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A Comparative Study of 0.0625% Levobupivacaine with Fentanyl Versus 0.1% Ropivacaine with Fentanyl for Continuous Epidural Labor Analgesia

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Abstract

Background: Ropivacaine and Levobupivacaine are newer local anesthetic agents in obstetric practice for labor epidural analgesia which have got advantages of less motor blockade and systemic toxicity compared to Bupivacaine. *Objective:* To compare the efficacy of equipotent doses of Ropivacaine 0.1% and Levobupivacaine 0.0625% with fentanyl as continuous infusion for labor epidural analgesia. *Study Design:* A Prospective randomized control trial. *Methods:* After obtaining the institutional ethics committee approval, Patients who met the inclusion criteria were randomly allocated to group B and group R (20 patients in each group) by computer generated random numbers. Patients were randomly assigned to receive either 10 ml of 0.2% ropivacaine or 10 ml of 0.125% levobupivacaine followed by infusion of 0.1% ropivacaine with fentanyl 2 mcg/ml or 0.0625% levobupivacaine with fentanyl 2 mcg/ml at 8 ml/hr continuous epidural infusion. Visual analogue scale (VAS) before epidural bolus dose and throughout the labor were recorded. Maternal heart rate, blood pressure, oxygen saturation, fetal heart rate, maximum sensory level achieved and degree of motor blockade were recorded every fifteen minutes. *Results:* The demographic variables were comparable between the two groups. There was no significant difference in the onset of pain relief, VAS scores during the infusion and level of Sensory block. There was no difference found in the hemodynamic parameters, delivery outcome, patient satisfaction and neonatal outcome. *Conclusion:* Epidural Levobupivacaine provides good and effective analgesia as Ropivacaine for labor pain and hence, a good alternate local anesthetic in labor epidural analgesia with cost limitations.

Keywords: Epidural; Labor analgesia; Levobupivacaine; Ropivacaine.

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Introduction

Labor pain is one of the most severe pain which may lead to unpleasant experiences when not adequately treated and it may lead to devastating consequences in the presence of cardiac comorbidities in a patient. Labor analgesia is an age-old practice started in 1847 with ether by JY Simpson and historic incident in labor analgesia by chloroform administration to Queen Victoria by John Snow in 1853.[1] Even though

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various non-pharmacological and pharmacological methods are available for labor analgesia, epidural analgesia remain the gold standard and most practiced technique. The advantages are continuous and effective analgesia with minimal systemic side effects to mother and foetus compared to inhalational agents and systemic opioids. Also, it has got the advantage of conversion to anesthesia for cesarean section.

Lower concentrations of local anesthetics reduce the motor blockade and when combined with opioids like fentanyl improves the quality of analgesia.[2,3,4] Bupivacaine is the commonly used local anesthetic which provides good analgesia but with high motor blockade potential and cardiotoxicity on systemic absorption. Ropivacaine produces more sensory and less motor blockade than bupivacaine with less systemic toxicity.[5,6,7] Levobupivacaine is one of the newest local anesthetic with good sensory and minimal motor blockade effects and minimal cardiotoxicity.[8] This study is done to compare the efficacy of Ropivacaine and Levobupivacaine in providing epidural analgesia for labor.

Materials and Methods

This study was a prospective randomized double blinded control trial involving 40 parturients (20 in each group) in a tertiary care hospital after obtaining institutional ethics committee approval.

Primigravida as well as multigravida patients with previous normal delivery of age group between *18 and 35* belonging to ASA physical status I and II who were in active labor with cervical dilatation of *3 to 4 cm* were included in the study. Those who have contraindications to epidural block, failed epidural block and complications associated with pregnancy like preterm labor, multiple gestation and previous cesarean sections were excluded.

All the patients meeting the inclusion criteria were counselled for labor analgesia and informed consent obtained after explaining the procedure. History of the patient was collected and routine basic blood investigations done as per our hospital protocol. Patients were then randomly allocated into two groups (R and B) by computerized randomized list.

Before epidural placement 18G intravenous cannula was established in all patients and monitors like pulse oximeter and non-invasive BP were applied. Under strict aseptic precautions, lumbar epidural space identified by loss of resistance technique to air with 18G Tuohy needle and *10 ml* LOR syringe. Epidural catheter threaded 5 cm into the space and secured in position. Epidural test dose given after negative aspiration for blood or CSF. Initial bolus of *10 ml* of 0.2% Ropivacaine (group R) or 0.125% Levobupivacaine (group B) was given. Additional *5 ml* boluses were given if VAS score was more than 3 even after *15 mins* of initial bolus dose. Analgesia was maintained with continuous infusion of 0.1% Ropivacaine with *2 mcg/ml* fentanyl (group R) or 0.0625% Levobupivacaine with *2 mcg/ml* fentanyl (group B) at *8 ml/hr* using a syringe pump. Further boluses of *5 ml* of Ropivacaine 0.2% or Levobupivacaine 0.125% were given for breakthrough pain. The total number of boluses required were recorded. The study was concluded at the time of normal or assisted vaginal delivery or when decided for cesarean section. Epidural anesthesia was provided through the catheter in cases converted to cesarean section.

Both the patient and anesthesiologist in labor room were blinded to the study solutions. Various maternal parameters like pulse rate, systolic and diastolic blood pressure, oxygen saturation, level of sensory blockade, VAS score displays in (**Fig. 1**) and modified Bromage scale for motor blockade shows in (**Table 1**), Foetal heart rate was monitored continuously.

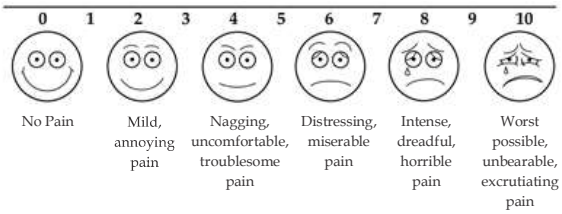

Fig. 1: Visual analog scale

Table 1: Assessment of motor block by modified Bromage scale

Grade 0	No motor block
Grade 1	Inability to raise extended leg, able to move knees and feet
Grade 2	Inability to raise extended leg and move knee, able to move feet
Grade 3	Complete motor block of the lower limbs

The clinical outcomes like time to achieve adequate pain relief (VAS ≤ 3), maximum sensory level attained, degree of motor block, duration of labor, mode of delivery, patient satisfaction, neonatal outcome (APGAR score) were studied and compared in both the groups.

Results

20 patients were studied in each group who were comparable in terms of demographic data like age,

weight, height and ASA physical status. Parity and cervical dilation at the onset of labor were also comparable between the groups.

The mean onset of pain relief in group B (*11.65 ± 1.60 mins*) though slightly less than in group R (*12.5 ± 1.39 mins*) displays in (**Fig. 2** and **Table 2**). This variable does not have any statistical significance difference ($p = 0.08$). Statistical analysis was calculated using student independent *t*-test. In group B 45% had a sensory level of T6 and 60% had T8 level, whereas in group R 50% had T8 and 45% had T6. The statistical analysis was done by Chi–square test and it was found to be statistically insignificant displays in (**Fig. 3**). On comparing the VAS score, there was a noticeable decrease in the pain levels after administration of epidural local anesthetic. The pain levels did not go above visual analog score of 3 during infusion in both the groups displays in (**Fig. 4**). The variation in pain scores did not have any statistical significance. The motor blockade was not present in both the groups and all patients had grade 0 in modified bromage scale and hence statistically insignificant.

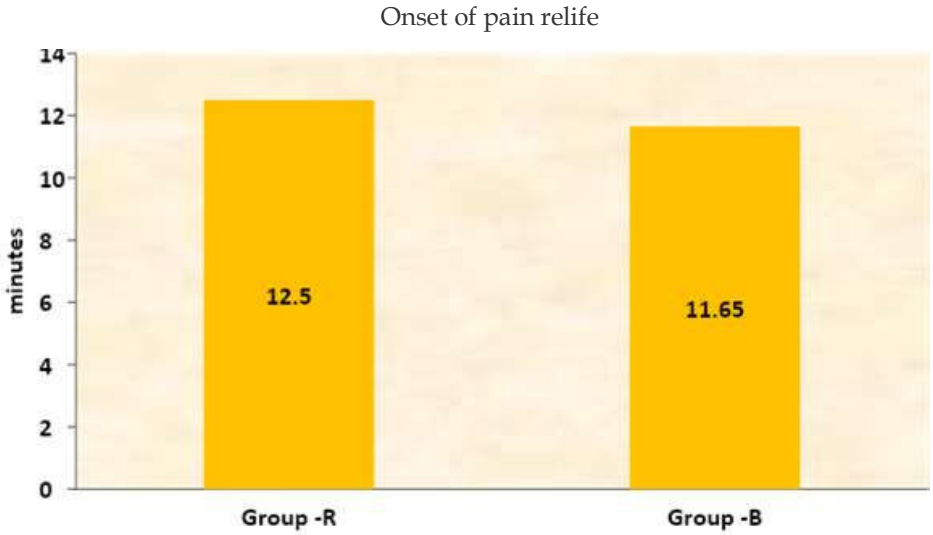

Fig. 2: Comparison of onset of pain relief between the two groups. Both groups were comparable with no statistical significance.

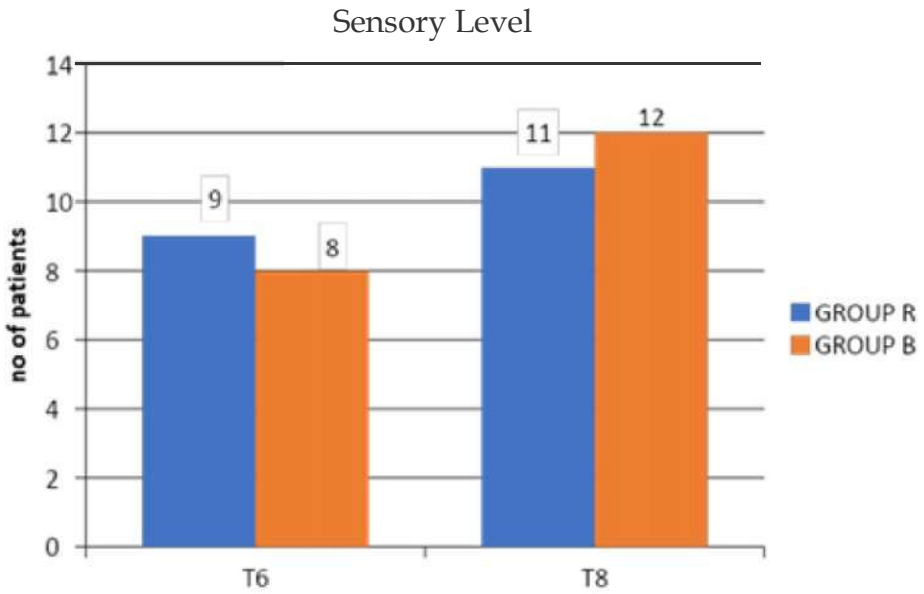

Fig. 3: Comparison of sensory level between the two groups. Both groups were comparable with no statistical significance.

Table 2: Comparison of various parameters between the groups

Parameters	Group B	Group R	*p* - value
Onset of analgesia (*min*)	11.65 ± 1.6	12.5 ± 1.39	*p* = 0.08*
Duration of labor (*min*)			
I stage	182.65 ± 21.99	183.50 ± 25.06	*p* = 0.91*
II stage	29.71 ± 2.22	30.39 ± 2.30	*p* = 0.38*
Nature of delivery (normal/assisted/ LSCS)	15/2/3	15/3/2	*p* = 0.81*
Patient satisfacation (Good/Fair/Poor)	14/6/0	14/6/0	*p* = 1.00*
APGAR Score (out of 10)			
1 *min*	7.85	7.80	*p* = 0.68*
5 *min*	8.90	8.85	*p* = 0.64*

*All are statistically insignificant

The mean duration of labor in 1st stage in group B (182.65 ± 21.99) though slightly less than in group R (183.50 ± 25.06) which carries no statistically significant difference ($p = 0.11$). The mean duration of 2nd stage of labor in group B (29.71 ± 2.22) though slightly less than in group R (30.39 ± 2.30) without any statistically significant difference ($p = 0.89$). Statistical analysis was calculated using student independent *t*-test.

The hemodynamic variables like pulse rate, systolic and diastolic blood pressure of the mother and fatal heart rate recorded at regular intervals were analysed between the groups at various time points and found to be comparable.

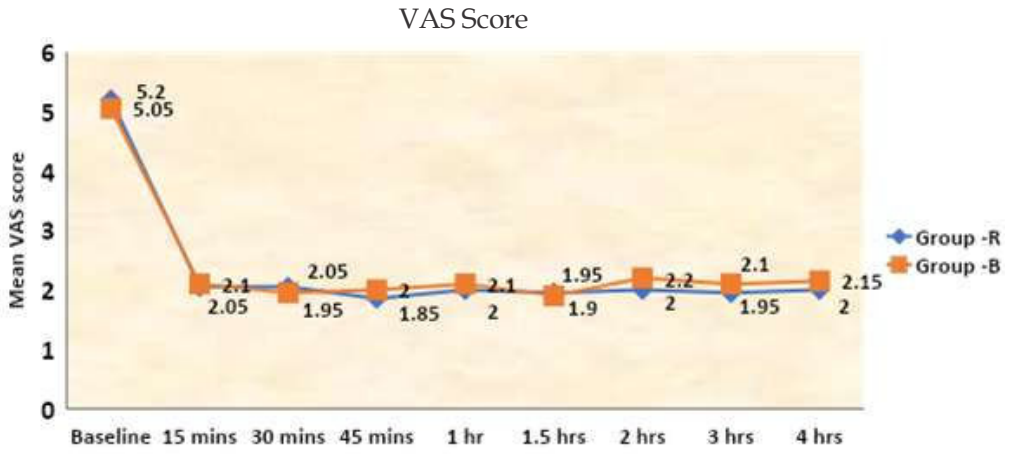

Fig. 4: Comparison of VAS score between the groups. Patients in both the groups had drastic reduction in VAS score after bolus dose and score of less than 3 was maintained throughout the labor and statistically insignificant when compared.

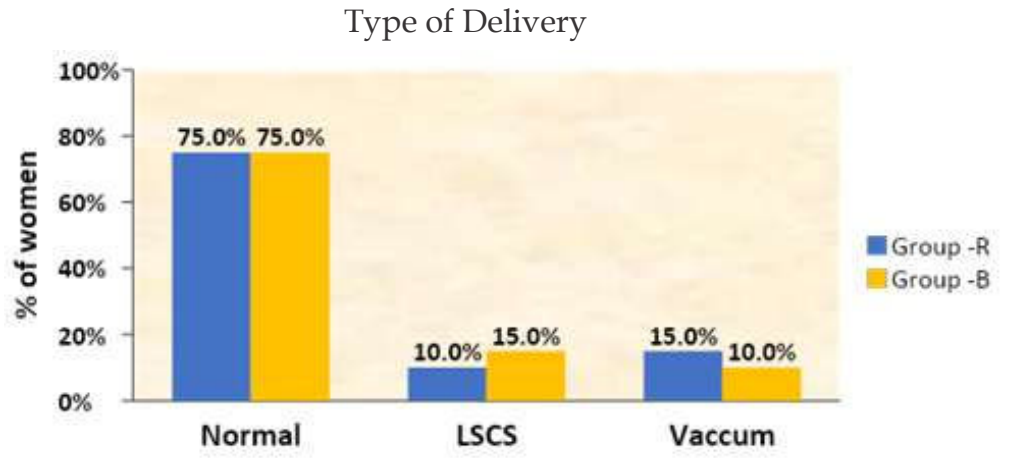

Fig. 5: Comparison of type of delivery between the two groups. Both groups were comparable with no statistical significance.

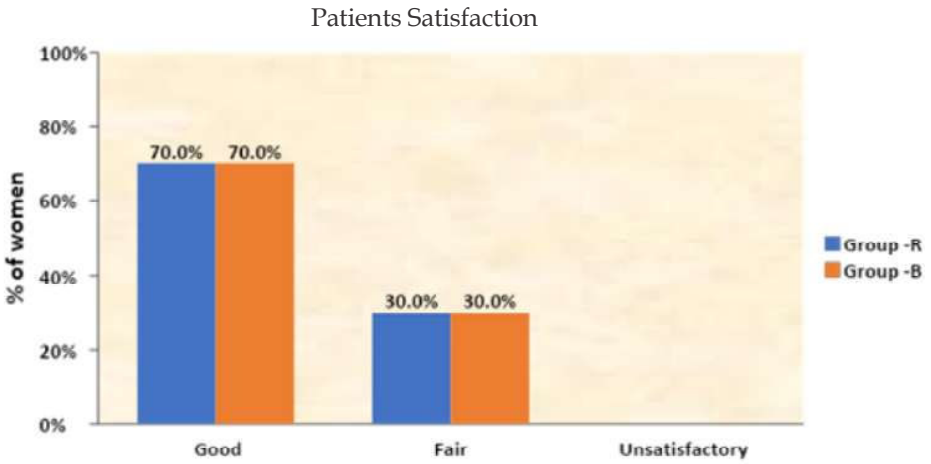

Fig. 6: Comparison of patient satisfacation between the two groups. Both groups were comparable with no statistical significance.

Group R had 75% of normal delivery, 10% had LSCS and 15% had vacuum where as in Group B, 75% of normal delivery, 15% had LSCS and 10% had vacuum displays in (**Fig. 5**). Their distribution among groups was not significant (p = 0.81) in statistical analysis calculated using chi-square test. The overall patient satisfaction was graded as good, fair and unsatisfactory. Group R as well as Group B, both groups had 70% good satisfaction and 30% fair satisfaction displays in (**Fig. 6**). Their distribution among groups was not statistically significant (p = 1.00) with chi-square test. The neonatal outcome was rated with APGAR score at *1 and 5 mins*. The chi-square test reveals that the values were not statistically significant at *1 and 5 mins*. Two patients in group R and one patient in group B had nausea. Hypotension was present in 2 patients in group R and 3 patients in group B. We observed that the complications in both the group were statistically insignificant in ANOVA two-way test.

Discussion

In our study, we used initial bolus of *10 ml 0*.125% Levobupivacaine and 0.2% ropivacaine and maintained with low concentration of equipotent doses of 0.0625% Levobupivacaine with fentanyl *2 mcg/ml* and 0.1% ropivacaine with fentanyl *2 µg/ml* at a rate of *8 ml/hr* as continuous infusion the parturients were comparable in regards to age, comorbid conditions, ASA grading, parity and Cervical dilatation in both the groups.

Pain Relief

In our study. we found that the mean VAS score was around 5.2 in Levobupivacaine group and 5.01 in ropivacaine group. This has been reduced to 2.01 in Levobupivacaine group and 2.05 in ropivacaine group *15 mins* after epidural administration of local anesthetic. The VAS score was further reduced to a minimum. There was no clinically demonstrable difference in the onset of pain relief. The patient satisfaction was also comparable between the two groups.

This was consistent with the results obtained by Supandji M[9] *et al*. when they compared 0.2% ropivacaine and 0.2% levobupivacaine. The Preblock visual analog scale (VAS) score and VAS score after five, ten, *15, 20, 25* and *30 min* from time (0) and VAS at time of request for additional analgesia (time) were recorded and it was found to be comparable in both the groups.

Purdie and McCrady in 2004[10] demonstrated that 0.1% ropivacaine and 0.1% levobupivacaine with 0.00002% fentanyl provided comparable pain relief labor epidural analgesia and also insignificant differences in terms of local anesthetic consumption, onset and duration of analgesia, sensory and motor blockade, mode of delivery, neonatal outcome and patient satisfaction. Similar results are encountered in other studies[11,12] comparing ropivacaine and levobupivacaine for labor analgesia.

Motor Blockade

Both Ropivacaine and Levobupivacaine did not cause motor blockade in our study as the concentrations used were low which was demonstrated in similar other studies.[9,10,11] Finegold *et al.*[13] and Halpern *et al.*[14] demonstrated the superiority of ropivacaine to bupivacaine regarding motor blockade in labor epidural analgesia but

Beilin *et al.*[15] found levobupivacaine produced less motor blockade than ropivacaine and bupivacaine. However, Wang *et al.*[16] observed no differences in motor blockade among bupivacaine, ropivacaine and levobupivacaine in low concentrations.

Mode of Delivery

In our study. we had comparable numbers in mode of delivery between Levobupivacaine group and Ropivacaine group with no statistical significance. Our study results coincide with the study done by Hui-Ling Lee *et al.*[12] comparing Levobupivacaine 0.06% and Ropivacaine 0.08% with fentanyl and found that there was no difference in mode of delivery in both the groups. Finegold *et al.*[13] observed an instrumental vaginal delivery rate of 18% in ropivacaine group and 28% in bupivacaine.

Fetal and neonatal outcome

In our study. the foetal heart rate during the process of labor analgesia was within normal limits. There was no incidence of post epidural foetal bradycardia. The APGAR score was also not statistically significant. This was consistent with the studies done by Hui Ling Lee *et al.*[12] and Beilein *et al*.[15] comparing ropivacaine and levobupivacaine.

Complications

The complications like nausea, vomiting and hypotension were observed in both the groups and it was found to be statistically insignificant.

Conclusion

Our study concludes that pain relief offered by epidural Levobupivacaine is as good and effective as epidural Ropivacaine. It is comparable in terms of pain relief, motor blockade, sensory level achieved, patient satisfaction and neonatal outcome. Hence, Levobupivacaine is an effective alternative to Ropivacaine in labor epidural analgesia with cost limitations.

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Presentation at a meeting: Nil

Conflicting Interest: Nil

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