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Ropivacaine 0.2% Versus Bupivacaine 0.125% with Fentanyl-A Comparison during Epidural Labour Analgesia

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Abstract

Background: Current low concentration epidural labour analgesic techniques are becoming widely accepted because it has provided greater comfort during labour , at the same time allows the mother to participate during the delivery, allowance of any instrumental delivery or caesarian section if required with the same anesthesia through top up via epidural catheter and devoid of side effects of spinal analgesia and inhalational analgesia. This study evaluates the low concentration agents & combination of adjuvant in epidural labour analgesia.

Material & methods: The study was conducted in G.O.T of Department of Obstetrics and Gynaecology, N.S.C.B Medical College, Jabalpur in 60 randomly selected patients, divided into group A (0.125% bupivacaine and fentanyl 2µg/ml) and groupB (0.2% ropivacaine) during the year 2009 – 2010.

Results: In this study, top ups were given to the patients when VAS > 5. The number of top ups were significantly higher in the group A, i.e., 56.7% parturient required single Top UP and 30% parturient required 2 Top Ups vs 66.7% parturient required single Top Up and 6.7% parturient required 2 Top Ups in group B. In group A 26.7% participants developed I^0 motor blockade according to modified bromage scale assessment and in group B, 20% participants had I^0 motor blockade. (P>0.05). In group A, 10% participants had LSCS because of foetal bradycardia and 90% women delivered spontaneously. In group B, 6.7% participants were taken for LSCS because of foetal bradycardia while remaining 93.3% participants delivered spontaneously (P>0.05). APGAR Score at 1 min and 5 min in both the groups were statistically insignificant (P> 0.05).

Conclusion: 0.2% Ropivacaine was superior in quality of analgesia according to VAS in 1st stage of labour. It required fewer top ups. So, better maternal satisfaction.

Keywords-Epidural analgesia in labour, patient-controlled analgesic techniques, safety, cesarean delivery.

Introduction

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Lumbar epidural is considered the gold standard for analgesia in labour. It is recommended by WHO.[1] Epidural analgesia involves the placement of a catheter into the epidural space. It allows repeated or continuous administration of medications. The medication mixture consists of a local anaesthetic, often with an opioid. This mixture allows for use of lower concentrations of each agent and thereby minimizes the potential for adverse effects. Lower concentrations of local anaesthetic cause less motor blockade. Lower concentrations of opioids result in less systemic effect for the woman and foetus.[2]

The commonly used local anaesthetics are bupivacaine and ropivacaine. They are equivalent in outcome and adverse effects.[3] The most common used opioids are fentanyl.[4]

Once an epidural catheter is inserted, local anaesthetic, with or without opioid, are used to provide analgesia.[5]

Epidural opioids act synergistically with local anaesthetics. The minimum local analgesic concentration (MLAC) is the median effective concentration to produce analgesia. Fentanyl is short-acting. It reduces the MLAC of bupivacaine by 31%–72% depending on the dose used.[6]

The National Health Service guide line on labour epidural advices use of 10–12.5 mg bupivacaine as initial test dose. It is 10ml epidural mix (0.1% Bupivacaine + 2mcg/ml fentanyl) or 4 ml 0.25% Bupivacaine or 3 ml 2% Lidocaine. The maintenance of analgesia is done with intermittent boluses, continuous infusion and Patient controlled epidural analgesia. 20 ml epidural mix dose can be repeated at hourly intervals.[7] Dura puncture epidural is a technique of perforating the dura with spinal needle. It introduces a conduit for translocation of drugs from the epidural space into subarachnoid space. It provides faster onset of analgesia. It has less maternal and foetal side effects compared to CSE. But it was associated with increased instrumental delivery.[8]

A meta-analysis found that labour epidural was significantly associated with increased incidence of operative vaginal delivery.[9]

A result of Cochrane review on 21 RCTs (48 publications) showed that labour epidural has no significant impact on the risk of cesarean section.[10]According to Cochrane review by Smyth R, Howell C there was no evidence of significant difference in the 5-min APGAR score of neonates born of mothers with epidural and those treated with opiates.[10]

Early or late initiation of epidural analgesia for labour have similar effects on rate of cesarean section, instrumental birth, duration of labour, Apgar score or umbilical arterial PH.[11]

Aims & objectives

- To compare the effect of combination of 0.125% Bupivacaine and 2µg/ml Fentanyl with 0.2% Ropivacaine on the onset & duration of analgesia and motor blockade.
- To compare their effect on the progression of labor.

Material & methods

The present study was conducted in G.O.T of Department of Obstetrics and Gynaecology, N.S.C.B Medical College Jabalpur in 60 randomly selected patients, divided into group A (0.125% bupivacaine and fentanyl 2µg/ml) and groupB (0.2% ropivacaine) during the year 2009 – 2010.

Inclusion criteria

1. Age 18-35 years.
2. Booked primi / multigravida between 37-42 weeks with single live intrauterine foetus in vertex position.
3. Patients with cervical dilatation 3-5 cm with good uterine contractions.

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4. ASA Grade I and II.

Exclusion criteria

1. Allergic to local anesthetic drug
2. Bleeding diathesis.
3. Anticoagulant therapy or prolonged aspirin ingestion.
4. Pre-existing neurological or spinal disease.
5. Cardiovascular or Respiratory impairment.
6. Local or Systemic infection.
7. Cephalopelvic disproportion, previous history of caesarean section or complicated labor.
8. Any complication of pregnancy like obstetric hemorrhage, eclampsia etc.
9. Non-reassuring FHR prior to procedure.

History was obtained in detail, general and systemic examination was done, obstetric examination including P/A, P/V was done.

Complete hemogram, urine, blood group, bleeding time, clotting time, and blood sugar were done. Patients and relatives were explained about the procedure, advantages, disadvantages and the importance of their co-operation. Written and informed consent of the patient and their relatives was obtained. Patients were randomly divided into 2 groups of 30 each. Xylocaine sensitivity was done.

- Each patient's B.P. in supine, left lateral and right lateral position was recorded to rule out supine hypotension syndrome.
- I.V. line secured and preloading was done with 1000 ml of Ringer lactate. Pulse rate and SpO_2 were noted.
- The progress of labor and FHR was assessed by obstetrician.
- In left lateral position under aseptic precautions, painting and draping was done.
- 2-3 ml of 2% lignocaine was infiltrated in skin and subcutaneous tissue of L2-L3 or L3-L4 interspace.
- After making a subcutaneous tissue track with 18G hypodermic needle, 18G tuohy epidural needle was introduced in midline with laterally facing bevel. The space was identified with "loss of resistance technique" with air in LOR syringe.
- 18G epidural catheter was threaded 4-5 cm into space, needle removed and catheter fixed with gauge piece and adhesive tape.
- 3 ml of study test dose was given to detect inadvertent intrathecal or intravascular placement of catheter after aspiration for CSF or blood.
- All epidural injections were given slowly in incremental doses directly talking to and evaluating the patient.

Group A: (n=30) patients were given 3+10ml=13ml of 0.125% bupivacaine and 2µg/ml fentanyl.

Group B: (n=30) patients were given 3+10ml=13ml of 0.2% ropivacaine.

- The table was tilted to a modified Trendelenburg position to achieve sensory level block of T10-L1 in 1st stage of labor without paralysis of perineal muscles (S2-S4).
- Continuous pulse, B.P. monitoring was done at 2 min intervals for 1st 30 min after injection and then every 15 min. FHR monitored every 15 min and continuous SpO2 monitoring done.
- In case of slight pain, top up dose of 5ml 0.125% bupivacaine + 2 mcg/ml inj. Fentanyl or 5ml 0.2% ropivacaine were given to the two groups respectively.
- Progress of labour and cervical dilatation were assessed by the obstetrician.
- In 2^{nd} stage of labor, patient was placed in 30° head up tilt or sitting position after top up dose to block the pain of perineal stretching, achieving sensory level of block of T_{10}-S_4.

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- The onset of pain relief and the need for subsequent top ups were noted.
- Level of analgesia was checked. Sensory level was checked by temperature, touch and pressure. Motor block was assessed by modified bromage scale, Assessment of pain was done by 0-10 Visual analogue pain scale (VAS). All patients were observed for nausea, vomiting and pruritus.
- After the delivery of baby, neonatal APGAR scores were studied and mother was followed-up in puerperium for development of headache, hypotension, backache, fever etc.
- All the data obtained were subjected to statistical analysis using student t test to analyze values between the two groups. Chi square test was used to study significance of changes over time using the p values as tests of significance. **A p value of <0.05 was considered significant.**

Pain score (0=No pain, 10=Worst possible pain)

- **Quality of Analgesia grading-**
- **Excellent**: Completely pain free after 1st or 2nd injection until the delivery
- **Good**: Satisfied but some pain experienced for a short period during labour and delivery.
- **Incomplete**: Significant pain relief but experienced some pain most of time during labour and delivery.
- **Failure**: Pain experienced most of the time during labour and delivery.
- **Not possible to evaluate**: Delivery by cesarean section or instrumental deliveries.

Results

Table-1-Onset of analgesia (min) between two groups

Group	Mean	±SD	No. of patients
A	16.17	2.214	30
B	22.07	3.039	30
Total	**19.12**	**3.975**	**60**

Group A showed mean onset of analgesia at 16.17 ± 2.214 min and group B had a mean onset of analgesia was 22.07 ± 3.039 min & was significantly less in group B. (P< 0.0001). (Table 1)

Table-2-Duration of analgesia in both groups

Group	Mean	Std. Deviation	N
A	161.33	30.25	30
B	182.83	41.37	30
Total	**172.08**	**37.53**	**60**

In this study, Group A showed mean duration of analgesia 161.33 ±3.25 and Group B had mean duration of analgesia 182.83 ±41.37 min. It was significantly prolonged in group B with longer active phase of 1st stage of labour. (Table 2)

Table-3-Quality of analgesia during labour in both groups

	Group-A(n=30)	Group-B(n=30)	P value
Pain free at 30 min	25	23	0.51
Analgesia during 1st stage of labour			
VAS=0cm	9	17	0.037
VAS<1cm	15	18	0.43
VAS<3cm	22	25	0.34

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Analgesia during 2nd stage of labour			
VAS=0cm	9	13	0.28
VAS<1cm	12	14	0.60
VAS<3cm	18	21	0.41

In this study, top ups were given to the patients in distressing pain or when VAS > 5. The number of top ups were significantly higher in the group A, i.e.,56.7% parturients required single Top UP and 30% parturient required 2 Top Ups vs 66.7% parturient required single Top Up and 6.7% parturient required 2 Top Ups in group B. (Table 3)

Table-4- Motor blockade in both groups

Motor Blockade	A	B	Total
0^0	22 73.3%	24 80.0%	46 76.7%
I^0	8 26.7%	6 20.0%	14 23.3%
Total	**30**	**30**	**60**

χ^2=0.37; p>0.05

This table depicts comparison of motor blockade between the two studied groups.

In group A 26.7% parturient developed I^0 motor blockade according to modified bromage scale assessment and in group B 20% parturient had I^0 motor blockade. (P>0.05). (Table 4)

Table-5- Mode of delivery in both groups

Mode of Delivery	A	B	Total
CS	3 10.0%	2 6.7%	5 8.3%
VD	27 90.0%	28 93.3%	55 91.7%
Total	**30**	**30**	**60**

χ^2 =0.22; p>0.05

In this study, in group A, 10% participants had LSCS because of foetal bradycardia and 90% women delivered spontaneously.

In group B 6.7% participants were taken for LSCS because of foetal bradycardia while remaining 93.3% parturient delivered spontaneously (P>0.05). (Table 5)

Table-6- APGAR Score (At 1minute) in both groups

APGAR Score	Group		Total
	A	B	
5-7	16 53.3%	11 36.7%	27 45.0%
>7	14 46.7%	19 63.3%	33 55.0%
Total	**30**	**30**	**60**

X^2=1.68; P>0.05

Table-7- APGAR Score at 5 min

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APGAR Score	Group		Total
	A	B	
>7	30 100%	30 100%	60 100%
Total	**30 100%**	**30 100%**	**60 100%**

This table depicts comparison of APGAR Score at 1 min and 5 min between the two studied groups.

At 1 min APGAR Score of group A and group B were found to be > 5 in 53.3% and 36.7% neonates respectively.

At 5 min APGAR Score of group A and group B were found to be > 7 in all neonates.

APGAR Score at 1 min and 5 min in both the groups were statistically insignificant (P> 0.05). (Table 6 & 7).

Discussion

Epidural analgesia is safe for both mother and baby and now a days, is considered as gold standard for labour pains. In this study, Group A showed mean onset of analgesia at 16.17 ± 2.214 min and group B had a mean onset of analgesia was 22.07 ± 3.039 min & was significantly less in group B. (P< 0.0001). (Table 1)

In this study, Group A showed mean duration of analgesia 161.33 ±3.25 and Group B had mean duration of analgesia 182.83 ±41.37 min. It was significantly prolonged in group B with longer active phase of 1st stage of labour. (Table 2)

In this study, top ups were given to the patients in distressing pain or when VAS > 5 with 0.125 % Bupivacaine 10 ml with 2 □g/ml Fentanyl in group A and 0.2% Ropivacaine 10 ml in group B. The number of top ups were significantly higher in the group A, i.e., 56.7% parturient required single Top UP and 30% parturient required 2 Top Ups vs 66.7% parturient required single Top Up and 6.7% parturient required 2 Top Ups in group B. (Table 3)

Chourasia A et al[12] found that there was no statistical difference in the Vas score of both the groups at the time of epidural insertion. But, mean Vas score of group 1 was significantly lower than group 2 at 0, 5, 15, 30, 60, 120, 180, 240, 300 and 360 minutes. In group 1, the mean Vas score started to decrease in 5 minutes and reached to <1 in 30 minutes. It remained 13 or less throughout labour. However, in group 2 mean VAS score remained above 90. It increased as the labour progressed.

In this study, in group A 26.7% participants developed I^0 motor blockade according to modified bromage scale assessment and in group B, 20% participants had I^0 motor blockade. (P>0.05) (Table 4)

In this study, in group A, 10% participants had LSCS because of foetal bradycardia and 90% women delivered spontaneously.

In group B, 6.7% participants were taken for LSCS because of foetal bradycardia while remaining 93.3% participants delivered spontaneously (P>0.05). (Table 5)

Chourasia A et al[12] found that second stage of labour was significantly prolonged in group 1 with p value of 0.001. No statistical difference in duration of 1st and 3rd stages of labour was observed. Second stage was significantly prolonged in group 1. Mean FHR in both the groups remained comparable throughout labour

Kearns RJ et al[13] found that there were 303,013 spontaneous vaginal deliveries (69.6%), 70, 899 emergency cesarean deliveries (16.3%), 52,799 instrumental deliveries (12.1%), 8540 rotational deliveries (2.0%), and 28 unpredicted breech extractions (<0.01%).

In this study, 1 min APGAR Score of group A and group B were found to be > 5 in 53.3% and 36.7% neonates respectively.

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At 5 min APGAR Score of group A and group B were found to be > 7 in all neonates. APGAR Score at 1 min and 5 min in both the groups were statistically insignificant (P> 0.05) (Table 6 & 7)

Chourasia A et al found that maximum number of babies had APGAR of > 7 at 1 min and 5 min in both the groups. There was no statistical difference in APGAR score in both the groups (p value 0.46 and 0.55) at 1 min and 5 min respectively.Kearns RJ et al found that epidural use was associated with increased risk of neonatal resuscitation (Cadj RR, 1.07; 95% CI, 1.03-1.11) and neonatal unit admission (Cadj RR, 1.14; 95% CI, 1.11-1.17)

Conclusion

In this study, 0.2% Ropivacaine was superior in quality of analgesia according to VAS in 1st stage of labour. It required fewer top ups. So, better maternal satisfaction.

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