Section: Obstetrics and Gynaecology

Original Research Article

PROSPECTIVE COMPARATIVE STUDY OF THE FETOMATERNAL OUTCOME OF EPIDURAL ANALGESIA IN VAGINAL DELIVERIES USING A COMBINATION OF ROPIVACAINE WITH FENTANYL AND LEVOBUPIVACAINE WITH FENTANYL, IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Epidural analgesia with low-concentration local anaesthetic-opioid combinations is the gold standard for intrapartum pain relief. This study compared the fetomaternal outcomes of epidural analgesia using ropivacaine-fentanyl and levobupivacaine-fentanyl. **Materials and Methods:** In this prospective, randomised, double-blind trial conducted at a tertiary care centre in Tamil Nadu over 12 months, 40 term parturients with singleton cephalic pregnancies in active labour were randomised into two groups: Group A received 0.1% ropivacaine with fentanyl, and Group B received 0.1% levobupivacaine with fentanyl. Maternal haemodynamics, labour characteristics, foetal monitoring, mode of delivery, neonatal outcomes, maternal complications, and satisfaction were recorded. **Result:** The mean age was 22.8±2.3 years in Group A and 23.2±2.1 years in Group B (p=0.609). Mean gestational age, height, and weight were 39.01±0.68 vs 38.82±0.75 weeks, 156.4±3.65 vs 154.9±4.26 cm, and 60.65±3.28 vs 61.35±4.60 kg, respectively (p>0.05). The pulse rate was slightly higher in Group A (79.4±3.7 vs. 76.2±3.1 bpm, p=0.005), with comparable systolic and diastolic blood pressures. Onset of analgesia was 12.15±1.9 vs 12.75±1.52 min (p=0.277). Stage I, II, and III durations were 223.5±27 vs 225±11.9 min, 53.5±8.3 vs 51±7.7 min, and 6.4±0.94 vs 6.05±0.69 min (p>0.05). Top-up requirements and oxytocin augmentation were also similar between the groups. Vaginal delivery occurred in most patients; mean birth weights were 2.80±0.28 vs 2.71±0.26 kg; Apgar scores at 1 and 5 minutes were 7.45±0.69 vs 7.8±0.41 and 8.5±0.61 vs 8.8±0.41, respectively (p>0.05). Maternal complications were minimal, and satisfaction was high in both groups. **Conclusion:** Ropivacaine-fentanyl and levobupivacaine-fentanyl provide rapid, effective, and safe analgesia during labour, with comparable maternal and neonatal outcomes.

INTRODUCTION

Labour pain is often regarded as one of the most intense experiences that a woman undergoes, and it is different from the usual pain associated with injury or illness.[1] The management of labour pain has been the main focus of obstetric care, as it impacts both maternal comfort and childbirth. In addition to influencing the psychological experience, severe unrelieved pain can lead to increased catecholamine secretion, uteroplacental vasoconstriction, and reduced placental perfusion, which can affect foetal oxygenation and well-being.[2] Among the various analgesic techniques, epidural analgesia is commonly known as the most effective method for providing effective and prolonged pain relief during labour. This technique provides long-term pain relief while keeping the mother alert to participate in the labour process, making it a preferred choice during pregnancy.[3]

Epidural analgesia works by administering local anaesthetic agents into the epidural space surrounding the spinal cord to block motor spinal nerve roots and sensory roots in the pelvic, lower

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extremity, thoracic, and abdominal areas.[4] Combining local anaesthetics with opioids is common, and this approach improves both pain relief and the overall quality of labour. This method has improved the obstetric outcomes by reducing the concentration of local anaesthetics, the incidence of motor block, easing maternal mobility, and decreasing the need for instrumental deliveries.[5] Local anaesthetics, such as ropivacaine and levobupivacaine, are frequently used in addition to opioids, which have enhanced the analgesia by acting on opioid receptors in the central nervous system.[6] Ropivacaine, an amide local anaesthetic with a prolonged duration, reversibly blocks sodium ion entry into nerve fibres and has become a common choice due to its high efficiency and reduced motor block.[7] Levobupivacaine, the S-enantiomer of bupivacaine, is another commonly used local anaesthetic like ropivacaine. Levobupivacaine is equally efficacious as bupivacaine, but has a better pharmacokinetic profile and is considered to have a better safety profile.[8] Both ropivacaine and levobupivacaine are associated with good analgesic effects and a lower incidence of adverse effects; furthermore, they are also commonly used along with fentanyl for better analgesic effects.[5]

Fentanyl, a potent synthetic opioid, is similar to morphine but provides a better analgesic effect. While fentanyl is mostly considered safe for labour use, it is still associated with several complications, such as respiratory depression, delirium, and a few adverse fetomaternal outcomes when combined with other agents.[9,10] Although several studies have analysed their combined analgesic efficacy, there are still limited comparative studies differentiating their impact on fetomaternal outcomes.

Comparing the fetomaternal outcomes of the ropivacaine-fentanyl and levobupivacaine-fentanyl regimens will help clinicians provide maximum pain relief with minimal adverse effects, by improving the safety, quality, and overall outcomes of intrapartum care. Thus, this study aimed to compare the fetomaternal outcomes of epidural analgesia during labour using a combination of ropivacaine and fentanyl with levobupivacaine and fentanyl. This study will evaluate key outcomes, including maternal satisfaction, mode and duration of labour, neonatal Apgar scores, and incidence of foetal distress.

MATERIALS AND METHODS

This prospective, randomised, double-blind, controlled study was conducted in the Department of Obstetrics and Gynaecology at Government Theni Medical College and Hospital, Tamil Nadu, over 12 months (February 2024 to January 2025). The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all patients before enrolment.

Inclusion Criteria

Women with a singleton pregnancy in cephalic presentation at term gestation (≥37 weeks) who were in active labour with cervical dilatation > 3 cm and had provided consent to receive epidural analgesia.

Exclusion criteria

Contraindications to epidural analgesia (coagulopathy, severe thrombocytopenia, infection at the puncture site, hypovolemia, or raised intracranial pressure), had a known allergy to local anaesthetics or opioids, had a history of previous caesarean section or uterine surgery, presented with multiple gestation or foetal anomalies or refusal of consent.

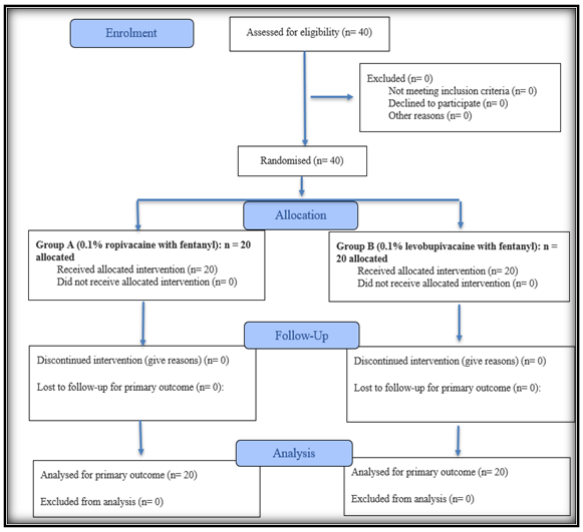

Figure 1: Consort flow diagram

Methods:

Patients were randomised into groups A and B (n = 20 each) using a computer-generated randomisation list. The study solutions were prepared by an anaesthesiologist not involved in patient care or data collection to ensure blinding of both patients and observers. Group A received 0.1% ropivacaine with fentanyl, whereas Group B received 0.1% levobupivacaine with fentanyl. All eligible women were counselled upon admission, and maternal demographic details, including age, parity, gestational age, height, and weight, were recorded upon admission. Intravenous access was established with an 18-G or 16-G cannula, and the patients were preloaded with 500 mL of Ringer's lactate. Under strict asepsis, the epidural space was identified at the L2-L3 or L3-L4 interspace using a Tuohy needle and the loss of resistance technique, following which an 18-G catheter was introduced with 3-4 cm retained in the epidural space. The study drug was administered once the patient was in active labour (cervical dilatation 3-5 cm).

Maternal haemodynamics, such as pulse rate and systolic and diastolic blood pressure, were monitored at defined intervals throughout labour. Labour characteristics, including cervical dilatation at initiation, onset of analgesia, duration of each stage of labour, top-up requirements, and oxytocin augmentation, were documented using a partograph and direct observation. Foetal well-being was assessed using cardiotocography (CTG) and intermittent auscultation, with abnormal patterns

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classified as late or variable decelerations. The mode of delivery was recorded as spontaneous vaginal, instrumental, or caesarean. Neonatal outcomes included birth weight and Apgar scores at 1 and 5 minutes. Maternal complications, such as nausea and back pain, were noted during labour and the immediate postpartum period. Maternal satisfaction with epidural analgesia was assessed using a Likert scale ranging from "unsatisfied" to "very satisfied".

Statistical analysis

Data were analysed using IBM-SPSS (v.25) and are presented as mean, standard deviation, frequencies, and percentages. Comparisons were done using the chi-square test, and a p-value < 0.05 was considered significant.

RESULTS

Most patients were aged 21–25 years (50% in Group A vs. 55% in Group B), with no significant difference (p = 0.609). Primigravida women predominated in both groups (85% vs. 90%), and the differences was not significant (p = 0.976) [Table 1].

Table 1: Comparison of age and parity among groups

Parameter	Categories	Group A	Group B	p-value
Age (years)	<20	7 (35%)	6 (30%)	0.609
	21–25	10 (50%)	11 (55%)	
	26–30	3 (15%)	3 (15%)	
Parity	Primi	17 (85%)	18 (90%)	0.976
	Multi	3 (15%)	2 (10%)	
Categories		**Groups**		**p-value**
		A	**B**	
Age (years)	<20	7 (35%)	6 (30%)	0.609
	21–25	10 (50%)	11 (55%)	
	26–30	3 (15%)	3 (15%)	
Parity	Primi	17 (85%)	18 (90%)	0.976
	Multi	3 (15%)	2 (10%)	

The mean gestational age, height, and weight were similar across the groups, with no significant differences (p = 0.407, 0.239, and 0.583, respectively). The pulse rate was significantly higher in Group A than in Group B (79.4 ± 3.7 vs. 76.2 ± 3.1 bpm, p = 0.005); however, the systolic BP (SBP) and diastolic BP (DBP) were similar (p = 0.609 and 0.574, respectively) [Table 2].

Table 2: Comparison of gestational age, height and weight, maternal haemodynamics among groups

Parameter	Categories	Group A	Group B	p-value
Mean gestational age (weeks)		39.01 ± 0.676	38.82 ± 0.754	0.407
Height (cm)		156.4 ± 3.65	154.9 ± 4.26	0.239
Weight (kg)		60.65 ± 3.28	61.35 ± 4.60	0.583
Maternal haemodynamics	Pulse rate (bpm)	79.4 ± 3.7	76.2 ± 3.1	0.005
	Systolic BP (mmHg)	113.5 ± 6.7	112.5 ± 5.5	0.609
	Diastolic BP (mmHg)	72.1 ± 2.97	71.5 ± 2.59	0.574

The mean cervical dilatation at the time of intervention was similar (4.25 ± 0.55 cm in Group A vs. 4.4 ± 0.51 cm in Group B, p = 0.374). The durations of the first, second, and third stages of labour were also comparable between the groups (p = 0.821, 0.33, and 0.187, respectively). There was no significant difference in the mean top-up requirement (2.55 ± 0.51 vs. 2.5 ± 0.51, p = 0.759) or the need for oxytocin augmentation (95% vs. 90%, p = 1) [Table 3].

Table 3: Comparison of labour characteristics among groups

Parameter	Group A	Group B	p-value
Cervical dilatation (cm)	4.25 ± 0.55	4.4 ± 0.51	0.374
Onset of analgesia (min)	12.15 ± 1.90	12.75 ± 1.52	0.277
Stage I duration (min)	223.5 ± 27.0	225 ± 11.9	0.821
Stage II duration (min)	53.5 ± 8.29	51 ± 7.71	0.33
Stage III duration (min)	6.4 ± 0.94	6.05 ± 0.69	0.187
Top-up requirement	2.55 ± 0.51	2.5 ± 0.51	0.759
Oxytocin augmentation	19 (95%)	18 (90%)	1

Most patients had a normal CTG pattern (90% in Group A vs. 95% in Group B, p = 0.598), with a few cases of late or variable deceleration. The majority of patients had vaginal deliveries (90% vs. 95%), and no caesarean sections were reported (p = 1). The mean birth weights were comparable (2.80 ± 0.28 kg vs. 2.71 ± 0.26 kg, p = 0.256). The Apgar scores at both 1 and 5 minutes were slightly higher in Group B, but were significant (p = 0.058 and 0.075, respectively) [Table 4].

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Table 4: Comparison of CTG findings, mode of delivery, and neonatal outcomes among groups

Parameter	Categories	Group A	Group B	p-value
CTG pattern	No abnormality	18 (90%)	19 (95%)	0.598
	Late deceleration	1 (5%)	0	
	Variable deceleration	1 (5%)	1 (5%)	
Mode of delivery	Spontaneous vaginal	18 (90%)	19 (95%)	1
	Outlet forceps	2 (10%)	1 (5%)	
	Caesarean section	0	0	
Neonatal outcomes	Mean birth weight (kg)	2.80 ± 0.28	2.71 ± 0.26	0.256
	Apgar score at 1 min	7.45 ± 0.69	7.8 ± 0.41	0.058
	Apgar score at 5 min	8.5 ± 0.61	8.8 ± 0.41	0.075

The majority of patients reported no complications (90% vs. 85%, p = 0.834), and only a few had complications such as nausea and back pain. Approximately 80% of both groups expressed neutral to satisfied responses, but the differences were not significant (p = 0.883) [Table 5].

Table 5: Comparison of complications and maternal satisfaction among groups

Parameter	Categories	Group A	Group B	p-value
Complication	Nausea	1 (5%)	1 (5%)	0.834
	Back pain	1 (5%)	2 (10%)	
	None	18 (90%)	17 (85%)	
Satisfaction level	Unsatisfied	3 (15%)	2 (10%)	0.883
	Neutral	8 (40%)	9 (45%)	
	Satisfied	8 (40%)	7 (35%)	
	Very satisfied	1 (5%)	2 (10%)	

DISCUSSION

Epidural analgesia is the most effective and commonly used method for labour pain relief, with various combinations of local anaesthetics and opioids evaluated among different populations for their efficacy and safety. This study compared the fetomaternal outcomes of ropivacaine with fentanyl and levobupivacaine with fentanyl in parturients during labour. The two groups had comparable distributions of maternal age, parity, mean gestational age, height, and weight. Primiparous women were predominant in both groups, and the differences were not significant. Maternal blood pressure was also comparable, although the pulse rate was significantly higher in Group A. Similarly, Thammaiah et al. reported a mean age of 26.4 years for Group L and 24.88 years for Group R, with no significant difference between the groups (p = 0.23). Also, no significant difference in parity between the groups.[11]

Kulkarni and Patil observed that the mean age was 22.23 years in the ropivacaine group and 22.87 years in the bupivacaine group. Primigravida women were predominant in both groups (63% and 60%), with no significance.[12] Purdie et al. reported that gestational age (41 weeks each), height (162.1 ± 6.9 vs. 161.5 ± 7.4 cm), and weight (65.8 ± 12.9 vs. 65 ± 13.9 kg) were similar across both groups.[13] Kamath et al. reported that HR, SBP, and DBP remained linear and similar across both groups with no significance.[14] Thus, suggesting that our findings are similar to previous studies and there is no association of age, parity, gestational age, height, or weight with the administration of ropivacaine or levobupivacaine.

In our study, cervical dilatation, onset of analgesia, labour stage duration, top-up requirements, and oxytocin augmentation were similar between the groups and were not significant. Thammaiah et al. reported that the mean cervical dilatation at the time of intervention was 3.40 cm in the ropivacaine group and 3.48 cm in the levobupivacaine group, with no significant difference found.[11] Kumar et al. observed a similar 1st stage duration between both groups (5.91 ± 2.26 vs. 6.12 ± 1.97 hrs), while the 2nd stage was longer in group B (39.12 ± 11.67 vs. 34.66 ± 10.9 minutes), but none of these differences were significant.[15] Purdie et al. reported that the rescue top-ups used were 95 ml in Group L and 115 ml in Group R, with no significance.[13] Sharma et al. reported that patients who required oxytocin augmentation were similar between both groups, but no significant difference was noted.[16] Thus, our findings and those of previous studies suggest that there is no difference in the onset of analgesia, labour stage durations, top-up requirements, and oxytocin augmentation across both groups.

In our study, the CTG patterns and mode of delivery were comparable across groups, while the maternal complications were minimal and occurred at similar rates in both groups. Both groups had good neonatal outcomes, including birth weight and Apgar scores, and the majority had a good satisfaction level; however, these associations showed no significant differences. Mantripragada et al. reported that the side effect profile and mode of delivery were similar in both groups, though vaginal delivery was more frequent in the ropivacaine group; the difference was not significant. All babies had good Apgar scores and birth weights, which were comparable between the groups.[17] Atienzer et al. also reported that all the babies had good Apgar scores or >7 at 5 minutes, and it was similar in both groups, with no significance.[18] Bindra et al. reported that a few patients in both groups experienced some complications, such as bradycardia (7 vs. 5), hypotension (9 vs. 4), nausea (5

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each), shivering (5 each), and pruritus (1 each). However, none of the groups were significantly associated with any of the complications.[19] Thammaiah et al. reported that the majority of the patients in both groups had good satisfaction, while none were satisfied, but there was no significant difference.[11] Hence, indicating that both analgesic methods are associated with good fetometernal outcomes with no significant difference between them.

This study supports the role of low-concentration local anaesthetic-opioid combinations as the gold standard for intrapartum analgesia, ensuring maternal comfort without compromising foetal wellbeing. Future larger multicentre studies with long-term follow-up are needed to validate these findings, evaluate long-term maternal and neonatal outcomes, and provide evidence-based guidelines for the correct choice of epidural analgesic combinations in various obstetric populations.

Limitations

The small sample size restricts the generalisability of the findings to larger populations. As the study was conducted at a single tertiary care centre, the results may not accurately represent the diversity of populations in other settings. Only cephalic singleton term pregnancies were included, thereby excluding other foetal presentations and high-risk cases. Patient satisfaction was self-reported, which may have been influenced by subjective bias.

CONCLUSION

Both ropivacaine and levobupivacaine provided a rapid onset of analgesia, maintained stable maternal haemodynamics, and provided effective pain relief throughout labour. Maternal and neonatal outcomes, including duration of labour, mode of delivery, Apgar scores, and birth weights, were comparable between the groups. Maternal satisfaction was high in both groups, with minimal and non-significant complications observed. Given their similar efficacy and safety profiles, the choice between ropivacaine and levobupivacaine can be guided by drug availability, cost, and institutional protocols.

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