A STUDY COMPARING DIFFERENT CONCENTRATIONS OF ROPIVACAINE 0.125% VS. 0.2%, WHEN GIVEN WITH FENTANYL 2 MCG/ML FOR EPIDURAL LABOUR ANALGESIA Vindhya K¹

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ABSTRACT

BACKGROUND

Epidural administration of local anaesthetics, with or without opioids, is commonly used for the relief of pain in labor. Lower concentration of local anesthetics is used for providing labor epidural analgesia.

MATERIALS AND METHODS

After approval of the Institutional Ethical Committee, this study was conducted at a teaching hospital in GGH, Kakinada on 50 term parturients. 50 parturients of ASA I & II, primi or multi gravida with singleton pregnancy having vertex presentation were taken up for the study. They were randomly divided into 2 groups–Group R1 and Group R2 each comprising of 25 parturients. Study patients (n=50) were randomly assigned to one of two groups of 25 each. They received aliquots of epidural injection using either, 10 ml of ropivacaine 0.125 % with 2 μ g/ml fentanyl (group R1) or 10 ml of ropivacaine 0.2% with 2 μ g/ml fentanyl (group R2).

RESULTS

Demographic data, obstetric data, and injection delivery interval were comparable in both groups. Effective labor analgesia with no motor blockade was observed in both groups. Duration of analgesia after initial bolus dose was also significantly longer in group R2 (126.45 \pm 12.34 min) than in group R1 (73.05 \pm 27.4min). Ropivacaine at both concentrations (0.2% vs. 0.125%) along with fentanyl 2µg / ml decreased visual analog scale (VAS) scores to <3 in all parturients uniformly. Mean VAS scores were significantly less in group R2 than in group R1 at 5,60, and 90 min. Requirement of top-up doses was significantly less in group R2 as compared to group R1. Consumption of ropivacaine was comparable in both the groups (58.23 \pm 5.48 mg in group R1 and 65.88 \pm 6.29 mg in group R2, but consumption of fentanyl was significantly more in group R1 (94.31 \pm 4.93 mg) as compared to group R2 (31.58 \pm 2.38 mg). There were no significant changes in haemodynamics, nor adverse effects related to neonatal or maternal outcomes in both groups.

CONCLUSION

We conclude that both the concentrations of ropivacaine (0.2% and 0.125%) with fentanyl were effective in producing epidural labor analgesia. 0.2% concentration was found superior in prolonging the duration, lesser breakthrough pain requiring lesser top-ups, and a lesser consumption of opioids. Our study favors, the use of 10ml of 0.2% ropivacaine with 2mcg/ml fentanyl over 0.125% ropivacaine for labor analgesia.

KEYWORDS

Parturition, G08.686.784.769.490, Opiate Alkaloids, D03.132.577, Amides, D02.065.

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BACKGROUND

The pain of child birth is the most severe pain women will endure in their life time. Pain less labor, a complete freedom from labor pains, is a dream of every parturient woman. Of various labor analgesic techniques, epidural analgesia is the most effective form of analgesia. The benefits are effective pain relief without appreciable motor block, decrease in

Financial or Other, Competing Interest: None. Submission 21-06-2017, Peer Review 28-06-2017, Acceptance 05-07-2017, Published 07-07-2017. Corresponding Author: Dr. Vindhya K, Associate Professor, Department of Anaesthesia, Rangaraya Medical College, Kakinada. E-mail: vindhyakakulau@gmail.com DOI: 10.18410/jebmh/2017/662 maternal catecholamines. It also allows us to rapidly achieve surgical anaesthesia through the same catheter. Obstetric epidural analgesia may be associated with prolonged labor and increased incidence of instrumental deliveries and Caesarean section for dystocia.^{1,2} Ropivacaine is a new longacting local anaesthetic, chemically homologous to bupivacaine manufactured as the pure S-enantiomer, whereas the others are racemic mixtures. Ropivacaine, an amide local anesthetic is less cardio toxic as well as it may also be more selective for sensory fibers when compared to other local anesthetics, producing less motor block.³

Aims and Objectives

Aim of the study was to compare the effects of selected concentrations of ropivacaine in labor analgesia.



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The objective of this study was to evaluate the efficacy of 0.125% and 0.2% ropivacaine both mixed with fentanyl 2 mcg/ml for epidural labor analgesia regarding their sensory and motor block characteristics as well as the foetomaternal outcomes.

MATERIALS AND METHODS

A total of 50 parturients in active labor were randomly assigned to two groups of 25 each, to receive an epidural injection of 10 ml ropivacaine 0.125% with fentanyl (2 mcg/ml) in group R1 and 10 ml of ropivacaine 0.2% with fentanyl (2 mcg/ml) in group R2 as initial bolus dose. Same dose regimen was used as subsequent top-up dose on patients demand for pain relief. The duration and quality of analgesia, motor block, top-up doses required, consumption of ropivacaine and fentanyl and foetomaternal out come in both groups were compared. After informed consent patients were subjected to a thorough pre-anesthetic evaluation. The study drug was administered epidurally as intermittent bolus doses (top-ups) through epidural catheters. Epidural catheter was inserted via an appropriate lumbar inter vertebral space at L3-L4 under strict aseptic precautions. After excluding intra vascular-subarachnoid placement of the epidural catheter, patients received 10 ml of epidural ropivacaine 0.125% with fentanyl 2µg/ml or ropivacaine 0.2% with fentanyl 2µg/ml. Subsequent top-up doses of 10 ml were given on patient request. Before placement of the epidural catheter, VAS score was noted with VAS 0 = no pain and 10 = the worst imaginable pain along with base line vitals. This dose was defined as first initial bolus dose and time was noted. The adequacy of analgesia was assessed 5 min after the first initial bolus dose of study drug had been administered. Analgesia was considered adequate if pain score was < 3. If analgesia was not adequate 15 min after the first initial dose, an additional 10 ml of study medication (second initial dose) was administered, and analgesia reassessed in the same manner. If pain relief was in adequate 15 min after the second initial dose of ropivacaine; the epidural anesthetic was classified as block failure, and patient withdrawn from the study. Presence of motor block in the lower extremities was assessed using a Breen modified Bromage scale (BMBS). VAS and BMBS was assessed every 15 min. All parturient were given a trial walk to assess their ability to ambulate. An additional dose of ropivacaine 10ml was given as a top-up dose on patient request, Epidural analgesia was continued through the second stage of labor.

Data Recording

Demographic data (age, weight, height) Pain score (VAS), sensory and motor block using a cardiotocograph, and any evidence of fetal heart rate decelerations was recorded. Neonatal assessment was performed by assessing the Apgar score at 1 and 5 min characteristics and vital parameters (pulse, mean arterial pressure,) were recorded at 0 (before epidural), 5,15 min and then every 15 min till 1 hour and then every 30 min until the delivery. Sensory block height was assessed by loss of sensation top in prick (blunt head of a pin). Fetal heart rate was monitored.

Inclusion Criteria

American Society of Anesthesiologists (ASA) grade I and II parturients. Uncomplicated pregnancy in a vertex presentation Primi or multi parous, Age 20-30 yrs. Singleton vertex presentation, Previous Normal Vaginal Delivery. Dilatation 3-5 cm.

Exclusion Criteria

Patient refusal Infection Fixed cardiac out put Severe coagulopathy Platelet count <75000/mm.

RESULTS

Effective labor analgesia with no motor blockade was observed in both groups. The mean age in group R1 was 22.2 ± 1.82 years which was lesser when compared to group R2 (23.3 \pm 1.06 years). Height, weight and parity did not show much variation in both groups (Table 1). Duration of analgesia after initial bolus dose was also significantly longer in group R2 (126.45 \pm 12.34 min) than in group R1 (73.05 ± 27.4 min) (Table 2). Mean VAS scores were significantly less in group R2 than in group R1 at 5, 15, and 30 min (Table 3). Requirement of top-up doses was less in group R2. 72% of the 25 patients of group R2 were managed with bolus dose only. In group R1 only 40% of the 25 patients could be managed with bolus dose. Seven patients required one top up dose, 5 patients required two top up doses and three patients required 3 top up doses in group R1. In group R2 five patients required one top up dose two patients required 2 top up doses and none required third dose (Table 4). Consumption of ropivacaine was comparable in both the groups (58.23 ± 5.48 mg in group R1 and 65.88±6. 29 mg in group R2, but consumption of fentanyl was significantly high in group R1 (94.31 \pm 4.93 mg) as compared to group R2 (31.58 ± 2.38 mg), P < 0.001 (Table 5). There were no significant changes in haemodynamics, nor adverse effects related to neonatal or maternal out comes in both groups.

	Group R1	Group R2		
Age	22.2 ± 1.82	23.3 ± 1.06		
Weight (kg)	55 ± 4	56 ± 5		
Height (cm)	158 ± 4.6	156 ± 4.25		
Primi gravidae	14	13		
Multi gravidae	11	12		
Table 1. Demographic Data				

	Group R1	Group R2
Duration of Analgesia with bolus Dose (minutes)	73.05 ± 27.24	126.45 ± 10.42

Meantime to First Top UP (minutes) 6		1.34 ± 12.32	124.38 ± 12.34		
Meantime to Second Top UP 69 (minutes)		9.86 ± 09.34	126.45 ± 10.34		
Table 2. Block Characteristics					
Parameter		Group R1	Group R2		
Parameter Before Bolus Dose		Group R1 9.85	Group R2 9.92		
Parameter Before Bolus Dose 5 min After Bolus Dos	se	Group R1 9.85 4.8	Group R2 9.92 1.63		
Parameter Before Bolus Dose 5 min After Bolus Dos 15 min After Bolus	se .	Group R1 9.85 4.8 0.55	Group R2 9.92 1.63 000		
Parameter Before Bolus Dose 5 min After Bolus Dos 15 min After Bolus 30 min After Bolus	se .	Group R1 9.85 4.8 0.55 0.30	Group R2 9.92 1.63 000 0.000		

Parameter	Group R1	Group R2			
Bolus Dose only	10	18			
Bolus Dose + 1 Top-UP	7	5			
Bolus Dose + 2 Top-UP	5	2			
Bolus Dose + 3 Top-UP	3	0			
Table 4. Dose Requirement					

Total Dose	Group R1	Group R2			
Ropivacaine (mg)	58.23 ± 5.48	65.88 ± 6.29			
Fentanyl (mcg)	94.31 ± 4.93	64.58 ± 2.83			
Table 5. Total Drug Consumption					

P<0.001.

DISCUSSION

Painless labor, a complete freedom from labor pains, is a dream to every parturient woman. Of various labor analgesic techniques, epidural analgesia is the most effective form of analgesia. The benefits are effective pain relief without maternal motor block, decrease in appreciable catecholamines, means to rapidly achieve surgical anaesthesia. The obstetric epidural analgesia maybe associated with prolonged labour and increased incidence of instrumental deliveries and Caesarean section for dystocia.^{1,2} Ropivacaine is a new long-acting local anaesthetic, chemically homologous to bupivacaine manufactured as the pure S-enantiomer, whereas the others are racemic mixtures. Ropivacaine, an amide local anesthetic is less cardio toxic as well as it may also be more selective for sensory fibers when compared to other local anesthetics, producing less motor block.³ The less pronounced motor block in the ropivacaine group may have enabled more active participation and more effective bearing down, resulting in the increased incidence of spontaneous vaginal delivery. At the same time, a lesser reduction in the tone of the pelvic diaphragm might have enabled normal rotation of the fetal head during the second stage.⁴ However, Russelland Reynolds, when comparing epidural labour pain relief with plain bupivacaine 1.25 mg or bupivacaine 0.625 mg with low-dose fentanyl or sufentanil could not demonstrate a difference in spontaneous deliveries between these groups, although motor block was significantly lower in the latter group.⁵ Ropivacaine is characterized by lower CNS and cardiovascular toxicity than bupivacaine at equal doses.⁶ Meister et al, administered 0.125% bupivacaine or 0.125% bupivacaine with Fentanyl 2 µg/ml for labor analgesia and found both the drugs were equipotent as demonstrated by mean hourly drug use, sensory level stop in prick, and over all patient satisfaction.⁷ Whether epidural analgesia has adverse effects on the progress and outcome of labor has been the topic of much debate.8 One of the factors implicated in the association between epidural analgesia and increased rates of operative delivery was motor block from the epidural local anesthetic. This may decrease maternal mobility, reduce maternal effort in the second stage, and may also predispose to in adequate rotation of the fetal presenting part secondary to relaxation of pelvic floor muscles. All of these factors may potentially contribute to an increased requirement for assisted vaginal or cesarean delivery. Motor block from local anesthetic can be minimized either by reducing the concentration of the local anesthetic or by choosing a local anesthetic with a high differential sensory: motor block ratio, such as Ropivacaine.9 The advantage of using a small concentration of local anesthetic was well demonstrated in Comparative Obstetric Mobile Epidural Trial (COMET). This showed that the instrumental vaginal delivery rate was less frequent when a small dose epidural regimen (Bupivacaine 0.1% with Fentanyl 0.0002%) was compared with a traditional epidural regimen (Bupivacaine 0.25%). They found that instrumental vaginal delivery was less frequent in women who received Ropivacaine compared with those who received Bupivacaine. In contrast, in our study, where we used smaller concentration of the study drugs, there was no significant difference in the mode of delivery in both the groups. On the other hand, other authors found that ropivacaine 0.2% offers adequate analgesia more often than either 0.15% or 0.1% and the resultant motor blocks and hemodynamic effects were minimal.¹⁰ Addition of fentanyl 2 mcg/ml to 0.1% ropivacaine improved analgesia to a quality similar to 0.2% ropivacaine.¹¹ In the present study, epidural labor analgesia with ropivacaine 0.125% or 0.2% both combined with fentanyl (2 mcg/ml) produced adequate labor analgesia in all the 50 parturients in both groups. Duration of analgesia of initial bolus dose was also significantly more with 0.2% ropivacaine in our study. Addition of adjuvant opioids led to further increase in duration of analgesia. Time of first top-up was also significantly more in 0.2% group, which was in concordance with other studies. Requirement of top-up doses was also significantly less frequent in 0.2% group, but total dose of ropivacaine was comparable in two groups. In the present study, no motor block was observed in both groups. We also observed slight fall in the MAP and heart rate, but none of the patients had episodes of hypotension and bradycardia.

CONCLUSION

We conclude that both the concentrations of ropivacaine (0.2% and 0.125%) with fentanyl were effective in producing epidural labor analgesia. 0.2% concentration was found superior in prolonging the duration, lesser breakthrough pain requiring lesser top-ups, and a lesser consumption of opioids. Our study favors, the use of 10 ml of 0.2% ropivacaine with 2 mcg/ml fentanyl over 0.125% ropivacaine for labor analgesia.

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