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EFFECT OF DIFFERENT CONCENTRATIONS OF LEVOBUPIVACAINE ON LABOUR EPIDURAL ANALGESIA: A SINGLE-CENTER OBSERVATIONAL STUDY

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ABSTRACT

Background: Levobupivacaine, the S-enantiomer of bupivacaine, is preferred for obstetric anaesthesia. The lower concentrations of levobupivacaine produce a differential neuraxial block, wherein sensory fibres are blocked with preservation of the motor function.

Aim: This study aims to evaluate and compare the effects of three different concentrations of levobupivacaine (0.25%, 0.125%,0.0625%) on the sensory and motor block, as well as the mode of delivery, during labour epidural analgesia.

Methods: Forty five parturients undergoing normal vaginal delivery under labour analgesia were divided into three groups according to the concentration of levobupivacaine. Each participant received an initial bolus of 10 ml of desired concentration, followed by further doses either on demand or at 90 minutes interval. Sensory block was assessed using the Visual Analog Scale (VAS), while motor block was evaluated with the Bromage Score. Assessments were performed at the baseline, 5, 15 minutes, and then at 30 minute intervals. The incidence of instrumental delivery and cesarean section was recorded.

Results: The VAS was significantly lower with levobupivacaine concentration of 0.25% and 0.125% than 0.0625%. Motor block in the form of Bromage score 1, was observed in 29% of parturients receiving 0.25% levobupivacaine, with 21% of the cases necessitating cesarean delivery. No motor block was observed in the groups receiving 0.125% or 0.0625%.

Conclusion: Levobupivacaine at a concentration of 0.125% is emerged as the optimal choice for labour epidural analgesia, as it provides adequate analgesia without causing motor impairment resulting in a lower incidence of instrumental delivery or cesarean section.

Keywords: Levobupivacaine, Labour Epidural analgesia, Visual Analog scale, Modified Bromage score

INTRODUCTION

Labour pain is recognized as one of the most severe forms of pain experienced by women, and effective pain relief is a cornerstone of modern obstetric care.[1] According to the American Society of Anesthesiologists (ASA), "in the absence of medical contraindications, maternal request is considered a sufficient medical indication for providing pain relief during labour."[2] Despite this clear guidance, at our institute, labour analgesia for vaginal deliveries was not routinely offered prior to this study. This practice was largely based on the misconception that labour epidural analgesia increases the rates of cesarean sections and instrumental deliveries. However, accumulating evidence from contemporary studies demonstrates that low-concentration local anaesthetic regimens do not significantly increase cesarean delivery rates, and the modest

increase in instrumental vaginal delivery rates is influenced by a variety of confounding factors rather than analgesia itself.[3,4]

Levobupivacaine, a long-acting amide local anaesthetic, has gained popularity for labour epidural analgesia due to its favourable safety profile and minimal motor block at lower concentrations. Nonetheless, there remains uncertainty regarding the optimal concentration that balances effective analgesia, maternal satisfaction, and the avoidance of adverse obstetric outcomes.[5] Therefore, our study aims to observe the effects of three different concentrations of levobupivacaine on the incidence of instrumental deliveries and caesarean sections in women receiving labour epidural analgesia.

This study was conducted to compare the effects of three different concentrations of levobupivacaine on the analgesic efficacy, sensory and motor block as well as the mode of delivery during labour epidural analgesia.

Additionally, Study was also performed to compare the analgesic efficacy of different concentrations of levobupivacaine in labour analgesia. And also, to assess hemodynamics of parturient compare the sensory and motor block and to evaluate the incidence of mode of delivery.

MATERIALS AND METHODS

This was a hospital based Observational Study performed in Department of Obstetrics and Gynecology, Jorhat Medical College and Hospital, Jorhat, Assam in the period of 1 year (October 2023 to September 2024)

Study was conducted on 45 pregnant females for normal vaginal delivery. Patients were divided into 3 groups, Group A: received 0.25% of Levobupivacaine, Group B: received 0.125% of Levobupivacaine, and Group C: received 0.0625% of Levobupivacaine by Sampling method: Consecutive sampling. Ethical approval was gained before initiation of study.

Age 20-40 years. Singleton pregnancy with cephalic presentation, in active labour with cervical dilatation <4 cm, Gestational age >38 weeks were the inclusion criteria of the study. Patients with parturient with PIH, History of cardiac, liver, or kidney diseases, allergy to amide local anaesthetics and coagulopathy were excluded.

Parturients explained about the procedure and possible risks and complications. Informed consent of the parturient were taken. Pre-anaesthetic evaluation done. Patient shifted to Operation theatre.

Procedure

- A 18G cannula given and IVF RL 500ml connected. All the standard monitors connected and ECG, NIBP and SPO2 were recorded
- Under all aseptic condition, Epidural space identified using the loss of resistance technique in L3-L4 space.
- A 18G touhoy needle was used to introduce a 20 G multiorifice catheter. (5-6cm)
- VAS was assessed before giving the first dose. Vitals recorded.
- Parturient were randomly assigned to give 10 ml of 3 different concentrations of Levobupivacaine (0.25%, 0.125% and 0.0625%)
- After the administration of analgesia, the variables of interest were measured initially, and at 15, 30, 60, 90, 120 and 180 min.
- A repeat dose of 10 ml of aliquots was given if patient demanded or at 90 minutes interval

Outcome Assessment

- **Onset of sensory block -** Time from injection of the epidural bolus dose till the occurrence of the first painless contraction and the achievement of VAS <3
- **Degree of sensory block** - VAS, motor block and vital signs (heart rate and mean blood pressure)
- **Motor block -** Bromage score
- **Duration of delivery**
- **Incidence** of instrumental delivery and caesarean section.

For statistical analysis, appropriate statistical software SPSS ver. 22 and MS Excel was utilized. The statistical analysis of the quantitative data is provided by the mean and standard deviation. Comparison between the groups were done using analysis of variance (ANOVA). For comparing categorical data; Chi square test was performed. 'p' values of <0.05 is considered as statistically significant between the groups.

RESULT

Out of 45 cases, 3 cases were excluded from study as they did not meet the inclusion criteria and 3 cases underwent caesarean section. The three groups were demographically comparable, with no statistically significant difference in age, weight, height and duration of delivery. ($p>0.05$). Although, duration of delivery was slightly longer in Group 2. The table 1 shows the demographic data of participants in the three groups. Age, weight, height, and duration of delivery were similar among Group 1 (n=11), Group 2 (n=14), and Group 3 (n=14), with no significant differences. This indicates that the groups were comparable.

The table 2 and graph 1 shows the variation in Heart rate at different time intervals, Group 2 (97.32 ± 12.54) has slightly higher mean HR as compared to Group 1 (92.80 ± 7.32) and 3 (92.07 ± 9.80) across time intervals. A statistically significant difference is observed only at 30 minutes ($p = 0.046$), suggesting that HR at this time point is influenced by the concentration between the three groups. At all other time intervals(p-values>0.05), indicating no statistically significant differences in HR among the three concentrations.

From the table 3 and graph 2, it is observed that there were significant differences in MAP at specific time intervals: 15 min, 30 min, and 120 min, indicating that the concentration affects MAP at these points. There is significant fall in MAP after 30 minutes for all the 3 groups. Highest fall in MAP was seen in Group 1 (82.58 ± 9.020) at 120 minutes. ($p<0.03$).

We observed that at 15, 30, 60, 90, 120, and 180 minutes, there was a statistically significant ($p<0.05$) differences in the VAS Score between the groups, suggesting that the VAS scores at these intervals are affected by the concentration. (Table 4 and Figure 4)

The comparison of motor block, sensory level, and delivery outcomes among the three groups shows notable differences. A Bromage score of 1, indicating mild motor block, was seen only in Group 1 (42.8%), while none of the participants in Groups 2 and 3 experienced motor block. The sensory block level was similar across groups, ranging around T8–T11. Regarding delivery outcomes, spontaneous vaginal delivery (SVD) was achieved in all participants in Groups 2 and 3 (100%), compared to 78.6% in Group 1. Cesarean deliveries occurred only in Group 1 (21.4%), while no instrumental deliveries were reported in any group. Overall, Groups 2 and 3 showed better obstetric outcomes and less motor block compared to Group 1 as shown in Table 5.

DISCUSSION

Burke et al.[6] (1999) conducted a randomized, multicentre, double-blind study on 137 pregnant women to compare 0.25% levobupivacaine with 0.25% bupivacaine. Their findings demonstrated that both drugs provided equivalent analgesic efficacy, with similar onset and quality of pain relief. The incidence of motor block was also comparable between the two groups- 34% in the levobupivacaine group and 37% in the bupivacaine group after the first top-up dose- suggesting no significant difference in motor blockade. These results are similar to the findings in our study, which also observed comparable analgesic efficacy and motor block profile.

In a subsequent study, RR Rodriguez et al.[7] (2014) performed a randomized, controlled, triple-blind clinical trial involving 114 parturients, comparing two concentrations of bupivacaine. They reported significantly lower pain scores (VAS) with 0.25% bupivacaine after 30 minutes ($p=0.02$), although no significant differences were observed in maternal vital signs, except for minor variations in heart rate and blood pressure at different time intervals. Our observations were consistent with these findings, showing similar pain relief and hemodynamic stability between groups.

Baliuliene et al.[8] (2018) performed a double-blind RCT assessing low concentrations (0.0625%, 0.1%, 0.125%) of bupivacaine or levobupivacaine via patient-controlled epidural analgesia in 237 parturients. Lower concentrations reduced total anesthetic dose ($P<0.0001$) and cesarean rates (e.g., 0.1% bupivacaine vs. 0.1% levobupivacaine, $P=0.005$), with higher doses increasing motor block ($P=0.033$); satisfaction was similar across groups which aligns with our study.

Asfour et al.[9] (2018) compared three concentrations of levobupivacaine (0.25%, 0.125%, and 0.0625%) in a comparative study of 60 pregnant women. The authors noted lower VAS scores with 0.25% and 0.125% levobupivacaine compared to 0.0625%, indicating superior analgesia with higher concentrations. However, a higher incidence of motor block (39%) was associated with the 0.25% concentration, of which 43% required cesarean delivery. In our study, a similar trend was observed, where 42.8% of patients receiving 0.25% levobupivacaine developed mild motor block (Bromage 1), and 50% of these cases necessitated cesarean section.

Li Zhang et al. [10] (2021) conducted a meta-analysis of nine randomized trials involving 1334 women, comparing moderately high-dose plain local anaesthetics with low-dose local anaesthetic–opioid combinations for labour analgesia. They found no significant differences in assisted vaginal delivery odds ratio [OR] = 1.18; 95% confidence interval [CI], 0.93-1.49) or Caesarean section rates (OR = 0.96; 95% CI, 0.71-1.29), but higher concentrations were associated with increased motor block (OR = 4.05; 95% CI, 2.19-7.48)and reduced pruritus(OR = 0.07; 95% CI, 0.03-0.16. Our findings align with this pattern, as 0.125% levobupivacaine in our study provided effective analgesia with favourable maternal outcomes, whereas 0.25% resulted in more motor block and higher Caesarean rates.

Halliday et al.[11] (2022), in a network meta-analysis of 32 randomized trials comparing high (>0.1%), low (>0.08% to≤0.1%) or ultra-low (≤0.08%) concentration local anaesthetic (bupivacaine or equivalent) for labour epidural, demonstrated that lower concentrations of local anaesthetic for labour epidural analgesia are associated with favourable obstetric outcomes, including higher spontaneous vaginal delivery rates, reduced motor block, and shorter second-stage duration, without compromising analgesia or maternal satisfaction. These findings complement our results, wherein 0.25% and 0.125% levobupivacaine provided superior pain relief compared with 0.0625%; however, the higher concentration (0.25%) was associated with motor block in 29% of parturients and coincided with a 21% cesarean delivery rate. In contrast, no motor impairment was observed at 0.125% or 0.0625%, supporting the premise that intermediate or lower concentrations achieve effective analgesia while minimizing motor effects. This aligns with Halliday et al.'s observations that ultra-low or low concentrations preserve motor function and improve delivery outcomes, highlighting the clinical value of dose optimization to balance analgesia and mobility during labour.

Overall, these studies collectively indicate that both levobupivacaine and bupivacaine at equivalent concentrations provide effective analgesia in labour, with levobupivacaine offering a comparable safety and efficacy profile. However, higher concentrations tend to increase the incidence of motor block, emphasizing the importance of using the lowest effective concentration to achieve satisfactory analgesia with minimal motor impairment.

CONCLUSION

Levobupivacaine at a concentration of 0.125% is emerged as the optimal choice for labour epidural analgesia, as it provides adequate analgesia without causing motor impairment resulting in a lower incidence of instrumental delivery or caesarean section.

Limitations: Trend of lower uptake of epidurals by parturient in our settings and resource limited setting as well as large sample size required to predict result. Factors influenced like mode of delivery are the timing of amniotomy, maternal fever, neonatal birth weight. As this study is a hospital based observational study, further Randomised Controlled Trials can confirm causal relationships under controlled conditions.

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Conflict of Interest: None

Funding: None Declared.

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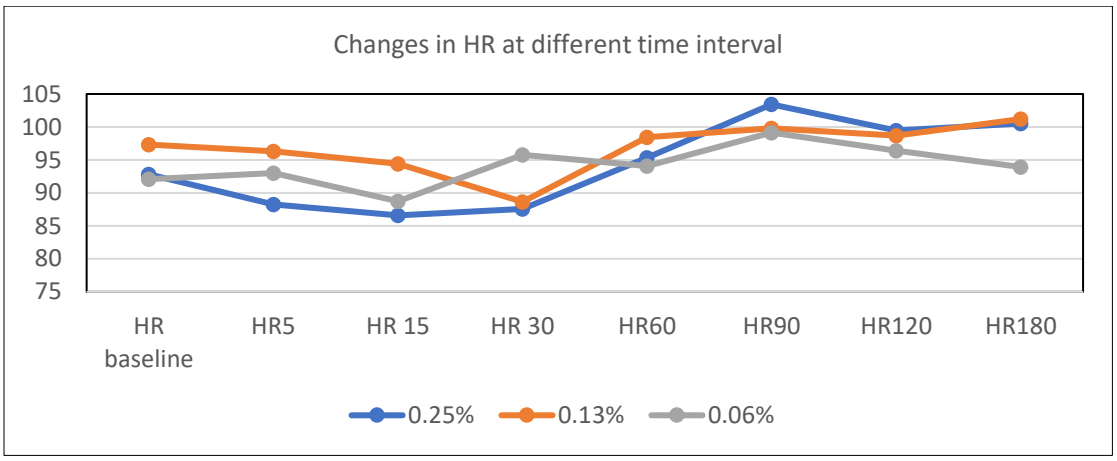
	Group 1(n=11) 0.25%	**Group 2(n=14) 0.125%**	**Group 3(n=14) 0.0625%**	**p-value**
Age (years)	28.25 ± 6.851	26.07 ± 4.196	26.71 ± 4.445	0.615
Weight(kg)	58.58 ± 6.762	59.14 ± 7.921	58.93 ± 6.650	0.818
Height(cm)	155.33 ± 4.793	157.86 ± 5.187	159.21± 6.387	0.915
Duration of delivery	185.25 ± 31.311	210.64 ± 58.066	205.5± 34.793	0.483

Table 1: Demographic Data

Conc. % / Duration	**Group 1(n=11) 0.25%**	**Group 2(n=14) 0.125%**	**Group 3(n=14) 0.0625%**	**p value**
HR 0	92.80 ± 7.32	97.32 ± 12.54	92.07 ± 9.80	0.388
HR 5	88.25 14.111	96.29 ± 6.742	93.00 ± 10.590	0.293
HR 15	86.59 12.91	94.41 ± 11.89	88.73 ± 7.99	0.213
HR 30	87.56 ± 10.10	88.64 ± 8.34	95.79 ± 7.55	0.046
HR 60	95.33 ± 12.529	98.43 ± 11.889	94.07 ± 13.252	0.081
HR 90	103.42± 14.457	99.79 ± 12.324	99.14 ± 13.427	0.111
HR 120	99.45 ± 19.74	98.69 ± 10.21	96.39 ± 13.57	0.868
HR 180	100.53 ±18.70	101.2± 8.83	93.91 ± 11.29	0.338

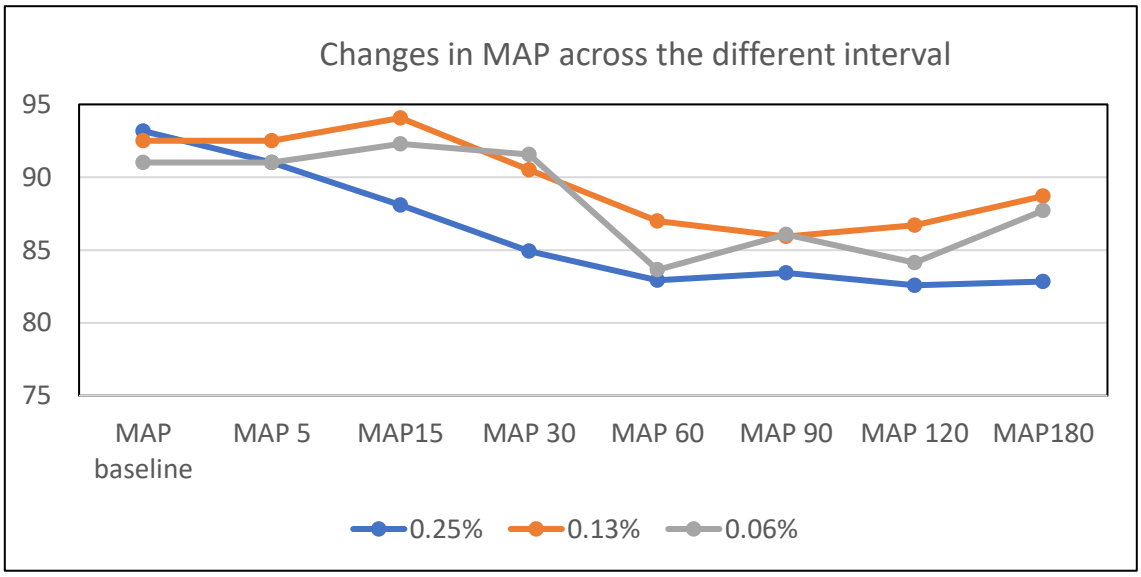
Table 2: Variations of Heart Rate (HR) at different time intervals with different concentration of Levobupivacaine



Graph 1. Variation in Heart Rate at Different time intervals

Conc. % /Duration	Group 1 (n=11) 0.25%	Group 2 (n=14) 0.125%	Group 3 (n=14) 0.0625%	P value
MAP 0 min	93.17 ± 4.448	92.5 ± 9.582	91.00 ± 10.713	0.225
MAP 5 min	91.00 ± 5.705	92.5 ± 9.582	91.00 ± 10.713	0.114
MAP 15 min	88.08 ± 9.317	94.07 ± 8.606	92.29 ± 10.299	0.036
MAP 30 min	84.92± 9.199	90.50 ± 9.197	91.57 ± 8.907	0.004
MAP 60 min	82.92 ± 9.681	87.00 ± 8.086	83.64 ± 9.386	0.265
MAP 90 min	83.42 ± 10.202	85.93 ± 8.871	86.07 ± 7.343	0.406
MAP120 min	82.58 ± 9.020	86.71 ± 8.241	84.14± 9.347	0.033
MAP 180 min	82.83 ±13.197	88.71± 10.462	87.71 ± 8.999	0.853

Table 3: Variations of Mean Arterial Pressure (MAP) at different time intervals with different concentration of Levobupivacaine

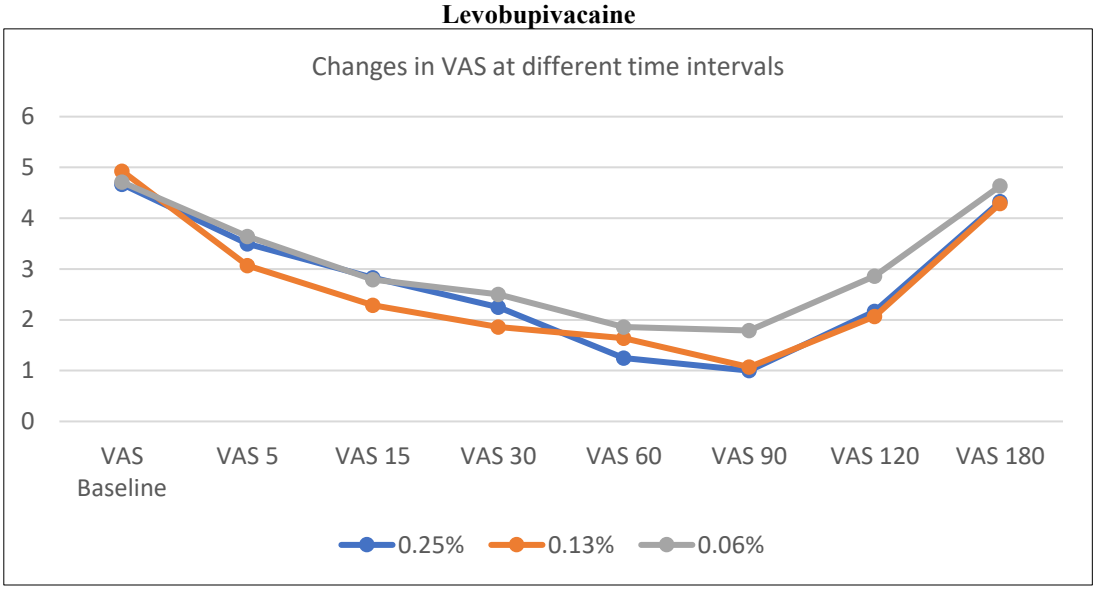


Graph 2. Variation in Mean arterial pressure at different time intervals

Conc. %/ Duration	Group 1 (n=11) 0.25%	Group 2 (n=14) 0.125%	Group 3 (n=14) 0.0625%	P value
VAS 0	4.67 ±1.073	4.93 ± 1.492	4.71 ± 1.139	0.376
VAS 5	3.5 ±0.905	3.07 ± 0.917	3.64 ± 1.277	0.129
VAS 15	2.83± 0.718	2.29 ± 0.825	2.79 ± 0.893	0.000
VAS 30	2.25 ± 0.622	1.86 ± 0.535	2.50 ± 0.941	0.000

VAS 60	1.25 ± 0.622	1.64 ± 1.082	1.86 ± 0.770	0.009
VAS 90	1.00 ± 0.603	1.07 ± 0.829	1.79 ± 1.051	0.001
VAS 120	2.17 ± 1.193	2.07 ± 0.829	2.86 ± 1.099	0.001
VAS 180	4.33 ± 0.778	4.29± 0.914	4.64 ± 1.277	0.002

Table 4: Variations of Visual Analog Score(VAS) at different time intervals with different concentration of Levobupivacaine



Graph 3. Variation in Visual Analog scale at different time intervals

Parameters	Group 1(n=14) 0.25%	Group 2(n=14) 0.125%	Group 3(n=14) 0.0625%
Bromage score(1)	6(42.8%)	0	0
Sensory level	T9 (T8-T11)	T10(T8-T11)	T10(T8-T11)
SVD	11(78.6%)	14(100%)	14(100%)
Instrumental delivery	0	0	0
Cesarean delivery	3(21.4%)	0	0

Table 5 : Motor block, sensory level and modes of delivery

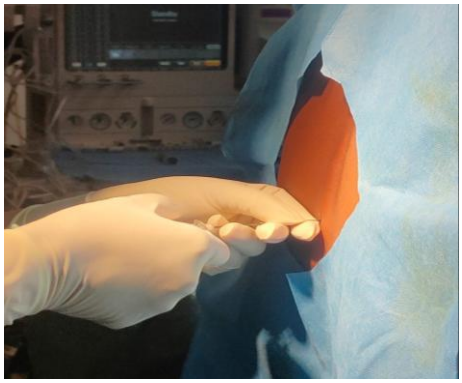


Figure 1: Administration of Epidural Analgesia in Operation Theatre