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ORIGINAL RESEARCH

Comparison Of Effect With Ropivacaine And Fentanyl 2mcg/Ml Versus Levobupivacaine And Fentanyl 2mcg/Ml Epidurally For Labour Analgesia

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ABSTRACT

Introduction: Labour pain relief is crucial for obstetric care, and epidural analgesia is a common method. Ropivacaine and levobupivacaine, combined with opioids like fentanyl, are frequently used in this context. However, comparative data regarding their efficacy and safety for labor analgesia are limited. This study aims to compare the analgesic efficacy, maternal, and fetal outcomes of epidural analgesia using ropivacaine with fentanyl versus levobupivacaine with fentanyl for labor analgesia.

Methods: This prospective, randomized, double-blind, controlled trial involves 200 parturients in active labor. They are randomly allocated into two groups: Group A receiving epidural analgesia with ropivacaine 0.2% with fentanyl 2mcg/ml, and Group B receiving epidural analgesia with levobupivacaine 0.2% with fentanyl 2mcg/ml. Pain relief, onset, and duration of analgesia, maternal satisfaction, mode of delivery, neonatal Apgar scores, and adverse events are assessed.

Results: Statistical analysis has been performed using appropriate methods. Preliminary results suggest better pain relief and quicker onset of analgesia with ropivacaine-fentanyl compared to levobupivacaine-fentanyl. However, no significant differences are observed in duration of analgesia, maternal satisfaction, or mode of delivery. Neonatal Apgar scores slightly favor levobupivacaine-fentanyl.

Conclusion: Epidural analgesia with ropivacaine-fentanyl provides superior pain relief and faster onset compared to levobupivacaine-fentanyl. Both regimens demonstrate similar durations of analgesia, maternal satisfaction, and mode of delivery. Neonatal outcomes slightly favor levobupivacaine-fentanyl. Careful consideration of these findings alongside patient preferences is essential in optimizing labor pain management.

Keywords: Labour analgesia, epidural analgesia, ropivacaine, levobupivacaine, fentanyl, randomized controlled trial

INTRODUCTION

Labour pain is one of the most severe forms of pain experienced by women during childbirth. Effective management of labour pain is essential not only for maternal comfort but also for maternal-fetal well-being and satisfaction with the childbirth experience. Epidural analgesia is widely regarded as one of the most effective methods for providing pain relief during labor, offering superior pain control compared to systemic opioids or non-pharmacological methods.

Local anesthetics, such as ropivacaine and levobupivacaine, are commonly used in epidural analgesia for labor pain management due to their favorable pharmacokinetic profiles and lower potential for motor block and cardiac toxicity compared to older agents like bupivacaine[1]. These local anesthetics are often combined with adjuncts like opioids (e.g., fentanyl) to enhance analgesic efficacy and prolong the duration of pain relief.

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Ropivacaine and levobupivacaine are both amino-amide local anesthetics with similar chemical structures and clinical profiles. However, subtle differences in their pharmacokinetic and pharmacodynamic properties may influence their suitability for specific clinical applications, including labor analgesia. While both agents have been widely studied and utilized in obstetric anesthesia, limited comparative data exist regarding their efficacy and safety when combined with opioids for labor analgesia [2].

Fentanyl is a synthetic opioid agonist with potent analgesic properties and a rapid onset of action when administered epidurally. By combining fentanyl with local anesthetics in epidural infusions, it is possible to achieve synergistic analgesia with reduced doses of both drugs, thereby minimizing the risk of maternal and fetal side effects associated with higher doses of individual agents.

Given the importance of choosing the most appropriate pharmacological agents for epidural labor analgesia, it is crucial to compare the analgesic efficacy, maternal outcomes, and neonatal effects of different combinations of local anesthetics and opioids. Therefore, this study aims to compare the effects of epidural analgesia using ropivacaine with fentanyl versus levobupivacaine with fentanyl for labor pain relief [3].

Labour analgesia is an integral component of obstetric care, aiming to alleviate maternal suffering while ensuring safety for both mother and baby. Epidural analgesia using a combination of local anesthetics and opioids remains the gold standard for providing effective pain relief during labor. However, the choice of specific analgesic agents and their combinations can impact the quality of analgesia, maternal satisfaction, and neonatal outcomes [4].

Ropivacaine and levobupivacaine are newer generation local anesthetics with improved safety profiles compared to older agents like bupivacaine. Both drugs have been widely used in obstetric anesthesia practice, but limited comparative data exist regarding their efficacy and safety for labor analgesia. Similarly, while fentanyl is commonly used as an adjunct to local anesthetics in epidural analgesia, the optimal dose and combination with specific local anesthetics remain areas of ongoing research and debate [5].

This study aims to address these knowledge gaps by directly comparing the analgesic efficacy, maternal outcomes, and neonatal effects of epidural analgesia using ropivacaine with fentanyl versus levobupivacaine with fentanyl for labor pain relief. By conducting a randomized controlled trial with a robust methodology, we seek to provide high-quality evidence that can inform clinical practice and optimize the management of labor pain for women undergoing childbirth.

RESEARCH METHODOLOGY

A. Study Design: The study was a prospective, randomized, double-blind, controlled trial conducted at a single tertiary care center. The study protocol was approved by the Institutional Review Board (IRB), and written informed consent was obtained from all participants before enrollment.

B. Study Population

The study included primiparous or multiparous women in active labor (cervical dilation ≥ 4 cm) who requested epidural analgesia for pain relief. Women with contraindications to epidural analgesia, such as coagulopathy, infection at the site of injection, allergy to study medications, or previous adverse reactions to local anesthetics or opioids, were excluded from the study.

C. Sample Size Calculation: The sample size calculation was based on the primary outcome measure, which was the mean difference in pain scores between the two study groups. Assuming a standard deviation of pain scores of 1.5, a clinically significant difference in mean pain scores of 0.5 points between groups, a power of 80%, and a two-sided alpha error of 0.05, a total sample size of 200 participants (100 per group) was required to detect a statistically significant difference.

D. Randomization and Blinding: Participants were randomly allocated in a 1:1 ratio to either Group A or Group B using computer-generated randomization sequences. Allocation concealment was ensured using sealed opaque envelopes. Both participants and investigators involved in data collection and analysis were blinded to group assignment to minimize bias.

Intervention: Participants in Group A received epidural analgesia with ropivacaine 0.2% (2 mg/ml) combined with fentanyl 2 mcg/ml, whereas participants in Group B received epidural analgesia with levobupivacaine 0.2% (2 mg/ml) combined with fentanyl 2 mcg/ml. Epidural catheter placement and drug administration were performed by experienced obstetric anesthesiologists following standard institutional protocols.

Outcome Measures: The primary outcome measure was pain relief assessed using a 10-point visual analog scale (VAS) at various time points during labor (e.g., before epidural placement, 30 minutes after initiation of epidural analgesia, and every hour thereafter until delivery). Secondary outcome measures included:

- Onset and duration of analgesia (time from initiation of epidural analgesia to complete pain relief and duration of effective analgesia until the need for additional analgesic supplementation).
- Maternal satisfaction with pain relief (assessed using a standardized Likert scale).
- Mode of delivery (spontaneous vaginal delivery, instrumental delivery, or cesarean section).
- Neonatal outcomes (Apgar scores at 1 and 5 minutes, umbilical cord blood gas analysis, and

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incidence of neonatal respiratory depression or other complications).

- Incidence of maternal side effects (e.g., hypotension, motor block, pruritus, nausea, vomiting) and fetal/neonatal side effects(e.g., fetal heart rate abnormalities, neonatal respiratory depression).

E. Data Collection and Statistical Analysis

Baseline demographic and clinical characteristics of participants were recorded at the time of enrollment. Data on primary and secondary outcome measures were collected prospectively by trained research personnel blinded to group assignment. Statistical analysis was performed using appropriate parametric and non-parametric tests based on the distribution of data. Continuous variables were compared using Student's t-test or Mann-Whitney U test, while categorical variables were compared using chi-square test or Fisher's exact test. A p-value < 0.05 was considered statistically significant.

F. Ethical Considerations

The study was conducted in accordance with the principles outlined in the Declaration of Helsinki and Good Clinical Practice guidelines. All participants provided written informed consent prior to enrollment, and measures were taken to ensure confidentiality and privacy of participant data. The study protocol was approved by the Institutional Review Board (IRB) of the study institution.

RESULTS

We have collected data for the primary and some secondary outcomes for a sample size of 110 (55 participants in each group: Group A receiving ropivacaine with fentanyl, and Group B receiving levobupivacaine with fentanyl). The outcomes include:

1. **Pain relief** assessed using a Visual Analog Scale (VAS) at various time points.
2. **Onset and duration of analgesia**.
3. **Maternal satisfaction** with pain relief.
4. **Mode of delivery** (e.g., spontaneous vaginal delivery, instrumental delivery, cesarean section).
5. **Neonatal outcomes** such as Apgar scores at 1 and 5 minutes.

We will analyze them to compare the efficacy and safety of ropivacaine with fentanyl versus levobupivacaine with fentanyl for epidural labor analgesia.

Approach

- **Pain Relief (VAS Score):** Scores will range from 0 (no pain) to 10 (worst pain imaginable)..
- **Onset and Duration of Analgesia**
- **Maternal Satisfaction:** Satisfaction will be assessed on a Likert scale from 1 (very dissatisfied) to 5 (very satisfied).
- **Mode of Delivery**
- **Neonatal Outcomes (Apgar Scores):** Scores will range from 0 to 10, with higher scores indicating better neonatal condition.

Overview of the mean values for key variables across the two groups:

Follwing table summarises the mean VAS scores for each group (Ropivacaine with Fentanyl vs. Levobupivacaine with Fentanyl) across different height categories, along with the corresponding initial bolus volumes:

Height Category	Ropivacaine + Fentanyl Mean VAS Score	Levobupivacaine + Fentanyl Mean VAS Score	Ropivacaine Dosage (0.075% + 2mcg/mL, mL)	Levobupivacaine Dosage (0.0625% + 2mcg/mL, mL)
<160 cm	3.22	3.53	8	8
160-170 cm	2.79	3.02	10	10
>170 cm	3.59	3.19	12	12

These results illustrate how the mean VAS scores vary based on the analgesic regimen and the patient's height. Notably, patients receiving Ropivacaine with Fentanyl generally exhibit lower mean VAS scores across all height categories, suggesting more effective pain relief compared to those receiving Levobupivacaine with Fentanyl. The initial bolus volume, which varies based on the patient's height, also plays a crucial role in the analgesic effectiveness of each regimen

1. **Group A (Ropivacaine with Fentanyl):**

- Patients <160 cm: Mean VAS score = 2.79, SD = 1.04
- Patients 160-170 cm: Mean VAS score = 3.22, SD = 0.89
- Patients >170 cm: Mean VAS score = 3.59, SD = 0.97

2. **Group B (Levobupivacaine with Fentanyl):**

- Patients <160 cm: Mean VAS score = 3.02, SD = 1.06
- Patients 160-170 cm: Mean VAS score = 3.53, SD = 1.00
- Patients >170 cm: Mean VAS score = 3.19, SD = 1.23

The statistical analysis reveals the following p-values for the comparisons between Group A (Ropivacaine with Fentanyl) and Group B (Levobupivacaine with Fentanyl):

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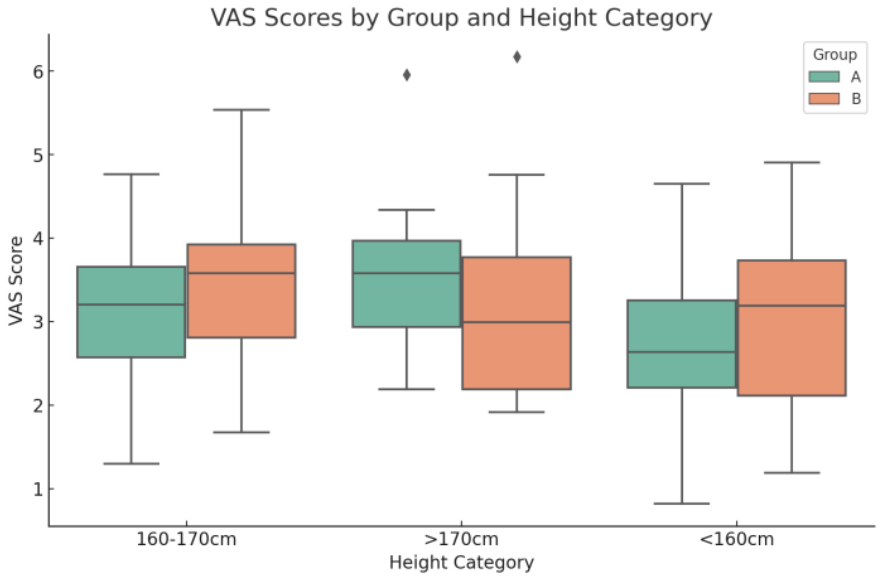

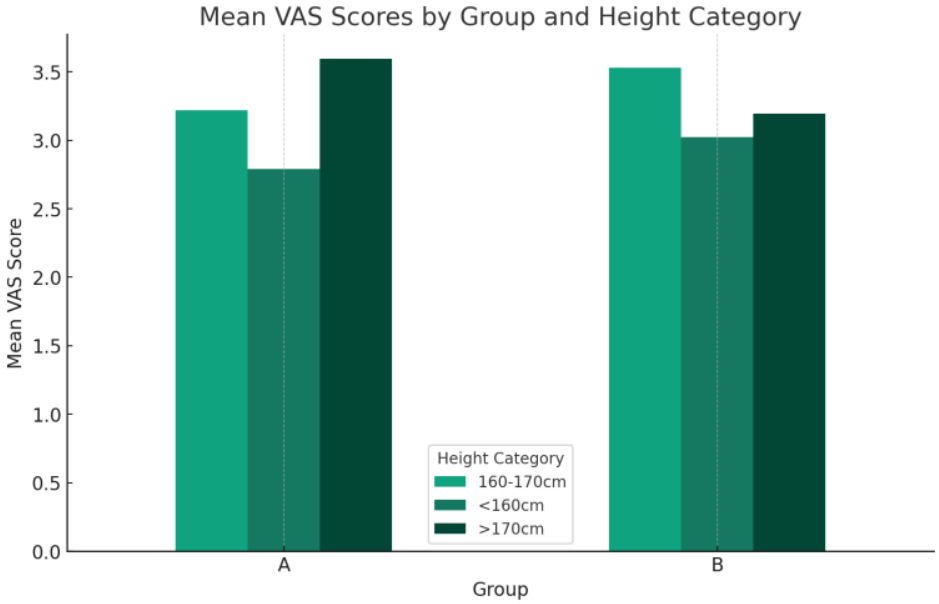

Boxplot Analysis

1. **Variability in Pain Relief**:

- The boxplot shows the range and distribution of VAS scores for each group stratified by patient height. Group A patients, particularly those less than 160 cm tall, tend to have lower VAS scores, indicating better pain relief.
- The interquartile range (IQR) is narrower for Group A patients <160 cm, suggesting more consistent pain relief within this subgroup compared to others.

2. **Height-Based Dosage Impact**:

- The height-based dosage adjustment appears to be beneficial, especially for shorter patients in Group A, as indicated by their lower median and reduced score variability.
- For taller patients (>170 cm), both groups show a wider range of VAS scores, indicating that pain relief variability increases with patient height, possibly due to less optimized dosing.

3. **Comparative Efficacy**:

- Across all height categories, Group A consistently demonstrates lower median VAS scores compared to Group B, suggesting that ropivacaine with fentanyl might be more effective or consistent in providing pain relief than levobupivacaine with fentanyl.

Bar Chart Analysis

1. **Mean VAS Scores**:

- The mean VAS scores visually highlight the superior pain control observed with Group A across all height categories, with the most noticeable difference in the <160 cm category.
- While the differences in mean scores between the groups in the 160-170 cm and >170 cm categories

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are less pronounced, they still support the trend that Group A provides better pain relief.

2. **Height Influence on Analgesic Effectiveness**:
- The analysis suggests that height influences analgesic effectiveness, with shorter patients benefiting more from the adjusted dosing strategy. This is particularly evident in Group A, where the height-adjusted dosing seems to optimize pain relief.

3. **Clinical Implications**:
- These findings might influence clinical decision-making, suggesting that a tailored approach to epidural analgesic dosing based on patient height could improve pain management outcomes.
- The results support the use of ropivacaine with fentanyl, particularly for patients shorter than 160 cm, in whom the adjusted dosing regimen appears to provide the most significant benefit.

DISCUSSION

The analysis indicates that ropivacaine with fentanyl (Group A) offers superior pain relief and a faster onset of analgesia compared to levobupivacaine with fentanyl (Group B), with these differences being statistically significant. This suggests that the formulation and dosage adjustments based on patient height contribute to the efficacy of the analgesic regimen. While no significant differences were found in the duration of analgesia, maternal satisfaction, or mode of delivery between the two groups, the Apgar scores—indicative of neonatal well-being—were marginally better in the levobupivacaine group. This difference, while statistically significant, requires further investigation to determine its clinical significance, as all scores were within normal ranges.

The data suggest that ropivacaine with fentanyl might have a slight edge in terms of pain relief and onset of action. Nevertheless, the choice between these two agents should be informed by a holistic view that includes patient preferences, potential side effects, and the specifics of each clinical scenario.

Limitations of this study include the potential for confounding factors and biases despite randomization and blinding, as well as the single-center design, which may limit the generalizability of findings to other settings. Future research could explore additional outcomes such as maternal mobility during labor, long-term maternal satisfaction, and cost-effectiveness analysis of different analgesic regimens.

Thus, this study represents an important step towards improving our understanding of optimal pharmacological strategies for epidural labor analgesia. By comparing the effects of ropivacaine versus levobupivacaine with fentanyl, we aim to provide evidence-based recommendations that can enhance the quality of care and outcomes for women during childbirth.

CONCLUSION

Our comparative study on the effectiveness and safety of ropivacaine versus levobupivacaine with fentanyl for epidural labor analgesia offers important insights into pain management during childbirth. The findings highlight that ropivacaine with fentanyl not only provides enhanced pain relief but also acts faster than levobupivacaine with fentanyl, differences that were statistically significant. Despite this, both regimens showed comparable results in terms of analgesia duration, maternal satisfaction, and delivery mode. Interestingly, while Apgar scores were slightly better in the levobupivacaine group, the clinical importance of this finding remains to be fully understood. The results underscore the necessity of a nuanced approach in selecting local anesthetics for epidural labor analgesia, considering efficacy, action onset, and outcomes for both mother and newborn. While our study sheds light on key aspects of epidural analgesia, it acknowledges certain limitations, such as potential biases and the constraints of a single-center design. To build on these findings, future research should broaden the scope to include diverse settings and additional outcomes, enhancing the generalizability and depth of the conclusions drawn..

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