Original Article

Indian Journal of Anesthesia and Analgesia
Volume 9 Number 2 March-April 2022
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.9222.8

A Comparative Study of 0.1% Ropivacaine with Fentanyl and 0.1% Ropivacaine with Clonidine for Epidural Labour Analgesia

Varalakshmi Karasala[1], Mukesh Somvanshi[2], Archana Tripathi[3], Upendra Kumar[4]

Author's Affiliation: [1]Post Graduate Student, [2,3]Senior Professor, [4]Medical Officer, Department of Anesthesiology and Critical Care, Government Medical College and AG Hospitals, Kota, Rajasthan 324005, India.

Abstract

Background: Pain relief in labour has always been surrounded with myths and controversies. Hence providing effective and safe analgesia during labour has remain an ongoing challenge. This study was undertaken to compare fentanyl and clonidine with ropivacaine in epidural labour analgesia.

Methods: A total of 60 term parturients with uncomplicated pregnancy, vertex presentation, posted for on-demand epidural labour analgesia were divided into two groups. Group RF (n=30) patients received 10ml solution comprising 0.1% ropivacaine with fentanyl 20mcg. Group RC (n=30) patients received 10ml of 0.1% ropivacaine with clonidine 60mcg. Characteristics of the block, onset and duration of analgesia and total analgesic requirements were noted. Pain and overall satisfaction scores were assessed with a 10-point visual analogue scale. Mode of delivery and neonatal APGAR scores were recorded.

Result: At baseline, groups were matched demographically, haemodynamically as well as for intensity of pain. A significant difference among groups in VAS was observed from 120min intervals and lowest values were in group RC. No significant difference was observed in haemodynamic parameters, mode of delivery and expulsive efforts. Total analgesic dose and top up dose requirement was more in group RF. Six percent of patients in group RF and 10 percent of patients in group RC developed nausea.

Conclusion: Ropivacaine 0.1% was effective in decreasing labour pain without any motor blockade. Clonidine was superior to fentanyl as an adjuvant in labour without any significant feto-maternal adverse effects.

Keywords: Ropivacaine, fentanyl, clonidine, epidural labour analgesia.

How to cite this article:

Varalakshmi Karasala, Mukesh Somvanshi, Archana Tripathi, Upendra Kumar/A Comparative Study of 0.1% Ropivacaine with Fentanyl and 0.1% Ropivacaine with Clonidine for Epidural Labour Analgesia/Indian J Anesth Analg. 2022;9(2):63-67.

Corresponding Author: Upendra Kumar, Medical Officer, Department of Anesthesiology and Critical Care, Government Medical College and AG Hospitals, Kota, Rajasthan 324005, India.
E-mail: drupendra1010@gmail.com
Received on: 29.01.2022, **Accepted on:** 28.02.2022

Introduction

The labour is reported to be one of the most painful experiences in a women's life. Pain relief in labour has always been surrounded with myths and controversies. Hence providing effective and safe analgesia during labour has remain an ongoing challenge. Advances in the field of labour analgesia have tread a long journey from the days of ether and chloroform in 1847 to the present day practice of comprehensive programm of labour pain management using evidence based medicine.

Ropivacaine is an amide local anaesthetic with a chemical structure similar to bupivacaine. A number of studies[1-3] suggested that ropivacaine is associated with less CNS and CVS toxicity and produces less motor block than bupivacaine and these qualities make ropivacaine advantageous for management of painless labour. Reduction in the concentration of local anaesthetics and addition of adjuvants like opioids and non opioids has been advocated to improve the results and minimize risks in epidural labour analgesia. This allows the patient to be ambulatory with preservation of motor function and subjective somatic sensation of lower limbs.

Several studies[4,5] have shown that addition of clonidine/fentanyl improves the quality of anaesthesia, reduces the dose requirement of local anaesthetic agent and provided better haemodynamic stability. Hence this study was undertaken to compare the effects of addition of fentanyl or clonidine added to 0.1% ropivacaine for epidural labour analgesia when given as intermittent top up doses.

Methods

After institutional ethical committees approval and written informed consent, the present study was conducted on sixty term parturient of ASA grade 1 or 2 with singleton pregnancy in vertex presentation and parturient in active labour with cervical dilatation 3-6 cm requesting pain less labour were included in the study. Exclusion criteria were: ASA grade 3 and 4, patient refusal, bleeding disorders, thrombocytopenia, history of allergy to local anaesthetics, hypovolaemia, local sepsis, patient with antepartum haemorrhage, severe eclampsia, cephalopelvic disproportion, and cervical dilatation>6cm. This double blind study was conducted on 60 patients who were randomly divided into 2 groups of 30 patients each.

Group RF (n=30): Patients were administered 0.1% ropivacaine 10 ml and fentanyl 20 mcg.

Group RC (n=30): Patients were administered 0.1% ropivacaine 10 ml and clonidine 60mcg. After confirming the active first stage of labour and cervical dilatation 3-6 cm, epidural block was performed after proper positioning of the patient. An intravenous access was secured and at least 500 ml of ringer lactate solution was given. Standard monitoring were applied like ECG, NIBP, pulse oximetry. Under all aseptic precautions, epidural space was identified in sitting position with midline approach using 18 gauge Tuohy's needle in L3-4 or L4-5 interspace with loss of resistance to air technique and after confirmation of epidural space, catheter was threaded cephalad 3 to 4 cms into epidural space and patient had been shifted in supine position with wedge under left buttock. After negative aspiration for blood and CSF, a test dose of 3ml of lignocaine 1.5% with 1:2,00,000 adrenaline was administered through the catheter to exclude intravenous or subarachnoid catheter placement.

Five minutes after administering the test drug, 10 ml of study drug of either 0.1% ropivacaine with fentanyl 20mcg or 0.1% ropivacaine with clonidine 60mcg was given. Following 10 min of drug administration, patient was asked to lift legs straight without flexing the knees. When patient was able to lift legs easily without bending knees, she was asked to take a trial walk.

Next top up doses were given on demand. Before giving each top up dose, aspiration was done. Following every top up dose, patients were monitored carefully for 10 min to detect any weakness or inadequate analgesia. When analgesia was inadequate (VAS>3), top up was repeated upto maximum of 20 ml at a time. The study was ended at the time of vaginal delivery, assisted or not, or when the decision was made to perform a caesarean delivery.

Parturient's vital parameters like pulse, blood pressure, respiratory rate, VAS score, motor power grade, foetal heart rate and any side effects or complaints were noted before block and after block at 0, 15, 30, 45, 60, 90, 120, 150 and 180 min interval. Mode of delivery was recorded and neonates were evaluated by means of Apgar score at 1 and 5minutes. Total analgesic dose of local anaesthetic and total number of top up doses were also recorded. After delivery epidural catheter was removed. Parturient were interviewed a day after delivery for satisfaction level and quality of analgesia on four point scale (Excellent, Good, Fair and Poor). Statistical analysis of data was done using Student's 't test and Chi-square test. Ap–

value less than 0.05 was considered as statistically signifcant.

Results

As shown in table no 2, demographic and obstetric variables were comparable in both groups. The difference in onset of analgesia was not significant statistically. At baseline no significant difference was observed in VAS score between the groups, however, VAS score was significantly less from 120min in group RC than group RF.

Table 1: Modified Bromage score.

Grade	
0	Normal movement in hip, knee and foot, No motor block
1	Weakness in hip muscles, Inability to raise extended leg
2	Weakness in knee muscles, Inability to flex knee
3	Motor block of hip, knee, Inability to flex ankle joint

Table 2: Demographic and obstetric characteristics.

Variables	Group RF	Group RC
Age (yr)	24.26± 3.63	23 ± 3.1
Weight (kg)	67.73 ± 3.88	69.77 ± 4.5
Height (cm)	158.20 ± 2.37	158.97± 2.72
Duration of labor (min) First stage	208± 70.03	224 ± 63.38
Second stage	43 ± 14.57	46 ± 15.67
Onset of analgesia (min)	22.17 ± 1.70	21.87 ± 1.80
Duration of effective analgesia(min)	65.33 ±7.30	107.67 ±4.50
Level of sensory block	T8 (T7-T9)	T8 (T7-T9)
Mode of delivery, no (%) Vaginal delivery	28 (93.33)	26 (86.67)
Forceps delivery	2(6.67)	4(13.33)
Cesarean delivery	0	0
Total dose of Study drug (mg)	R=38.77 ±8.20 F=20	R=24.37 ± 6.57 C=60
Total number of top up doses	3.4±1.13	1.9±0.52
APGAR Score at 1 min	8.33 ± 1.06	8.6 ± 0.49
5 min	9.83 ± 0.79	10
Patient satisfaction, no (%) Excellent	3(10)	24 (80)
Good	26 (86.67)	6(20)
Fair	1 (3.33)	0
Poor	0	0

Values are expressed as mean ± SD, no (Percentage) and median (range), Group RF vs RC

R=Ropivacaine, F=fentanyl, C=Clonidine

Table 3: Motor block.

Bromage Score Grade	Group RF no (%)	Group RC no (%)
0	30 (100)	30 (100)
1	0	0
2	0	0
3	0	0

The difference in duration of analgesia was statistically significant in both groups ($p<0.05$). This duration of analgesia was significantly prolonged in group RC than group RF. According to modified Bromage scale (Table 1), none of the parturient developed motor block in both groups (Table 3).

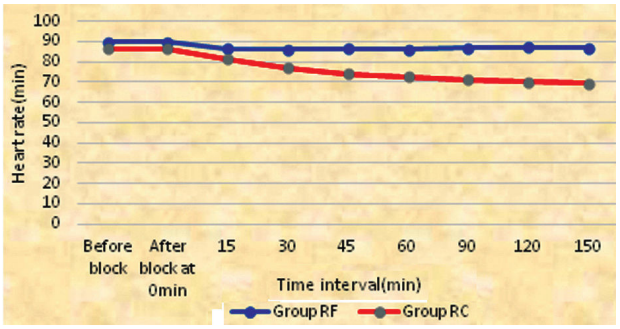

Fig. 1: Heart rate per min.

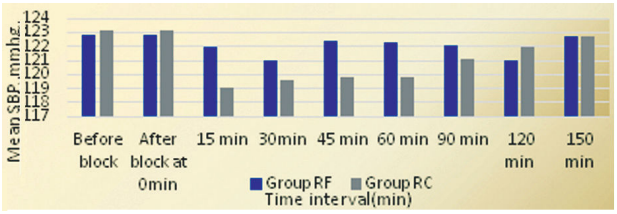

Fig. 2: Systolic blood pressure (mmhg).

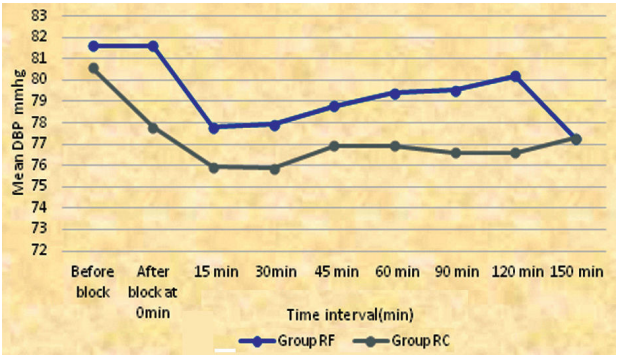

Fig. 3: Diastolic blood pressure (mmhg).

At all the time intervals during the study heart rate was less in group RC when compared with group RF (Fig. 1). However, the difference in heart rate was statistically insignificant at all the time

except at 150min after epidural at which heart rate was significantly lower in group RC compared to group RF. The mean systolic and diastolic blood pressure decreased slightly after the initial dose of the drug until 15-30 minutes, thereafter remained stable in both groups (Fig. 2 and 3). The changes in the value of mean systolic and diastolic blood pressure in the two groups were statistically insignificant ($p<0.05$).

The difference in total dose of study drugs used in this study was statistically significant (Table 2). The difference in mean total number of top up doses was statistically significant in both groups (Table 2). No significant difference was observed among groups for mode of delivery (normal, forceps assisted or cesarean). A significantly higher nuber of patients had excellent patient acceptance in group RC as compared to group RF (Table 2).

None of the patient had APGAR score <7 at 1min and 5min interval (Table 2). On comparing adverse effects six percent of patients in group RF and ten percent of patients in group RC developed nausea and two patients had vomiting in group RC. Only one patient in group RF and two patients in group RC developed retention of urine and two patients in group RF and one patient in group RC had pruritus.

Discussion

Safe foetal outcome without any adverse maternal effect is the chief goal of pain relief during labour and lumbar epidural analgesia is the most efficient and widely employed modality for this. Of all the available methods of labour analgesia, epidural analgesia is the most effective form of analgesia and satisfies the basic requirements of labour analgesia by fulfilling the objective of decreasing the pain of labour without affecting other sensations such as a desire to push and to allow normal walking while preserving the tone of pelvic floor muscles as well as retaining the sensation of the baby's head in the vagina; thus allowing labour to proceed unhindered. Thus it is considered as gold standard in obstetric care.

Ropivacaine has been used in neuraxial, epidural and subarachnoid anaesthesia. It has a profile similar to bupivacaine but with less neuro and cardi-toxic effect.[6] Opioids are the most widely used class of adjuvant to epidural local anaesthetic in labour analgesia practice. Fentanyl and remifentanyl are the two most commonly used opioid for this purpose. The dose of fentanyl used in our study was 2mcg/ml of drug solution in loading bolus.

Clonidine being alpha-2 agonist, is known to increase the effectiveness of local anaesthetic agent in epidural labour analgesia in many studies.[7,8] The dose of clonidine used in our study was 1mcg/kg in loading bolus, which approximates to 50-70mcg/kg clonidine in loading bolus. Previous studies[9] have shown that clonidine used in doses greater than 100mcg have been associated with maternal and foetal bradycardia, maternal hypotension while doses less than 30mcg are ineffective in increasing the potency of local anaesthetics, but 60mcg clonidine is effective in labour analgesia when given with local anaesthetics. So we used the clonidine in 60mcg/kg dose as obese and malnourished patients were excluded from our study.

The VAS score of the two groups were comparable at baseline and throughout the labour and no significant difference was found between the groups except at 120min. Although, at 120min the difference in VAS was statistically significant, however, it was clinically insignificant as at 120min the mean VAS in both groups was less than 2 which was clinically acceptable grade of analgesia. Thus we can say that both drug solutions used in our study were able to achieve adequate and acceptable analgesia in laboring females.

At all the time intervals during the study, patient remained stable haemodynamically in both groups. The results of our study correlates with Ahirwar A et al.[10] We preloaded the patients to avoid any hypotension due to sympathectomy and it seems that preloading is adequate to prevent any episode of hypotension associated with initiation analgesia. No patient in any of the group required vasopressor for treatment of hypotension: therefore we can say that there is no risk of hypotension with the use of epidural analgesia with the drug combinations used in our study.

In group RF, two patients required instrumental vaginal delivery while in group RC instrumentation was required in four patients. The rate of normal vaginal delivery in group RF and group RC were 93% and 87% respectively. Previous studies[11,12,13] found that the rate of spontaneous delivery was similar in both fentanyl and clonidine groups which is also seen on our study.

As shown in table 2, the total dose of ropivacaine required and the total number of top up doses required were less in group RC than in group RF. Thus clonidine seems to be more effective as it reduced the total dose of ropivacaine and total number of top up doses required during first and second stage of labour. The dose sparing effect

of clonidine on ropivacaine was also proven by Kumari I et al[14] and Topcu I et al.[15]

Conclusion

Thus we conclude that both drug combinations of 0.1% ropivacaine with fentanyl and 0.1% ropivacaine with clonidine were effective in controlling labour pain and 0.1% concentration of ropivacaine was sufficient for labour analgesia without causing any motor weakness which can affect the ambulation of the patient or the maternal expulsive efforts.

The addition of fentanyl and clonidine can decrease the requirement of ropivacaine and helps in the reduction of local anaesthetic toxicity. Clonidine and fentanyl does not cause any adverse foetal or maternal outcomes. Thus in our study, we found that both fentanyl and clonidine have dose sparing effect on 0.1% ropivacaine with stable haemodynamics and no significant feto-maternal adverse effects. However, clonidine is better than fentanyl in dose sparing effect with longer effective duration of analgesia, better quality of analgesia and excellent patient acceptance for epidural labour analgesia.

References

1. David C. Campbell, Rhonda M. Zwack, Lesley-Ann L. Crone, Ray W. Yip. Ambulatory labor epidural analgesia: bupivacaine versus ropivacaine. Anesth Analg 2000; 90: 1384–9.
2. P. D. W. Fettes, C. S. Moore, J. B. Whiteside, G. A. Mcleod, J. A. W. Wildsmith. Intermittent vs continuous administration of epidural ropivacaine with fentanyl for analgesia during labour. Br J Anaesth 2000; 97: 359–64.
3. Firoz Satpathy, Archana Tripathi, Mukesh Somvanshi, Pallavi Huilgol. A comparative study of 0.1% ropivacaine with fentanyl and 0.1% bupivacaine with fentanyl for epidural labour analgesia. Ind J Anesth Analg.2020;7:41-5.
4. Helene Finegold, Gordon Mandell, Sivam Ramanathan. Comparison of ropivacaine 0.1%-fentanyl and bupivacaine 0.125% -fentanyl infusions for epidural labour analgesia. Can J Anesth 2000; 47(8): 740–45.
5. Meister GC, D' Angelo R, Owen M, Nelson KE, Gaver R. A comparison of epidural analgesia with 0.125% ropivacaine with fentanyl versus 0.125% bupivacaine with fentanyl during labor. Anesth Analg 2000;90:632-7.
6. Scott DB, LeeA, Fagan D, Bowler GMR, Bloomfield P and Lundh R. Acute toxicity of ropivacaine compared with that of bupivacaine. Anesth Analg 1989;69:563-9.
7. Claes B, Soetens M, Zundert AV, Datta S. Clonidine added to bupivacaine-epinephrine-sufentanyl improves epidural analgesia during childbirth. Reg Anesth Pain Med.1998;23(6):540-47.
8. Aveline C, Metaoua SE, Masmoudi A, Boelle PY, Bonnet F. The effect of clonidine on the minimum local analgesic concentration of epidural ropivacaine during labour. Anesth Analg. 2002;95(3):735-40.
9. Roelants F. The use of neuraxial adjuvant drugs (neostigmine, clonidine) in obstetrics. Curr Opin Anaesth. 2006;19(3):233-37.
10. Ahirwar A, Prakash R, Kushwaha BB, Gaurav A Chaudhary AK, Verma R,et al. Patient Controlled Epidural Labour Analgesia (PCEA): A comparison between ropivacaine, ropivacaine-fentanyl, ropivacaine-clonidine. J Clin Diagn Res 2014;8:GC09-13.
11. Ismet T, E Tuna, T Selcen, K Oznar, I Rusen, S Melek. The Comparison of Efficiency of Ropivacaine and Addition of Fentanyl or Clonidine in Patient Controlled Epidural Analgesia for Labor. The Int J Anesth.2006;(11):2.
12. Smedvig JP, Soriede E, Gjessing L. Ropivacaine 1mg/ml, plus fentanyl 2mcg/ml for epidural analgesia during labour. Acta Anaesthesiol Scand.2001;45(5):595-99.
13. Celleno D, Capogna G, Costantino P, Zangrillo A. Comparison of fentanyl with clonidine as adjuncts for epidural analgesia with 0.125% bupivacaine in the first stage of labor. Int J Obstetr Anesth. 1995;4(1):26-9.
14. Kumari I, Sharma K, et al., Comparison of Ropivacaine 0.2% with or without clonidine 1mcg/ kg for epidural labor analgesia: A randomized controlled study. J Anaesthesiology pharmacol 2018;34;B-22.
15. Topcu I, Erincler T, Tekin S,Karaer O, Isik R, Sakarya M. The comparision of efficiency of ropivacaine and addition of fentanyl or clonidine in patient controlled epidural analgesia for labour.Internet J Anesthesiol 2006;11:1-7.