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Comparative evaluation of epidural 0.125% and 0.0625% levobupivacaine with fentanyl for labour analgesia

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Abstract:
Labour pain requires effective epidural analgesia, yet optimal levobupivacaine concentrations balancing sensory relief with minimal motor blockade remain clinically debated. Therefore, it is of interest to compare the 0.125% levobupivacaine-fentanyl versus 0.0625% levobupivacaine-fentanyl in 100 patients, assessing analgesia onset/duration, VAS pain scores, motor block, maternal hemodynamics, labor outcomes and neonatal APGAR scores. Both concentrations provided comparable effective analgesia, but the lower dose (0.0625%) showed reduced motor blockade while maintaining equivalent pain relief profiles. Maternal hemodynamic stability and neonatal APGAR scores showed no significant intergroup differences across both treatment arms. Thus, data shows that establishing lower-concentration levobupivacaine-fentanyl as a safer alternative preserving maternal mobility without compromising labor analgesia efficacy.

Keywords: Labour analgesia, levobupivacaine, epidural analgesia, fentanyl, motor block, obstetric anesthesia

Background:
Labour pain is commonly considered to be one of the worst types of acute pain women undergo during childbirth. It occurs as a result of a complicated interaction of visceral and somatic factors, including uterine contractions, cervical dilatation and pressure on pelvic structures. Poor analgesia in labour can result in maternal stress, catecholamine discharge and poor maternal and infant outcomes, such as long labour and infant distress. Hence, safe and effective labour analgesia is an essential aspect of contemporary obstetric care **[1]**. Epidural analgesia is regarded as the gold standard method of managing labour pain because it has greater analgesic effects and is more flexible in terms of dosing. It offers segmental analgesia and minimal systemic exposure to drugs and can be titrated based on the phase of labour. Different types of local anesthetics have been employed over the years to administer epidural analgesia with an increased focus on decreasing the motor blockade and still providing sufficient analgesia **[2, 3]**. The S (-)-enantiomer of bupivacaine, levobupivacaine, has become a favorite agent because of its better safety profile. Levobupivacaine exhibits less cardiotoxicity and neurotoxicity than racemic bupivacaine, which is why it is especially safe to use in obstetrics **[4]**. It also offers good sensory blockade at reduced motor blockade, thus enabling maternal involvement in labour and decreasing the rates of instrumental delivery **[5]**. Introduction of opioids like fentanyl to epidural local anesthetics has been reported to increase analgesic effect and also enable lower concentration of local anesthetics to be used. This is a synergistic combination because the two agents are targeting different pain pathways-local anesthetics inhibit nerve conduction, whereas opioids are influencing the spinal receptors to reduce pain perception. Consequently, opioid-adjuvated epidural preparations have the potential to deliver better analgesia at lower overall drug doses and fewer adverse effects **[6, 7]**. The recent developments in obstetric anesthesia have concentrated on lower concentrations of local anesthetics to reduce motor blockades and enhance maternal mobility during labour. Comparative studies on various levels of levobupivacaine have indicated that dilute solutions, in combination with opioids, could offer similar analgesia with better safety and patient satisfaction **[8, 9]**. Nevertheless, it is still a matter of debate on the best concentration that would strike the right balance between analgesic effect and the preservation of motor functions. Although 0.125% levobupivacaine has been extensively used in clinical practice, lower concentrations like 0.0625% are also being considered. The reason of employing ultra-low concentrations is to attain effective sensory blockage with minimum motor impairment, thus early ambulation and minimized labour complications **[10]**. Therefore, it is of interest to conduct this study in order to optimize labour analgesia regimes and enhance maternal care in obstetric practice.

Materials and Methodology:
Study design:
This was a prospective, randomized, comparative clinical study conducted in the Department of Anaesthesiology in collaboration with the Department of Obstetrics and Gynaecology at Nandkumar Singh Chouhan Government Medical College and Hospital, Khandwa, MP, India.

Study population:
A total of 100 patients admitted for vaginal delivery and requesting labour analgesia were included in the study, after obtaining written informed consent.

Inclusion criteria:
[1] ASA physical status I and II
[2] Age between 18–35 years
[3] Singleton pregnancy
[4] Cephalic presentation
[5] Term gestation (≥37 weeks)
[6] Cervical dilatation 3–5 cm at the time of epidural placement

Exclusion criteria:

[1] Patient refusal
[2] Contraindications to epidural anesthesia (coagulopathy, infection at site)
[3] Allergy to study drugs
[4] High-risk pregnancy (*e.g.,* severe preeclampsia, placenta previa)
[5] Previous cesarean section
[6] Fetal distress at admission

Randomization and group allocation:
Patients were randomly allocated into two equal groups (n = 50 each) using a computer-generated randomization table:
[1] **Group A:** Epidural 0.125% levobupivacaine + fentanyl
[2] **Group B:** Epidural 0.0625% levobupivacaine + fentanyl

Procedure:
After obtaining informed consent, all patients were preloaded with intravenous fluids. Standard monitoring (heart rate, blood pressure, SpO_2) was instituted. Epidural analgesia was administered in the lumbar region (L2–L3 or L3–L4 interspace) using a loss-of-resistance technique. After confirming correct placement, a test dose was given to rule out intrathecal or intravascular injection.
[1] **Group A:** Received 10 ml of 0.125% levobupivacaine with fentanyl (2 µg/ml)
[2] **Group B:** Received 10 ml of 0.0625% levobupivacaine with fentanyl (2 µg/ml)
Top-up doses were administered as required based on patient demand and pain scores.

Parameters assessed:
Primary outcome:
[1] Pain relief assessed using Visual Analog Scale (VAS)

Secondary outcomes:
[1] Onset time of analgesia
[2] Duration of analgesia
[3] Degree of motor block (Modified Bromage scale)
[4] Maternal hemodynamic parameters
[5] Mode of delivery (normal/instrumental/cesarean)
[6] Duration of labour stages
[7] Neonatal outcome (APGAR score at 1 and 5 minutes)
[8] Maternal satisfaction

Data collection:
Pain scores and vital parameters were recorded at baseline and at regular intervals (every 5–15 minutes initially, then hourly). Motor block was assessed periodically.

Statistical analysis:
Data were entered into Microsoft Excel and analyzed using statistical software (SPSS version 25).
[1] Continuous variables were expressed as mean ± standard deviation
[2] Categorical variables were expressed as percentages
[3] Student's t-test was used for comparison of means
[4] Chi-square test was used for categorical data
[5] A p-value < 0.05 was considered statistically significant

Results:
A total of 100 patients were enrolled and randomly allocated into two equal groups of 50 each. Group A received epidural 0.125% levobupivacaine with fentanyl, while Group B received 0.0625% levobupivacaine with fentanyl. All participants completed the study and were included in the final analysis. The demographic variables including age, weight, gestational age and cervical dilatation at the time of epidural placement were comparable between the two groups, with no statistically significant differences ($p > 0.05$). This confirms that both groups were well matched at baseline, minimizing confounding bias. The onset of analgesia was significantly faster in Group A (8.6 minutes) compared to Group B (9.8 minutes), with a p-value of 0.02. Similarly, the duration of analgesia was significantly longer in Group A (92.5 minutes) than Group B (78.4 minutes), indicating superior pharmacodynamic efficacy at the higher concentration. Baseline VAS scores were comparable between groups (~7.7–7.8), confirming similar initial pain intensity. At 30 minutes, both groups demonstrated a substantial reduction in pain (>70% reduction), with no statistically significant difference ($p = 0.28$). At 2 hours, both groups maintained low VAS scores, with Group A showing slightly better pain control, though not statistically significant. Overall, both regimens provided effective analgesia, but Group A demonstrated marginally superior onset and duration **(Table 1)**. Motor block was significantly higher in Group A compared to Group B. A majority of patients in Group B (84%) had no motor blockade, compared to only 60% in Group A. Mild motor block was observed in 36% of Group A versus 16% in Group B. Moderate motor block occurred only in Group A (4%). This difference was statistically significant ($p = 0.01$), indicating that the lower concentration (0.0625%) is associated with better preservation of motor function. Maternal complications such as hypotension and nausea/vomiting were comparable between the groups ($p > 0.05$), suggesting similar safety profiles **(Table 2)**. A higher percentage of normal vaginal deliveries was observed in Group B (84%) compared to Group A (76%), although the difference was not statistically significant. Instrumental and cesarean delivery rates were slightly higher in Group A, possibly related to increased motor block. Neonatal outcomes, as assessed by APGAR scores at 1 and 5 minutes, were comparable between groups ($p > 0.05$), indicating no adverse fetal effects. Maternal satisfaction was high in both groups, with slightly higher satisfaction in Group B (88%) compared to Group A (80%), though this difference was not statistically significant **(Table 3)**. The first stage of labour was slightly prolonged in Group A by approximately 5.1%, but this difference was not statistically significant ($p = 0.08$). The second stage of labour was significantly longer in Group A by about 16.7%, indicating a meaningful prolongation likely related to increased motor blockade ($p = 0.03$). The third stage of labour showed a minimal increase of 3.7% in Group A, which was not statistically significant ($p = 0.42$) **(Table 4).**

Table 1: Comparison of analgesic profile

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Parameter	Group A (0.125%)	Group B (0.0625%)	p-value
	Mean ± SD	Mean ± SD	
Onset of analgesia (min)	8.6 ± 2.4	9.8 ± 2.7	0.02*
Duration of analgesia (min)	92.5 ± 18.2	78.4 ± 16.9	0.01*
Baseline VAS	7.8 ± 0.9	7.7 ± 1.0	0.64
VAS at 30 min	2.1 ± 0.8	2.3 ± 0.9	0.28
VAS at 2 hrs	2.4 ± 1.0	2.6 ± 1.1	0.35

Statistically significant

Table 2: Motor block and maternal outcomes

Parameter	Group A (%)	Group B (%)	p-value
No motor block	30 (60%)	42 (84%)	0.01*
Mild motor block	18 (36%)	8 (16%)	
Moderate motor block	2 (4%)	0 (0%)	
Hypotension	6 (12%)	4 (8%)	0.51
Nausea/Vomiting	5 (10%)	3 (6%)	0.46

Statistically significant

Table 3: Labour and neonatal outcomes

Parameter	Group A	Group B	p-value
Normal vaginal delivery	38 (76%)	42 (84%)	0.31
Instrumental delivery	8 (16%)	6 (12%)	
Cesarean section	4 (8%)	2 (4%)	
APGAR (1 min)	7.8 ± 0.6	7.9 ± 0.5	0.42
APGAR (5 min)	8.9 ± 0.4	9.0 ± 0.3	0.36
Maternal satisfaction (good)	40 (80%)	44 (88%)	0.27

Table 4: Duration of labour stages

Labour Stage	Group A (0.125%)	Group B (0.0625%)	% Difference	p-value
	Mean ± SD (min)	Mean ± SD (min)	(A vs B)	
First Stage	310 ± 45	295 ± 40	5.1% longer in A	0.08
Second Stage	42 ± 10	36 ± 8	16.7% longer in A	0.03*
Third Stage	8.5 ± 2.0	8.2 ± 1.8	3.7% longer in A	0.42

Statistically significant

Discussion:

The current research compared the effectiveness and safety of two levels of levobupivacaine with fentanyl in the analgesia of labour. The results indicate that both concentrations are effective analgesics, but there are considerable differences in motor blockade and functional outcomes. Pain management in labour is a very important aspect of obstetric care and epidural analgesia is the most effective modality. Levobupivacaine use has been widely accepted because of its better safety profile than bupivacaine especially in cardiotoxicity and neurotoxicity. Fentanyl addition also increases the analgesic effect by activating spinal opioid receptors, which enables lower local anesthetic levels **[3]**. The onset of analgesia was much quicker in the 0.125% group in the current study. This observation is in line with other researchers who have demonstrated that an increase in the concentration of local anesthetics gives a faster onset because of increased diffusion across nerve membranes. But the clinical importance of a difference of about 1 minute might be small in normal obstetric practice. The higher concentration group also had a significantly longer period of analgesia, which is consistent with the results of previous trials. This is explained by the fact that more drugs are available at the site of action and this leads to the long-term blockage of the nerves. Nevertheless, top-up doses in the lower concentration group did not have a significant effect on the quality of analgesia. Epidural administration of pain relief as measured by VAS scores was similar between groups. Both groups showed over 70 percent reduction in pain scores in 30 minutes, which means that the lower concentration of levobupivacaine can be adequately replaced by fentanyl. Recent randomized trials have found similar results in the comparison of dilute local anesthetic-opioid combinations **[8]**. Najeeb *et al.* reported that continuous epidural infusion of 0.0625% bupivacaine with fentanyl provided rapid and prolonged analgesia without significant hemodynamic changes or motor blockade, with comparable neonatal APGAR scores **[11].** Similarly, Shivani *et al.* found that 0.0625% bupivacaine with fentanyl provided labour analgesia comparable to 0.1% ropivacaine with fentanyl, with similar maternal satisfaction, fetal heart rates and adverse-event profiles **[12].** Kulkarni and Patil also reported comparable analgesic efficacy and hemodynamic stability between bupivacaine-fentanyl and ropivacaine-fentanyl; although ropivacaine was associated with lower VAS scores at selected time points and better maintenance of heart rate **[13].** These findings further support the effectiveness and safety of dilute local anesthetic-opioid combinations for labour analgesia. The most significant results of this study are that the motor blockade is reduced significantly in the 0.0625% group. It is in line with the principle of differential blockade, in which sensory fibers are more sensitive to local anesthetics than motor fibers. Low doses selectively inhibit sensory fibers but do not affect motor activity. This is especially beneficial in labour, where it enables better mobility of the maternal and active involvement in the delivery. The clinical implications of the lower concentration group of reduced motor blockades are significant. It is linked to a reduced rate of instrumental deliveries and cesarean section as was the case in this study. The differences were not statistically significant, but the trend leans towards using dilute solutions. Studies have reported similar observations **[10, 14]**. The groups had similar maternal hemodynamic parameters and side effects, which suggested that both regimens are safe. The rate of hypotension was low and was in line with earlier research **[15]**. Adding fentanyl did not cause any major side effects of opioids, including respiratory depression, probably because of low dose. There was no difference in neonatal outcomes, as measured by APGAR scores, between the two groups, which mean that both regimens do not have a negative impact on fetal well-being. This concurs with various studies that have shown that epidural levobupivacaine is safe in obstetric practice **[17, 18]**. The time of labour stages tended to be longer in Group A than Group B, but this was not consistent throughout the labour stages suggesting that although both regimens are effective, the lower concentration (0.0625%) could be more conducive to labour processes, especially to prevent the extension of the second stage. This concurs with earlier research **[14]**. Both groups had high maternal satisfaction, which showed that epidural analgesia was effective. The marginally greater satisfaction of the lower concentration group can be explained by the increased

mobility and decreased motor block, which contributed to the increased overall childbirth experience **[18]**. Recent literature endorses the tendency of applying ultra-low doses of local anesthetics with opioids. Research has showed that these regimens offer sufficient analgesia with less motor blockade and better obstetric outcomes. Moreover, improved recovery measures in obstetrics focus on early ambulation and minimum intervention, which is enabled by low-dose epidural methods **[16, 19]**. Even with these benefits, higher concentrations are still desirable in some cases where thick and fast analgesia is needed. Thus, the concentration should be decided on a case-by-case basis depending on patient characteristics and clinical setting.

Conclusion:

Epidural levobupivacaine 0.125% and 0.0625% with fentanyl are both effective as labour analgesia. Nonetheless, levobupivacaine 0.0625% provides similar analgesic effects and much less motor blockage, improved maternal mobility and desirable labour outcomes. Therefore, the lower concentration regimen can be regarded as a more favorable and safer choice of labour analgesia.

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