

Comparative study of epidural ropivacaine with fentanyl versus bupivacaine with fentanyl for labour analgesia

Bariki Santosh Kumar¹, Pradeep Kode^{2*}, Deepraj Singh B³, D Dharmarajuloo⁴

^{1,2}Assistant Professor, ³Professor & HOD, ⁴Professor, Department of Anaesthesiology, Bhaskar Medical College and General Hospital, Yenkapally Village Moinabad Mandal Rangareddy District, Telangana - 501504, INDIA.

Email: pradeepkode@yahoo.com

Abstract

Background: The labour process is considered to be one of the most painful experiences in a woman's life. Long acting local anaesthetics like bupivacaine and ropivacaine have been increasingly used along with adjuvants such as opioids (eg. fentanyl, sufentanil) to provide safe, effective and adequate pain relief during labour. Present study was aimed to compare epidural ropivacaine with fentanyl versus bupivacaine with fentanyl for labour analgesia at a tertiary hospital. **Material and Methods:** Present study was hospital based, prospective, prospective, randomized study, conducted in parturients 18-40 years, term singleton pregnancy with vertex presentation with spontaneous or induced labour. ASA1 and ASA2 with uncomplicated pregnancy. Parturients were randomized into 2 groups by computer generated random number tables into Group B - parturients received 0.1% bupivacaine with fentanyl 2µg /ml, as 10 ml initial bolus and Group R - parturients received 0.1% ropivacaine with fentanyl 2µg /ml, as 10 ml initial bolus. **Results:** The mean age (years), weight, height, parity distribution, mean period of gestation were comparable ($p>.05$) in both the groups. Onset of analgesia was in 11.93 ± 5.18 mins in group B as compared to 12.4 ± 5.51 min in group R, difference was not significant statistically. Mean VAS at end of 1st stage and 2nd stage was comparable in both the groups and difference was not significant statistically. Mean dose of local anaesthetic drug, total dose of local anaesthetic drug (mg/hour) and total dose of fentanyl (mcg) were comparable ($p>.05$) in both the groups and difference was not significant statistically. The mean duration of labor, mode of delivery and mean APGAR scores were comparable($p>.05$) in both the groups. **Conclusion:** We noted that 0.1% of ropivacaine with fentanyl and 0.1% of bupivacaine with fentanyl achieve equally effective and excellent labour analgesia with no motor blockade, without compromising fetomaternal outcome.

Keywords: ropivacaine, fentanyl, bupivacaine, labour analgesia.

*Address for Correspondence:

Dr Pradeep Kode, Assistant Professor, Department of Anaesthesiology, Bhaskar Medical College and General Hospital, Yenkapally Village Moinabad Mandal Rangareddy District, Telangana - 501504, INDIA.

Email: pradeepkode@yahoo.com

Received Date: 03/09/2021 Revised Date: 16/10/2021 Accepted Date: 23/11/2021

This work is licensed under a [Creative Commons Attribution-NonCommercial 4.0 International License](https://creativecommons.org/licenses/by-nc/4.0/).



Access this article online

Quick Response Code:



Website:
www.medpulse.in

DOI:
<https://doi.org/10.26611/10152116>

lead to the release of adrenaline which results in prolonged labor and the increase in the level of noradrenaline by 25% decreases uterine blood flow by 50%. Maternal cardiac output, systemic vascular resistance and oxygen demand will be increased.^{1,2} An ideal labor analgesic technique should provide adequate and satisfactory analgesia without any motor blockade or adverse maternal and fetal effects. Among the variety of labor analgesia techniques, epidural analgesia remains gold standard for providing pain relief during labor.^{3,4} Ropivacaine and bupivacaine are amino-amide local anaesthetics which structurally belong to the group of n-alkyl substituted pipecoloxylidide. Ropivacaine has propyl group in comparison to butyl group of bupivacaine on the amine portion of pipecoloxylidide.⁵ Long-acting local anaesthetics like bupivacaine and

INTRODUCTION

The labour process is considered to be one of the most painful experiences in a woman's life. Pain and anxiety

ropivacaine have been increasingly used along with adjuvants such as opioids (eg. fentanyl, sufentanil) to provide safe, effective and adequate pain relief during labour.⁶ Present study was aimed to compare epidural ropivacaine with fentanyl versus bupivacaine with fentanyl for labour analgesia at a tertiary hospital.

MATERIAL AND METHODS

Present study was hospital based, prospective, prospective, randomized study, conducted in Department of Anaesthesiology, Bhaskar Medical College and General Hospital, Yenkapally, India. Study duration was of 2 years (August 2018 to July 2020). Study was approved by institutional ethical committee.

Inclusion criteria: Parturients 18-40 years, term singleton pregnancy with vertex presentation with spontaneous or induced labour. ASA1 and ASA2 with uncomplicated pregnancy attending obstetric department, requested labour analgesia for pain relief. Cervix dilatation 4-6 cm and effacement 20-50 percent. Reactive NST. Pre rupture of membrane less than 6 hours and clear liquor after Artificial Rupture of Membrane. Not having any contraindication to epidural analgesia.

Exclusion criteria: Hypersensitivity to study drugs. Bleeding disorders, decreased platelet counts. Spinal column deformities, spine surgery. Malpresentation, cephalopelvic disproportion, previous lower segment cesarean section and placenta previa, medical Disorders complicating pregnancy excluding preeclampsia with non-severe features, delivery within 2 hours of labour analgesia. Not willing to participate

Initial assessment was done and patients fit for present study were considered for study. Study was explained to patients and a written informed consent was taken from all participants. Parturients were randomized into 2 groups by computer generated random number tables into

Group B - parturients received 0.1% bupivacaine with fentanyl 2 μ g /ml, as 10 ml initial bolus.

RESULTS

In present study 60 parturient females fulfilling the inclusion criteria were randomized into two groups of 30 each. The mean age (years), weight, height, parity distribution, mean period of gestation were comparable ($p>.05$) in both the groups. Mean cervical dilatation (cm) at time of giving epidural analgesia in group B was 3.3 ± 1.3 cm and in group R was 3.3 ± 1.4 cm and difference was not significant statistically.

Table 1: General characteristic

Parameter	Group B (n=30) (Mean \pm SD)	Group R (n=30) (Mean \pm SD)	p-value
Age (in years)	23.61 ± 3.31	23.96 ± 3.01	0.72
Weight (in kgs)	57.01 ± 6.19	55.92 ± 6.75	0.47
Height (in feet)	5.41 ± 0.31	5.31 ± 0.24	0.51
Parity			--
Multigravida	9 (30%)	9 (30%)	
Primigravida	21 (70%)	21 (70%)	
Gestational age (in weeks)	38.92 ± 1.51	38.40 ± 1.73	0.77

Group R - parturients received 0.1% ropivacaine with fentanyl 2 μ g /ml, as 10 ml initial bolus.

Patients were shifted to operation theatre, baseline parameters {heart rate (HR), non-invasive blood pressure (NIBP) and oxygen saturation (SpO₂)} noted, preloaded with 500-1000 ml of Ringer lactate solution and epidural catheter was inserted under aseptic conditions. There was a provision of patient controlled epidural boluses of 5ml of the respective drugs with a lockout interval of 12 min and a continuous background infusion of 5 ml/ hour in both the groups using PCA pump. A baseline visual analog pain score (VAS based on a 0–100mm scale, 0 mm = no pain and 100 mm = worst pain imagined) was also obtained. The patient was monitored for HR, NIBP, motor block and SpO₂ every 5 minutes for 20 minutes after bolus and thereafter hourly throughout the study period. After 1 hour monitoring patients were shifted to labour room for monitoring of the mother and foetus during the course of labour. Partographic monitoring of fetal heart rate was done throughout the labour. The other variables measured were total consumption of anaesthetic drugs during the course of labour, time of onset of sensory block, any side-effects like nausea and vomiting, duration of second stage of labour, mode of delivery and Apgar scores at 1 and 5 minutes. Parturient females were assessed on the basis of visual analogue scale (VAS) on a scale of 0 to 10, 0 being no pain and 10 was worst pain possible. Neonatal assessment was done by assessing APGAR score at 1 and 5 min by neonatologist. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Cervical dilation (in cms)	3.3 ± 1.3	3.3 ± 1.4	0.81
----------------------------	---------------	---------------	------

Onset of analgesia was in 11.93 ± 5.18 mins in group B as compared to 12.4 ± 5.51 min in group R, difference was not significant statistically ($p=0.64$). Mean VAS at end of 1st stage and 2nd stage was comparable ($p>0.05$) in both the groups and difference was not significant statistically. Mean dose of local anaesthetic drug, total dose of local anaesthetic drug (mg/hour) and total dose of fentanyl (mcg) were comparable ($p>0.05$) in both the groups and difference was not significant statistically.

Table 2: Analgesia characteristics

Parameter	Group B (n=30) (Mean±SD)	Group R (n=30) (Mean±SD)	p-value
Onset of analgesia (minutes)	11.93 ± 5.18	12.4 ± 5.51	0.64
Mean VAS End of 1 st stage	2.5 ± 1.3	2.1 ± 1.1	0.19
Mean VAS End of 2 nd stage	1.6 ± 1.4	1.9 ± 1.2	0.11
Sensory level-number (%)			0.52
T8	13 (43.3%)	12 (40 %)	
T10	17 (56.7%)	18 (60 %)	
Anaesthetic drug			
Dose of LA (mg)	45.5 ± 8.91	43.9 ± 9.13	0.53
Total dose LA (mg/hour)	7.38 ± 3.1	8.1 ± 2.7	0.31
Total dose fentanyl (mcg)	78.3 ± 20.19	80.2 ± 18.82	0.68

The mean duration of labor, mode of delivery and mean APGAR scores were comparable ($p>0.05$) in both the groups. In group B, 26 (86.67 %) delivered by normal vaginal delivery, 4 (13.33 %) delivered by Caesarean section for fetal distress, non-progress of labour and deep transverse arrest. Whereas in group R, 27 (90 %) delivered by normal vaginal delivery and 3(10 %) delivered by caesarean section for fetal distress and non-progress of labour. Side effects such as hypotension, nausea/ vomiting, drowsiness and pruritus were managed conservatively and comparable ($p>0.05$) in both the groups and difference was not significant statistically.

Table 3: Maternal and neonatal findings

Maternal and neonatal findings	Group B (n=30) (Mean±SD)	Group R (n=30) (Mean±SD)	P value
Duration of labour (Mean±SD)			
1 st stage (hours)	5.91 ± 2.26	6.12 ± 1.97	0.56
2 nd stage (minutes)	39.12 ± 11.67	34.66 ± 10.94	0.75
Mode of delivery			0.89
Normal vaginal delivery	26 (86.67 %)	27 (90 %)	
Caesarean section	4 (13.33 %)	3 (10 %)	
APGAR score			
At 1 min	8.12 ± 1.64	8.54 ± 1.45	0.77
At 5 min	8.43 ± 0.60	8.70 ± 0.69	0.81
Side effects			0.23
No side effects	26 (86.67 %)	27 (90 %)	
Hypotension	2 (6.67 %)	1 (3.33 %)	
Nausea/ vomiting	2 (6.67 %)	1 (3.33 %)	
Drowsiness	1 (3.33 %)	0	
Pruritus	0	1 (3.33 %)	

DISCUSSION

Untreated labour pain has been explained as a cause of chronic pain, postpartum stress syndrome, and undesired psychological and physiological consequences.^{2,3} Neuroaxial technique of epidural analgesia is the most popular and effective method of pain relief in labour. The major advantages are no risk of gastric aspiration, avoidance of depressant general anaesthetic drugs and allows the mother to be awake to participate in the delivery. Ideal analgesic drugs should have a long duration of action with less motor blockade, limited perinatal transfer, and no adverse effects on the mother and fetus.⁷

Apart from sharing various physicochemical properties with bupivacaine, onset time and duration of action of ropivacaine are also similar to the former but with less motor blockade when same volume and concentration are used. This property is attributed to lower potency when compared to bupivacaine.⁶ Fentanyl is a highly lipid soluble drug, and when placed in the epidural space, peak concentration is reached in about 20 minutes. The low incidence of side effects associated with epidural fentanyl has been explained by the lipid solubility of the agent, which is so great that only low concentration of drug reaches the brain stem. The drug does not impair uterine

contractility, which is an essential part of the normal birth process.⁴ Paddalwar S. *et al.*⁸ noted that ropivacaine showed no difference in the mean VAS scores and the quality of analgesia, as compared to Bupivacaine. At 20 min, all the patients in both groups were absolutely pain free with the VAS score of 0. No patient in group R developed motor block, whereas five patients in group B developed grade 2 (mild) motor block. APGAR scores were comparable in both the groups. They concluded that ropivacaine is equipotent, produces less motor block, has no adverse effect on the course and duration of labor, and can be used safely. Similar findings were noted in present study. In study by Anita Birda *et al.*⁹ group I patients received 0.1% levobupivacaine with 2 µg/ml fentanyl and group II patients received 0.1% ropivacaine with 2 µg/ml fentanyl. The mode of delivery found was instrument-assisted vaginal delivery seen in 8 in group I and 6 in group II, caesarean seen 7 in group I and 8 in group II and normal vaginal delivery seen 5 in group I and 6 in group II. The mean total number of manual rescue boluses was 0.68 in group I and 1.05 in group II and first requirement of manual rescue bolus was 2.65 in group I and 3.14 in group II and demand boluses per hour was 0.36 in group I and 0.08 in group II. Levobupivacaine and ropivacaine with fentanyl were equally effective in labour epidural analgesia. Similar findings were noted in present study. A meta-analysis reported that ropivacaine produced lesser motor blockage compared to bupivacaine which was supposed to cause increased rate of instrumental delivery.⁸ However, the COMET trial demonstrated that onset, duration, quality of analgesia, and mode of delivery was comparable, except frequent incidence of motor block with bupivacaine.⁹ A meta-analysis conducted by Li *et al.* showed that, combined with fentanyl, bupivacaine and ropivacaine exhibited comparable efficacy and safety. It also added that bupivacaine-fentanyl combination led to shorten second stage of labor and mothers in ropivacaine-fentanyl group experienced lower incidence of motor blockage.¹⁰ The major limitations of present study were small sample size as well as effect of factors like the timing of amniotomy, maternal fever, neonatal birth weight, which can influence the mode of delivery are not considered for evaluation.

CONCLUSION

We noted that 0.1% of ropivacaine with fentanyl (2 µg/mL) and 0.1% of bupivacaine with fentanyl (2 µg/mL) achieve equally effective and excellent labour analgesia with no motor blockade, without compromising fetomaternal outcome.

REFERENCES

- Bilic N, Djakovic I, Klican-jaic K, Rudman SS, Ivanec Z. EPIDURAL ANALGESIA IN LABOR - controversies. *Acta Clin Croat* 2015;54(3):330e6.
- Fortescue C, Wee MYK. Analgesia in labour: non-regional techniques. *Br J Anaesth CEACCP* 2005;5:9e13.
- Rmd S, Cj H. Epidural versus non-epidural or no analgesia in labour, 4; 2010 (Review).
- Cambic CR, Wong CA. Labour analgesia and obstetric outcomes. *Br J Anaesth*. 2010;105:50-60.
- Lee HL, Lo LM, Chou CC, Chuah EC. Comparison between 0.08% ropivacaine and 0.06% levobupivacaine for epidural analgesia during nulliparous labour. *Chang Gung Med J* 2011;34:286-91.
- Shaikh SI, Rohini K. Comparison of Epidural Bupivacaine 0.5% With Epidural Ropivacaine 0.75% for lower limb Orthopedic Procedures. *Internet Journal of Anesthesiology* 2012;30(2):110-3.
- Zhao Q, Yan C, Fang B, et al. Efficacy and side effects comparison of bupivacaine and ropivacaine with fentanyl for labor analgesia under combined spinal and epidural analgesia. *Int J Clin Exp Med* 2018; 11(8): 8003-10.
- Paddalwar S, Nagrale M, Chandak A, Shrivastava D, Papalkar J. A randomized, double-blind, controlled study comparing Bupivacaine 0.125% and Ropivacaine 0.125%, both with Fentanyl 2 µg/ml, for labor epidural analgesia. *Indian J Pain* 2013;27:147-53.
- Anita Birda, Mohammed Irshad Sheikh, Sudeshana Goswami, Sagar Bijarniya, Comparative evaluation of efficacy of 0.1% levobupivacaine with fentanyl and 0.1% Ropivacaine with fentanyl during Labour epidural analgesia, *International Journal of Health and Clinical Research*, 2021;4(9):150-152
- Velde M Van De. Modern neuraxial labor analgesia: options for initiation, maintenance and drug selection. *Elsevier* 2009;56(9):546e61
- Obstetric C, Epidural M, Comet T, Group S. Effect of low-dose mobile versus traditional epidural techniques on mode of delivery: a randomised controlled trial, 358; 2001. p. 19e23.
- Li Y, Hu C, Fan Y, Wang H, Xu H. Epidural analgesia with amide local anesthetics, bupivacaine, and ropivacaine in combination with fentanyl for labor pain relief: a meta-analysis. *Med Sci Mon Int Med J Exp Clin Res* 2015 Jan;21: 921e8.

Source of Support: None Declared
Conflict of Interest: None Declared