

Comparison of three different concentrations of epidural ropivacaine (0.05%, 0.1% & 0.2%) for labor 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 labor 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 20 parturients in each group. Group 1 received 0.05% ropivacaine with 2 mcg/mL fentanyl, Group 2 received 0.1% ropivacaine with 2 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% & ropivacaine 0.2% 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, Labor analgesia, Ropivacaine, Fentanyl.

Introduction

Pain in labor is an extremely agonising experience for most women. Various methods have been tried since time immemorial to alleviate this pain. The modern concept of obstetric analgesia can be said to have begun with James Young Simpson. He used ether in obstetric practice in 1847, few months after its first public demonstration by Morton in 1846. In his search for a better agent, Simpson also pioneered the use of chloroform for obstetric pain relief. Over the time so many methods have been introduced 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 closest to the ideal in being effective in alleviating labor pain and in being safe for both the mother and the foetus. 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 anaesthetics which produce selective sensory blockade, thereby sparing the motor fibres.

The use of ropivacaine for labor analgesia is increasing, in part because this local anesthetic is 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 concentrations 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 2 mcg/mL of fentanyl to find out minimum effective concentration of ropivacaine that can be used safely in epidural labour analgesia.

Materials and Methods

After approval from the institutional ethics committee 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 5 min, with a cervical dilation of more than 3 cm 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, spinal column deformities or a contraindication to epidural analgesia were excluded.

Parturients were then allocated randomly using computer generated random number list kept in sealed opaque envelopes to one of three groups with 20 parturients in each group. Group 1 received 0.05% ropivacaine with 2 mcg/mL fentanyl, Group 2 received 0.1% ropivacaine with 2 mcg/mL fentanyl and Group 3 received 0.2% ropivacaine with 2 mcg/mL fentanyl.

Epidural analgesia was performed after hydrating the parturients with intravenous 500 ml of Ringer Lactate solution. Under strict aseptic precautions, an 18 G Touhy's needle (Portex, Smiths Medical India Pvt Ltd.) was inserted into the epidural space at the L3-4 or L4-5 intervertebral space in the sitting position with loss of resistance technique. Epidural catheter was then gently threaded through the lumen of the tuohy needle to a depth of 5 cm into the epidural space in cephalad direction. Catheters were aspirated gently for return of blood or cerebrospinal fluid and then tested by the injection of 3 mL of 2% lidocaine with 15 mcg of epinephrine. Any changes in heart rate, blood pressure 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 2 mcg/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 15 min, an additional 5 ml of the same anaesthetic solution was given every 5 minutes when visual analog scale (VAS) > 4 or on demand of patient even if VAS < 4 with limit of not exceeding total 30 ml in one hour.

Each patient was asked to indicate her pain score on marked 10 cm VAS score (0 = no pain, 10 = Worst possible pain) at time zero and at 30 min intervals till delivery. Also patients were asked about her satisfaction and quality of the analgesia given. Assessment of motor block was done using modified

Bromage score. (0=no paralysis, 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 30 min after bolus injection of three different concentrations for Groups I, II and III. Subsequently maternal blood pressure was measured every 30 min. Maternal hypotension (systolic BP less than 90 mmHg or decrease of at least 20% of systolic BP) was treated with intravenous crystalloids and phenylephrine if needed. Neonatal evaluation included Apgar scores at 1 and 5 min.

Statistical Analysis

A sample size of 20 in each group was calculated with power of study 80% and type 1 error of 5%. To compensate for a possibility of exclusion of some parturient we recruited additional 5 patients. After completion of the study data were presented as mean \pm standard deviation. 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

Demographic data were similar in both the group (Table 1). Ropivacaine 0.05% with 2 mcg/mL of fentanyl produced adequate analgesia for labour and delivery in only 50% of parturients while ropivacaine 0.1% & ropivacaine 0.2% with 2 mcg/mL of fentanyl produced adequate analgesia in 90% of parturients (Table 2). Mean VAS pain scores at baseline and throughout labor showed no difference between groups 2 and group 3. Ropivacaine upto 0.2% with 2 mcg/mL of fentanyl was not associated with any significant motor blockade. Ropivacaine with 2 mcg/mL of fentanyl in all three groups was not associated any clinically significant haemodynamic changes.

Nausea and pruritis were the only side effects observed in a minority of patient (Table 3). There was no significant change in the mode of delivery using three different concentrations of ropivacaine with 2 mcg/mL of fentanyl. Ropivacaine with 2 mcg/mL of fentanyl in all the three groups did not produce any neonatal depression as assessed by Apgar score in neonates at 1 minute and 5 minutes.

Table 1: Demographic variables

	Group - I	Group - II	Group - III	P value
Age (yr)	25.85 \pm 4.004	23.25 \pm 3.007	24.8 \pm 3.37	NS
Height (cm)	154.66 \pm 5.69	152.14 \pm 6.34	154.57 \pm 5.24	NS
Weight (kg)	57.3 \pm 6.85	55.4 \pm 7.728	53.8 \pm 4.786	NS
Duration of 1st stage (min)	283.75 \pm 168.31	257 \pm 191.62	294.5 \pm 174.28	NS
Duration of 2nd stage (min)	49.25 \pm 28.25	43.94 \pm 31.33	50.78 \pm 29.167	NS
Mode of delivery (n)				NS
Spontaneous	15	14	14	

Instrumental (C/S)	4 1	5 1	4 2	
Apgar scores (%) First minute	6.85 + 0.7881	6.70 + 0.786	6.80 + 0.6708	NS
Apgar scores (%) Fifth minute	9.65 + 0.7592	9.50 + 0.6070	9.45 + 0.5982	NS
VAS	5.66±1.493	3.14 ±2.627	3.085±2.608	0.0008 (significant)

Table 2: Quality of analgesia

Score	Group - I		Group - II		Group - III	
	Cases	%	Cases	%	Cases	%
Excellent	---	---	9	45	10	50
Good	8	40	5	25	4	20
Fair	2	10	4	20	4	20
Poor	10	50	2	10	2	10

Table 3: Complications/side effects

	Group - I		Group - II		Group - III	
	Cases	%	Cases	%	Cases	%
Hypotension	0	---	---	---	---	---
Bradycardia	0	---	---	---	---	---
Nausea/Vomiting	2	10%	4	20%	5	25%
Pruritus	---	---	1	5%	1	5%
None	18	90%	16	80%	15	75%
Total	20	100	20	100	20	100

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 analgesia is increasing, in part because this local anesthetic is 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, a trend toward 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 3 cm or more. In the present study, the epidural analgesia was instituted with cervical dilation being between 4–6 cm.¹³⁻¹⁵

In the present study, hypotension has been taken as systolic blood pressure less than 90 mm Hg or greater 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 no parturients showed any significant hypotension.¹⁴

The 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

All the neonates in the three groups had an Apgar score > 6 at 1 minute and Apgar score > 9 at 5 minutes. This is similar to the study of Emmanuel Boselli et al who found that 94% of neonates at 1 minute had scores >7 and 98% of neonates had an Apgar of > 7 at 5 minutes while using 0.10% of ropivacaine.¹⁵

In the present study, visual analogue scale has been used to assess the quality of pain relief. Each patient was asked to indicate her pain scores on an unmarked

10 cm visual analog scale (0= no pain, 10= Worst possible pain) at time zero and at 30min intervals till 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

Sixty to seventy percent parturients in group II (0.1% ropivacaine with 2 mcg/mL fentanyl) and only 50% of parturients in group I experienced complete relief which concurs with the study done by Jaime Fernandez-Guisasola et al (2001) who had 78.7% parturients having satisfactory analgesia during labor using 0.1% ropivacaine with fentanyl.¹³

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 10% in group I as compared to 20% in group II & and 25% in group III which is statistically significant ($p < 0.05$). This is in contrast with the study by David C Campbell et al where they found no incidence of nausea or vomiting using ropivacaine in combination with 2 mcg/mL fentanyl.¹⁴ The study done by Emmanuel Boselli 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 2 mcg/mL fentanyl. This combination did not produce any significant hemodynamic changes or motor blockade. It also did not affect the progress of labour or neonatal outcome.

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