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Original Research Article

A COMPARATIVE STUDY OF THE EFFECTIVENESS OF 0.125% LEVOBUPIVACAINE WITH BUPRENORPHINE (15 µG/ML) VERSUS 0.125% LEVOBUPIVACAINE WITH DEXAMETHASONE (4 MG) IN EPIDURAL LABOUR ANALGESIA

A. R. Rakshini Shrinidhi[1], K. Mohan[2], Yedama Poojitha[3], Alekya Sai Guntupalli[4]

[1]Postgraduate Resident (JR-III), Department of Anaesthesiology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India.
[2]Professor and Head, Department of Anaesthesiology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India.
[3]Senior Resident, Department of Anaesthesiology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India.
[4]Senior Resident, Department of Anaesthesiology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India.

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Corresponding Author:
Dr. A. R. Rakshini Shrinidhi,
Email: a.rakshinishrinidhi@gmail.com

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ABSTRACT

Background: Epidural analgesia is the gold-standard technique for labour pain relief. Adjuvants combined with dilute local anaesthetics improve analgesic quality while limiting motor blockade. Comparative data on buprenorphine versus dexamethasone as adjuvants to levobupivacaine for epidural labour analgesia remain limited. **Objective:** To compare the effectiveness of 0.125% levobupivacaine with buprenorphine 15 µg/mL versus 0.125% levobupivacaine with dexamethasone 4 mg for epidural labour analgesia. **Materials and Methods:** In this prospective comparative study conducted over 18 months at PES Institute of Medical Sciences and Research, Kuppam, 58 primigravida parturients in spontaneous labour were allocated to receive epidural 0.125% levobupivacaine with either buprenorphine 15 µg/mL (Group LB, n=29) or dexamethasone 4 mg (Group LD, n=29). Onset of analgesia, Visual Analogue Scale (VAS) pain scores, Modified Bromage score, sensory block characteristics, local anaesthetic consumption, labour progress, neonatal outcome, and maternal adverse effects were recorded and compared using Student's t-test and chi-square test, with $p<0.05$ considered significant. **Results:** Baseline demographic and haemodynamic parameters were comparable between groups. Group LB demonstrated significantly faster onset of analgesia (9.58 ± 0.50 vs 12.62 ± 0.62 min), lower VAS scores at all post-epidural intervals, fewer epidural top-ups (1.5 ± 0.51 vs 2.5 ± 0.51), and lower total levobupivacaine consumption (18.53 ± 6.36 mg vs 31.47 ± 6.36 mg) compared with Group LD (all $p<0.001$). Motor blockade, sensory block height, labour duration, mode of delivery, and neonatal Apgar scores were similar between groups ($p>0.05$). Pruritus was significantly more frequent in Group LB (13.6% vs 0%, $p=0.03$), with no serious maternal or fetal adverse events in either group. **Conclusion:** Epidural buprenorphine (15 µg/mL) combined with 0.125% levobupivacaine provides faster onset, superior analgesic quality, and a local-anaesthetic-sparing effect compared with dexamethasone (4 mg), without compromising maternal haemodynamics, labour progress, or neonatal outcome. Mild opioid-related pruritus was the principal trade-off.

INTRODUCTION

Labour pain is among the most intense forms of pain experienced by women, and its effective relief reduces stress-related catecholamine release, thereby improving uteroplacental perfusion and maternal–fetal outcomes.[1,2] Epidural analgesia is widely regarded as the gold-standard technique for labour pain relief because of its superior efficacy, flexibility, and minimal systemic effects.[3] Pain intensity is commonly quantified using the Visual Analogue Scale (VAS), while motor blockade is assessed using the Modified Bromage score, both of which allow objective comparison of analgesic regimens.[4,5]

Levobupivacaine, the pure S-enantiomer of bupivacaine, is preferred in obstetric practice for its reduced cardiotoxicity and lower propensity for motor blockade relative to the racemic drug.[6,7] To improve analgesic quality while permitting the use of dilute local anaesthetic concentrations, adjuvants such as opioids and corticosteroids are frequently co-administered epidurally. Buprenorphine, a highly lipophilic partial μ-opioid agonist with high receptor affinity, provides prolonged analgesia through spinal opioid-receptor-mediated inhibition of nociceptive transmission.[8,9] Dexamethasone, a potent long-acting corticosteroid, is proposed to prolong analgesia through anti-inflammatory and neuronal membrane-stabilising mechanisms, offering a non-opioid alternative that avoids opioid-related side effects such as pruritus and respiratory depression.[10,11]

Despite the widespread use of both agents, direct comparative evidence on buprenorphine versus dexamethasone as adjuvants to levobupivacaine for epidural labour analgesia is limited, particularly with regard to onset, analgesic quality, local-anaesthetic-sparing effect, and safety.3 This study was therefore undertaken to compare 0.125% levobupivacaine with buprenorphine 15 μg/mL against 0.125% levobupivacaine with dexamethasone 4 mg for epidural labour analgesia, with respect to analgesic onset and quality (VAS), duration of analgesia, drug consumption, motor blockade (Bromage score), labour progress, neonatal outcome, and maternal adverse effects.

Aims and Objectives

To compare the effectiveness of 0.125% levobupivacaine with buprenorphine 15 μg/mL versus 0.125% levobupivacaine with dexamethasone 4 mg in epidural labour analgesia, with respect to:

1. Onset and quality of analgesia, assessed using the Visual Analogue Scale (VAS).
2. Duration of effective analgesia and total local anaesthetic (levobupivacaine) consumption.
3. Degree of motor blockade, assessed using the Modified Bromage score.
4. Maternal haemodynamic stability and progress of labour.
5. Neonatal outcome and incidence of maternal adverse effects.

MATERIALS AND METHODS

Study design and setting

This prospective, comparative clinical study was conducted in the Department of Anaesthesiology at PES Institute of Medical Sciences and Research (PESIMSR), Kuppam, Andhra Pradesh, over a period of 18 months (April 2024 to October 2025), following approval by the Institutional Human Ethics Committee (Approval No. PESIMSR/IHEC/C-1/2024, dated 16 March 2024) and the Institutional Dissertation Committee. Written informed consent was obtained from all participants.

Participants

Primigravida women aged 21–36 years, of ASA physical status I or II, with a singleton pregnancy in vertex presentation at 37–40 weeks of gestation, in the first stage of labour with cervical dilatation of 3–5 cm and normal fetal heart rate (140–160 beats/min), were included. Women with allergy to the study drugs, contraindications to epidural analgesia, deranged coagulation profile, severe anaemia, local infection at the injection site, or psychiatric illness precluding cooperation were excluded.

Sample size and allocation

Sample size was calculated from a prior comparative study of levobupivacaine with buprenorphine versus dexamethasone,12 yielding a minimum of 20 subjects per group; this was increased to 29 per group (total n=58) to allow for attrition. Participants were randomly allocated by the chit (odd/even) method into Group LB (0.125% levobupivacaine with buprenorphine 15 μg/mL) or Group LD (0.125% levobupivacaine with dexamethasone 4 mg).

Procedure

After baseline obstetric assessment and intravenous preloading with 500 mL Ringer's lactate, the epidural space was identified in the sitting position at the L3–L4 interspace using the loss-of-resistance technique, and a catheter was advanced 3–4 cm into the epidural space. The allocated study drug was administered as the initial bolus, with additional 5 mL top-up doses given for VAS >4. Sensory block was assessed by loss of temperature discrimination, motor block by the Modified Bromage scale, and pain by VAS (0–10) at fixed intervals until delivery. Apgar scores were recorded at 1 and 5 minutes, and maternal adverse effects were documented throughout.

Statistical Analysis

Data were entered in Microsoft Excel and analysed using SPSS version 23.0. Continuous variables are expressed as mean ± standard deviation and compared using Student's t-test; categorical variables are expressed as frequencies and percentages and compared using the chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

Fifty-eight parturients (29 per group) completed the study. Baseline demographic characteristics, including age, body mass index, gestational age, cervical dilatation, ASA status, and baseline vital parameters, were comparable between the two groups (all p>0.05), confirming adequate group matching. [Table 1]

Table 1: Baseline demographic and clinical characteristics

Parameter	Group LD (n=29)	Group LB (n=29)	P value
Age (years), mean ± SD	27.93 ± 3.55	29.03 ± 4.31	0.32
BMI (kg/m²), mean ± SD	23.56 ± 1.62	23.94 ± 2.08	0.38

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Gestational age (weeks)	38.42 ± 0.76	38.39 ± 0.81	0.89
Cervical dilatation (cm)	4.38 ± 0.62	4.36 ± 0.71	0.91
Heart rate (bpm)	100.72 ± 5.21	100.18 ± 4.87	0.67
Systolic BP (mmHg)	118.22 ± 6.41	118.44 ± 5.63	0.88
Mean arterial pressure (mmHg)	90.71 ± 4.62	91.62 ± 3.41	0.36
SpO_2 (%)	97.58 ± 0.91	97.52 ± 1.08	0.79

Heart rate, systolic and diastolic blood pressure, mean arterial pressure, and oxygen saturation remained stable and comparable between groups at all observed time points following epidural administration ($p>0.05$ throughout), indicating that neither regimen adversely affected maternal haemodynamics or oxygenation.

Pain scores decreased progressively in both groups following epidural administration; however, Group LB showed significantly lower VAS scores at every post-epidural interval compared with Group LD ($p<0.001$ from 1 minute onward), indicating both faster onset and superior quality of analgesia with buprenorphine. [Table 2]

Table 2: Pain scores (Visual Analogue Scale) at selected time intervals

Time	Group LD	Group LB	P value
Baseline	7.62 ± 0.73	8.08 ± 0.74	0.07
1 min	6.88 ± 0.35	6.12 ± 0.33	<0.001
5 min	4.95 ± 0.34	4.12 ± 0.32	<0.001
10 min	3.95 ± 0.34	3.12 ± 0.32	<0.001
20 min	2.88 ± 0.36	2.18 ± 0.36	<0.001
60 min	2.92 ± 0.32	2.12 ± 0.32	<0.001

Onset of analgesia, time to achieve T10 sensory level, and time to first painless uterine contraction were all significantly shorter in Group LB ($p<0.001$), while the maximum Bromage score and the distribution of highest sensory block level achieved were comparable between groups ($p=0.18$ and $p=0.34$, respectively), indicating that the faster and superior analgesia with buprenorphine was not accompanied by increased motor blockade or a wider sensory spread. [Table 3]

Table 3: Sensory and motor block characteristics

Parameter	Group LD	Group LB	P value
Time to onset of analgesia (min)	12.62 ± 0.62	9.58 ± 0.50	<0.001
Time to T10 sensory level (min)	14.62 ± 0.62	11.62 ± 0.50	<0.001
Time to first painless contraction (min)	15.62 ± 0.62	12.62 ± 0.50	<0.001
Maximum Bromage score	0.28 ± 0.45	0.12 ± 0.33	0.18

Group LB required significantly fewer epidural top-ups (1.5 ± 0.51 vs 2.5 ± 0.51) and a significantly lower total levobupivacaine dose (18.53 ± 6.36 mg vs 31.47 ± 6.36 mg) compared with Group LD ($p<0.001$ for both), demonstrating a clear local-anaesthetic-sparing effect of buprenorphine. [Table 4]

Table 4: Drug requirement and labour/neonatal outcomes

Parameter	Group LD	Group LB	P value
Number of epidural top-ups	2.5 ± 0.51	1.5 ± 0.51	<0.001
Total levobupivacaine dose (mg)	31.47 ± 6.36	18.53 ± 6.36	<0.001
Duration of 1st stage of labour (min)	374.50 ± 12.40	424.10 ± 12.10	0.44
Duration of 2nd stage of labour (min)	42.30 ± 1.52	40.20 ± 1.48	0.47
Time from epidural to delivery (min)	254.20 ± 12.10	314.60 ± 11.90	0.06
Apgar score at 1 min	8	8	—
Apgar score at 5 min	9	9	—

Mode of delivery did not differ significantly between groups (25 vaginal deliveries in Group LD vs 21 in Group LB, $p=0.28$), and neonatal Apgar scores at 1 and 5 minutes were identical and satisfactory in both groups. Maternal adverse effects were infrequent overall; pruritus occurred exclusively in Group LB (4/29, 13.6%) and was statistically significant ($p=0.03$), consistent with the known opioid side-effect profile, while hypotension, nausea/vomiting, and shivering were comparable between groups. [Table 5]

Table 5: Maternal adverse effects

Adverse effect	Group LD, n (%)	Group LB, n (%)	P value
Hypotension	1 (3.4)	0 (0)	0.31
Nausea/vomiting	3 (10.2)	2 (6.8)	0.63
Pruritus	0 (0)	4 (13.6)	0.03
Shivering	2 (6.8)	1 (3.4)	0.55

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DISCUSSION

This study compared two mechanistically distinct epidural adjuvants to 0.125% levobupivacaine for labour analgesia: buprenorphine, an opioid acting via spinal μ-receptors, and dexamethasone, a corticosteroid acting through anti-inflammatory and membrane-stabilising mechanisms.[8,10] Baseline demographic and haemodynamic parameters were well matched between groups, consistent with previously reported labour analgesia cohorts.[13-15]

Both regimens preserved maternal haemodynamic stability and respiratory parameters throughout labour, consistent with earlier reports of minimal cardiovascular disturbance with low-concentration levobupivacaine-based epidural techniques.[13,14]

No clinically significant hypotension, bradycardia, or respiratory depression was observed in either group, including the buprenorphine group, in keeping with the ceiling effect on respiratory depression conferred by buprenorphine's partial agonist activity.[15,9]

The principal finding of this study was the significantly faster onset and superior quality of analgesia with buprenorphine, reflected in consistently lower VAS scores at every post-epidural interval. This is consistent with the classic observations of Lanz et al., who demonstrated prolonged, effective epidural analgesia with buprenorphine attributable to its high lipid solubility and strong spinal opioid-receptor affinity.[16] Similar superiority of buprenorphine over dexamethasone in analgesic quality has been reported in regional block studies.[17,18] In contrast, while dexamethasone has been shown to reduce analgesic consumption and prolong analgesia relative to levobupivacaine alone, its effect appears less pronounced than that achieved with opioid adjuvants.[19,20]

Motor block, assessed by the Bromage score, was minimal and comparable between groups, confirming that the enhanced analgesic efficacy of buprenorphine was not achieved at the expense of motor function — an important consideration for maternal mobility and effective bearing-down efforts in the second stage of labour.[5,13] Similarly, the extent of sensory block spread did not differ between adjuvants, suggesting that the observed differences in analgesic quality reflect pharmacodynamic differences at the spinal cord level rather than differential cephalad spread of the local anaesthetic.[14]

The local-anaesthetic-sparing effect observed with buprenorphine, evidenced by fewer top-ups and lower total levobupivacaine consumption, corroborates earlier findings of reduced supplemental analgesic requirement with epidural buprenorphine.[16,18] This sparing effect is clinically relevant, as it may translate into reduced risk of local anaesthetic systemic toxicity and dense motor blockade over prolonged labour.

Labour progress, mode of delivery, and neonatal Apgar scores were comparable between the two adjuvants, consistent with prior evidence that appropriately dosed epidural analgesia — regardless of opioid or non-opioid adjuvant — does not adversely affect labour physiology or immediate neonatal wellbeing.[13,15] Pruritus, a well-recognised opioid-related side effect, was significantly more frequent with buprenorphine, mirroring previous reports comparing opioid and steroid epidural adjuvants.[16,18] In the present study this was mild and self-limiting, without need for specific intervention.

CONCLUSION

Epidural 0.125% levobupivacaine combined with buprenorphine 15 μg/mL provided faster onset, superior analgesic quality, and a clear local-anaesthetic-sparing effect compared with 0.125% levobupivacaine combined with dexamethasone 4 mg, without compromising maternal haemodynamic stability, motor function, labour progress, or neonatal outcome. Mild opioid-related pruritus was more frequent with buprenorphine but was clinically inconsequential. Buprenorphine may therefore be considered a more effective adjuvant to levobupivacaine for epidural labour analgesia, while dexamethasone remains a reasonable non-opioid alternative where avoidance of opioid-related side effects is prioritised.

Limitations

This was a single-centre study with a relatively small sample size, and the anaesthesiologist administering the epidural drug could not be blinded, which may have introduced observer bias in assessment of subjective outcomes. Long-term maternal outcomes and detailed neonatal neurobehavioural assessment were not evaluated.

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