
Ropivacaine	30	60.60±4.810	

SD: Standard deviation

Table 5: The mean duration of labor in both groups with SD and *P* value

Group	<i>n</i>	Mean±SD	<i>P</i> -value
Bupivacaine	30	251±50.74	0.49
Ropivacaine	30	242±50.40	

Level of Sensory Block

The level of sensory block achieved in each patient is variable and the dermatomal level achieved is a non-numerical variable. Therefore, we considered the most frequent value (mode) achieved in percentage in all the 60 patients and also separately in Group B and Group R.

A total of 60 patients, 44 patients (73.3%) achieved a level of T_8 , 11 patients (18.3%) achieved a level of T_6 , and 5 patients (8.3%) achieved a level of T_{10} .

In Group B, 23 patients (76.7%) achieved T_8 , 4 patients (13.3%) achieved a level of T_{10} , and 3 patients (10%) achieved a level of T_6 . In Group R, 21 patients (70%) achieved T_8 , 8 patients (26.7%) achieved T_6 , and 1 patient (3.3%) achieved T_{10} with P value 0.125 which was not significant.

In a similar study done by Meister *et al.*, the level of sensory block achieved in the bupivacaine-fentanyl group was T₈ (T_{6,9}) and in the ropivacaine-fentanyl group it was T₇ (T_{6,8}). They have considered the combined median (25–75th percentile).

In another study done by Kalra *et al.*, the level of sensory blockade achieved was expressed as number of patients who achieved T₆, T₈, and T₁₀, respectively, in fentanyl-bupivacaine group and sufentanyl-bupivacaine group. It was 2, 27, and 6 patients in the B - F Group and 2, 28, and 5 patients in B - SF Group.

Similar studies conducted by Polley *et al.* and Chua *et al.* also found that the most frequent sensory level achieved was T₈.

Our results are concurring with the above studies.

Degree of Motor Block

The degree of motor blockade produced depends on the volume and concentration of drug used and also on the additional supplementation given from time to time. The degree of motor block was assessed at 20 min and every 30 min thereafter, until delivery. The degree of motor block was assessed using Bromage score. The degree of motor block in each patient varied from time to time. Results are expressed in various studies as a mean, median, and highest Bromage score achieved.

Our results were expressed as a trend of mean Bromage score in all 30 patients in both groups at 20 min and every 30 min thereafter for the entire duration of labor. Furthermore, the overall mean Bromage score was calculated for the entire duration in each group. In our study, the mean Bromage score in Group B was 0.65 with SD 0.42 and Group R was 0.35 with SD 0.27 and $P = 0.02$ which was statistically significant, but clinically, there was no difference with respect to mode of delivery. This is probably due to the low concentration (0.125%) of drug used for the study. A statistically significant difference in motor blockade in the groups may be attributable to the relative potencies of the drugs.

Since most of our patients had a Bromage score 0 or 1, we decided to test whether this statistically significant value had any clinical significance. Therefore, we considered the most frequent Bromage score reached in all patients in

both groups. We found that 46.6% of patients in Group B and 73.3% of patients in Group R had Bromage score 0, and 46.6% of patients in Group B and 26.6% of patients in Group R had Bromage score 1, and 6.6% patients in Group B had a Bromage score of 2, while this number was 0 in Group R.

In a similar study conducted by Paddalwar *et al.*, 2016, found in her study that no patient of 30 patients in group Ropivacaine developed motor block, whereas 5 patients in group bupivacaine developed Grade 2 (mild) motor block, which means the ability to weakly flex the knees (Bromage scale). P -value was 0.02, which was statistically significant, although the degree of block was mild. Distribution of Bromage scoring in both groups showed statistical significance ($P < 0.05$).

In a study conducted by Girard *et al.* comparing epidural bupivacaine versus ropivacaine (0.125%) both with 1 µg/mL fentanyl in laboring patients. They did not find any difference in the incidence of motor block between parturients receiving either ropivacaine or bupivacaine each at 0.125% with 1 µg/mL fentanyl for epidural labor analgesia. 15 parturients (45%) in the bupivacaine group and 17 (63%) in the ropivacaine group did not show any motor block (Bromage = 0) throughout labor. There were no differences in motor block between the two drugs (Chi-square = 1.84, $P = 0.4$). Indeed, there were more parturients without motor block in the ropivacaine group than in the bupivacaine group (45% vs. 63%). However, this difference was neither statistically significant nor clinically relevant.

In another study conducted by Merson *et al.* found that the incidence of motor blockade was 71% in the high (0.25%) bupivacaine group and 47% in the high (0.25%) ropivacaine group. It was 38% in the low (0.125%) bupivacaine group and only 0.06% in the low (0.125%) ropivacaine group. The overall odds ratio between higher and lower doses of either drug was 3.93. It was 9 for high doses of bupivacaine and ropivacaine. This indicates that overall there is a four-fold increase of motor blockade with bupivacaine and 9 times when higher doses are used. However, they did not find any clinically significant difference when mode of delivery was considered.

In the meta-analysis conducted by Guo *et al.* of epidural analgesia with bupivacaine and fentanyl versus ropivacaine and fentanyl for pain relief in labor, 15 randomized

Table 6: The number of patients who achieved most frequent sensory level in both the groups and all the patients over entire duration with P value

Number of Patients	Sensory level	Group B (%)	Group R (%)	Total (%)	χ^2 (P -value)
Number of patients (percentages)	T6	3 (10)	8 (26.7)	11 (18.3)	0.125
	T8	23 (76.7)	21 (70)	44 (73.3)	
	T10	4 (13.3)	1 (3.3)	5 (8.3)	
	Total	30 (100)	30 (100)	60 (100)	

controlled trials, recruiting 2097 parturient mothers overall, were selected for the meta-analyses showed 187 of 1015 women in ROPI-FEN group and 335 of 1022 women in BUPI-FEN group developed notable motor blocks as measured by modified Bromage scores. Both the odds ratio-based models revealed ROPI-FEN group to be significantly superior to BUPI-FEN combination.

Incidence of motor blocks was significantly lower in ROPI-FEN administered women, percent women who developed motor block measurable with Bromage scale were 18.4% in ROPI-FEN and 32.8% in BUPI-FEN treated groups. Incidence of motor blocks increased significantly with increasing concentration of bupivacaine but not significantly with ropivacaine. Overall, there was no significant relationship between fentanyl concentration and incidence of motor blocks.

Meister *et al.* in a similar study using 0.125% of both bupivacaine and ropivacaine with 2 µg/mL of fentanyl assessed the most intense motor blockade experienced by each patient at any assessment interval throughout labor. They found that 68% and 28% of patients had a Bromage score of 0, 32% and 68% had a Bromage score of 1.0%, and 4% had a Bromage score of 3 with ropivacaine and bupivacaine, respectively, indicating that bupivacaine produced a significant motor block when compared to ropivacaine.

Fernandez-Guisasola *et al.* who studied equipotent doses of bupivacaine (0.0625%) with fentanyl and (0.1%) ropivacaine with fentanyl found that the degree of motor blockade was similar at all-time intervals at which it was assessed. 5 (9.8%) patients in Group B and 3 (6.3%) in Group R had some degree of motor blockade which was not statistically significant.

In a study conducted by Bawadane *et al.* did not find any difference regarding motor blocks in the two groups of 0.1% ropivacaine versus 0.1% bupivacaine for extradural analgesia. This may be attributed due to lower concentration of local anesthetic used in it.

In all studies, the degree of motor blockade produced by bupivacaine is statistically significant when compared to ropivacaine, but clinically, there was no difference when compared with mode of delivery in all the studies.

VAS

After the initial bolus dose, analgesia was maintained by intermittent bolus injections of 5 mL every 40–60 min. Patients who experienced inadequate analgesia (VAS >4) during the process were supplemented with additional 5 mL of solution up to a maximum of 10 mL/h until the delivery of the baby.

Pain was assessed by VAS before initiating the epidural (zero time) and after 5, 10, 20, 30, 45, and 60 min and every 30 min after that, until delivery. The VAS score in each patient varied from time to time. Results are expressed in various studies as a mean or median (25–75th percentile) of VAS.^[7]

Our results were expressed as a trend of mean VAS score in all 30 patients of each group at 0, 5, 10, 20, 30, 45, and 60 min and every 30 min after that, until delivery. Before epidural injection, the mean score was 7.9 and 7.6 in Group B and Group R, respectively. After administration of the drug the mean VAS score in Group B was 1.53 with SD 0.46 and Group R was 1.54 with SD 0.46 and $P = 0.08$ which was statistically not significant. The trend of the mean VAS was similar and there was not much variation between the groups at different time intervals.

Paddalwar *et al.* in another similar study compared the analgesic potency of 0.125% bupivacaine and 0.125% ropivacaine, both with fentanyl 2 µg/mL. They measured pain by the VAS before initiating the epidural and at 5, 10, 15, 20, 30, 60, and 90 min and every 30 min after that, until delivery. The mean baseline VAS score in Group R was 9.60 ± 0.968 , whereas in Group B, it was 9.17 ± 0.98 . At 20 min, all the patients in both the groups were pain free with a VAS score of 0–2. Distribution of VAS at various intervals in both the groups was comparable and showed no statistical significance.

In a similar study done by Meister *et al.*, equi-concentration solutions (0.125%) of bupivacaine-fentanyl and ropivacaine-fentanyl were compared for their analgesic efficacy. They used the numeric rating scale (NRS) for grading of pain before initiating epidural and 60 min after initiation. They found that the mean NRS before epidural initiation was 9 with a SD of 1 in bupivacaine-fentanyl and 8 with a SD of 1 in ropivacaine-fentanyl groups. 60 min after initiation, it was 0.4 with SD 1 in bupivacaine-fentanyl group and 0.3 with SD of 1 in ropivacaine-fentanyl group. They found no statistical significance between the drugs.

Similar studies done by Kalra *et al.*, Fernandez-Guisasola *et al.*, and Guo *et al.* also found that there was no difference between the mean VAS scores between bupivacaine and ropivacaine at different time intervals and also the average scores over the entire duration.

Our results are concurring with the above studies.

Hemodynamics

During the procedure, the following hemodynamics such as oxygen saturation, heart rate, non-invasive blood pressure, and FHR were monitored. These parameters were

monitored at 0, 5, 10, 20, 30, 45, and 60 min and every 30 min after that, until delivery.

Oxygen Saturation

Our results were expressed as a trend of mean SPO₂ in both the groups for the entire duration and also the overall mean SPO₂ in the 2 groups. The mean SPO₂ in Group B was 98.7% with SD 0.57 and in Group R was 99.1% with SD 0.59 with $P = 0.009$ which was statistically significant. Changes in the SPO₂ between the two groups were statistically significant, but clinically, there was not much difference between the two groups. Trend diagram also shows that not much variation between two curves of Group B and Group R.

Heart Rate

Our results were expressed as a trend of mean HR in both the groups for the entire duration and also the overall mean HR in the 2 groups. The mean heart rate in Group B was 81.8 with SD 10.81 and in Group R was 83.40 with SD of 7.52 with P -value of 0.49 which was statistically not significant.

Similar results were found in the studies of Paddalwar *et al.*, Meister *et al.*, and Lacassie *et al.*

Non-Invasive Blood Pressure (SBP, Diastolic Blood Pressure [DBP], Arterial Pressure [MAP])

Our results were expressed as a trend of mean systolic, mean arterial, and diastolic pressure in both the groups for the entire duration and also the overall mean systolic, mean arterial, and diastolic pressure in the 2 groups.

The mean SBP in Group B was 116.6 with SD 6.91 and in Group R was 116.4 with SD of 7.13 with $P = 0.909$ which was statistically not significant.

The mean DBP in Group B was 74.40 with SD 4.41 and in Group R was 79.6 with SD of 3.77 with $P = 0.001$ which was statistically significant.

The mean MAP in Group B was 88.2 with SD 4.61 and in Group R was 91.5 with SD of 4.76 with $P = 0.0008$ which was statistically significant.

The changes in SBP, DBP, and MAP between the two groups were statistically significant, but clinically, there was not much difference between the two groups. The trend diagrams show that there is not much variation between the curves of Group B and Group R.

In many similar studies conducted by Paddalwar *et al.*, Meister *et al.*, and Polley *et al.*, etc., the changes in SBP, DBP, and MAP were not statistically significant between the two groups.

In our study, the significant statistical difference between the two groups may be attributed to differences in the sample sizes, variations in the doses and concentrations of drug used and method of supplementation. In our study, analgesia was maintained by intermittent bolus injections of 5 ml every 40–60 min. Patients who experienced inadequate analgesia (VAS >4) during the process were supplemented with additional 5 ml of solution up to a maximum of 10 mL/h until the delivery of the baby.

FHR

FHR was monitored using Doppler at 0, 5, 10, 20, 30, 45, and 60 min and every 30 min after that, until delivery. Our results were expressed as trend of mean FHR at regular time intervals and also the overall mean. The mean FHR in Group B was 140.9 with SD 5.22 and in Group R was 140.3 with SD of 2.63 with $P = 0.577$ which was statistically not significant.

Paddalwar *et al.* in a similar study compared the mean FHR at 0, 5, 10, 15, 20, and 30 min and every 30 min after that, until delivery. They found that the trend of mean FHR in both the groups were comparable with $P > 0.05$.

In a study done by Chua *et al.* FHR was monitored continuously throughout labor and they did not find any variation in FHR in both groups. The FHR was comparable with $P > 0.05$.

Finegold *et al.* in his study monitored FHR every hour from the initiation of epidural until the patient was 10 cm dilated. The mean FHR was 132 ± 16 bpm in bupivacaine group and 131 ± 21 in ropivacaine group. They found no difference existed between the groups ($P > 0.05$).

Adverse Effects

In our study, there were no clinically significant adverse effects such as bradycardia, hypotension, and desaturation which required active intervention.

CONCLUSION

In our study comparing equi-concentration (0.125%) bupivacaine-fentanyl 2 µg/mL and (0.125%) ropivacaine-fentanyl 2 µg/mL for epidural labor analgesia results indicate that both are equally effective clinically by intermittent epidural supplementation in providing excellent labor analgesia with hemodynamic stability, minimal motor blockade, mode of delivery, and maternal satisfaction without serious maternal or fetal side effects. The reported benefit of ropivacaine over bupivacaine such as lower motor blockade and lesser cardiotoxicity are more apparent when higher concentrations are used.

We conclude that there is clinically no significant difference between bupivacaine and ropivacaine for epidural labor analgesia when lower concentrations (0.125%) of the drug with fentanyl (2 µg/mL) as an adjuvant are used.

This study was undertaken to compare equi-concentration of bupivacaine-fentanyl and ropivacaine-fentanyl for epidural labor analgesia in primigravida patients.

- Group B - received 0.125% bupivacaine with 2 µg/mL fentanyl.
- Group R - received 0.125% ropivacaine with 2 µg/mL fentanyl.

With aseptic precautions epidural catheter was inserted and drug was given. Sensory level, motor blockade, VAS, hemodynamics, FHR, mode of delivery, patient satisfaction, and total dose of local anesthetic used were recorded.

Our results indicate that both are equally effective clinically in:

- Providing excellent labor analgesia,
- Hemodynamic stability,
- Maternal satisfaction without serious maternal or fetal side effects,
- Total local anesthetic dose used,
- Statistically significant motor blockade produced by bupivacaine compared to ropivacaine does not change mode of delivery at lower concentrations.

We conclude that lower concentration of bupivacaine or ropivacaine with opioids provide excellent analgesia for most obstetric patients.

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