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Research Article

A Comparative Study of Effectiveness of 0.125% Levobupivacaine with Fentanyl 2mcg/ml versus Levobupivacaine with Dexamethasone 4mg in Epidural Labor Analgesia

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Abstract
Background: Epidural analgesia is widely accepted as the gold standard for pain relief during labor due to its superior efficacy and maternal satisfaction. Levobupivacaine, a safer alternative to bupivacaine, is often combined with adjuvants like fentanyl or dexamethasone to enhance its analgesic profile.
Objective: To compare the effectiveness and safety of 0.125% levobupivacaine with fentanyl 2 mcg/ml versus 0.125% levobupivacaine with dexamethasone 4 mg for epidural labor analgesia.
Methods: Sixty primigravida women in active labor were randomly divided into two groups: Group LF received 0.125% levobupivacaine with fentanyl 2 mcg/ml, and Group LD received 0.125% levobupivacaine with dexamethasone 4 mg. Parameters assessed included onset and duration of analgesia, total number of top-ups, maternal hemodynamic stability, motor blockade, maternal satisfaction, and neonatal APGAR scores.
Results: Both combinations provided effective labor analgesia. Group LF had a significantly faster onset of analgesia (7.93±1.01 vs 8.83± 0.70), longer duration of analgesia (90.03± 5.14 vs 58.37± 4.80), lesser total drug usage (30.42± 2.71 vs 39.17± 3.26) required fewer top-ups (2.87± 0.43 vs 4.27± 0.52) and less VAS scores with greater maternal satisfaction and fewer opioid related side effects. Hemodynamic parameters and neonatal outcomes were compared and major adverse effects were observed in either group.
Conclusion: Both regimens are safe and effective for epidural labor analgesia. However, the addition of fentanyl to levobupivacaine prolongs the duration of analgesia and reduces the need for additional doses, making it a valuable alternative to opioid-based combinations.

Keywords: Epidural Analgesia, Levobupivacaine, Fentanyl, Dexamethasone, Labor Pain, APGAR Score.

INTRODUCTION

Labor is an extremely painful process. Labor pain can have deleterious effects on the mother, fetus and labor outcome. Among the various methods of obstetric analgesia, epidural analgesia is the most common technique, which provide the best effectiveness/safety ratio. Epidural anesthesia is an effective methods of providing analgesia during labor. Compared with other forms of pain relief, epidural analgesia is associated with maximal level of maternal satisfaction.[1]

Pain management remains a primary concern for women during labour. A woman's confidence in her ability to cope with the birthing process is considered one of the most accurate indicators of her pain perception in the early stages of labour.[2] Overall satisfaction with childbirth is largely influenced by the effectiveness of pain relief.[3] Moreover, a positive doctor-patient relationship and the opportunity for active involvement in decision-making significantly contribute to maternal satisfaction.[3,4] Therefore, it is essential for healthcare providers to engage in open discussions with expectant mothers during pregnancy, addressing available labour analgesia options, potential concerns, and setting realistic expectations about the childbirth experience.

Labour has long been recognized as a profoundly painful and challenging experience for women, especially prior to the advancements of the last century. Over time, numerous strategies have been attempted to manage labour pain.

However, these methods were not widely embraced until the late 1800s, largely due to dominant medical and religious ideologies of the time. Labour involves a complex interplay of physical changes, emotional intensity, and pain. Historically, the pain associated with childbirth was thought to serve a vital biological role, and efforts to suppress it were believed to potentially endanger the mother and fetus, interfere with uterine contractions, or extend the duration of labour. Today, regional analgesia has emerged as the most commonly used and preferred technique for managing labour pain, surpassing other forms of analgesia on a global scale.[1]

The McGill Pain Questionnaire places labour pain high on the intensity scale, ranking it between the severity of cancer-related pain and the pain experienced from a digit amputation. A major breakthrough in obstetric anaesthesia occurred when James Young Simpson administered chloroform to Queen Victoria during the delivery of her eighth child. This landmark event significantly contributed to the wider acceptance and advancement of pain relief in childbirth. The introduction of lumbar epidural analgesia marked a transformative shift in labour management, delivering substantial pain relief without notably affecting the progress or length of labour. When performed with skill and accuracy, epidural analgesia is considered one of the most effective techniques offering safety, affordability, and a high rate of success in pain management.[5]

Spinal and epidural analgesia are two localized techniques commonly employed to manage labour pain. In epidural analgesia, an indwelling catheter is placed within the epidural space, allowing for either continuous infusion or intermittent administration of local anaesthetics. Unlike spinal injections, the epidural space is relatively larger and thus requires a higher volume of anaesthetic to achieve effective analgesia. This method is frequently combined with general anaesthesia during surgical interventions in both paediatric and adult populations.[6,7] It is especially beneficial for elderly patients with comorbid conditions such as hypertension, chronic obstructive pulmonary disease, coronary artery disease, and renal dysfunction.[8,9] Additionally, regional anaesthesia can help minimize intraoperative hypotension, potentially reducing the incidence of postoperative cognitive disturbances such as delirium in older adults.[10]

Epidural drug administration is utilized in various clinical settings including peripartum care, intraoperative and postoperative pain control, and palliative care. Bupivacaine remains the most frequently used agent for labour epidural analgesia due to its reliability and effectiveness. However, newer agents like ropivacaine and levobupivacaine have been introduced to offer a safer profile, especially with respect to cardiac and neurological toxicity.[11,12] These agents, when administered in dilute concentrations for labour analgesia, are also advantageous in minimizing motor blockade. The addition of opioids further enhances the analgesic effect through synergistic action, as they bind to spinal opioid receptors. This allows for reduced doses of local anaesthetic, thereby lowering the risk of systemic toxicity.[13]

Various opioids such as morphine, meperidine, sufentanil, and fentanyl have been employed to manage pain during labour.[14] Among these, fentanyl is particularly favored due to its low cost, rapid onset of action, and relatively prolonged duration of pain relief all while producing minimal motor impairment. Dexamethasone contributes to pain relief by reducing inflammation, inhibiting nociceptive signal transmission via C-fibers, and suppressing abnormal neural discharges. Studies have shown that when dexamethasone is used alongside peripheral nerve blocks, it significantly prolongs the duration of postoperative analgesia.

In order to assess the efficacy of 0.125% levobupivacaine with fentanyl 2mcg/ml versus 0.125%levobupivacaine with dexamethasone4mg in epidural labour analgesia, the current study was carried out.

METHODOLOGY

Design: Randomized controlled trial.

Participants: Sixty primigravida women with gestational age ≥ 37 to 40 weeks undergoing normal vaginal delivery.

60 study subjects will be allocated into two groups using simple randomization technique with CHIT method, 60 chits with numbers (1–49)will be prepared and kept in box, third person will be asked to take a chit for every study subject, Odd number will be given

0.125% levobupivacaine with fentanyl 2mcg/ml drug and even numbers will be given 0.125% levobupivacaine with dexamethasone 4mg drug till the sample size meet.

Groups

Group LF: 0.125% levobupivacaine with fentanyl 2mcg/ml drug
Group LD: 0.125% levobupivacaine with dexamethasone 4mg drug.

Primary Outcomes

- Analgesic efficacy
- Onset of analgesia
- Total drug dose and top-up requirements

Secondary outcomes

- Hemodynamic stability
- Motor blockade (Bromage score)
- Maternal satisfaction
- Mode of delivery
- Neonatal outcome (APGAR score)
- Adverse effects

Statistical Analysis: Independent t-test and chi-square test, $p<0.05$ considered significant.

RESULTS

A total of 60 patients were enrolled and allocated into two groups: Group LF (n=30), who received 0.125% Levobupivacaine with Fentanyl 2mcg/ml and Group LD (n=30), who received 0.125% Levobupivacaine with dexamethasone 4mg.The. The groups were comparable in terms of demographic and baseline characteristics (Table 1)

Table 1: Demographic and Baseline Characteristics

Characteristics	Group LD	Group LF	p-value
Age (years)	22.03 ± 2.798	22.90 ± 2.928	0.2460
Weight (kg)	62.1 ± 3.96	62.6 ± 3.99	0.6279
Height (cm)	152.83 ± 2.94	153.03 ± 2.37	0.7727
Gestational Age (Weeks)	38.83 ± 0.91	39.13 ± 0.90	0.2049
Cervical Dilatation (cm)	4.40 ± 0.50	4.33 ± 0.48	0.5995

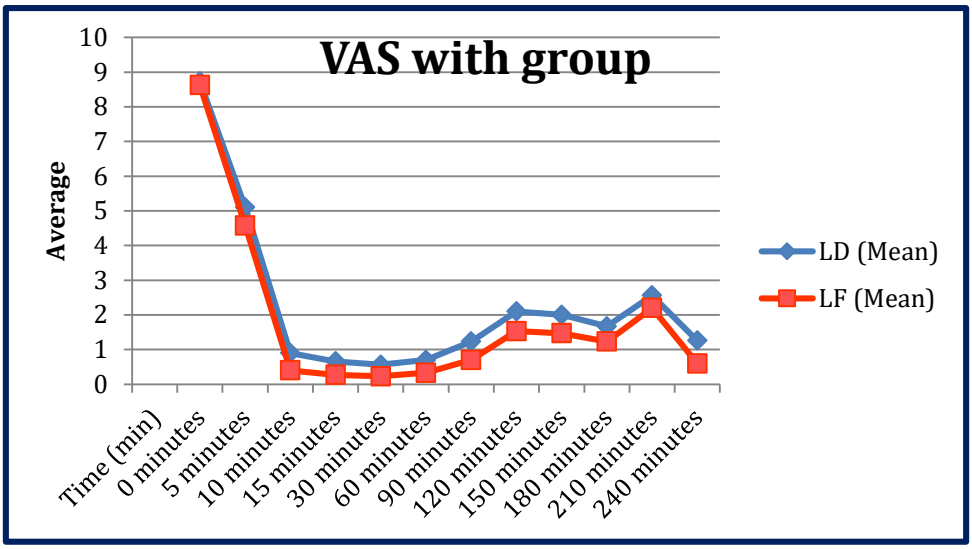
The two groups were comparable in terms of demographic and baseline characteristic and there were no significant intergroup differences.

Table 2: Comparison between the Parameters of two Groups

Parameter	Group LD	Group LF	p-value
Onset of Analgesia (min)	8.83 ± 0.70	7.93 ± 1.01	0.0002
Total Drug Usage	39.17 ± 3.26	30.42 ± 2.71	0.000
Duration of Analgesia (min)	58.37 ± 4.80	90.03 ± 5.14	0.000
Number of Top ups	4.27 ± 0.52	2.87 ± 0.43	0.000
Mode of Delivery (LSCS)	3.33%	6.67%	0.554
Side effects	3%	3%	1.000
Comfort Level	3.57 ± 0.50	3.77 ± 0.43	0.104

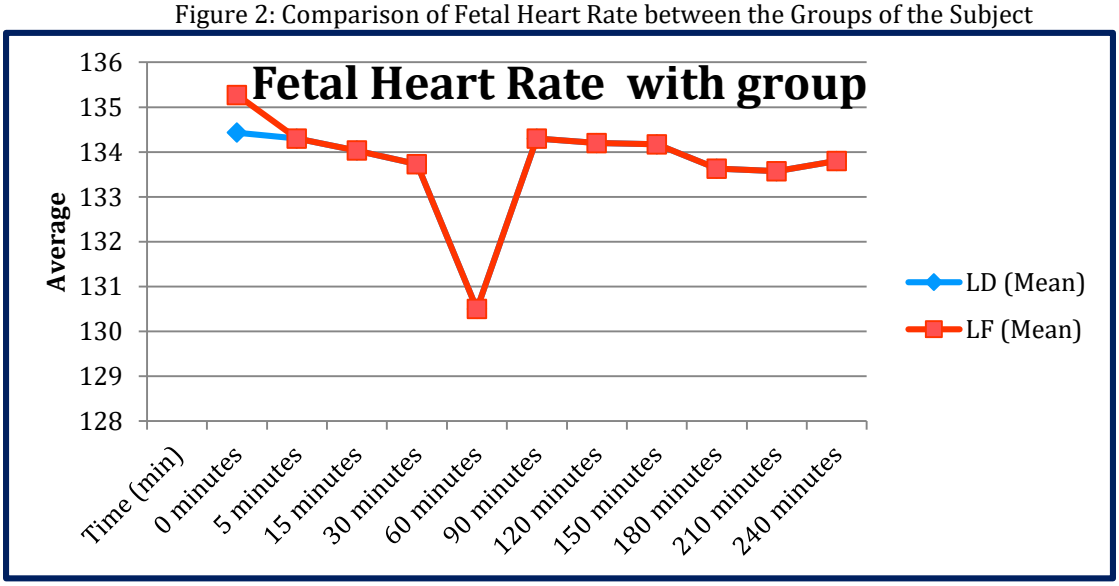
Hemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were recorded at baseline and at regular intervals. There were no significant intergroup differences in hemodynamic stability. Group LF demonstrated a significantly better and faster analgesia, better pain relief, quicker onset of analgesia (p=0.0002), longer duration of analgesia (p=0.000) with lesser usage of drug (p=0.000), lesser number of top ups (p=0.000) greater maternal satisfaction(p=0.104) and fewer opioid related side effects (p=1.000) without compromising maternal or neonatal safety.

Figure 1: Comparison of Vas between the Groups of the Subjects



Pain scores were measured at regular intervals as mentioned above. Mean VAS score was high within first 5min followed by lower scores. Mean VAS scores in Group LD at 5,10,15,30,60,90,120,150,180,210,240 minutes is high where as in Group LF the mean VAS scores are low making p value significant at 5,10,15,30,60,90,120,150,180,210,240 minutes.

Figure 2: Comparison of Fetal Heart Rate between the Groups of the Subject



The above table shows the fetal heart rate monitored throughout the labour. The mean FHR was calculated and P value was statistically not significant.

DISCUSSION

There are several ways to reduce birthing pain. Lumbar epidural analgesia is regarded as the gold standard approach since it is the only treatment that may effectively and totally eliminate pain, making labour a delightful process. The intermittent bolus dosage technique, as opposed to continuous infusion, resulted in a more uniform distribution[15] of the local anaesthetic agent in the spinal area, improving analgesia, allowing parturient mobility, and requiring less medication.[16]

The recently developed drug levobupivacaine has a better safety profile than bupivacaine, a higher sensory motor block differentiation ratio, and a lower risk of neurotoxicity and cardiotoxicity[17] when local anaesthetics and opioids are combined, the analgesic effect takes effect more quickly, there is no motor blockage, and the medications can be taken at low doses, which lowers the systemic toxicity of the local anaesthetics and the side effects of the opioids.[18]

Fentanyl is a synthetic opioid, 75–125 times more potent than morphine. Available as transdermal patches (25–100 mcg/hr) and transmucosal lozenges (200–1600 μg), it acts on μ and κ receptors, causing supraspinal analgesia, anaesthesia, and sedation. It has a fast onset, short duration, and a target site equilibration time of 6.4 minutes. Due to its high lipid solubility, it easily crosses barriers. Fentanyl is metabolized in the liver by N-demethylation via CYP3A4 to norfentanyl and other hydroxylated metabolites. Oral bioavailability is 33%, protein binding 84%, and it's mainly excreted renally. Effective plasma concentrations range between 1–3 ng/ml. Elimination half-life is1.5-6 hours with a clearance rate at1.5L/min which is prolonged in hepatic diseases.

Limitations

To evaluate the neuro behavioural outcome of the newborn, we used only the APGAR score.
Due to budgetary limitations, we did not test the pH of the umbilical cord blood to determine the impact of medications on the acid-base status of the foetus.

CONCLUSION

Levobupivacaine with Fentanyl provides a better analgesia, better pain relief, quicker onset of analgesia, longer duration of analgesia with lesser usage of drug, greater maternal satisfaction and fewer opioid related side effects without compromising maternal or neonatal safety.
These findings support Fentanyl as a clinically effective and well tolerated opioid adjuvant in epidural labour analgesia.

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Conflicts of Interest Statement

The authors declare no conflicts of interest.

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