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Comparison of different concentrations of epidural ropivacaine (0.05% 0.1% & 0.2%) for labour analgesia: A prospective randomized and double blind study

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Abstract
Introduction: *Epidural infusion of 0.2% ropivacaine is recommended by the manufacturer for labour analgesia, but lower concentrations may be effective. The present work is a clinical comparative study of different doses of ropivacaine i.e. 0.05%, 0.1% and 0.2%, each with 2 mcg/mL of fentanyl to find out minimum effective concentration of ropivacaine that can be used safely in epidural labor analgesia.*
Materials and Methods: *The study was conducted on sixty (60) parturient of ASA grade I and grade II physical status, in labor, with single fetus, vertex position, between 37-42 weeks gestation with regular contractions (true labor pain) with 4-6 cm cervix dilatation and who had requested labor analgesia. Parturients were then allocated randomly to one of three groups with 20parturients in each group. Group 1 received 0.05% ropivacaine with 2 mcg/mL fentanyl, Group 2 received 0.1% ropivacaine with2 mcg/mL fentanyl and Group 3 received 0.2% ropivacaine with 2 mcg/mL fentanyl. After completion of the study, the nonparametric data of the study was analyzed with Kruskal Wallis test and parametric data of the study was analyzed with ANOVA test and p value of <0.05 was taken as statistically significant.*
Results: *Patient demographics and labor characteristics were comparable in all the groups. Ropivacaine 0.05% with 2 mcg/mL of fentanyl produced adequate analgesia for labor and delivery in only 50% of parturient while ropivacaine 0.1% &ropivacaine0.2% with 2 mcg/mL of fentanyl produced adequate analgesia in 90% of parturient in group II and group III. Reduction in local anesthetic was not associated with any change in incidence of motor block or instrumental deliveries.*
Conclusion: *We concluded that the minimum concentration which can be used safely for labor analgesia with no adverse effect is 0.1% of ropivacaine with 2 mcg/mL fentanyl.*
Keywords: *epidural labour analgesia, Ropivacine, fentanyl.*

Introduction

Pain in labor is an extreme agonizing experience for most women. Various methods have been tried since time to alleviate this pain. The modern concept of obstetric analgesia can be said to have begun with James young Simpson. Heusedether in obstetric practice in 1847. Over the time so many methods have been introduce to alleviate pain during labor which include parenteral morphine, rectal preparations of paraldehyde and barbiturates and so many psychological methods. Other methods like acupuncture, transcutaneous

electrical nerve stimulation (TENS) have also been used. Among all the techniques available, the epidural method comes closes to the idea in alleviating labor pain. The concentration of local anaesthetics initially used was high enough to cause motor blockade. Concerns about this motor blockade and its effect in delaying the progress of labor has led to the use of low concentrations of local anesthetics which produce selective sensory blockade, thereby sparing the motor fibres. The use of ropivacaine for labor analgesia is increasing, in cause this local anestheticis considered to be less cardiotoxic than bupivacaine and because it may be associated with a decreased incidence of motor blockade.[1-3] The addition of opioids to the local anaesthetic reduces the concentration of the latter and hence associated side-effects and incidence of motor blockade.[4-7] Most studies on epidural labor analgesia have used bupivacaine or a mixture of bupivacaine and fentanyl, and only a few studies have evaluated ropivacaine.[5-8] Moreover, there is little information regarding the administration of various concentration of ropivacaine during labor. This study compared the administration of different doses of ropivacaine i.e. 0.05%, 0.1% and 0.2%, each with 2mcg/mL of fentanyl to find out minimum effective concentration of ropivacaine that can be used safely in epidural labour analgesia.

Materials and Methods

After obtain institutional ethical committee permission and written informed consent, nulliparous or primiparous parturient who were ASA physical status I or II and in the first stage of labor having contractions at least once every 5min,with a cervical dilation of more than 3cm and who requested epidural analgesia for pain relief were enrolled in the study. Women with severe medical or obstetrical complications, multiple gestation, hypersensitivity to study drugs, contraindications to neuraxial blocks.

Parturients were then allocated randomly using computer generated random number list, three groups with 20 parturients in each group .Group1 received 0.05% ropivacaine with 2mcg/mL fentanyl, Group2 received 0.1% ropivacaine with 2mcg/mL fentanyl and Group3 received 0.2%ropivacaine with 2mcg/mL fentanyl.

Epidural analgesia was performed after preloaded the parturients with iv 500ml of RL solution. Under strict aseptic precautions, an 18G Touhy's needle (PERIFIX 0-401 B-BROUN Pvt ltd.) was inserted into the epidural space at theL4-5 intervertebral space in the sitting position with loss of resistance technique. Epidural catheter was then placed 4 cms in epidural space

In cephalad direction. Catheters were aspirated gently for return of blood or CSF and then tested by the injection of 3mL of 2% lidocaine with 15mcg of epinephrine. Any changes in heart rate, blood pressure, amplitude of QRS complex in ECG or numbness in feet were looked for over the next 5 minutes. After 5min, 10ml of bolus dose of ropivacaine 0.05% or 0.1%, or 0.2%with 2mcg/Ml of fentanyl was given to each group. Following the initial bolus dose pain was assessed in parturients and if analgesia was not adequate at the peak of contraction after 15min,an additional 5ml of the same anaesthetic solution was given every 5minutes when visual analog scale (VAS) >4 or on demand of patient even if VAS<4 with limit of not exceeding total 30ml in one hour.

Pain assess by using VAS score and assessment to motor block will be by using modified Brom age score. (0=noparalysis, 1=unable to raise extended leg, 2=unable to flex knee, 3=unable to flex ankle). Foetal heart rate, maternal systolic and diastolic blood pressure, pulse rate were monitored at every 5 min for the first 30min after bolus injection of three different concentrations for Groups I, II and III. Subsequently maternal blood pressure was measured every 15min. Maternal hypotension (systolic BP less than 90mmHg or decrease of atleast 20% of systolic BP) from the baseline was treated with intravenous crystalloids and phenylephrine if needed. Neonatal status evaluated by using APGAR score at 0, 5 and at 10 min

Table1: Demographic variables

	Group 1	Group2	Group3	P-value
Age	20.5+- 4.5	22.4+-3.7	23.3+-3.6	NS
Height(cm)	154+-6	153.3+-6	152.2+-5.2	NS
Weight(kg)	58+-4	59.2+-5.1	54.7+_4.7	NS
Duration of first stage	276.7+-167.32	256+-188.4	284+-169.5	NS
Duration of second stage	48.6+-29	43.6+-31.7	51.2+-28.5	NS
Mode of delivery NVD	14	15	13	NS
INSRIUMENTAL DELIVERY C/S	4 1	4 2	5 1	NS

APGAR SCORE AT1MIN	7.2+-0.628	6.9+-0.78	7.1+-0.71	NS
AT 5 MIN	9.7+-0.8	9.6+-0.7	9.45+-0.7	NS
VAS	5.67+-1.5	3.3+-2.3	3+-2.5	0.00079 (SIGNIFICANT)

Table-2 –Quality Of Analgesia

	GROUP-1	GROUP-2	GROUP-3
SCORE	CASES/%	CASES/%	CASES/%
EXCELLANT	-/-	9/45%	11/55%
GOOD	7/35%	5/25%	6/30%
FAIR	3/15%	4/20%	3/15%
POOR	10/50%	2/10%	1/5%

Table-3 Complications/Side Effects

	GROUP-1	GROUP-2	GROUP-3
HYPOTENSION	NONE	NONE	NONE
BRADYCARDIA	2/20	4/20	5/20
N/V	NONE	1/20	1/20
PRURITUS	NONE	NONE	1/20

Discussion

The ideal labour analgesic technique should be effective, safe for the mother and the foetus, should be easy to administer, should provide consistent, predictable and rapid onset of analgesia in all stages of labour, should be devoid of motor blockade and should preserve the stimulus for expulsive efforts during the second stage of labour. It is now well recognized that the only consistently effective method of pain relief in labour is lumbar epidural analgesia.[9] However, labour epidural analgesia relying on high doses of local anaesthetics (LA) produced motor block interfering with labour and the mode of delivery. To reduce these side effects it has been a routine practice for more than 20 years to combine adjuvants with local anaesthetics.[10] The use of ropivacaine for labor analgesiais increasing, in part because this local anestheticis considered to be less cardiotoxic than bupivacaine and is associated with a decreased incidence of motor blockade.[11] Addition of opioids in the anesthetic solution allows the use of a smaller concentration of local anesthetic. Hence, the use of decreased concentrations of ropivacaine has been described in recent studies.[12] Most workers have commenced epidural analgesia when the cervical dilation was 3cm or more. In the present study, the epidural analgesia was instituted with cervical dilation being between 4–5cm.[13-15]

In the present study, hypotension has been taken as systolic blood pressure more than 20%decrease from baseline. No parturient in either group experienced any hypotension. This is consistent with the study done by David C. Campbell, et al (2000) where noparturients showed any significant hypotension.14The mode of delivery was spontaneous vaginal in most of the parturients i.e. 75% in group -I, 70% in group-II and 70%in group-III.

In the present study, 25% of parturients in group-I, 30% of parturients in group-II and 30% of parturients in group-III parturients needed instrumental and LSCS. This is similar to the observations of Emmanuel Boselli et al (2003) who observed spontaneous delivery in 73% and 83% using Ropivacaine 0.15% with sufentanyl & ropivacaine 0.10% with sufentanyl respectively.15 This is also similar to the study done by Wang Li-Zhong et al (2010) who used ropivacaine 0.15% for labor analgesia & had 82% of spontaneous vaginal deliveries.16 Motor blockade was assessed using the modified Bromage scale. No motor block was observed in any parturient in either group in the present study. This concurs with the studies of Emmanuel Boselli et al. Who found minimal or absent motor block in all groups.[15]

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All the neonates in the three groups had an Apgar score>8 at 1minute and Apgar score>9 at 5minutes. In the present study, visual analogue scale has been used to assess the quality of pain relief. Each patient was asked to indicate her10cm visual analog scale (0= no pain, 10= Worst possible pain) at time zero and at 30min interval still delivery. In addition each patient was asked about her satisfaction with and quality of the analgesia given. About 70-80% of parturients in group-III experienced satisfactory relief (VAS<5). This is similar to study done by M.Dresner et al (2000) who had 79.4%parturients having satisfactory analgesia during labor using 0.25% ropivacaine with fentanyl.[17]

In the present study, 90% of the parturients in group-I, 80% in group-II and 75% in group-III did not experience any side effects.

The most common side effect in all three groups was nausea or vomiting with an incidence of 6% in group-I as compared to 12%in group-II and 15% in group-III which is statistically significant ($p<0.05$). This is in contrast with the study by David C Campbell etal where they found no incidence of nausea and vomiting using ropivacaine in combination with 2mcg/mL fentanyl.14 The study done by Emmanuel Boseli et al observed nausea or vomiting in 10% and 13% of parturients using 0.1% & 0.15% of ropivacaine respectively.[18]

Conclusion

In view of the above we can conclude that the Minimum possible concentration that can be used for labor analgesia to provide optimal relief is 0.1% of ropivacaine with 2mcg/mL fentanyl. This combination did not produce any significant hemodynamic changes or motor blockade. It also did not affect the progress of labor or neonatal outcome

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