

Comparative Evaluation of 0.1% Levobupivacaine versus 0.1% Ropivacaine with Nalbuphine as Adjuvant in Epidural Labor Analgesia: A Randomized Controlled Study

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Abstract: **Background:** Epidural analgesia remains the gold standard for managing labor pain, combining local anesthetics with opioid adjuvants. Levobupivacaine and ropivacaine are widely preferred due to their favorable safety profiles; however, direct comparative evidence when combined with nalbuphine as an adjuvant is limited. **Objectives:** To compare the analgesic efficacy, hemodynamic stability, motor blockade, neonatal outcomes, and adverse effect profiles of 0.1% levobupivacaine with nalbuphine 5 mg (Group LN) versus 0.1% ropivacaine with nalbuphine 5 mg (Group RN) for epidural labor analgesia. **Methods:** This prospective randomized controlled study enrolled 72 ASA II primigravida parturients in active labor at MGM Hospital, Navi Mumbai between September 2022 and November 2023. Patients were allocated equally (n=36 per group) to receive either 0.1% levobupivacaine with 5 mg nalbuphine (Group LN) or 0.1% ropivacaine with 5 mg nalbuphine (Group RN) via the epidural route. Pain intensity was assessed using the Numeric Rating Scale (NRS), motor block by the Modified Bromage Score, and hemodynamic parameters, neonatal Apgar scores, and labor duration were recorded at standardized intervals. **Results:** Group LN demonstrated significantly faster onset of analgesia (4.6 ± 0.25 min vs. 5.6 ± 0.24 min, $p < 0.01$) and longer duration of analgesia (135.2 ± 12.5 min vs. 120.8 ± 9.7 min, $p < 0.01$) compared to Group RN. NRS scores were significantly lower in Group LN from 15 to 90 minutes ($p < 0.01$). Group LN also exhibited superior hemodynamic stability and shorter total labor duration. Neonatal Apgar scores were comparable between groups ($p > 0.05$). Adverse effects including hypotension, nausea/vomiting, urinary retention, pruritus, and postpartum hemorrhage were more frequent in Group RN. **Conclusion:** 0.1% Levobupivacaine with nalbuphine provides superior analgesic efficacy, better hemodynamic stability, shorter labor duration, and a more favorable safety profile compared to 0.1% ropivacaine with nalbuphine for epidural labor analgesia, making it the preferred agent in this clinical setting.

Keywords: Levobupivacaine; Ropivacaine; Nalbuphine; Epidural analgesia; Labor analgesia; Numeric Rating Scale; Motor blockade; Hemodynamic stability; Neonatal Apgar score

1. Introduction

Labor pain is an intense, complex physiological experience arising from uterine contractions and cervical dilatation during childbirth. It encompasses both visceral and somatic components and remains one of the most demanding pain challenges in clinical medicine. Effective pain control during labor is no longer viewed as optional; it is considered an essential component of modern obstetric care that directly influences maternal satisfaction, neonatal well-being, and overall delivery outcomes.

Neuraxial analgesia, particularly continuous epidural analgesia, has established itself as the most effective method for managing labor pain. Its advantages include titratable analgesia, preservation of maternal consciousness, avoidance of systemic opioid-related neonatal depression, elimination of aspiration risk, and the ability to convert seamlessly to surgical anesthesia when operative delivery becomes necessary. Moreover, epidural analgesia attenuates the maternal catecholamine response to pain, thereby improving uteroplacental perfusion and fetal oxygenation.

The ideal epidural analgesic agent for labor should provide rapid onset, long duration, excellent sensory block with minimal motor impairment, hemodynamic stability, and a negligible transfer across the placenta. Among available local anesthetics, levobupivacaine and ropivacaine have emerged as preferred agents due to their reduced cardiotoxicity and central nervous system (CNS) toxicity compared to racemic bupivacaine, while maintaining comparable analgesic potency. Both agents produce differential sensory blockade with relative sparing of motor fibers, which is particularly desirable in the obstetric setting.

Adjuvant opioids are routinely combined with local anesthetics in epidural regimens to enhance analgesic quality and reduce the total dose of local anesthetic required. Nalbuphine, a synthetic opioid with mixed kappa-agonist and mu-antagonist properties, offers a distinctive pharmacological advantage: it provides effective visceral and somatic analgesia through kappa receptor activation while its partial mu-antagonism limits opioid-associated side effects such as respiratory depression, nausea, vomiting, and pruritus. Furthermore, nalbuphine has a ceiling effect on respiratory depression, making it inherently safer than pure

mu-agonists. A single intravenous dose of nalbuphine has also been observed to shorten the first stage of labor, suggesting potential obstetric benefits beyond pain control.

Despite the individual merits of levobupivacaine and ropivacaine, rigorous comparative data on their combination with epidural nalbuphine specifically for labor analgesia remains scarce. Most existing comparative trials have employed fentanyl or sufentanil as the adjuvant opioid, and the pharmacological uniqueness of nalbuphine warrants dedicated investigation. Understanding which combination delivers superior analgesia with the best safety profile is clinically significant and could directly inform evidence-based protocols in obstetric anesthesia practice.

This randomized controlled study was designed to fill this gap by directly comparing the analgesic efficacy, hemodynamic effects, motor blockade, neonatal outcomes, labor progression, and adverse effect profiles of epidural 0.1% levobupivacaine plus nalbuphine versus epidural 0.1% ropivacaine plus nalbuphine in primigravida parturients undergoing active labor.

2. Methodology

2.1 Study Design and Setting

This was a prospective, randomized, double-blind, parallel-group controlled study conducted in the Department of Anaesthesiology at MGM Hospital, Kalamboli, Navi Mumbai, India. The study period extended from September 2022 to November 2023. Ethical approval was obtained from the Institutional Ethics Committee (IEC) of MGM Institute of Health Sciences (Deemed University), Kamothe, Navi Mumbai. Written informed consent was obtained from all participants prior to enrollment.

2.2 Sample Size

Sample size was calculated based on a prevalence estimate of 25%, with a 95% confidence interval and a margin of error of 10%, yielding a minimum sample of 72 participants. Patients were divided equally into two groups of 36 each.

2.3 Study Participants

Inclusion criteria: Primigravida patients aged 18–35 years with an uncomplicated singleton term pregnancy (ASA physical status II) in active labor who requested epidural analgesia were enrolled. Exclusion criteria included prior cesarean delivery, documented hypersensitivity to any local anesthetic agent, psychiatric disorders, spinal deformity, and patient refusal of neuraxial analgesia.

2.4 Randomization and Allocation Concealment

Eligible participants were randomly allocated to one of two groups using computer-generated random numbers. Allocation concealment was ensured through sequentially numbered, sealed, opaque envelopes opened only at the time of study drug preparation.

2.5 Intervention

Group RN (n=36): Received 5 mL of 0.2% ropivacaine diluted to 0.1% plus nalbuphine 5 mg (0.5 mg/mL), made up to a total volume of 10 mL with normal saline, administered epidurally.

Group LN (n=36): Received 2 mL of 0.5% levobupivacaine diluted to 0.1% plus nalbuphine 5 mg (0.5 mg/mL), made up to a total volume of 10 mL with normal saline, administered epidurally.

A 16G epidural catheter was placed at the L2–L3 or L3–L4 interspace under strict aseptic precautions. All patients received Ringer's Lactate co-loading at 15 mL/kg/min via an 18G intravenous cannula. Non-invasive monitoring of blood pressure, heart rate, and peripheral oxygen saturation (SpO₂) was maintained throughout the study period.

2.6 Outcome Measures

Primary outcomes: Onset of analgesia (time from drug administration to NRS score ≤ 3), duration of analgesia, and NRS pain scores assessed at 1, 15, 30, 45, 60, 75, and 90 minutes.

Secondary outcomes: Motor block (Modified Bromage Scale 0–3), systolic and diastolic blood pressure (prepartum at 0, 10, 20, 40, 60 min; intrapartum at 1, 15, 30, 45, 60, 75, 90 min), heart rate, neonatal Apgar scores at 1, 5, and 10 minutes, total duration of labor, and incidence of adverse effects (hypotension, nausea/vomiting, pruritus, urinary retention, postpartum hemorrhage).

2.7 Statistical Analysis

Data were expressed as mean \pm standard deviation (SD) and standard error of the mean (SEM). Between-group comparisons for continuous variables were performed using the independent samples t-test. A p-value of less than 0.05 was considered statistically significant. All analyses were performed using standard statistical software.

3. Results and Discussion

3.1 Demographic and Baseline Characteristics

A total of 72 primigravida parturients were enrolled, with 36 in each group. The two groups were well-matched at baseline with no statistically significant differences in age, height, weight, or gestational age ($p > 0.05$ for all). The mean age of study participants was 28.1 years (SD: 4.59). Mean gestational age was 38.5 ± 2.0 weeks in Group RN and 38.4 ± 2.1 weeks in Group LN. These comparable demographics ensured that any differences observed in study outcomes could be attributed to the study medications rather than confounding patient characteristics.

3.2 Onset of Analgesia

Group LN achieved a significantly faster onset of analgesia compared to Group RN. The mean onset time in Group LN was 4.6 ± 0.25 minutes, compared to 5.6 ± 0.24 minutes in

Group RN (t-statistic: 17.31, $p < 0.01$). This finding is consistent with the pharmacokinetic properties of levobupivacaine, which has a slightly higher lipid solubility and favorable pKa of 8.1, facilitating more rapid membrane penetration and nerve fiber blockade. Kaur et al. similarly reported significantly faster analgesic onset with levobupivacaine compared to ropivacaine in epidural labor analgesia (11.16 vs. 12.24 minutes, $p < 0.05$), corroborating our findings.

3.3 Duration of Analgesia

Group LN demonstrated a significantly longer duration of analgesia (135.2 ± 12.5 min) compared to Group RN (120.8 ± 9.7 min), with a statistically significant difference (t-statistic: -5.46 , $p < 0.01$). The extended analgesic duration with levobupivacaine is attributable to its higher protein binding capacity (97%) and sustained nerve channel blockade, reducing the need for top-up doses and enhancing patient comfort through a longer pain-free window during labor. These findings are in concordance with Kaur et al., who reported a longer mean analgesia duration of 172.16 minutes in the levobupivacaine group versus 158.52 minutes with ropivacaine.

3.4 Analgesic Efficacy – NRS Pain Scores

Both groups showed progressive pain score reduction following epidural drug administration. At 1 minute, NRS scores were statistically similar between the two groups (Group RN: 7.78 ± 0.93 ; Group LN: 7.86 ± 0.96 ; $p = 0.72$). However, beginning at 15 minutes, Group LN consistently recorded significantly lower NRS scores at every time point through 90 minutes ($p < 0.01$ for all). By 60 minutes, mean NRS scores were 4.31 in Group RN versus 1.63 in Group LN, reflecting markedly superior pain control with levobupivacaine-nalbuphine. This differential analgesic performance is likely the result of levobupivacaine's stronger binding affinity to sodium channels and the synergistic interaction with nalbuphine's kappa-agonist activity.

3.5 Hemodynamic Stability

Prepartum hemodynamic parameters (systolic BP, diastolic BP, and heart rate) were comparable between the two groups at all pre-drug time points ($p > 0.05$), establishing an equivalent baseline. Following epidural drug administration, both groups experienced reductions in blood pressure and heart rate; however, the pattern and magnitude of change differed significantly between groups. Group RN demonstrated sharp, statistically significant declines in intrapartum systolic and diastolic blood pressure from 15 minutes onward ($p < 0.05$), whereas Group LN exhibited gradual, controlled reductions that remained hemodynamically stable throughout the observation period. Similarly, intrapartum heart rate showed significant between-group differences from 15 minutes onward ($p < 0.05$), with Group LN maintaining more physiologically appropriate rates. This superior hemodynamic profile of levobupivacaine is clinically important in the obstetric setting, where maternal hypotension can compromise uteroplacental circulation and fetal oxygenation.

3.6 Motor Blockade – Modified Bromage Score

Assessment of motor function revealed an important distinction between the two drugs. In Group RN, 11 patients (30.6%) had no motor block (Bromage 0), 20 patients (55.6%) had Bromage Score 1, and 5 patients (13.9%) had Bromage Score 2; no patient developed complete motor block. In contrast, Group LN had no patients at Bromage 0, 10 patients (27.8%) at Bromage 1, 23 patients (63.9%) at Bromage 2, and 3 patients (8.3%) at Bromage 3 (complete block). Thus, ropivacaine demonstrated superior preservation of motor function, which is a clinically valuable attribute as it permits maternal ambulation and facilitates active participation during the second stage of labor. This differential motor-sparing effect of ropivacaine is well-documented and relates to its lower lipophilicity and consequent reduced penetration of large myelinated motor fibers.

3.7 Labor Characteristics

The duration of the first stage of labor was significantly shorter in Group LN (211 ± 12.7 min) compared to Group RN (283 ± 16.9 min, t-statistic: 4.82, $p < 0.05$). The total labor duration was also markedly reduced in Group LN (249 ± 6.4 min vs. 331 ± 12.6 min; $p < 0.05$). The second stage duration, however, did not differ significantly between groups ($p = 0.35$). The shorter first stage in the levobupivacaine group may reflect better attenuation of uterine contraction-related pain, potentially reducing maternal stress and catecholamine release, which in turn promotes more efficient uterine contractility and cervical dilatation.

3.8 Neonatal Outcomes

Neonatal Apgar scores at 1, 5, and 10 minutes were comparable between both groups. Group RN recorded mean Apgar scores of 9.76 ± 0.44 , 9.10 ± 0.82 , and 9.54 ± 0.61 at 1, 5, and 10 minutes, respectively. Group LN recorded 9.80 ± 0.51 , 9.25 ± 0.76 , and 9.72 ± 0.67 . No statistically significant differences were found ($p > 0.05$ at all time points), confirming that both epidural regimens are safe for the neonate. The use of nalbuphine as an adjuvant did not appear to adversely affect neonatal adaptation, consistent with previous reports on epidural nalbuphine in obstetric practice.

3.9 Adverse Effects

Group RN had a consistently higher incidence of adverse effects across all categories. Hypotension was observed in 19.4% of Group RN patients versus 11.1% in Group LN. Nausea and vomiting affected 8.3% vs. 2.8%, urinary retention 16.7% vs. 5.6%, pruritus 5.5% vs. 0%, and postpartum hemorrhage 11.1% vs. 2.8%. The lower adverse effect burden in Group LN supports the favorable safety profile of levobupivacaine-nalbuphine combination, likely reflecting the superior hemodynamic control and reduced vasodilatation associated with levobupivacaine. Atienzar et al. also reported reduced nausea and pruritus in the levobupivacaine group compared to ropivacaine, consistent with our results.

3.10 Comparative Discussion

The present study's findings align with the broader literature suggesting that while ropivacaine and levobupivacaine are equipotent in many respects, subtle pharmacokinetic and pharmacodynamic differences confer clinically meaningful advantages to one or the other depending on the clinical priority. Kumar et al. (2017) noted that levobupivacaine provided superior analgesic quality with reduced pain perception during uterine contractions, although they reported a higher rate of instrumental delivery. In contrast, our study—utilizing nalbuphine rather than fentanyl—showed no such trend toward operative delivery, possibly because nalbuphine's kappa-agonist activity reduces uterine contraction-associated visceral pain without impairing uterine contractility. Purdie and McGrady (2004) found no clinically significant differences between 0.1% ropivacaine and 0.1% levobupivacaine with fentanyl in PCEA settings; however, the use of nalbuphine in our study may account for the observed differences, underscoring the importance of adjuvant selection in epidural drug design.

4. Conclusion

This randomized controlled study provides robust clinical evidence that 0.1% levobupivacaine combined with nalbuphine 5 mg is superior to 0.1% ropivacaine combined with nalbuphine 5 mg for epidural labor analgesia in primigravida parturients. The levobupivacaine-nalbuphine combination achieves faster analgesic onset, longer duration of action, significantly lower pain scores across all time intervals, superior hemodynamic stability, shorter first-stage and total labor duration, and a more favorable adverse effect profile. Neonatal Apgar scores were comparable between both groups, confirming the safety of both regimens for the neonate.

The only domain where ropivacaine demonstrated a relative advantage was motor function preservation, with more patients in Group RN maintaining ambulatory capacity (Bromage Score 0–1). This may be clinically relevant in settings where mobile epidural techniques are preferred; however, this advantage did not translate into improved delivery outcomes in the present study.

Given the cumulative evidence from this study, levobupivacaine-nalbuphine should be considered the preferred epidural regimen for labor analgesia. Future multicenter randomized trials with larger sample sizes, extended follow-up, and inclusion of multipara patients are recommended to further validate these findings and explore dose-response relationships in diverse obstetric populations.

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