



A COMPARISON OF COMBINED SPINAL EPIDURAL ANALGESIA WITH 0.1% ROPIVACAINE WITH FENTANYL VERSUS 0.1% BUPIVACAINE WITH FENTANYL DURING LABOUR

Dr Komal Joshi^{*1}, Dr Surekha Saxena², Dr Uma Srivastava³, Dr Saroj Singh⁴

¹*Assistant Professor, Department of Anesthesia Government Medical College, Azamgarh

²Professor, Department of Anesthesia and Critical Care, SN Medical College, Agra

³Professor, Department of Anesthesia and Critical Care, SN Medical College Agra

⁴Professor, Department of Obstetrics and Gynecology, SN MEDICAL College Agra

***Corresponding Author:** Dr Komal Joshi

*Assistant Professor, Department of Anesthesia Government Medical College, Azamgarh,
Email: Drkomaljoshi@gmail.com

Abstract:

Background: Labour pain is among the most severe forms of pain and requires effective management for maternal well-being and optimal delivery outcomes. Combined spinal-epidural (CSE) analgesia is a widely accepted technique that provides rapid, effective, and sustained pain relief during labour. This study compares the efficacy and safety of 0.1% ropivacaine with fentanyl versus 0.1% bupivacaine with fentanyl in CSE analgesia.

Methods: This prospective, randomized, double-blind controlled study included 64 healthy term parturients in active labour, divided equally into two groups. Group R received intrathecal 2.5 mg ropivacaine with 25 µg fentanyl followed by 0.1% ropivacaine with fentanyl epidurally. Group B received the same regimen with bupivacaine. Pain relief was assessed using visual analogue scale (VAS) scores. Other parameters observed included onset and duration of analgesia, motor blockade (Bromage scale), need for rescue top-ups, maternal satisfaction, obstetrician satisfaction, neonatal Apgar scores, and mode of delivery.

Results: Demographic profiles and baseline characteristics were similar across groups. The onset and duration of spinal analgesia did not differ significantly. Pain relief was effective in both groups, with mean VAS scores remaining low and statistically comparable. Group R showed slightly fewer motor block incidences and lower need for top-ups, though not statistically significant. Neonatal outcomes, including Apgar scores and birth weights, were similar. Patient satisfaction was rated as excellent or good by over 96% in both groups.

Conclusion: Both 0.1% ropivacaine-fentanyl and bupivacaine-fentanyl combinations provided effective and safe labour analgesia with high maternal and clinician satisfaction. Ropivacaine demonstrated a tendency for less motor block and may be preferred in scenarios where ambulation is desirable, though both agents remain clinically equivalent for use in CSE.

Keywords: Labour analgesia, Combined spinal-epidural, Ropivacaine, Bupivacaine, Fentanyl, Maternal satisfaction etc.

Introduction:

Labour pain is one of the most severe forms of pain experienced by women and arises primarily from uterine contractions and cervical dilation. Effective pain control during labour is essential for maternal well-being and a positive childbirth experience. Poorly managed pain may contribute to maternal stress, fatigue, increased catecholamine release, and prolonged labour, potentially affecting neonatal outcomes [1,2].

Among the various methods available for labour analgesia, combined spinal-epidural (CSE) analgesia has emerged as a highly effective and safe technique. CSE combines the rapid onset of spinal analgesia with the flexibility and prolonged duration of epidural analgesia. It provides effective pain relief with minimal motor block, allowing the parturient to remain active during labour [3,4].

Bupivacaine, a widely used amide-type local anaesthetic, has been a standard choice for regional labour analgesia. It offers potent sensory blockade but is associated with dose-dependent motor block and cardiotoxicity, especially at higher concentrations [5]. Ropivacaine, a newer local anaesthetic and the pure S-enantiomer of bupivacaine, was introduced with the aim of reducing such adverse effects. It has a lower lipid solubility, resulting in reduced potency for motor fibres, which translates to less motor block while preserving analgesic efficacy [6,7].

When combined with opioids like fentanyl, both ropivacaine and bupivacaine demonstrate improved analgesia with reduced required dosages. Fentanyl acts on spinal opioid receptors and synergistically enhances the effect of local anaesthetics while minimizing their side effects [8]. Several studies suggest that ropivacaine-fentanyl mixtures offer equivalent or superior analgesia to bupivacaine-fentanyl, with less motor blockade and greater maternal satisfaction [9].

This study aims to compare 0.1% ropivacaine with fentanyl versus 0.1% bupivacaine with fentanyl when used in CSE analgesia during labour, evaluating onset, quality and duration of analgesia, maternal satisfaction, motor blockade, and fetal outcomes.

Material and Methods:

This prospective, randomized, double-blind controlled trial was conducted at S.N. Medical College, Agra, after obtaining ethics committee approval and informed consent. Sixty-four ASA I/II parturients (37–41 weeks gestation) in active labour with singleton, cephalic pregnancies were included.

Women who were either primigravida or multigravida, in active labour with cervical dilation greater than 4 cm and regular uterine contractions (at least 2 every 10 minutes lasting 30–40 seconds), carrying a term cephalic singleton pregnancy, and who had given written informed consent were included in the study. The exclusion criteria were non-cephalic presentations, cephalopelvic disproportion, bleeding disorders, antepartum haemorrhage, neurological conditions, morbid obesity, inability to use the PCA device, or unwillingness to participate.

Patients were randomly assigned to two equal groups (n=32) using sealed opaque envelopes based on a computer-generated randomization schedule. Group B received intrathecal 2.5 mg bupivacaine with 25 µg fentanyl, followed by 0.1% bupivacaine with fentanyl (2 µg/ml) via epidural. Group R received intrathecal 2.5 mg ropivacaine with 25 µg fentanyl, followed by 0.1% ropivacaine with fentanyl (2 µg/ml) epidurally.

Epidural catheterization was done at L2–L4 using an 18G Tuohy needle by a single anaesthesiologist. Correct catheter placement was confirmed with lignocaine-adrenaline test dose. Analgesia was administered via patient-controlled epidural analgesia (PCEA) without background infusion (5 ml bolus, 10 min lockout, max 30 ml/hr). A rescue dose (10 ml) was given if no relief occurred within 20 min.

Pain was assessed using a 100-mm VAS and 4-point verbal rating scale. Sensory block was monitored by pinprick and proprioception; motor block via modified Bromage scale. Ambulation and spontaneous micturition were documented. Labour outcome and neonatal results were observed. Maternal and obstetrician satisfaction were also evaluated.

Data were analyzed using SPSS v16.0. T-test, Chi-square, Mann-Whitney U, and Wilcoxon's tests were applied where appropriate. $P < 0.05$ was considered significant. A sample size of 30 per group was determined sufficient with 90% power and $\alpha = 0.01$.

Results:

This prospective, double-blind randomized controlled study included 64 parturients, equally divided into two groups: Group B (Bupivacaine + Fentanyl) and Group R (Ropivacaine + Fentanyl). Both groups were assessed for demographic similarity, analgesic characteristics, motor and sensory effects, labour outcomes, maternal and neonatal safety, and satisfaction levels.

As shown in Table 1, the mean age of participants in Group B was 25.85 ± 2.46 years, and in Group R, it was 25.65 ± 3.25 years ($p > 0.05$). Similarly, height, weight, gestational age, and cervical dilation at admission were statistically comparable across groups. The percentage of nulliparous women was 44% in Group B and 41% in Group R ($p > 0.05$). Oxytocin was used in 31% of Group B and 28% of Group R. These similarities confirm effective randomization and baseline equivalence between the two study groups.

Table 1: Demographic and Baseline Characteristics

Parameter	Group B (n=32)	Group R (n=32)	p-value
Age (years)	25.85 ± 2.46	25.65 ± 3.25	>0.05
Height (cm)	156.4 ± 4.99	157.6 ± 5.48	>0.05
Weight (kg)	54.25 ± 7.18	53.45 ± 7.52	>0.05
Gestational Age (weeks)	38.12 ± 1.36	38.25 ± 1.44	>0.05
Cervical Dilatation (cm)	5.12 ± 0.85	4.97 ± 0.83	>0.05
Nulliparity (%)	44% (14)	41% (13)	>0.05
Oxytocin Use (%)	31% (10)	28% (9)	>0.05

As presented in Table 2, the mean onset of spinal analgesia was 6.4 ± 2.1 minutes in both groups, indicating a rapid and similar onset time. The mean duration of spinal analgesia was slightly longer in Group R (71 ± 19.8 minutes) compared to Group B (62.5 ± 22.5 minutes), but the difference was not statistically significant. The total doses of local anaesthetic and fentanyl used were comparable in both groups.

Table 2: Onset, Duration of Analgesia and Drug Requirements

Parameter	Group B	Group R	p-value
Onset of spinal analgesia (min)	6.4 ± 2.10	6.4 ± 2.10	>0.05
Duration of spinal analgesia (min)	62.5 ± 22.5	71.0 ± 19.8	>0.05
Total local anaesthetic dose (mg)	31.28 ± 11.59	30.22 ± 8.59	>0.05
Total fentanyl dose (μ g)	56.90 ± 8.78	55.80 ± 8.48	>0.05

Table 3 shows that, the mean verbal analogue pain score (VAS) throughout labour was 22.36 ± 2.48 in Group B and 22.90 ± 3.34 in Group R, with no statistically significant difference ($p > 0.05$). The number of epidural top-ups required was also comparable between groups (2.3 in Group B vs. 1.92 in Group R). Cumulative pain assessments showed that 50% of patients in Group B and 38% in Group R reported complete pain relief (score 0), further confirming that both drug regimens provided effective analgesia.

Table 3: Pain Relief and Rescue Doses

Parameter	Group B	Group R	p-value
Mean VAS Score	22.36 ± 2.48	22.90 ± 3.34	>0.05
Number of rescue top-ups (mean)	2.3 ± 1.22	1.92 ± 1.28	>0.05
Cumulative pain-free score (%)	50%	38%	>0.05

Table 4 shows that the maximum motor block (Bromage score ≥ 1) was observed in 4 patients (12.5%) in Group B and 2 patients (6.25%) in Group R, not statistically significant. The average duration of motor block was slightly longer in Group B (30 ± 9.1 minutes) than in Group R (25 ± 21.2 minutes). No patients in either group experienced loss of proprioception. The highest sensory block achieved in most patients was at the T9 level in both groups.

Table 4: Motor and Sensory Block Characteristics

Parameter	Group B	Group R	p-value
Bromage score ≥ 1 (%)	4 (12.5%)	2 (6.25%)	>0.05
Duration of motor block (min)	30 ± 9.12	25 ± 21.21	>0.05
Loss of proprioception (%)	0	0	–
Highest sensory level (T9) (%)	75%	71.9%	>0.05

As can be seen in Table 5, the duration of the first and second stages of labour was similar in both groups, with no statistically significant difference. The majority of deliveries were spontaneous vaginal (93.75% in Group B and 90.63% in Group R). Neonatal outcomes were also comparable, with median Apgar scores of 8 at 1 minute and 10 at 5 minutes in both groups. Mean birth weights were 2.68 ± 0.34 kg in Group B and 2.73 ± 0.38 kg in Group R ($p > 0.05$). Patient satisfaction with analgesia was high, with >96% of parturients in both groups rating it as excellent or good. Obstetrician satisfaction levels mirrored these findings.

Table 5: Labour Outcome, Neonatal Results and Satisfaction

Parameter	Group B	Group R	p-value
1st stage of labour (min)	225.24 ± 55.65	239.25 ± 58.45	>0.05
2nd stage of labour (min)	40.35 ± 23.30	35.42 ± 21.89	>0.05
Spontaneous vaginal delivery (%)	93.75%	90.63%	>0.05
Caesarean section (%)	6.25%	9.38%	>0.05
Apgar score (1 / 5 min)	8 / 10	8 / 10	>0.05
Birth weight (kg)	2.68 ± 0.34	2.73 ± 0.38	>0.05
Patient satisfaction (Excellent–Good)	96.8%	100%	>0.05
Obstetrician satisfaction (Excellent–Good)	93.7%	96.9%	>0.05

Figure 1 illustrates the trend of pain scores (VAS) at different time points following intrathecal administration. Both Group B and Group R experienced a rapid decline in pain within the first 10–30 minutes post-injection, indicating effective onset of spinal analgesia. The VAS scores remained consistently low in both groups throughout the observation period, with minor fluctuations. Group R exhibited slightly lower scores at 30 and 180 minutes; however, the differences were not statistically significant ($p > 0.05$). This graphical trend supports the finding that both drug combinations offered sustained and comparable analgesic efficacy during labour.

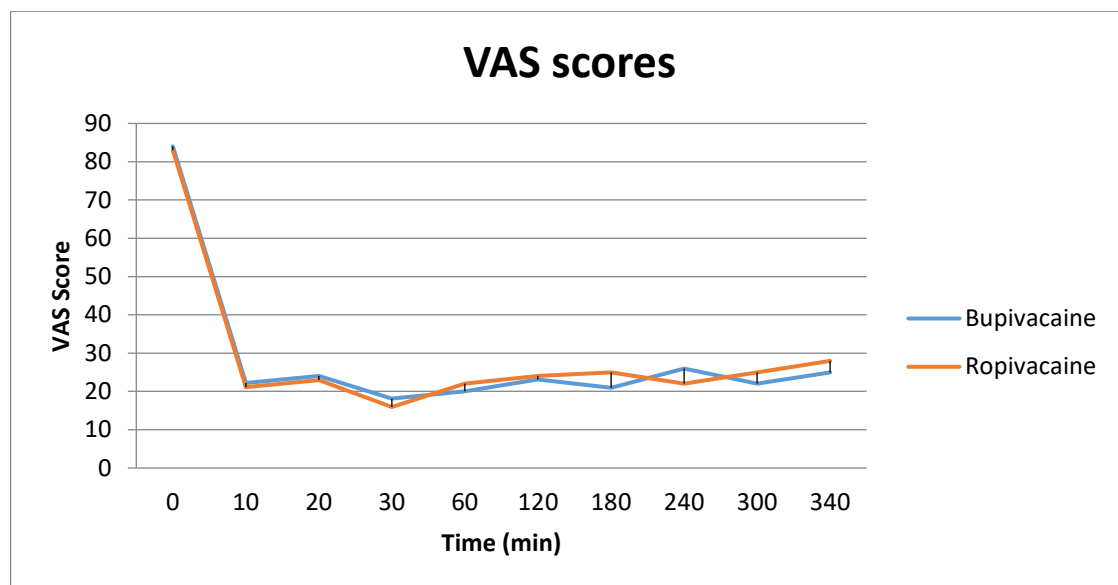


Figure 1: Mean VAS score over time

Figure 2 shows the number of parturients in each satisfaction category—Excellent, Good, and Fair—between Group B (Bupivacaine + Fentanyl) and Group R (Ropivacaine + Fentanyl). In both groups, the majority of women rated their analgesia experience as Excellent, with 28 patients in Group B and 29 in Group R. A small number in each group rated their experience as Good (3 in both), while only one patient in Group B reported a Fair level of satisfaction, and none did so in Group R. No patients in either group reported a Poor experience. This figure clearly demonstrates that both drug combinations provided a high degree of maternal satisfaction, with slightly higher scores in the ropivacaine group, though the difference was not statistically significant.

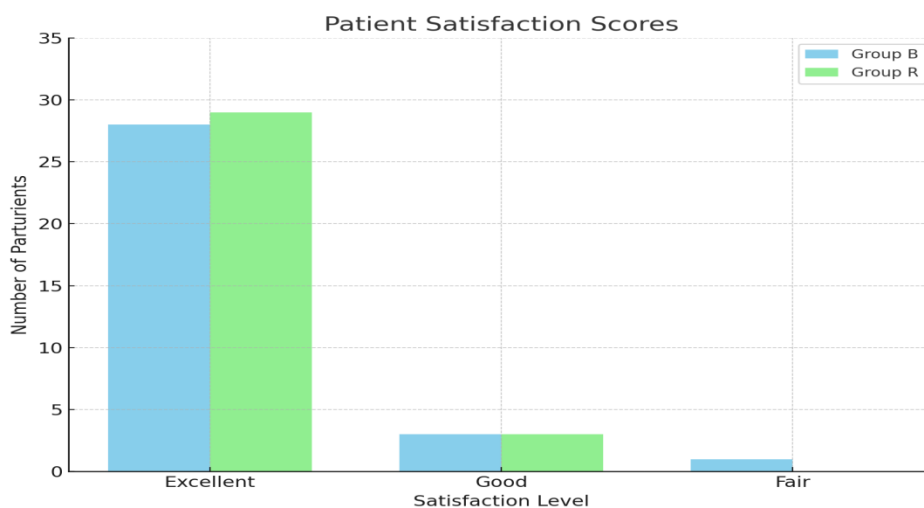


Figure 2: Patient Satisfaction Score in both the groups

Discussion:

This prospective, double-blind, randomized controlled study compared the efficacy and safety of two low-dose combined spinal-epidural (CSE) labour analgesia techniques using 0.1% ropivacaine with fentanyl versus 0.1% bupivacaine with fentanyl in term parturients. The primary outcomes analyzed included onset and duration of spinal analgesia, pain relief effectiveness, motor blockade, maternal and neonatal outcomes, and overall satisfaction.

The onset of spinal analgesia was similar in both groups, with mean onset times of 6.4 minutes. The duration of spinal analgesia, defined as the interval between intrathecal injection and the first epidural

top-up, was also statistically comparable. These results align with prior studies that show both bupivacaine and ropivacaine offer similar onset and duration when used in low doses combined with opioids [10,11].

Pain relief was measured using verbal analogue pain scores (VAS) and cumulative analgesia scores. Both groups reported excellent analgesia, with no statistically significant difference in cumulative VAS scores. These findings are supported by earlier research showing that ropivacaine and bupivacaine, when combined with fentanyl, offer equivalent sensory analgesia in labour [12,13].

Motor blockade, though mild in both groups due to the low concentration used, was slightly less frequent in the ropivacaine group. This reflects the known pharmacological property of ropivacaine to provide a greater sensory-to-motor block ratio than bupivacaine [14]. Preservation of motor function is advantageous during labour, as it may allow better maternal cooperation and ambulation, although no difference in ambulation or mode of delivery was observed in this study.

Neonatal outcomes, including Apgar scores and birth weights, were similar in both groups. No adverse effects on neonatal well-being were noted, corroborating existing evidence that low-dose CSE with either bupivacaine or ropivacaine is safe for the fetus [15,16].

Maternal hemodynamic stability was maintained in both groups, and no cases of severe hypotension were observed. Side effects such as nausea, pruritus, and shivering occurred in a few patients in both groups, with a slightly higher incidence of pruritus in the ropivacaine group. However, these were mild and self-limiting. Previous studies have attributed these effects primarily to the intrathecal fentanyl component rather than the local anesthetic [17].

Importantly, maternal and obstetrician satisfaction scores were high across both groups. Over 90% of parturients rated their analgesia experience as excellent or good, consistent with literature that highlights the acceptability of low-dose CSE techniques for labour analgesia [18].

Conclusion:

Both 0.1% ropivacaine-fentanyl and 0.1% bupivacaine-fentanyl combinations administered via the combined spinal-epidural route provide effective, safe, and satisfactory labour analgesia. Analgesic efficacy, onset time, duration of spinal block, total drug requirement, and maternal-neonatal outcomes were comparable between the two groups. Although ropivacaine was associated with slightly less motor blockade and fewer top-up doses, these differences were not statistically significant. The choice between the two drugs may thus be based on institutional preferences, availability, and specific clinical scenarios where motor block minimization is desired. Given the similar efficacy and safety profiles, both ropivacaine and bupivacaine remain viable options in modern obstetric analgesia. Further studies with larger sample sizes and longer follow-up may help determine whether the minimal differences observed in motor block or patient mobility could translate into clinically meaningful outcomes such as shorter labour duration, better ambulation, or lower intervention rates.

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Conflicts of interest: None

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