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Research Article

Comparative Study of 0.1% Bupivacaine with Fentanyl versus 0.1% Ropivacaine with Fentanyl for Epidural Labour Analgesia

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Abstract
Background: *Analgesia during labour provides painless delivery and reduces the stress response due to labour pain. Bupivacaine is commonly used local anaesthetic for labour analgesia, but it can produce motor blockade, ropivacaine provides ambulatory analgesia, opioids added to the local anaesthetic provides increased duration of analgesia, enhanced intensity of analgesia and decreases the dose of local anaesthetic.*
Method: *After approval from ethical committee at RIMS 60 ASA grade I/II primi parturients with singleton pregnancy, term gestation, cephalic presentation, in active first stage of labour, aged 18-35 years were included in the study. Patients were randomly allocated into two groups Group B (n = 30) & Group R (n = 30). Epidural technique was standardised and efficacy was compared between the groups.*
Results: *Bupivacaine and Ropivacaine provide equivalent labour analgesia. Motor blockade produced was minimal with ropivacaine when compared to bupivacaine.*
Keywords: *Epidural analgesia, Bupivacaine, Ropivacaine, Fentanyl.*

Introduction

A scientific definition of pain is 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage[1].

The American College of Obstetricians and Gynaecologists (ACOG) has defined *normal labour* as "the presence of uterine contractions of sufficient intensity, frequency, and duration to bring about demonstrable effacement and dilation of the cervix"[2].

A Canadian study comparing different pain syndromes found that average labor pain scores were higher in both nulliparous and multiparous women than the average scores previously recorded for out-patients with sciatic pain, toothache and fracture pain[3, 4]. However the average score is higher, its exact value differs greatly among parturients.

Central neuraxial analgesia is the gold standard technique for obstetric analgesia and anaesthesia. Patient satisfaction of birth experience is excellent

with neuraxial technique. Epidural blockade is most effective means of providing analgesia during labour.

Bupivacaine and ropivacaine are most commonly used local anaesthetic agents for labour analgesia. Bupivacaine was better than the older local anaesthetics, such as lidocaine, because of its increased duration of action, lower incidence of tachyphylaxis, and lesser intensity of lower limb motor block. Ropivacaine was synthesized in order to decrease the cardiotoxicity associated with bupivacaine and to further reduce motor blockage[5], considering the low doses used for labour, toxicity is rarely associated with either drug. There is some evidence to suggest that ropivacaine may produce less motor block in prolonged labours, but the difference may be attributable to differences in drug potency[6].

The discovery of opioid receptors in the spinal cord led to the use of opioid/local anaesthetic mixtures that further reduced maternal motor block and reduced the risk of local anaesthetic toxicity.

Material and Methods

This comparative clinical study of epidural labour analgesia for vaginal delivery with 0.1% bupivacaine and fentanyl versus 0.1% ropivacaine and fentanyl was conducted in 60 primigravida parturients, of ASA physical status I/II, in Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, after obtaining permission from the Institutional Ethical committee. Written informed consent was obtained from those who wished and opted for painless normal delivery. Only those who fulfilled the selection criteria were included in this study.

Inclusion Criteria

Full term singleton booked primigravida parturients, age between 18-35 years, height ≥ 140 cms, ASA physical status I/II, in active phase of first stage of labour with good uterine contractions and cervical dilatation 3-5 cm with vertex presentation.

Exclusion Criteria

ASA grade III/IV, age <18 years or >35 years, preterm gestation, fetal distress, patients who did not give consent.

Pre- Anaesthetic Evaluation

Informed written consent was obtained. Beside thorough clinical examination with relevant investigations was done. All parturients were made familiar with visual analogue scale (VAS) scoring beforehand and were explained to grade their pain on the scale.

Group Allocation

The parturients were randomized by computer generated randomization table into two groups of thirty each- Group B and Group R. The randomization sequence was prepared in double-blinded manner. The study blinding was disclosed after the statistical analysis.

(1) Group B (n=30): received 0.1% bupivacaine with fentanyl 2mcg/ml

(2) Group R (n=30): received 0.1% ropivacaine with fentanyl 2mcg/ml

Premedication's

All patients were premedicated with inj. Ranitidine (50 mg) i.v. and inj. Metoclopromide (10 mg) i.v. thirty minutes before epidural catheterisation.

Procedure

Parturients were shifted to the labour OT, multipara monitor was attached to the patients. Resuscitation equipments and medications were made available and prepared before starting epidural analgesia. The autoclaved epidural tray used for performing the block was obtained.

Under full aseptic precautions epidural space was identified in sitting position using 18G tuohy needle in L3-L4 or L4-L5 intervertebral space by midline approach with loss of resistance to saline technique. Epidural catheter was threaded 6 cm into cephalad epidural space. After negative aspiration for blood and CSF, test dose of 5 ml of prepared drug was administered. Watch for change in heart rate of 20 beats per minute from baseline in 15 seconds to rule out inadvertent

intravascular spread of drug. Watch for motor blockade in 3 to 5 minutes to rule out intrathecal spread. Parturients with test dose positive are excluded from the study. Five minutes after administering the test dose, loading dose of rest 10 ml of the study drug was administered in 5 ml aliquots at intervals of 5 minutes. Parturients not experiencing adequate analgesia in 20 min were supplemented with additional 15ml of the study drug. Following the loading dose additional supplements of the drug was administered based on the VAS score, Patients were monitored in labour ward, drugs and equipments were kept ready for resuscitation, if needed. Fetal heart rate monitoring and per vaginal examination for cervical dilation was done by obstetrician.

Monitoring

Vital parameters (pulse rate, mean arterial pressure, respiratory rate, SpO_2) was recorded at 0 (before epidural), 5, 15 min and then every 15 min till 1 hour and then every 30 minutes until the delivery. Onset of analgesia(OOA), sensory block height, quality of analgesia, duration of analgesia (DOA), number of top-ups(NOT), injection to delivery time(IDT), mode of delivery(MOD). VAS and MBS was assessed every 15 minutes. All parturients was given a trial walk to assess their ability to ambulate.

Onset of analgesia was defined as from time of first bolus dose to time of achieving VAS <3.

The adequacy of analgesia was assessed 15 minutes after the first initial bolus dose of study drug was administered. Analgesia was considered adequate if pain score was <3.

If pain relief was inadequate at the peak of a contraction, 15 minutes after the second initial dose; the epidural anaesthetic was classified as failure, and patient was withdrawn from the study.

Presence of motor block in the lower extremities was assessed using Modified Bromage scale and trial walk. (MBS: Grade 3 as complete motor block to Grade 0 as no motor block).

Sensory block height was assessed by loss of sensation to pin prick (blunt head of a pin).Visual analogue scale of 0-10 was used to determine pain.

Epidural analgesia was continued throughout the second stage of labour. At any point of time during the study period hypotension defined as systolic blood pressure of <90 mmHg was treated with bolus of 6 mg ephedrine. Bradycardia defined as heart rate <60 bpm was treated with bolus doses of 0.4 mg atropine sulphate.

The time taken by the parturient to request for subsequent top-up dose was recorded. Labour was managed according to our obstetrics department's protocols and mode of delivery (normal/ instrumental delivery/caesarean delivery) with injection to delivery time was noted.

Injection to delivery interval defined as the time from administration of first initial epidural dose until the delivery.

Fetal heart rate was monitored throughout the study with cardiotocograph by the obstetrician.

Neonatal assessment was performed by assessing the Apgar score of the neonate at 1 and 5min post delivery, by paediatrician.

Quality of analgesia was assessed by anaesthesiologist as

Grade 0 – Failure

Grade 1 – Incomplete

Grade 2 – Good

Grade 3 – Excellent

Grade 4 - Not possible to evaluate (NPE) if delivered by caesarean section.

Side effects including nausea, vomiting, hypotension, hypersensitive reaction, shivering, fever, drowsiness, pruritus, respiratory depression, retention of urine, and weakness in lower limbs was noted.

Statistical Methods

Data was collected and tabulated. Numerical variables were presented as mean & standard deviation (SD) while categorical variables were presented as frequency and percentage. As regard numerical variables; between groups comparison unpaired student- t test was used whenever appropriate; while for categorical variables chi-square test and fischer exact was used. p value less

than 0.05 was considered as statistically significant. SPSS version 20.0 was used for data analysis.

Observation and Result

The following observations were recorded and results were tabulated as below.

Table 1 showing onset of analgesia

Onset Of Analgesia (min)	Mean±SD	P value
Group B	12.37	<0.0001
Group R	18	

Table 2 showing duration of analgesia

Duration Of Analgesia (min)	Mean±SD	P value
Group B	203.76	0.909
Group R	203.13	

Table 3 showing number of top ups

Number of top ups	Mean±SD	P value
Group B	0.96	<0.0001
Group R	1.9	

Table 4 showing injection to delivery time

Injection delivery time (min)	Mean±SD	P value
Group B	203.76	0.909
Group R	203.13	

Table 5 showing percentage of different modes of delivery

Percentage(%)	Mode of delivery		
	SVD	AVD	LSCS
Group B n=30	93.3%	3.3%	3.3%
Group R n=30	93.3%	3.3%	3.3%

Table 6 showing motor blockage

	Modified Bromage Score			
	0	1	2	3
Group B	27	3	0	0
Group R	30	0	0	0

Discussion

Factors that have shown to correlate with great pain during labor and delivery include primigravida parturients, concentration of local anaesthetics, concentration of adjuvant, volume of drug in first bolus and then subsequent top-ups, intervals of monitoring were analyzed. In all the parturients, process of labor was augmented using oxytocin, thus all other above mentioned factors were comparable between two groups. Therefore, the difference in the VAS score and all other parameter can be attributed only to the drugs. We did not find any significant difference regarding motor blockade in the two groups. Gündüz *et al.*[7] used either 0.0125% bupivacaine + fentanyl or 0.125% ropivacaine + fentanyl. Their results indicated that ropivacaine is better than bupivacaine in preserving the ability of the parturient to micturate and ambulate. Lee *et al.*[8] analyzed epidural labor analgesia using ropivacaine or bupivacaine. Wherein analgesia was initiated with a 0.25% solution and maintained with a continuous infusion of a 0.1% solution with fentanyl 0.0002%. They found that 12.1% parturients in the bupivacaine group and 5.8% parturient in the ropivacaine group had motor block >Bromage 1. Higher motor block in their study may be due to higher concentration of local anesthetic drug used initially.

Studiesby Stienstra *et al.*, [9] Owen *et al.*, [10] McCrae *et al.* [11] also found that the incidence of motor block was similar in bupivacaine and ropivacaine groups. Ropivacaine may be more selective for sensory fibers than bupivacaine, due to its lower lipid solubility and hence limited penetration of large myelinated nerve fibers, which convey motor impulse. [10]

There was no difference in the mode of delivery in the two groups in the present study. Eddleston *et al.*, [12] compared bupivacaine and ropivacaine in a concentration of 0.25% for extradural analgesia in labor. They observed ropivacaine group had a higher incidence of spontaneous vaginal delivery (70.59% vs. 52.00%), but the difference was not statistically significant. Halpern and Walsh[13] performed a meta-analysis, comparing bupivacaine and ropivacaine for labor epidural analgesia. They found that there was no significant difference in the incidence of spontaneous vaginal delivery and mode of delivery was similar between two. Less pronounced motor block in ropivacaine may have

enabled more active participation and more effective bearing down resulting in increased incidence of spontaneous vaginal delivery. At the same time, less reduction in the tone of the pelvic diaphragm might have enabled normal rotation of the fetal head during the second stage [14]. Our findings regarding requirement of local anaesthetics and fentanyl are comparable with that of Owen *et al.* [15] who administered ropivacaine 0.075% and bupivacaine 0.075% each with fentanyl 2 mcg/mL for labor epidural analgesia. Multiple other investigators Stienstra *et al.*, [9] Writer *et al.*, [14] Campbell *et al.* [16] found that total drug requirement and hourly drug requirement was similar for bupivacaine and ropivacaine in labor epidural analgesia.

Similar pain scores in bupivacaine and ropivacaine group in the first stage and second stage of labor suggests equivalent quality of analgesia. Although three studies suggest, ropivacaine is less potent than bupivacaine the two drugs appear to be equipotent at clinically used concentrations. Polley *et al.*[17] and Capogna *et al.* [18] estimated the minimum local analgesic concentrations of ropivacaine and bupivacaine using an up-down sequential allocation study design. By definition, they estimated a dose of local anesthetic that produces labor analgesia in only 50% of the patients. In contrast, McDonald *et al.* [19] compared the spinal ropivacaine with spinal bupivacaine in volunteers, not in the labor or undergoing surgery. The applicability of the findings of these three studies to clinical practice remains unknown. In our study, findings suggest that 0.1% ropivacaine and 0.1% bupivacaine are equipotent as demonstrated by mean hourly drug use, VAS scores to pain, sensory levels to spirit swab, and overall patient satisfaction. Additional studies examining the relative potencies of ropivacaine and bupivacaine in the clinical setting are warranted.

There was no statistically significant difference in duration of first or second stage of labor between two groups. Owen *et al.* [15] during their comparative study using ropivacaine 0.075% and bupivacaine 0.075% each with fentanyl 2 mcg/mL for labor epidural analgesia found a similar result. In contrast to our result, Lee *et al.*,[8] in a study of epidural labor analgesia using ropivacaine or bupivacaine, initiated analgesia with a 0.25% solution and maintained with a continuous infusion of a 0.1% solution with fentanyl 0.0002%. They found that ropivacaine was associated with a shorter first stage of labor than bupivacaine, but the relative difference is probably of limited clinical importance. This may be due to higher concentration of local anesthetic used initially, which might have caused motor block, leading to prolongation of labor. Thus ropivacaine and bupivacaine in 0.1% concentration does not cause prolongation of labor, this may be attributed to lower concentration of local anesthetic drugs used in this study. In our study, no parturient in either group had any adverse effects. Although we have not compared intermittent bolus technique to continuous infusion technique but according to Fettes *et al*[20] intermittent top up technique is better than continuous infusion technique. Fettes *et al* [20] compared intermittent versus continuous administration of epidural ropivacaine with fentanyl for analgesia during labor and found that the intermittent group required fewer supplementary injections and less drug to maintain similar pain scores, compared with the continuous group. As our institute has very few PCEA pumps/infusion pumps and inability of patients to operate PCEA pumps, we chose a technique of intermittent top-ups.

Conclusion

With the observations from the present study the conclusion is

- Bupivacaine 0.1% with 2 mcg/ml Fentanyl and Ropivacaine 0.1% with 2 mcg/ml Fentanyl produced equivalent analgesia for labour without compromising fetal outcome and maternal safety.
- Ropivacaine produced minimal motor blockade when compared to Bupivacaine.

- The total local anaesthetic requirement was higher with Ropivacaine when compared to Bupivacaine.

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