



Walking Epidural: Levobupivacaine versus Ropivacaine

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Abstract

Background and Aims: Lumbar epidural analgesia is the gold standard technique for labour analgesia. This study was designed to evaluate the efficacy of local anaesthetics (0.1% levobupivacaine and 0.1% ropivacaine) with fentanyl 2µg/ml (quality of analgesia, motor blockade & duration of labour along with maternal satisfaction and foetal outcome) in epidural labour analgesia by intermittent bolus technique.

Material & Method: In this prospective, randomized, double blinded study, 60 primigravida were randomly assigned into two equal groups. Group A received 15ml 0.1% ropivacaine with 2µg/ml fentanyl and Group B received 15ml 0.1% levobupivacaine with 2µg/ml fentanyl. The onset, peak duration of analgesia, duration of labour and motor blockade was noted as primary outcome. Demographic profile, maternal satisfaction, mode of delivery and neonatal outcome were noted as secondary outcome.

Result: Levobupivacaine-fentanyl provided faster onset of analgesia, prolonged duration of action and reduced duration of labour with satisfactory maternal and foetal outcomes. However, ropivacaine-fentanyl provided better ambulation in parturients.

Conclusion: Low dose local anesthetics when used with the short acting opioids like fentanyl provide excellent maternal satisfaction, lesser or no motor blockade and good neonatal outcome.

Keywords: Epidural analgesia, levobupivacaine, ropivacaine, fentanyl.

Introduction

Pain during childbirth is called labour pain. It is the most severe pain women will endure in their life time. Some authors are in opinion that pain of childbirth increases the bond between mother and foetus. There are no other benefits for which a woman should be subjected to such terrifying pain. Rather severe pain may land up in maternal cardiac dysfunction and foetal distress.

Painless labour is every mother's right. Pain relief in labour has always been associated with myths and controversies. Hence, providing effective and

safe analgesia during labour has remained an ongoing challenge.

Modern neuraxial labour analgesia reflects a shift in obstetrical anesthesia, thinking away from a simple focus on pain relief and towards a focus on the overall quality of analgesia^[1].

With the advancement in the field of anaesthesiology, it is now possible to render pain free labour. Lumbar epidural analgesia is the gold standard technique for pain control in obstetrics that is currently available.

Ambulatory or Walking Epidural has gained popularity because of preservation of motor function and subjective somatic sensation. Epidural injection of a local anaesthetic combined with an opioid provides a more rapid onset of analgesia with little motor blockade. It allows both the drugs to be used in lower concentration, thereby reducing the risk of local anaesthetic systemic toxicity as well as opioid side effects^[2,3,4].

There are various studies by different researchers comparing low dose anaesthetics with or without opioids with varying results in terms of quality of analgesia, motor blockade, maternal satisfaction as well as neonatal outcome.

In this study, we hypothesize that intermittent bolus administration of low dose levobupivacaine (0.1%) with fentanyl (2µg/ml) provide better quality of analgesia than similar dose ropivacaine (0.1%) with fentanyl(2µg/ml).

Materials and Method

Following approval from Institutional Ethical Committee, 60 primigravida with uncomplicated singleton pregnancy were enrolled in our study. The study was conducted for a period of 2years in labour room of Obstetrics and Gynaecological dept. of VIMSAR, Burla. It is a prospective, randomized, double blinded study. Written informed consent was obtained from them.

Inclusion Criteria: 1. Age (18-35years), 2.ASA grade 1,2, 3. Singleton pregnancy, 4. Gestational age (18-35 years), 5. Vertex presentation, 6. Cervical dilatation: 4-5cm

Exclusion Criteria: 1. High risk pregnancies (twin, molar, breech), 2.Parturient having concomittent disease (diabetes, hypertension, tuberculosis, sickling, etc), 3.Known allergy to study drugs (levobupivacaine, ropivacaine, fentanyl), 4. Patients who have received other forms of analgesia, 5.Contraindications to epidural (kyphosis, scoliosis, local infection over lumbar spine region, bleeding diathesis).

Study Tools: 1.Epidural kit, 2.VAS scale(0-100), 3.Modified Bromage scale, 4.Apgar score

Study Drugs: 1.Levobupivacaine hydrochloride (0.1%), 2. Ropivacaine hydrochloride (0.1%), 3. Fentanyl citrate(2µg/ml)

Parturients were randomly assigned to one of the two groups: Group A and Group B of 30 each.

Group A: 30 parturients who received 0.1% Ropivacaine with fentanyl 2 µg/ml.

Group B: 30 parturients who received 0.1% Levobupivacaine with fentanyl 2 µg/ml.

Sample Size

According to previous study by Gautier et al^[5], the mean onset time for ropivacaine was 14 ± 6 min. On hypothesizing that levobupivacaine has better potency than ropivacaine to find a difference of 4min mean onset time with a power of 80% and α error 0.05, the sample size required was 29 in each group. Considering the dropouts, we have taken a sample size of 30 in each group.

Sample size formula:

$$[(Z\alpha/2 + Z\beta)2 \times \{2(\delta)2\}]$$

$(\mu1 - \mu2)2$

$\mu1$ = mean change in onset of analgesia in group A

$\mu2$ = mean change in onset of analgesia in group B

$\mu1-\mu2$ = difference in onset of analgesia between two groups

δ = standard deviation

$Z\alpha/2$ = level of significance, for 5% this is 1.96

$Z\beta$ = depends on power, for 80% this is 0.84

Methodology

An 18G IV cannula was inserted, NIBP and pulse oximeter monitors were attached and then patient was started on an infusion Ringer lactate solution. The patient was then positioned in sitting position. The best inter lumbar space between L3 and L4 was identified and infiltrated with 2% lignocaine. Once the catheter was satisfactorily inserted, a small test dose of local anaesthetic (3ml of 2% Lignocaine with Adrenaline 1:200000) was injected via the catheter to rule out intravascular or intrathecal placement of catheter. The study solution was prepared by an anaesthetist not directly involved in this study. If there were no signs of motor block (intrathecal placement) or tachycardia (intravascular placement) after

5minutes the patient was turned supine. A bolus dose 15ml of the test drug was given to either group.

Breakthrough pain was managed with 10ml top up dose of either 0.1% Ropivacaine with fentanyl or 0.1% levobupivacaine with fentanyl depending on the study group they were involved.

An observer not involved in epidural or drug administration was allotted to note down the following observations of two groups: 1.Onsetof analgesia measured by the time from administration of drug to first painless contraction, 2.Peak of analgesia is assumed when mother is most satisfactory, 3.Duration of analgesia is measured as the time from bolus dose to first top up requirement, 4.Quality of analgesia assessed by using VAS score, 5.Degree of motor blockade by using Modified Bromage Scale, 6.Duration of labour and modes of delivery, 7.Neonatal APGAR score, 8.Maternal satisfaction by Verbal Scoring System, VSS(0-3)

A Visual analogue scale (VAS) on a 10 cm line in which 0 cm represents no pain and 10 cm (100 mm) represents the worst imaginable pain, was used to assess pain.

A verbal scoring system (VSS) was used to correlate the VAS scores, and identify the time of onset of analgesia, as shown below: 0= can feel no pain or pressure, 1 = can feel contractions but no pain is there, 2= aware of pressure or tolerable discomfort, 3= distressing pain or pressure. The verbal scores were recorded together with the VAS scores. Sensory blockade was assessed by evaluating response to pinprick at 30 min intervals.

Motor blockade was assessed at 5 min, 10 min, 15 min, 30 min and henceforth at hourly intervals by using a modified Bromage scale for measuring ambulation during labour.

Modified Bromage scale: Score 0 = no weakness, able to straight leg raise against resistance, Score 1 = Inability to raise extended leg but able to flex knee, Score 2 = unable to flex knee but able to flex ankle, Score 3 = unable to move any joint of lower limb. Ambulation was allowed on demand

if score = 0, and there was no orthostatic hypotension and no obstetric contraindications existed. Parturients were encouraged to walk to the delivery table in the second stage under supervision of medical personnel's.

APGAR score of the newborn was recorded at 1 min and 5 min after birth with the help of a paediatrician. Mode of delivery, time from insertion of epidural catheter till delivery, duration of first stage and duration of second stage of labour were recorded. Maternal satisfaction was assessed 24 hours after delivery using a verbal scoring system (1= satisfied, 2= neutral, indifferent, 3= dissatisfied).

Systolic blood pressure was maintained throughout procedure at baseline levels with fluids, IV ephedrine, and IV phenylephrine as per requirement.

Statistical Analysis

All statistical analysis were performed using SPSS (Statistical package for social sciences) version 22 for windows. Descriptive statistics are presented as mean \pm 1SD. Component bar, line and pie diagrams were drawn as and when required. Independent sample & paired t-tests, chi-square tests, mean and standard deviation calculations and percentage calculations were done as required. The P-values obtained were interpreted as follows:>0.05=Not significant(NS), <0.05= Significant (S),<0.01=Definitely significant, <0.001=Highly significant

Result

The mean age (years) is 23.97 \pm 3.801 in group A and 23.33 \pm 3.058 in group B. The mean gestational age(weeks) in group A is 38.93 \pm 0.901 and in group B it is 38.50 \pm 0.900. The mean weight (kg) of patients in group A and B are 55.33 \pm 6.50 and 57.77 \pm 7.610 respectively. The mean height (cm) in group A is 156.11 \pm 3.484 and in group B is 154 \pm 3.451 (Table 1). All the demographic parameters are comparable in two groups.

The mean onset of analgesia is earlier in levobupivacaine group with longer mean duration of analgesia (table 2, figure 1). Ropivacaine group

is found to have long period of duration of labour. P-value is <0.05 which is statistically significant. (table 3)

On assessing the sensory and motor blockade, sensory blockade is comparable between two groups whereas motor blockade at the end of delivery is lesser in ropivacaine group, p-value (0.004) is statistically significant (table 4, figure 2). Ambulation is better in ropivacaine group. 26 out of 30 patients walked at once under supervision. (table 5, figure 3a, 3b)

Maternal satisfaction was satisfactory in both the groups. 28 patients in group A and 27 patients in

group B were able to feel contractions of uterus without pain. (figure 4)

86% in ropivacaine group and 90% in levobupivacaine group delivered by normal vaginal delivery, which was comparable and satisfactory in both the groups.(table 6, figure 5a, 5b)

The APGAR score at 1min was 6.87-1.592 in group A and 7.43-1.040 in group B .The scores at 5min was also satisfactory in both the groups.(table 7).

Table 1: Demographic Profile of Parturients

Variables	Group A (Mean±SD)	Group B (Mean±SD)
Age(years)	23.97±3.801	23.33±3.058
Gestational age(wks)	38.93±0.901	38.50±0.900
Height (cm)	156.11±3.484	154±3.451
Weight(kg)	55.33±6.50	57.77±7.610

Table 2: Onset of Analgesia, Peak of Analgesia, Duration of Analgesia

Time (min)	Group A (mean±SD)	Group B (mean±SD)	p-value
Onset of analgesia	16.33±4.299	13.83±2.745	0.011(S)
Peak of analgesia	19.20±4.460	21.73±4.373	0.033(S)
Duration of analgesia(1 st top-up time)	73.83±22.534	110.83±34.231	0.000(S)

Table 3: Duration of Labour

Time (min)	Group A (mean±SD)	Group B (mean±SD)	p-value
Duration of 1 st stage (epidural to full dilatation)	270.33±90.696	223.67±59.378	0.022(S)
Duration of 2 nd stage (full dilatation to delivery)	75.93±30.438	43.23±24.625	0.000(S)
Total duration of labour	346.27±111.767	266.90±76.343	0.002(S)

Table 4: Visual Analogue Scale (VAS), Modified Bromage Scale (MBS)

Variable	Group A (mean±SD)	Group B (mean±SD)	p-value
VAS before epidural	70.50±16.523	66.83±17.195	0.403(NS)
VAS at the end of delivery	8.33±6.205	10.86±8.353	0.191(NS)
MBS before epidural	00	00	-
MBS at the end of delivery	0.20±0.407	0.48±0.574	0.033(S)

Table 5: Degree of Ambulation

	Group A (mean±SD)	Group B (mean±SD)	Chi-square value	p-value
Walked atleast once	26	17	6.6484	0.009(S)
Did not ambulate	4	13		
Total	30	30		

Table 6: Mode of Delivery

	Group A (mean±SD)	Group B (mean±SD)	Chi square value	p-value
Vaginal delivery	26(86.6%)	27(90%)	0.1617	0.687(ns)
Instrumental assisted	4(13.3%)	3(10%)		
Total	30	30		

Table 7: APGAR Score

APGAR	Group A (mean±SD)	Group B (mean±SD)	p-value
1 min	6.87±1.592	7.43±1.040	0.108(NS)
5 min	8.77±0.774	8.83±1.085	0.785(NS)

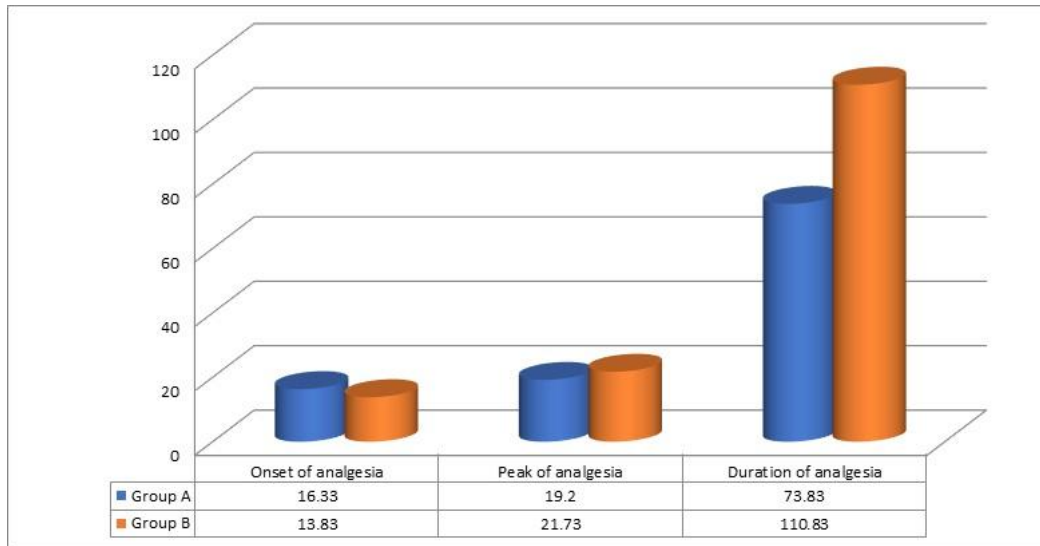


Figure 1: Onset of Analgesia, Peak of Analgesia, Duration of Analgesia

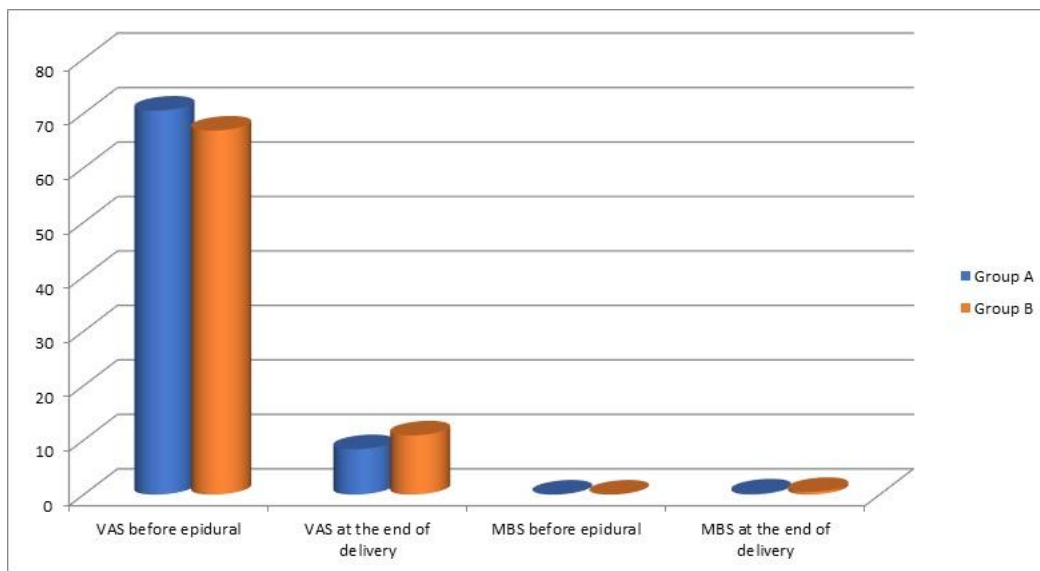


Figure 2: Visual Analogue Scale (VAS), Modified Bromage Scale (MBS)

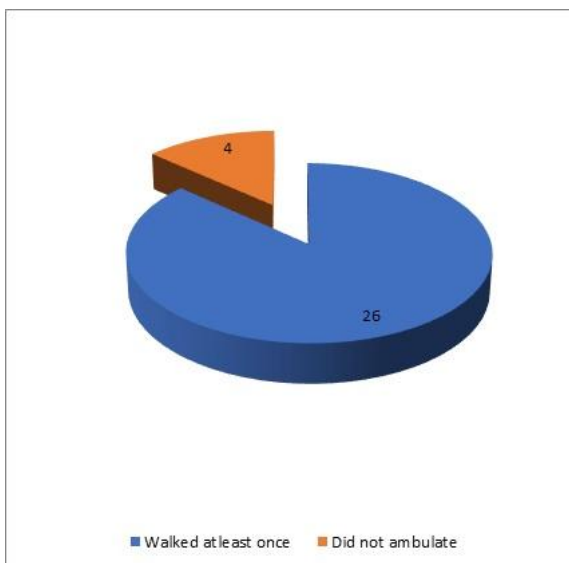


Figure 3a: Degree of Ambulation (Group – A)

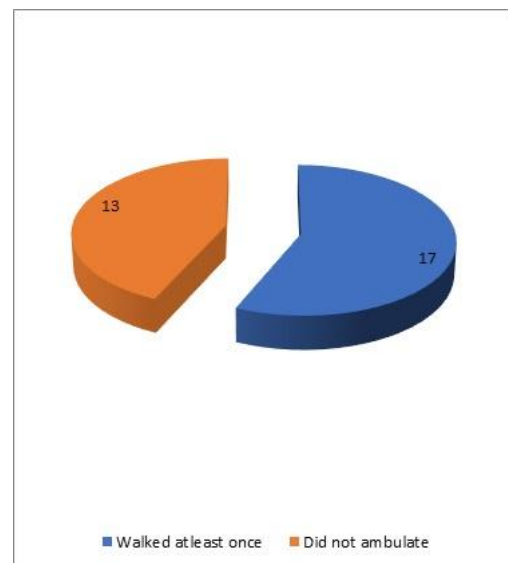


Figure 3b: Degree of Ambulation (Group – B)

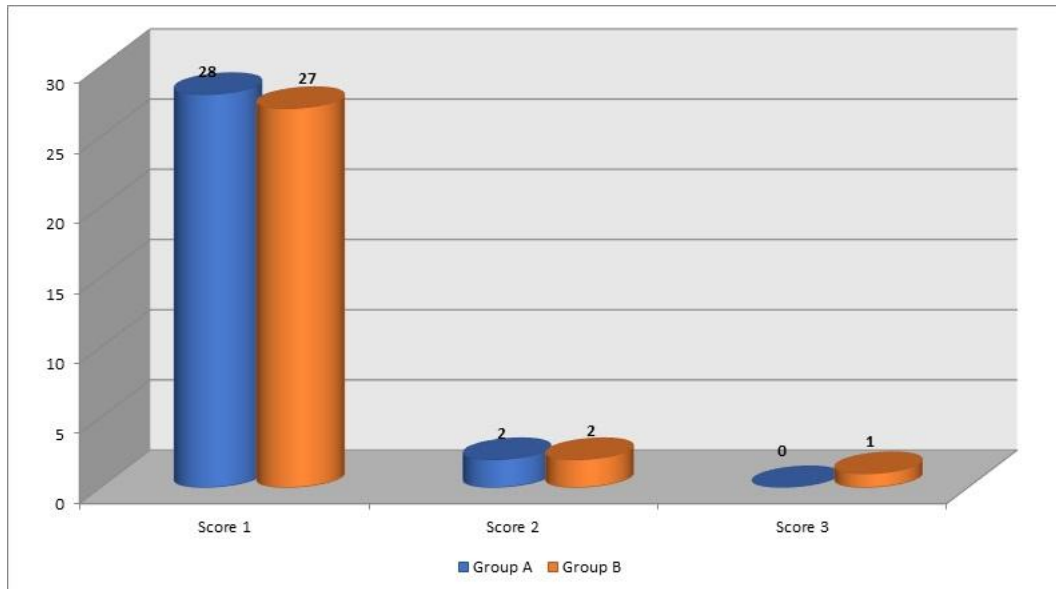


Figure 4: Maternal Satisfaction Score

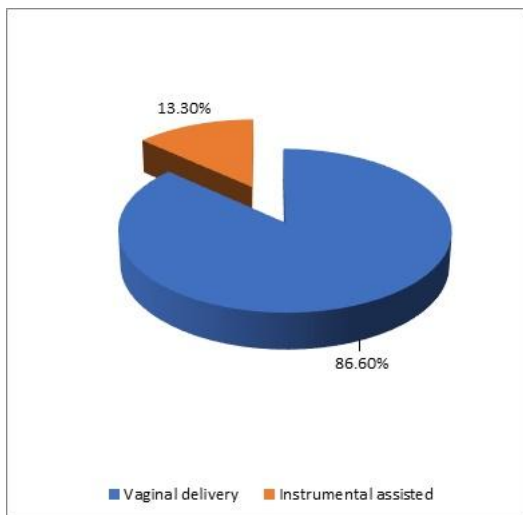


Figure 5a: Mode of Delivery (Group-A)

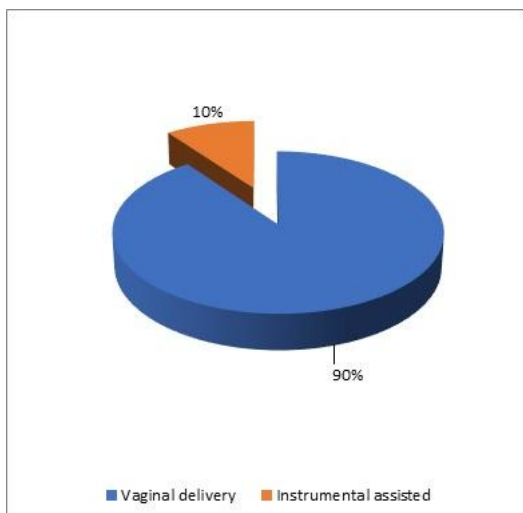


Figure 5b: Mode of Delivery (Group-B)

Discussion

The present piece of work “WALKING EPIDURAL: LEVOBUPIVACAINE VERSUS ROPIVACAINE” has compared the epidural 0.1% levobupivacaine with 2µg/ml fentanyl and 0.1% ropivacaine with 2µg/ml fentanyl with a view to unfold its various aspects.

Equipotent concentrations of ropivacaine and levobupivacaine with opioid in labour analgesia claimed that both are effective and safe at low doses. Robinson et al proved that adding fentanyl provided effective analgesia with minimum local anaesthetic dose.

Following successful studies from Kaynar and Shankar et al^[6], Capogna et al^[7], we preferred to provide analgesia by intermittent bolus technique.

In the ropivacaine-fentanyl group, the onset of analgesia was 16.33±4.299min which is more than 13.83±2.745min, observed in the levobupivacaine-fentanyl group. Onset of analgesia was faster in levobupivacaine group. Analgesia was established by 12-18min in both the groups. Purdie N.L. and McGrady E.M^[8] in 2004 using 0.1% ropivacaine and 0.1% levobupivacaine both with fentanyl recorded late onset of analgesia as compared to our study. They found 30 minutes in the 0.1% ropivacaine with fentanyl group and 38 minutes in the 0.125% levobupivacaine with fentanyl group.

The duration of analgesia in the ropivacaine group was found to be 73.83 ± 22.534 min and levobupivacaine group 110.83 ± 34.231 min. The higher mean duration of analgesia for levobupivacaine group could be due to more lipid solubility of the drug. They have a significant difference in the duration of analgesia during labour. My results were comparable to Supandji et al^[9] and Purdie et al^[8].

The mean duration of the first stage (active phase) from insertion of the epidural catheter to full dilatation of the cervix was 270.33 ± 90.696 minutes in the ropivacaine-fentanyl group, the corresponding value for the levobupivacaine-fentanyl group was 223.67 ± 59.378 minutes, and there was significant difference (p-value 0.022) between the two groups. My results were not similar to result obtained by Purdie et al^[8] who observed that both groups were statistically insignificant. Also, oxytocin infusion was judiciously used in the present study to maintain "normal" progress of labour when necessary. The mean duration of the second stage was 75.93 ± 30.438 minutes in the group receiving ropivacaine-fentanyl and 43.23 ± 24.625 minutes in the group receiving levobupivacaine-fentanyl.

The mean Visual Analogue Scale (VAS) scores (0-100mm) before giving epidural were 70.50 ± 16.523 and 66.83 ± 17.195 in groups A and B respectively. Corresponding values for the VAS scores at the end of delivery were 8.33 ± 6.205 for the ropivacaine-fentanyl group and 10.86 ± 8.353 for the levobupivacaine-fentanyl group. Quality of pain relief was adequate with VAS of <30 mm at most of the time intervals in both the groups. Analgesia scores between the two groups were not significantly different (p>0.05). Similar result was obtained by Purdie et al^[8] in 2004 and Sah N, Vallejo M et al^[10] in 2007

The mean value of Modified Bromage Scale (MBS) at the end of delivery was 0.20 ± 0.407 in group A and 0.48 ± 0.574 in group B. There was less motor blockade in parturients in ropivacaine group. 4 parturients in group A and 13 parturients in group B did not walk even once. Sah N, Vallejo

M et al^[10] in 2007, Purdie N.L. and McGrady E.M.^[8] in 2004 found no statistically significant differences in incidence or severity of motor block between the two groups.

Maternal satisfaction was high in both groups, with 93.3% in the ropivacaine-fentanyl group and 90% in the levobupivacaine-fentanyl group and they were satisfied with the procedure a day after delivery. The outcome is largely comparable in two groups (chi-square value is 0.3515 and p-value is 0.83)

The incidence of instrumental assisted vaginal delivery (AVD)- ventouse or forceps assisted was found to be 13.3% in ropivacaine group and 10% in levobupivacaine group. The incidence of instrumental delivery could be due to blunting of Ferguson's reflex and decreasing oxytocin secretions by local anaesthetics which leads to ineffective uterine contractions. In a similar study by Chuttani et al^[11], the incidence of instrumental AVD was found to be 43.3% in levobupivacaine group and 30% in ropivacaine group.

The APGAR score at 1min are 6.87 ± 1.592 and 7.43 ± 1.040 in group A and B respectively (p>0.05). The scores at 5min are 8.77 ± 0.774 and 8.83 ± 1.085 respectively in ropivacaine and levobupivacaine group. The above values were statistically insignificant in both the group. My results were comparable to the studies of Purdie et al^[8] and Lee et al^[12]. No foetal adverse event was noted throughout the study in both the groups.

Conclusion

We conclude that epidural labour analgesia is a novel approach to painless labour. Levobupivacaine-fentanyl provided faster onset of analgesia, prolonged duration of action and reduced duration of labour with satisfactory maternal and foetal outcomes. However, ropivacaine-fentanyl can be preferred when less or minimal motor block is primary concern. In total, low dose local anaesthetics with opioids provide excellent epidural labour analgesia without affecting maternal and foetal wellbeing.

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Conflicts of Interest: Nil

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