

# Comparative Study of Ropivacaine-Fentanyl Versus Bupivacaine-Fentanyl for Epidural Labour Analgesia -Prospective Randomised Control Study

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## ABSTRACT

**Background:** Ropivacaine has emerged as a promising alternative to Bupivacaine as a local anesthetic for epidural labor analgesia. Ropivacaine had shown lesser cardiotoxicity and less intense motor block compared to bupivacaine which makes it safer to use in obstetric populations during labor. The purpose was to compare the efficacy, safety, and maternal satisfaction associated with the use of Ropivacaine with fentanyl and Bupivacaine with fentanyl as epidural block for inducing labor analgesia.

**Methodology:** A Randomized controlled trial following single blinding method was conducted with 120 patients who were in active labor with vertex presentation in the age group of 18 - 35 years. They were randomly divided into two groups of equal numbers and one group of patients received 10 ml of 0.125 % ropivacaine along with 2 mcg/ml fentanyl and the other group of patients received 10 ml of 0.125% bupivacaine analgesia along with 2 mcg/ml fentanyl. Sensory and motor block assessment was done using standard scales. Hemodynamic parameters, adverse events and their obstetric outcomes were recorded and compared.

**Results:** Onset of analgesia and the VAS scores at 15<sup>th</sup> and 30<sup>th</sup> mins were almost similar in both the groups p (>.05). The duration of analgesia was significantly higher among the ropivacaine group in comparison with bupivacaine (126.4 mins vs 103.2 mins). Motor block assessment was found to be slightly favourable for ropivacaine compared to bupivacaine but was not statistically significant (p=0.077). Hemodynamic parameters were found to be safe and similar in both the groups. Similarly, is the obstetric outcome and there were no adverse events reported among the two groups.

**Conclusion:** Epidural labor analgesia using similar concentrations of ropivacaine or bupivacaine in combination with fentanyl produced comparable analgesic outcomes. Ropivacaine showed a slight advantage in terms of longer duration of analgesia while preserving motor function.

**Keywords:** Epidural analgesia, Ropivacaine, Bupivacaine, Labor analgesia

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## INTRODUCTION

Labour pain is intense, and effective analgesia can improve maternal comfort and satisfaction while allowing the parturient to remain awake and participate in the birthing process. Neuraxial analgesia, particularly epidural analgesia, is widely regarded as one of the most effective pharmacological methods for providing pain relief during labour. Advances in neuraxial techniques have focused on achieving effective analgesia with minimal maternal and fetal adverse effects and minimal motor blockade [1].

Bupivacaine has been widely used for epidural labour analgesia because of its prolonged duration of action and effective sensory analgesia. However, systemic toxicity, particularly cardiovascular toxicity following inadvertent intravascular administration, remains an important concern with bupivacaine [2]. Ropivacaine, a long-acting amide local anaesthetic, has emerged as an alternative to bupivacaine due to its relatively lower cardiotoxicity and greater differential between sensory and motor blockade. These make ropivacaine an attractive option for epidural analgesia during labour [3,4].

The addition of opioids such as fentanyl to dilute local anaesthetic solutions can enhance analgesia and permit the use of lower concentrations of local anaesthetics, potentially reducing motor blockade while maintaining adequate pain relief [1,5]. Clinical trials comparing ropivacaine-fentanyl with bupivacaine-fentanyl during labour have generally demonstrated comparable analgesic efficacy and maternal satisfaction, although differences in motor blockade have been reported across studies [5,6]. A meta-analysis of randomized controlled trials comparing epidural ropivacaine and bupivacaine found no significant differences in obstetric or neonatal outcomes, while findings regarding motor blockade were heterogeneous [4]. Gündüz et al.[5] reported equivalent analgesic efficacy and high maternal satisfaction with ropivacaine-fentanyl and bupivacaine-fentanyl, with no cases of motor blockade in either group.

Despite the available evidence, differences in drug concentrations, dosing regimens, analgesic techniques, and outcome assessment have contributed to variability among studies. Therefore, the present study was undertaken to compare the efficacy, safety, motor blockade, obstetric outcomes, and maternal satisfaction associated with ropivacaine-fentanyl and bupivacaine-fentanyl for epidural labour analgesia. The findings may contribute to the evidence base for selecting an appropriate local anaesthetic regimen for effective and safe labour analgesia.

## MATERIALS AND METHODS

A prospective randomized controlled trial was conducted by the department of anesthesiology in association with department of OBG in a Government Medical College Hospital, Salem for a duration of six months. A non-random purposive sampling technique was followed for

selecting the sample size. A time period of 6 months from the date of obtaining the ethical clearance certificate was fixed for obtaining the sample. A total of 120 patients in the age group of less than 35 and more than 18 years who were in active labor with vertex presentation and with ASA score of either 1 or 2 were included as our study subjects. Patients with contraindication for epidural catheter placement, height less than 150 cm, BMI more than 35kg/m<sup>2</sup>, patients having cephalopelvic disproportion or with history of bleeding diathesis were excluded from the study. Entire study subjects were divided into two groups consisting of 60 patients in each group. Group A subjects received 0.125 % ropivacaine and group B patients received 0.125% bupivacaine as the epidural agent of 10 ml along with 2 mcg/ml fentanyl as common adjuvant in both the groups. Single blinded technique was followed in which the subjects were unaware of which group they belong to and the investigator allocated the patients in both the groups following a simple random technique using a computer-generated random number table. If the last digit of the random number ends in an odd number that patient was allotted to group A and if the last digit is an even number the patient was labelled as group B. The primary outcome of the study was considered as the duration of analgesia, duration of motor block and incidence of adverse events.

Institutional Ethics Committee approval (No. 4341/ME-G/2022; dated 27/07/2022) was obtained before study initiation. All parturients were counselled regarding epidural labour analgesia, and written informed consent was obtained. Baseline heart rate, systolic and diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded. Under strict aseptic precautions, the epidural space was identified at L3–L4 using an 18-G Tuohy needle and the loss-of-resistance technique, and the catheter was placed at the same level. At cervical dilatation  $\geq 3$  cm, an initial 10-mL dose of the assigned study drug was administered. During labour, an additional 5-mL dose of the respective study drug was administered whenever the VAS score exceeded 3.

Sensory block assessment was done using pinprick. Onset of action, maximum level of attainment of the block and the time taken for it, duration of analgesia and any additional requirement of the drug to maintain the analgesia were recorded. Attainment of motor block was assessed using modified bromage scale. All data related to sensory and motor block were collected and analysed using SPSS version 24 statistical software. For all parametric data mean and SD was derived. Statistical inference was derived using T test and Chi-square test.

## RESULTS

The demographic parameters of the study subjects and the obstetric parameters such as gravida and cervical dilatation were almost matched between the two groups (table 1). After administering the study drug to the respective study groups sensory block parameters were assessed.

**Table 1: Demographic details and obstetric parameters of the study subjects among the two groups**

| Variable                  | Group A (n=60) (mean ± SD) | Group B (n=60) (mean ± SD) | P value |
|---------------------------|----------------------------|----------------------------|---------|
| Age                       | 29.1 ± 2.6                 | 30 ± 2.5                   | 0.712   |
| Weight                    | 67.1 ± 3.2                 | 70.3 ± 3.9                 | 0.635   |
| Height                    | 162.3 ± 3                  | 162.1 ± 3.2                | 0.852   |
| BMI                       | 25.6 ± 1.4                 | 27.1 ± 1.8                 | 0.774   |
| Primi-para*               | 32 (53.3%)                 | 34 (56.6%)                 | 0.582   |
| Cervical dilatation (cms) | 4.7 ± 0.9                  | 4.8 ± 0.8                  | 0.863   |

\*Frequency (%)

**Table 2: Comparison of sensory block parameters between the two groups**

| Variable                                          | Group A (n=60) (mean ± SD) | Group B (n=60) (mean ± SD) | P value |
|---------------------------------------------------|----------------------------|----------------------------|---------|
| Onset of analgesia (mins)                         | 14 ± 2.3                   | 14.4 ± 2.0                 | 0.843   |
| VAS score 15 mins after injection                 | 1.36 ± 0.72                | 1.52 ± 0.77                | 0.632   |
| VAS score 30 mins after injection                 | 1.54 ± 0.65                | 1.59 ± 0.71                | 0.706   |
| Max attainment of the dermatome level             | 7.53 ± 0.75                | 6.87 ± 0.83                | 0.473   |
| Time for attaining the max dermatome level (mins) | 10 ± 1.01                  | 10.30 ± 1.13               | 0.915   |
| Duration of analgesia (mins)                      | 126.4 ± 12.5               | 103.25 ± 10.88             | 0.0031  |

**Table 3: Comparison of motor block and hemodynamic parameters between the two groups**

| Variable                       | Group A (n=60) | Group B (n=60) | P value |
|--------------------------------|----------------|----------------|---------|
| <b>Bromage score</b>           |                |                |         |
| 1*                             | 43 (71.7)      | 31 (51.7)      | 0.077   |
| 2*                             | 11 (18.3)      | 18 (30.0)      |         |
| 3*                             | 6 (10.0)       | 11 (18.3)      |         |
| <b>Maternal blood pressure</b> |                |                |         |
| Systolic #                     | 111.1 ± 4.1    | 115.2 ± 5.2    | 0.682   |
| Diastolic #                    | 72.5 ± 3.2     | 75 ± 4.1       | 0.718   |
| <b>Maternal heart rate #</b>   | 82.3 ± 3.9     | 86 ± 4.5       | 0.668   |

\* Frequency (%). # mean ± standard deviation

**Table 4: Obstetric outcome among the study subjects between the two groups**

| Obstetric outcome       | Group A  | Group B    | P value |
|-------------------------|----------|------------|---------|
| Normal vaginal delivery | 42 (70%) | 43 (71.6%) | 0.861   |
| Instrumental delivery   | 15 (25%) | 13 (21.6%) |         |
| Caesarean section       | 3 (5%)   | 4 (6.6%)   |         |

The onset of analgesia was 14 mins among both the groups and the VAS score at 15 mins and 30 mins for assessing the pain was found to be more or less same (1.36 vs 1.52) among both the groups. The maximum attainment of the dermatome level was found to be slightly higher among the ropivacaine group compared to bupivacaine (7.53 vs 6.87) but it was only numerically higher but not statistically significant, whereas the time for attainment of the maximum dermatome was same among both the group (10 mins). The duration of analgesia was significantly higher among the ropivacaine group compared to bupivacaine (126.4 mins vs 103.2 mins). This was the only sensory block parameter that showed a positive effect towards ropivacaine (table 2). The motor block assessment was done using bromage scale and at 15 mins after administering the respective drugs majority of the study subjects in both the groups had score 1 (bromage scale). Group A had a higher pro-

portion of patients with Bromage score 1 (43 vs 31), though this difference was not statistically significant ( $p=0.077$ ) and similarly it was vice versa for score 2 (11 vs 18) and 3 (6 vs 11). So, a trend towards less motor blockade was observed among the ropivacaine group. The hemodynamic parameters such as systolic and diastolic blood pressure and the heart rate were more or less similar in both the groups and no significant differences in hemodynamic parameters were observed between groups. (table 3). This proves that both ropivacaine and bupivacaine are hemodynamically stable drugs and it is safe to be used for antenatal mothers in labor. Obstetric outcomes were assessed by mode of delivery such as normal vaginal delivery, instrumental delivery or caesarean section. It was found that there was no significant difference in the mode of delivery between the two groups ( $p=0.861$ ) (table 4). There were no adverse events reported between the two groups during the entire course of the study.

## DISCUSSION

This prospective, randomized controlled study compared the efficacy, safety, motor blockade, obstetric outcomes, and maternal satisfaction associated with ropivacaine-fentanyl and bupivacaine-fentanyl for epidural analgesia during labour. A total of 120 parturient were randomized equally into two groups. The baseline characteristics, including age, BMI, parity, and cervical dilatation at initiation of epidural analgesia, were comparable between the groups, indicating good baseline comparability. Similar comparability of demographic and obstetric characteristics has been reported in previous studies comparing ropivacaine-fentanyl and bupivacaine-fentanyl for labour analgesia [7,8].

In the present study, the onset of analgesia was comparable between the two groups, with mean onset times of 14.0 and 14.4 minutes in the ropivacaine-fentanyl and

bupivacaine-fentanyl groups, respectively. This finding is consistent with the meta-analysis by Guo S et al.[8], which reported no significant difference in the onset of analgesia between ropivacaine-fentanyl and bupivacaine-fentanyl for labour analgesia. Finegold H et al.[9] similarly reported comparable onset of analgesia between ropivacaine-fentanyl and bupivacaine-fentanyl infusions during epidural labour analgesia. In contrast, Chora I et al.[7] reported a significantly faster onset with bupivacaine than with ropivacaine, although both regimens provided effective analgesia. These differences may be related to variations in local anaesthetic concentration, loading dose, epidural technique, and assessment of onset of analgesia.

The present study demonstrated comparable pain scores between the two groups at 15 and 30 minutes after administration. This indicates that both ropivacaine-fentanyl and bupivacaine-fentanyl provided effective analgesia during the early period following epidural administration. Similar findings have been reported in randomized studies in which pain scores were comparable between the two regimens [7-9]. Finegold et al. found no significant difference in pain scores between ropivacaine-fentanyl and bupivacaine-fentanyl at different assessment points, while Chora et al. also reported equivalent analgesia with the two combinations [7,9]. The meta-analysis by Guo S et al. further supported comparable analgesic efficacy between the two regimens [8]. Thus, the present findings are consistent with the available evidence indicating that both local anaesthetics can provide satisfactory analgesia when combined with fentanyl.

In the present study, the maximum sensory dermatome level achieved was slightly higher in the ropivacaine-fentanyl group than in the bupivacaine-fentanyl group, but the difference was not statistically significant. This finding is consistent with previous labour epidural studies reporting comparable sensory levels between ropivacaine and bupivacaine [7,10,11]. Chora I et al.[7] reported no significant difference in sensory levels between the two regimens, while Sánchez-Conde P et al.[11] found comparable sensory blockade, with a T8-T10 level achieved in both groups. Bawdane KD et al.[10] also reported similar sensory blockade with low-concentration ropivacaine-fentanyl and bupivacaine-fentanyl. Therefore, the present findings suggest that, at the concentrations and dosing regimen used in this study, both local anaesthetics provided a comparable extent of sensory blockade.

Motor blockade was assessed 15 minutes after administration using the Bromage score. In the present study, a greater proportion of women in the bupivacaine-fentanyl group had a Bromage score of 1 compared with the ropivacaine-fentanyl group; however, the difference was not statistically significant. Therefore, the present

study demonstrates only a numerical trend towards less motor blockade with ropivacaine and does not establish a statistically significant difference between the regimens. Nevertheless, the direction of the finding is consistent with previous evidence. Halpern SH et al.[12] reported significantly less motor blockade with ropivacaine than with bupivacaine in women receiving low-concentration epidural analgesia with fentanyl. Merson similarly found significantly less motor blockade with ropivacaine than with bupivacaine during continuous labour epidural analgesia [13]. In contrast, Chora I et al.[7] and Bawdane KD et al.[10] reported no statistically significant difference in motor blockade between the two regimens. These differences may reflect variations in local anaesthetic concentration, loading dose, opioid adjuvant, and epidural administration technique.

Maternal haemodynamic parameters remained stable in both groups throughout the study, with no statistically significant differences in heart rate, blood pressure, or mean arterial pressure. Similar findings have been reported in previous studies comparing ropivacaine-fentanyl and bupivacaine-fentanyl during labour [7,9,10]. Chora I et al.[7] and Bawdane KD et al.[10] reported comparable haemodynamic parameters between the two groups, while Finegold H et al.[9] also found no clinically important differences in maternal haemodynamic variables. These findings indicate that, at the concentrations and dosing regimens studied, both combinations provided effective analgesia without clinically important differences in maternal haemodynamic stability.

The obstetric outcomes in the present study were also comparable between the two groups. This finding is consistent with previous randomized studies. Halpern SH et al.[12] reported no significant difference in operative delivery or other obstetric and neonatal outcomes between low-concentration bupivacaine and ropivacaine administered with fentanyl. Lee BB et al.[14] similarly found no difference in the mode of delivery or major obstetric and neonatal outcomes between epidural ropivacaine and bupivacaine with fentanyl. Bawdane KD et al.[10] also reported comparable duration of labour, mode of delivery, and neonatal outcomes between the two regimens. Chora I et al.[7] likewise found no significant difference in labour duration or mode of delivery. Thus, the present findings are consistent with evidence suggesting that the choice between ropivacaine and bupivacaine, when used in dilute epidural regimens with an opioid, does not necessarily result in major differences in obstetric outcomes.

Maternal satisfaction is an important component of evaluating labour analgesia because the effectiveness of an epidural regimen extends beyond pain reduction alone. In the present study, maternal satisfaction was comparable between the two groups. Similar findings have

been reported in previous studies [7,8,12]. Halpern SH et al.[12] reported that satisfaction with mobility was higher with ropivacaine, whereas satisfaction with analgesia at delivery was higher with bupivacaine. This indicates that maternal satisfaction may represent several dimensions of the labour experience and should not be interpreted solely as a measure of analgesic efficacy. Individual expectations, psychological support, mobility, and the overall birth experience may also influence satisfaction.

Overall, the findings of the present study indicate that ropivacaine-fentanyl and bupivacaine-fentanyl provided comparable analgesia, sensory blockade, haemodynamic stability, obstetric outcomes, and maternal satisfaction. Although a numerical tendency towards less motor blockade was observed with ropivacaine, the difference was not statistically significant in the present study. This finding is compatible with previous studies showing that ropivacaine can provide analgesia comparable to bupivacaine and, in some dosing regimens, may be associated with less motor blockade [9,12,13]. However, the available evidence does not establish universal superiority of either drug, and differences in concentration, dose, opioid combination, and administration technique should be considered when interpreting comparative results [15].

The study has several limitations. First, the sample size may have limited the ability to detect relatively small differences between the two treatment groups, particularly for outcomes such as motor blockade and maternal satisfaction. Second, the single-centre design may limit the generalizability of the findings to other institutions and patient populations. Third, the single-blinded design may have introduced the possibility of assessment or performance bias. Finally, maternal satisfaction is subjective and may be influenced by factors beyond the analgesic regimen, including individual expectations, psychological factors, labour support, and the hospital environment. Larger multicentre randomized studies with standardized analgesic protocols and multidimensional assessment of maternal satisfaction may provide further evidence regarding the comparative effects of these two epidural regimens.

## CONCLUSION

The findings suggest that ropivacaine-fentanyl may offer advantages over bupivacaine-fentanyl in terms of maternal mobility and satisfaction, without compromising safety. As the field of obstetric care continues to evolve, it is imperative that clinicians remain informed about the latest evidence-based practices to optimize pain management strategies for laboring women. The pursuit of improved maternal experiences during labor is not only a clinical goal but also a fundamental aspect of providing compassionate and patient-centered care. Further research is essential to build upon these findings and to ensure that the choices made in labor analgesia align

with the best interests of both mothers and their newborns.

**Individual Author's Contribution:** **SK** contributed to data collection and manuscript preparation. **SD** contributed to data collection and manuscript preparation. **MP** contributed to data collection and manuscript preparation. **KP** contributed to the study conception, study design, and manuscript preparation. **SR** contributed to manuscript preparation.

**Availability of data:** The data that support the findings of this study are available from the corresponding author on reasonable request.

**Declaration of Non-use of generative AI Tools:** This article was prepared without the use of generative AI tools for content creation, analysis, or data generation. All findings and interpretations are based solely on the authors' independent work and expertise.

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