COMPARISON OF ROPIVACAINE (0.125%) AND ROPIVACAINE (0.125%) WITH CLONIDINE (75µG) FOR LABOUR ANALGESIA: A RANDOMIZED CLINICAL TRIAL

Sanjot Ninave[1], Swati Agarwal[2]

[1]Professor, Department of Anaesthesiology, Jawaharlal Nehru Medical College, Sawangi, Wardha.
[2]Postgraduate Trainee, Department of Anaesthesiology, Jawaharlal Nehru Medical College, Sawangi, Wardha.

ABSTRACT

BACKGROUND

To compare the effects of Clonidine (75 µg) added to Ropivacaine (0.125%) with Ropivacaine (0.125%) alone for epidural labour analgesia.

MATERIALS AND METHODS

After informed consent, 40 pregnant women in ASA I / II randomly underwent epidural labour analgesia using 10 ml of Ropivacaine 0.125% (R group) or 10 ml of Ropivacaine 0.125% plus 75 µg Clonidine (RC group). Pain intensity, level of sensory block, and duration of epidural analgesia were evaluated in the labouring mother. The newborns were evaluated using APGAR scores.

RESULTS

In RC group, the duration of analgesia was significantly prolonged as compared to R group and there was no difference in duration of labour, mode of delivery or foetal outcome. Patient satisfaction was better with clonidine added to ropivacaine.

CONCLUSION

The study demonstrates that addition of clonidine improves epidural analgesic effect along with ropivacaine.

KEYWORDS

Labour Analgesia, Epidural, Ropivacaine, Clonidine.

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BACKGROUND

The pain of childbirth is the most painful experience for women and maternal request is a sufficient indication for providing her pain relief during labour. The contemporary goal of providing maternal labour analgesia is the relief of the suffering and the pain of labour and delivery, with minimal effects on maternal safety, awareness, motor functions, progress of labour and foetal wellbeing.

Ropivacaine has been introduced into obstetric anaesthetic practice with the proposed advantage of causing less motor blockade. It has a higher threshold than Bupivacaine for causing cardiovascular and CNS toxicity.[1,2] Being less lipophilic, it causes less penetration of large myelinated nerve fibres, thus having a less propensity to cause motor blockade when used in lower concentration or dose.[3]

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Corresponding Author:
Dr. Swati Agarwal,
Flat No. 202, Datta Residency,
JNMC Campus, Sawangi,
Wardha, Maharashtra – 442001.
E-mail: swati_agrwl@yahoo.com
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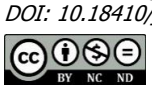

Clonidine is an α_2-adrenergic agonist that produces analgesia via a non-opioid mechanism, by increasing the quality and duration of epidural analgesia without causing the side effects of opioids which are generally preferred as an adjunct for epidural analgesia.[4] The optimal epidural dose would lie between 60 µg to 75 µg: a dose lower than 60 µg is ineffective, whereas a dose larger than 100 µg induces sedation and hypotension.[5] Landau et al demonstrated a dose sparing effect of clonidine (75 µg) with different doses of Ropivacaine.[6]

We undertook this study to compare the effects of addition of Clonidine (75 µg) to Epidural Ropivacaine (0.125%) for labour analgesia, with regard to duration of analgesia, duration of labour, mode of delivery, foetal outcome, patient satisfaction and side effects.

MATERIALS AND METHODS

The study was conducted in the Department of Anaesthesia, Jawaharlal Nehru medical college, Datta Meghe institute of medical sciences, Sawangi (Meghe) Wardha after obtaining permission from Institutional Ethical Committee. After counselling and written informed consent for labour analgesia from ASA grade I and II full term cephalic singleton parturients, were divided into two study groups of 20 each randomly. Preanaesthetic checkup was done followed by necessary investigations. At cervical dilation of 3-4 cms confirmed by obstetrician, patient was shifted to

induction room and connected with basic monitors to record pulse, blood pressure, pulse oximetry and ECG.

Patients were placed in left lateral position and preloaded with 500ml of Ringer lactate after securing intravenous access. Baseline pain score was taken using Numerical Rating Scale (NRS) with 0 being no pain and 10 being worst pain imaginable. Epidural catheter was placed in lumbar epidural space L3-L4 under all aseptic precautions with 18G Tuohy's needle. Epidural space was confirmed by loss of resistance and hanging drop technique, 18G multipore epidural catheter 3-4 cm was threaded into the epidural space.

The patients were divided randomly into two groups of 20 each.

Group 1- Patients received 10 ml of Ropivacaine (0.125%) alone,

Group II- Patients received 10 ml Ropivacaine (0.125%) with Clonidine (75µg) through the epidural catheter using all aseptic precautions. Patient were placed supine and a wedge was placed under the right hip to prevent aorto-caval compression. The doses were given in graded fashion, while checking for intrathecal response. Patients were monitored for blood pressure (every 5 minutes for 30 minutes from drug administration and then every 30 minutes) and heart rate continuously. Fetal wellbeing was assured by cardiotocogram. Administration of IV fluids and oxygen was considered as per individual case. After delivery of baby inj. oxytocin was added to the fluid.

Onset of analgesia is defined as the time taken to decrease NRS by two levels. If the patient did not reach NRS 3 by first dose, they were administered repeat dose consisting of 3-5 ml of 0.125% ropivacaine in both the groups after waiting for 15 minutes.

Duration of analgesia is defined as time taken when top up was needed, that is when NRS goes above 5. Top up consisted of 5-7 ml 0.125% ropivacaine, then 3-5 ml after 15 minutes titrated to patient satisfaction (NRS = 3). Total volume of drug needed for each patient was noted.

Duration of labour was checked: (I) from 7 cm (insertion of catheter) to full dilatation, (II) -second stage.

Need for instrumentation (forceps delivery or ventouse) as well as incidence of caesarean section was noted. Foetal outcome was assessed by APGAR at 1, 5 and 10 minutes.

Patient satisfaction was graded on a scale of 0 to 10 after delivery. Side effects, if any were noted with respect to hypotension (more than 20% decrease in systolic blood pressure), bradycardia (heart rate <50 bpm), need for urinary catheterization, sedation (recorded with a four-point score: 0 = no sedation, 1 = slight sedation or patient responding to verbal stimulation, 2 = moderate sedation or patient responding to tactile stimulation, and 3 = deep sedation or patient not responding to tactile stimulation), respiratory depression, nausea and vomiting.

The data were analyzed statistically. For the categorical variables, the proportions of the variances in the two groups were compared using the chi-squared test with calculation of the Z^2 statistic and p value, or using Fisher's exact test.

RESULTS

In each group, there were 20 patients. The demographic data (Table 1) did not differ between the two groups. The mean duration of labour did not differ significantly in either group (R vs RC, 196.13 vs 186.13 min). All patients in R group had normal vaginal delivery but 2 patients in RC group had LSCS due to nonprogress of the labour. The new-borns did not differ in weight or gestational age. The Apgar score at 5 min was statistically insignificant (p = .066) between the two group.

There was no difference in the pain before epidural blockade between the two groups. In RC group, 19 out of 20 patients experienced onset of analgesia within 5 mins of drug administration whereas patients in R group experienced onset of analgesia within 10 mins. This difference in onset of analgesia is significant between the groups till 10 min post drug administration but not beyond 10 mins duration. There were no differences in the level of sensory blockade.

The mean duration of epidural analgesia was significantly longer in RC group as compared to R group (298.25 vs. 211.8 minutes). Supplementary analgesia (bolus dose) was not required in either groups. Maternal hypotension occurred in 1(5%) patient in the R group and 2 (10%) patients in the RC group during the resolution of delivery (without any significant difference). One (5%) patient in RC group had nausea along with hypotension and the other had nausea and vomiting with hypotension.

Patient satisfaction was recorded subjectively on a scale of 0 to 10 as per her experience she noted throughout the labour analgesia process and turned out to be more favourable for RC group (p=0.0039) as they experienced prolonged pain relief.

	R group	RC group
Maternal Characteristics		
Age	24.36 ± 2.48	23.53 ± 2.82
Weight	62.1 ± 3.75	62.05 ± 6.1
Height	154.18 ± 2.82	154.98 ± 2.91
Obstetrical Characteristics		
Gestational Age	38.9 ± 1.2	38 ±1.0
Duration of Labour	196.13	186.13
Mode of Delivery		
Normal Vaginal	20	18
Instrumentation	0	0
Caesarean Section	0	2
Neonatal Characteristics		
Birth Weight	2.3 ±.2	2.4 ± .5
Apgar Score	8.43 ± 0.50	8.36 ± 0.49 0.6573

Table 1. Patient Demography

	R group	RC group	p value
Analgesia			
VAS before epidural	10	10	
VAS at 5 min	9.1 ± 0.31	7.25 ± 0.97	<0.0001
VAS at 10 min	5.05 ± 0.69	3.5 ± 0.82	<0.0001
VAS at 30 min	1.9 ± 0.64	1.75 ± 0.64	0.4632
Duration	211.8 ± 6.45	298.25 ± 16.24	<0.0001
Side effects			
Nausea	1	2	
Vomiting	0	1	
Sedation	0	4 pts with score 1	
Hypotension	1	2	
Fetal bradycardia	0	0	
Respiratory depression	0	0	
Satisfaction scale	8.85 ± 0.88	9.55 ± 0.51	0.0039

Table 2. Analgesia and Side Effects

DISCUSSION

Epidural analgesia is the most effective method of providing pain relief during labour. We have done a comparative study of labour analgesia comparing ropivacaine alone and in combination with clonidine.

Both the groups were comparable demographically Groups were comparable with regard to demographic data and cervical dilation upon entry, duration of labour, mode of delivery, and Apgar scores.

There was no difference in the duration of labour between two groups. This observation remains similar to other studies of local anaesthetic alone and in combination with clonidine.[7,8] This result is against the study conducted by Cigarini I and others, who found that addition of clonidine to local anaesthetic increases the duration of labour.[9]

In our study, onset of analgesia was significantly shorter, and duration of analgesia was longer among women receiving clonidine with ropivacaine 0.2% (8 mL). Our result corroborates with the study of Lanadu et al and Nakamura et al.[10]

Several studies had been conducted to examine the effect of clonidine with ropivacaine in variety of surgeries e.g. peripheral blocks[11,12] as a spinal adjunct for orthopaedic surgery[13] or by the caudal route for paediatric surgery,[14] and all the studies had showed prolonged duration of analgesia.

We did not observe significant sedation in patients receiving clonidine or any episode of foetal bradycardia. Neonatal outcome was similar with regards to Apgar score at 1 and 5 minutes in both the groups. It is consistent to findings in other studies.[9,15]

CONCLUSION

The study demonstrates that Clonidine (75 μg) can be used as a useful adjunct to Ropivacaine to improve epidural labour analgesia without any significant side effects in the parturient.

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