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Epidural Labour Analgesia with Ropivacaine 0.125% with Fentanyl Vs Bupivacaine 0.125% with Fentanyl- A Double Blind Randomised, Prospective, Comparative Study

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Abstract
Objective: *A prospective, randomized, double-blind, comparative study was conducted to compare the efficacy of Ropivacaine 0.125% with Fentanyl 2 μg/ml and Bupivacaine 0.125%, both with Fentanyl 2 μg/ml , in labor epidural analgesia and their effect on duration and course of labor.*
Background: *Ropivacaine was introduced as S-enantiomer. In various human and animal studies, it was found to be less cardiotoxic and has high sensory : motor differential blocking property. Both these characteristics are beneficial for labor epidural analgesia.*
Materials and Methods: *Eighty pregnant women of ASA grade I and II, who were primigravida or multigravida, with singleton vertex presentation in established labor were randomly selected and divided into two groups of 40 each. Group A patients received Ropivacaine 0.125% with Fentanyl 2 μg/ml and group B patients received Bupivacaine 0.125% with Fentanyl 2 μg/ml as intermittent bolus doses epidurally. After taking consent from them, epidural catheter was placed in L2-3/3-4 space, followed by administration of study drugs given as top-up doses intermittently. Maternal heart rate, systolic blood pressure (SBP), Visual Analogue Scale (VAS) score, fetal heart rate (FHR), Bromage score, level of sensory analgesia, APGAR score at 1 and 5 min, and duration of labor were recorded.*
Results: *The groups were similar in demographic attributes and obstetric variables In our study we found no significant difference according to* ***VNRS at different time interval except at 2hour and 4 hour time interval where mean VNRS was significantly more in group B as compared to group A.*** *The total number of bolus requirement is more in group A as compared to group B. In our study the duration of first stage of labour was 158.28±14.54 minutes in ropivacaine group and 178.28±15.18 minutes in the bupivacaine group. It was significantly lower in group A as compared to group B in stage 1. During second stage of labour, The mean duration was 15.45 min in ropivacaine group and 24.63 min in bupivacaine group. This difference was statistically significant. In our study, main duration of 3rd stage of labour was 6.68 min in ropivacaine group (Group A) and 8.20 min in bupivacaine group (Group B), this difference was statistically significant. APGAR scores were comparable in both the groups.*
Conclusion: *We conclude that Ropivacaine is equipotent, produces less motor block, has no adverse effect.*
Keywords: *Analgesia, Labour Epidural, Ropivacaine, Bupivacaine.*

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I. Introduction

Labour signifies one of the most happiest as well as one of the most painful moments in a woman's life. If not dealt with properly, it can lead to unpleasant experiences and mental agony. The pleasure of child birth accompanied with the fear of intense labour pain.

The first recorded incident of labour analgesia in USA was for Fanny Longfellow in 1847 with Ether. The second women, Emma Darwin who was wife of the eminent naturalist Charles Darwin was administered

Chloroform during labour. But the third incident influenced the history of labour analgesia in a profound way which was the administration of Chloroform to Queen Victoria by Dr. John Snow for delivery of Prince Leopold on April 7, 1853.

Since, it had a royal patronage, this made labour analgesia famous as well as more acceptable.The advancement in field of labour analgesia have passed a long way from the days of ether and chloroform in 1847. James Young Simpson , the Professsor in Edinburg, Scotland was the first to use Ether for pain relief during labour in young women with Rickets and severely deformed pelvis.

The different methods of pain relief were tried from 1840s to 1960s which includes inhalational agents, systemic agents [opioids, ketamine, Twilight sleep (morphine + scoploamine)], local blocks.

There are various modalities for labor analgesia available currently which includes both pharmacological and non – pharmacological techniques.

Non - pharmacological techniques includes of psychoprohylaxis, hypnosis, TENS (transcutaneous electrical nerve stimulation), biofeedback, and acupuncture.

Pharmacological methods comprises inhalational agents (sevoflurane, entonox) and opioids (fentanyl ,morphine, remifentanyl as PCEA. These have systemic side effects on both the mother and fetus and may also interfere with the progress of labour.

Pharmacological methods includes regional anaesthesia. It comprises both regional blocks and central neuraxial blocks. Though regional blocks give good pain relief but they are associated with technical difficulties as well. Para-cervical plexus blocks are not recommended these days because of their association with high incidence of fetal bradycardia. Pudendal nerve blocks are commonly used in second stage of labour.

Table: 1 Advance techniques for regional labour analgesia[3]

Initiation: Objectives to suit the needs of different stages of labour

1.	Combined spinal-epidural technique.
2.	Preprocedural or real-time ultrasound guidance.
3.	Continuos intrathecal analgesia
4.	Single-shot spinal analgesia

Maintainance: Aim to minimize lower limb motor blockage and incidence of breakthrough pain

1.	Mixture of low-dose local anaesthetic and lipophilic opioid
2.	Continuos infusion
3.	Patient-controlled epidural analgesia
4.	Programmed intermittent boluses
5.	Computerised-integrated background infusion

Bupivacaine, Levobupivacaine & Ropivacaine are widely used for epidural analgesia in labour.[10] The use of bupivacaine is limited due to risks of motor blockade (associated with maternal dissatisfaction and increased instrumental deliveries) and cardiac toxicity.

Ropivacaine, a newer local anesthetic released in 1996, has similar pharmacokinetic and pharmacodynamic properties as Bupivacaine. This newer local anesthetic confers less lower-extremity motor block than Bupivacaine after epidural administration, which may be advantageous. Increasing motor block to the perineal or abdominal muscles from epidural local anesthetic may interfere with normal internal rotation of the fetal head,whereas minimizing motor block during labor may allow fornormal progression of labor that may translate into fewer instrumental deliveries and more vaginal deliveries, although this is controversial.

This study compares the efficacy of ropivacaine with fentanyl and bupivacaine with fentanyl in regards to pain relief, motor block, labour characteristics.

II. Materials And Methods

This prospective randomized double blind comparative study was conducted involving 80 parturients (40 in each group) attending the Dept. of Obstetrics & Gynaecology, at Mahatma Gandhi Hospital, Jaipur. After getting approval from Institutional ethics committee and scientific committee, all patients admitted to the labour room were counseled about labour analgesia. The procedure was explained to the patient. Informed consent was obtained. Detailed history of the patient was collected. Routine investigations include blood grouping, hemoglobin and platelet count were performed as per our hospital labour protocol. Patients fulfilling the inclusion criteria and who gave consent were then randomly allocated to one of the study groups on the basis of chit and box method.

Inclusion Criteria:
1. Normal singleton pregnancies.
2. Age – 19-35 years
3. ASA status- I & II
4. Patients in a first stage of labour with cervical dilatation: 3-5 cm.

Exclusion Criteria
1. Patients unwilling for labour analgesia
2. Multiple or preterm gestation
3. Allergy to any study drug
4. Deranged coagulation profile
5. Parturients with h/o Eclampsia, pre-eclampsia, seizures, hypertensive disorders.
6. Cervical dilatation > 5cm.
7. Spinal deformities and infection at injection site.
8. Previous cesarean section.

Materials Needed:
1. 18 G Tuohy needle
2. 20 G epidural catheter
3. 2 cc,5 cc,10 cc sterile syringes
4. Bowl, Swabs, Chlorhexidine solution, Sponge holding forceps.
5. Sterile gown, Gloves, Cap & Mask
6. Tegaderm for fixing catheter.
7. Local anaesthetic solution – 2% Lignocaine
8. 2% lignocaine with adrenaline vial, 0.125% Bupivacaine vial, 0.125% Ropivacaine ampoule, Fentanyl - 100µg.
9. Emergency kit with including laryngoscope, nasal airway, oral airway, cuffed endotracheal tubes of appropriate size, suction apparatus with suction catheter, Inj. Adrenaline, Inj. Atropine, Inj. Thiopentone, Inj. Succinylcholine, Oxygen cylinder.
10. Monitor for cardiac monitoring for ECG, Non-invasive blood pressure, Respiratory rate, Oxygen saturation.

III. Methodology

An 18G IV cannula was inserted and patient was started with IV fluid Ringer lactate solution.

The patient was then positioned in sitting position based on the anaesthetist convenience and her back aligned with the edge of the bed. Under all aseptic precautions, the skin over the lower thoracic and lumbar region was cleaned and area draped. The best inter-lumbar space between L1 and L4 was identified and infiltrated with 2% lignocaine.

The skin pierced with 18G needle in the lumbar inter-vertebral space. The epidural needle was inserted in manner bevel facing upward and pushed till it pierced the inter-spinous ligament. The stylet was then removed. A 10ml LOR (Loss of Resistance) syringe filled with either Air was attached to the hub of the epidural needle. The needle was then slowly advanced with pressure exerted on the air column through the plunger of the LOR syringe. The epidural space was recognized with LOR to injection of air. Aspiration was done to identify surety of dura-mater was not punctured. If CSF was aspirated, the needle was removed and reintroduced in a different space. If CSF was not aspirated, the LOR syringe was removed. A 20G fine epidural catheter was pierced through the needle into the epidural space. The epidural needle was removed. The catheter was placed such that the length of 5cm of catheter remained in the epidural space. Careful aspiration of the catheter was again done to check for CSF or blood.

Once the catheter was satisfactorily sited, the puncture site was cleaned and an occlusion dressing applied over it. A small test dose of local anaesthetic (3ml of 2% Lignocaine with Adrenaline) was injected via the catheter to rule out intravascular or intra-thecal placement of catheter. If there were no signs of motor block (intra-thecal placement) or tachycardia (intravascular placement) after 5 minutes the patient was turned supine. A bolus dose of the test drug was given followed by intermittent bolus. The bolus and intermittent bolus protocol of each study group were as follows:

Study Drugs Protocol

Group	Bolus	Intermittent Bolus
A	15ml of 0.125% Ropivacaine + 2µg/ml Fentanyl	8ml/hr of 0.125% Ropivacaine with 2µg/ml Fentanyl.
B	15ml of 0.125% Bupivacaine + 2µg/ml Fentanyl	8ml/hr of 0.125% Bupivacaine with 2µg/ml Fentanyl.

Parameters Monitored:

1. Maternal Heart rate
2. Maternal Blood pressure
3. Maternal respiratory rate & oxygen saturation.
4. Verbal numerical rating scale (VNRS) OF 10 point used for pain relief
5. Motor block by Bromage score (0-3)

Clinical Outcome Studied:

1. Pain relief
2. Duration of labour
3. Mode of delivery - Vaginal - Spontaneous / Assisted Cesarean section
4. Neonatal outcome - APGAR score, NICU admission.
5. Motor block

The outcomes of the patients measured were hemodynamics, pain score, bolus requirement, duration of labour, motor block, mode of delivery, neonatal outcome, and complications if any.

IV. Result

Table 2: Demographic parameter

	Ropivacaine (Group A)	Bupivacaine (Group B)	p Value
Age(years)	22.83+1.35	22.60+1.464	0.48
Weight(kg)	72.85+3.378	70.88+6.493	0.09
Gravida			
Primi	33(82.5%)	37(92.5%)	-
Multi	7(17.5%)	3(7.5%)	
ASA			
I	39(97.5%)	38(95.0%)	-
II	1(2.5%)	2(5%)	
Cervical Dilatation			
3cm	22(55%)	18(45%)	-
4cm	18(45%)	22(55%)	
5cm	0	0	

Table 3: Epidural Placement

	Group A	Group B	P Value
Epidural Space			
• **L2-L3**	19(37.5%)	19(37.5%)	
• **L3-L4**	21(42.5%)	21(42.5%)	1.0
• **L4-L5**	0	0	

Table 3: Hemodynamic Parameter

HR	GROUP A (n=40)	GROUP B (n=40)	P VALUE
0 min	**84.28+2.75**	**85.25+3.08**	**0.14**
15 min	**83.25+6.24**	**80.55+6.04**	**0.05**
45 min	**82.43+9.62**	**82.20+8.80**	**0.91**

1hr	**83+9.08**	**84.6+8.88**	**0.42**
2hr	**81.5+9.57**	**80.88+6.92**	**0.73**
3hr	**80.55+9.20**	**80.03+8.24**	**0.78**
4hr	**80.25+6.97**	**77.88+7.29**	**0.14**
5hr	**83.0+10.72**	**76.67+4.04**	**-**

Table 4: Blood Pressure-SBP

	GROUP A	GROUP B	P VALUE
0 min	**130.53+8.32**	**127.25+8.13**	**0.07**
15 min	**131.0+7.8**	**127.20+10.81**	**0.07**
45 min	**116.90+10.655**	**117.89+12.96**	**0.90**
1 hr	**110.13+9.95**	**109.13+10.27**	**0.66**
2 hr	**111.45+9.74**	**109.86+8.74**	**0.39**
3 hr	**111.58+7.21**	**111.68+6.85**	**0.94**
4 hr	**111.70+6.85**	**110.98+8.28**	**0.67**
5 hr	**114.40+3.05**	**108.33+7.63**	**-**

Table 5: Blood Pressure-DBP

	GROUP A	GROUP B	P VALUE
0 min	79.15+7.23	79.05+6.02	0.94
15 min	79.20+7.63	80.80+8.23	0.37
45 min	68.03+7.23	71.43+8.20	0.10
1 hr	67.68+6.78	67.63+6.97	0.97
2 hr	72.0+7.66	73.5+6.37	0.34
3 hr	74.18+6.78	72.40+5.67	0.20
4 hr	77.15+6.646	76.95+6.78	0.89
5 hr	67.80+3.76	71.33+2.08	-

Table 6: MAP

	GROUP A	GROUP B	P VALUE
0 min	**96.44+6.74**	**95.11+6.31**	**0.36**
15 min	**93.17+6.64**	**92.62+8.57**	**0.74**
45 min	**86.24+7.68**	**86.71+9.59**	**0.28**
1 hr	**82.33+7.51**	**81.43+7.70**	**0.59**
2 hr	**85.28+7.82**	**85.43+6.77**	**0.92**
3 hr	**86.63+6.39**	**85.45+5.74**	**0.39**
4 hr	**88.65+5.14**	**88.35+6.07**	**0.81**
5 hr	**83.20+3.42**	**83.33+3.78**	**-**

Table7: Respiratory Rate

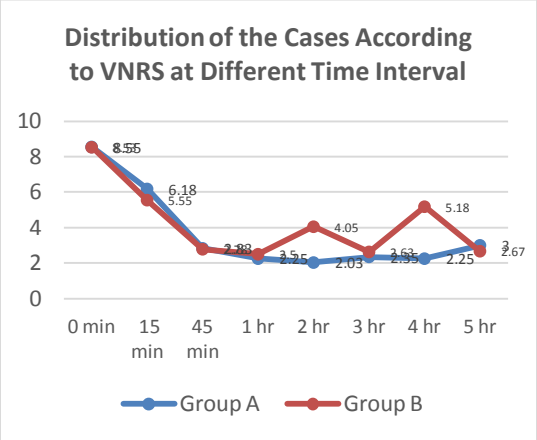
	GROUP A	GROUP B	P VALUE
0 min	**14.45+1.94**	**14.98+1.73**	**0.20**
45 min	**15.55+1.55**	**15.05+1.48**	**0.14**
3 hr	**15.03+1.25**	**14.63+1.27**	**0.16**

Table 8: SPO_2

	GROUP A	GROUP B	P VALUE
0 min	**100.0+0%**	**100.0+0.0%**	**1.0**
45 min	**99.90+0.30%**	**99.67+0.65%**	**0.06**
3 hr	**99.83+0.44%**	**99.80+0.46%**	**0.80**

Table 9: VNRS

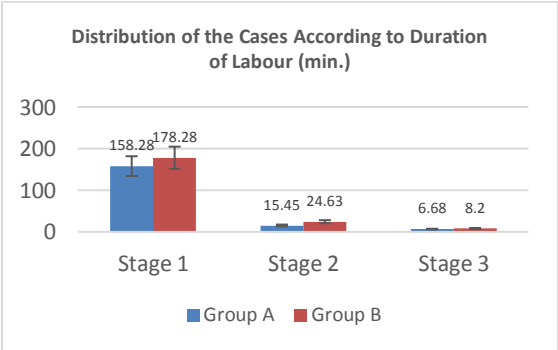
Group		**VNRS 0 min**	**VNRS 15m**	**VNRS 45m**	**VNRS 1hr**	**VNRS 2hr**	**VNRS 3hr**	**VNRS 4hr**	**VNRS 5hr**
Group A	N	40	40	40	40	40	40	40	
	Mean	8.55	6.18	2.83	2.25	2.03	2.35	2.25	3.0
	SD	0.50	1.43	1.43	1.17	1.02	1.21	1.19	1.0
Group B	N	40	40	40	40	40	40	40	
	Mean	8.53	5.55	2.78	2.50	4.05	2.63	5.18	2.67
	SD	0.55	0.95	1.18	1.35	0.81	1.32	0.71	1.52
P Value		0.92	0.05	0.96	0.46	<0.001	0.35	<0.001	
		NS	NS	NS	NS	S	NS	S	NS



There was a noticeable decrease in the pain levels immediately after bolus. The pain levels did not go above VNRS of 4 during infusion in both the groups. Increase in pain scores occurred during the 2nd & 4th hour in group B which was statistically significant.

Table 10: Duration of Labour (min.)

Group		Stage 1	Stage 2	Stage 3
Group A	N	40	40	40
	Mean	158.28	15.45	6.68
	SD	14.54	2.98	1.27
Group B	N	40	40	40
	Mean	178.28	24.63	8.20
	SD	15.18	2.43	9.11
P Value LS		<0.001 S	<0.001 S	<0.001 S



Mean duration of labour (min.) was significantly lower in group A as compared to group B in stage 1, stage 2 and stage 3.

Table 11: Mode of Delivery

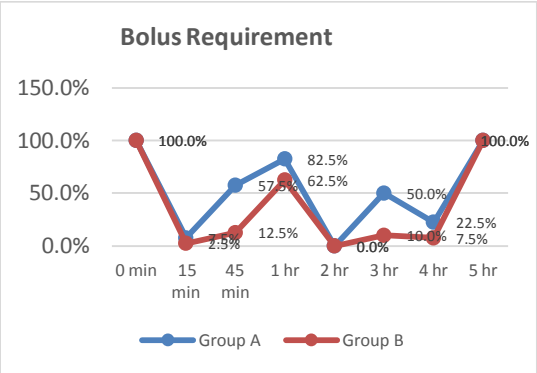
Mode of Delivery	Group A		Group B		Total
	No	%	No	%	No
VA	4	10.0	9	22.5	13
VS	33	82.5	30	75.0	63
LSCS	3	7.5	1	2.5	4
Total	40	100.0	40	100.0	80

Chi-square = 3.06 with 2 degree of freedom; P = 0.21

Spontaneous vaginal deliveries in groups was equal (82.5% of group A and 75.0% of group B). Assisted vaginal deliveries (10% in group A and 22.5% in group B) and lower segment cesarian section (7.5% of group A and 2.5% of group B).

Table 12: Bolus Requirement

		Group A		Group B		P Value
		No	%	No	%	
0 min	15 ml	40	100.0	40	100.0	NA
15 min	Nil	37	92.5	39	97.5	0.61
	8 ml	3	7.5	1	2.5	
45 min	8 ml	23	57.5	5	12.5	<0.001
	NIL	17	42.4	35	87.5	
1 hr	8 ml	33	82.5	25	62.5	0.04
	NIL	7	17.5	15	37.5	
2 hr	8ml	0	0	0	0	
	NIL	40	100.0	40	100.0	NA
3 hr	8 ml	20	50.0	4	10.0	<0.001
	NIL	20	50.0	36	90.0	
4 hr	8 ml	9	22.5	3	7.5	0.11
	NIL	31	77.5	37	92.5	
5hr	NIL	5	100.0	3	100.0	NA



Total no. of boluses required in Group A was 33 and Group B was 25 at various time interval which was proportionally high in Group A (p<0.001).

Table 13: FHR

	GROUP A	GROUP B	P VALUE
0 min	**154.18+11.03**	**155.85+10.93**	**0.49**
15 min	**152.53+8.75**	**155.78+6.11**	**0.05**
45 min	**156.43+7.72**	**156.88+8.47**	**0.80**

Table 14: APGAR SCORE

	GROUP A	GROUP B	P VALUE
APGAR 1	**7.55+05.0%**	**8.70+0.46%**	**0.26**
APGAR 5	**7.43+0.50%**	**8.58+0.50%**	**0.25**

V. Discussion

In our study we have compared Ropivacaine (0.125%) with fentanyl 2µg/ml versus Bupivacaine (0.125%) with fentanyl 2µg/ml for labor epidural analgesia.

The MLACs of epidural ropivacaine and bupivacaine have not been compared previously; however, both local anesthetics have been compared to bupivacaine in three different types of studies using MLAC methodology. The analgesic potency of ropivacaine was found to be 40% less than that of racemic bupivacaine, with a ropivacaine: bupivacaine potency ratio of 0.6 (95% CI, 0.49–0.74). Levobupivacaine and racemic bupivacaine were identified by Lyons et al to having same analgesic properties, with a levobupivacaine: bupivacaine potency ratio of 0.98 (95% CI, 0.67–1.41).

Pain Relief: Pain is a subjective circumstance and it is difficult to measure. There are many types of scales to measure pain - verbal rating scale, verbal numerical rating scale (VNRS), visual analog scale (VAS) etc. In our study we used VNRS as the pain scoring system because it was easy for patients to understand and compliance being better. In our study we found no significant difference according to **VNRS at different time interval except at 2hour and 4 hour time interval where mean VNRS was significantly more in group B as compared to group A.** The total number of bolus requirement is more in group A as compared to group B.

Sunanda et al, 2013; they compared ropivacaine 0.125% with fentanyl 2µg/ml (Group R1) vs ropivacaine 0.2%

with fentanyl 2µg/ml (Group R2) in epidural labour analgesia in both groups. Mean VAS scores for group R2 was lower than group R1 at the intervals of 5min, 60min, and 90 min, the p value was less than 0.01. Consumption of ropivacaine was comparable in both the groups, in group R1 (33.75 ± 12.16 mg and group R2 (31.50 ± 6.62 mg) p value was greater than 0.05, the consumption of fentanyl was significantly much more in group R1 (54.00 ± 19.45) as compared to group R2 (31.50 ± 6.62), p value was less than 0.001.

Bolus Requirements: In our study we have found that the number of additional boluses required by Group A was 33 (82.5%) and Group B was 25 (62.5%) at various time interval which was proportionally high in Group A as compared to Group B.

Snehal Shrikant Shenvi et al 2018, a comparative study on the effects of 0.1% bupivacaine (Group B) and 0.15% ropivacaine (Group R) for epidural analgesia during labour. A total of 80 parturients were participated in this study which were randomly classified into two groups, Group B (n=40) and Group R (n=40), 7 parturients in Group B and 6 in Group R required rescue top up, however this difference was statistically insignificant (P value equals to 0.99).

Duration of Labour: In our study the duration of first stage of labour was 158.28±14.54 minutes in ropivacaine group and 178.28±15.18 minutes in the bupivacaine group. It was significantly lower in group A as compared to group B in stage 1.The mean duration was 15.45 min in ropivacaine group and 24.63 min in bupivacaine group. This difference was statistically significant.

In our study, main duration of 3rd stage of labour was 6.68 min in ropivacaine group (Group A) and 8.20 min in bupivacaine group (Group B), this difference was statistically significant.

Takako Hamada et al 2013 , Comparison between 0.06% and 0.1% levobupivacaine combined with 2 µg/mL of fentanyl for epidural Labor Analgesia, there were 46 women fulfilling the inclusion criteria: 23 women with 0.06% levobupivacaine combined with 2 µg/mL of fentanyl (0.06% group), and 23 women with 0.1% levobupivacaine combined with 2 µg/mL of fentanyl (0.1% group). No significant differences were found between the groups in patient characteristics, the duration of labor in 1 st stage in 0.1% Group (n=23) was 613.5 (+/− 263.9) and 0.06% Groups (n=23) was 747.0 (+/− 297.1).

VI. Conclusion

This study shows that pain relief by epidural bupivacaine is as good and effective as epidural ropivacaine. The duration of labour is been decreased with ropivacaine as compared to bupivacaine, as well as there were also more number of boluses has been required in Group A (ropivacaine 0.125% with fentanyl 2µg/ml) as compared to Group B (bupivacaine 0.125% with fentanyl 2µg/ml) but the mode of delivery, neonatal outcome and complications are comparable between the two groups.

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