A Comparison of Low – Concentration Ropivacaine (0.075%) with Fentanyl Versus Bupivacaine (0.05%) with Fentanyl for Labour Epidural Analgesia

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ABSTRACT

Introduction: Providing effective as well as safe analgesia to the parturients in labour is always a concerned for the anaesthesiologists. We conducted this study to compare the analgesic efficacy and fetomaternal outcome of ropivacaine and bupivacaine at equianalgesic dose with fentanyl in low dose infusion.

Material and Methods: This prospective, single blind study was carried on 60 nulliparous parturients of ASA grade I and II, with uncomplicated singleton, term pregnancy. The patients were randomly divided into two groups, to receive bolus dose of either 20 ml of 0.075% Ropivacaine and 0.05% Bupivacaine with fentanyl 2 µg/ml in Group RF and Group BF respectively, followed by infusion at the rate of 10ml/hr. Onset of analgesia, motor block, maternal hemodynamics, mode of delivery and foetal outcome was assessed.

Results: Visual Analog Scale (VAS) score < 3 was achieved in 25 min in Group RF as compared to 30 min in Group BF. At 30 min, 77% parturients achieved T_{10} as compared to 50% in group BF. Maternal haemodynamics, APGAR score, umbilical cord blood analysis was comparable in both the groups. None of the patients had motor block in both groups. The percentage of instrumental delivery was more in Group RF.

Conclusions: The onset of analgesia was faster in Group RF as compared to Group BF. However once the analgesia was established, both the groups had effective and satisfactory analgesia throughout the labour with good foetal outcome. The incidence of instrumental delivery was more in Group RF.

Keywords: Labour Analgesia, Continuous Infusion, Instrumental Delivery, Low Dose, APGAR Score

INTRODUCTION

The labour pain which is considered as the most painful experience for many women is associated with adverse effects on both maternal and foetal physiology. The stress of labour can cause maternal hyperventilation and increased catecholamine concentration which may result in maternal and foetal hypoxemia.[1,2] Thus effective and safe labour analgesia has been considered as important component of anaesthesia.

Labor analgesia has come a long way since the use of choloroform by John snow in 1853 for Queen Victoria.[3,4] The American Society of Anaesthesiologists (ASA) and the American College of Obstetricians and Gynaecologists (ACOG) recommended epidural analgesia as the most flexible, effective analgesic modality in obstetrics with the fewest depressant side-effects on the central nervous system.[5]

Since 1996, ropivacaine has been used widely in different concentrations (0.0625% - 0.2%) for labour analgesia as it is associated with reduced systemic toxicity and a better preservation of motor function.[6,7] However various studies based on the concept of low dose and minimal local anaesthetic dose and volumes (MLAD and MLAV) found that by decreasing the concentration of bupivacaine, an equivalent labour analgesia can be achieved at reduced dose of bupivacaine with fewer incidences of motor block and instrumental delivery.[8]

Therefore numerous studies have been conducted by various authors to find the lowest possible concentration of ropivacaine and bupivacaine which can provide effective labor analgesia with greater margin of safety to mother as well as foetus.[9,10] Hence, we conducted this study to compare the analgesic efficacy and fetomaternal outcome of ropivacaine and bupivacaine at equianalgesic dose with fentanyl in low dose infusion. The aim of the study was to compare the analgesic effect (in terms of onset of analgesia), maternal haemodynamics, degree of motor block, obstetric outcome (in terms of operative delivery rate) and foetal outcome between the groups. Further we also assessed patient and obstetrician satisfaction along with complications associated with the procedure.

MATERIAL AND METHODS

This prospective, single blinded, randomized study was conducted in a tertiary hospital after obtaining approval from institutional ethical committee. Sixty nulliparous parturients belonging to American Society of Anaesthesiologists (ASA) grade I and II with vertex presentation, term,

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How to cite this article: Pratibha Panjiar, Pramod Gupta, Anoop Raj Gogia. A Comparison of low – concentration ropivacaine (0.075%) with fentanyl versus bupivacaine (0.05%) with fentanyl for labour epidural analgesia. International Journal of Contemporary Medical Research 2019;6(5):E5-E9.

DOI: http://dx.doi.org/10.21276/ijcmr.2019.6.5.9

singleton pregnancy with cervical dilatation 4-6 cm and who requested for epidural for pain relief were included in the study. Parturient with pregnancy induced hypertension, spinal deformity, infection at the needle site, coagulation abnormalities, allergic to study drugs were excluded from the study. The patients were randomly allocated to two groups, **Group RF:** Ropivacaine (0.075%) with fentanyl (2µg/ml) (n = 30) and **Group BF:** Bupivacaine (0.05%) with fentanyl (2 µg/ml) (n = 30). Randomization was done by computer generated random numbers which were transferred to sealed envelopes.

Written informed consent was obtained from all patients. After taking proper history, baseline vitals [Heart Rate, Mean Arterial Blood Pressure (MAP), Respiratory Rate (R/R), oxygen saturation (SpO_2)] were recorded in between contractions. Ringers' lactate 500ml was infused through 18 G intravenous canula. Patient was explained about the pain assessment by the 10 point Visual Analog Scale (VAS), where 0 represents no pain and 10 represents the worst imaginable pain.

With patient in sitting/left lateral position, local infiltration with 2% xylocaine (2ml) was given at $L_2 - L_3/L_3 - L_4$ intervertebral space under all aseptic precautions. The epidural space was identified with 16 gauge Tuohy needle using loss of resistance technique with air.[11] Epidural catheter was advanced 5 cm into the epidural space and secured it in place.[12] Patient was then turned to the supine position with 15 to 30 degree left lateral tilt on a wedged pillow. Test dose of 3ml of 1% lignocaine was given after gentle aspiration.[13-15] Bolus dose of 20ml of either ropivacaine (0.075%) with fentanyl 2mcg/ml or bupivacaine (0.05%) with fentanyl 2mcg/ml was then administered through the catheter at 5ml aliquots in every 10 minutes interval. At the end of 30 minutes the continuous infusion of the studied drug was started at the rate of 10ml/hr till the end of delivery. In case of inadequate analgesia (bilateral sensory block < T_{10} or VAS > 3), 5ml of study solution was repeated.

Patient was monitored for pain score (VAS), vital parameters (heart rate, mean arterial pressure (MAP), respiratory rate, SpO_2), sensory and motor block, and foetal heart rate at 5 minutes interval till 30 min that is time at which initial analgesia was established and then half hourly till delivery. Sensory block was assessed bilaterally in the mid clavicular line using short bevealed 27G needle. Time taken to achieve VAS score < 3 and sensory block till T_{10} in each group was noted. Modified Bromage Scale was used to assess motor block (0 = no motor block, 1 = inability to raise the extended leg but able to move the knee and foot, 2 = inability to raise the extended leg and to move the knee, but able to move the foot 3 = complete motor block of the lower limb).[16] Mode of delivery and incidence of urine retention in each group was noted. Neonatal APGAR scores was recorded at 1 min, 5 min and 10 min and umbilical cord blood sample was taken for pH, pO_2, pCO_2 assessment. Total dose of local anaesthetic used was then calculated. Other complications like vomiting, pruritis, dural puncture, hypotension, bradycardia were also noted. Ephedrine/atropine was administered with fall of >20% of basal value of mean arterial blood pressure (MAP) and heart rate (HR). Lastly, patient's and obstetrician satisfaction scoring was done as excellent, good, poor to assess quality of analgesia and patients effort to bear down during contraction respectively.

The data was entered into Microsoft Excel format 2003 and was analyzed using SPSS statistical software. Sample size determination was done by prospective power analysis. A power calculation determined that a sample size of 25 patients per group was required to demonstrate a 15% difference in the incidence of motor block, which was calculated from previous studies[4] and assuming alpha 0.05 and power 80%. To allow for potential dropouts a total of 60 patients (30 per group) were recruited. A p value of < 0.05 was considered significant. The data for continuous variables was analysed in terms of mean and standard deviation or median with interquartile range. The statistical significance of different variables was determined by student (t) test / non parametric Wilcoxons Mann Whitney test as appropriate. The chi square / fisher exact test was applied for categorical variable.

RESULTS

The demographic variables of the parturient in both the groups were comparable with regards to age, height and weight as shown in Table 1. The onset of analgesia assessed by VAS (<3) and sensory block (up to T_{10}), is faster in group RF as compared to group BF. The mean VAS was comparable in both the groups at all points of observation throughout the study except at time 20, 25, 30 minutes where p value is significant (p< 0.05) as shown in Figure 1.The onset of sensory block is shown in Table 2. At 30 min, 77% parturients achieved T_{10} as compared to 50% in group BF.

The mean heart rate and MAP were comparable in both

Variables	Group RF (n = 30)	Group BF (n = 30)	P value
Age (in years)	22.03 ± 2.83	22.50 ± 1.97	0.463
Height (cm)	153.40 ± 1.73	153.46 ± 2.00	0.891
Weight (kg)	62.97 ± 5.17	61.03 ± 5.07	0.149

Table-1: Patient Demographic Data (Mean ± SD)

Time	Sensory Level	Group RF (n)	(%)	Group BF (n)	(%)
10 min	T12	0	0	0	0
	T10	0	0	0	0
15 min	T12	11	37	1	3
	T10	0	0	0	0
20 min	T12	23	77	13	43
	T10	2	7	1	3
25 min	T12	28	93	27	90
	T10	10	33	6	20
30 min	T12	30	100	30	100
	T10	23	77	15	50
1 hour	T12	30	100	30	100
	T10	30	100	30	100

Table-2: Onset of Sensory Block

Mode of delivery		Group RF		Group BF	
		No. of patients	% of patients	No. of patients	% of patients
Normal vaginal		27	90%	30	100%
Instrumental Delivery	Forceps assisted	2	10%	0	0%
	Vacuum Assisted	1		0	
Caesarean		0	0%	0	0%

Table-3: Mode of delivery

Parameters	Time/Values	Group RF (n = 30)	Group BF (n = 30)	P Value
APGAR Score (Mean ± SD)	1 minute	7.70 ± 0.651	8.00 ± 0.643	0.078
	5 minute	8.63 ± 0.669	8.87 ± 0.507	0.133
	10 minute	9.33 ± 0.547	9.53 ± 0.629	0.194
Umbilical Cord Blood Gas Analysis (Mean ± SD)	pH	7.30 ± .025	7.31 ± .030	0.083
	pO_2	21.45 ± 1.119	20.81 ± 1.763	0.098
	pCO_2	48.02 ± 1.66	46.86 ± 2.79	0.055

Table-4: Neonatal Outcome

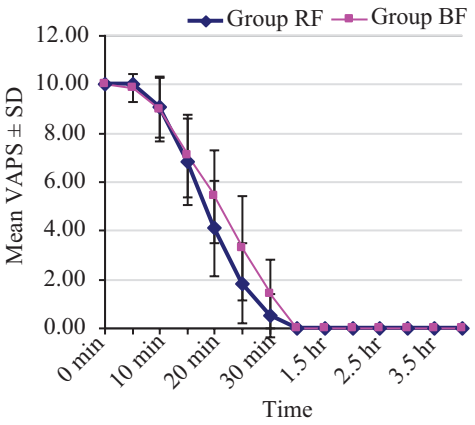

Figure-1: Mean Visual Analog Scale ± SD

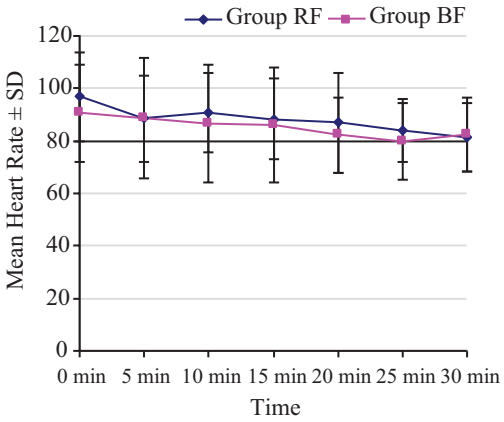

Table-2: Onset of Sensory Block

groups as shown in Table 3 and Figure 5. Bromage degree was 0 in all the patients as none of the patient in either group had motor block in our study. No supplemental dose was required in both the groups after the start of infusion till the delivery.

10% of patients in Group RF had instrumental delivery (2 forceps, 1 vacuum). None of the patient in either group had caesarean delivery. There was no incidence of urine retention in any of the patient in both the groups. Both the groups were comparable with respect to mean APGAR scores at 1 min, 5 min, 10 min and to mean pH, pO_2, pCO_2.

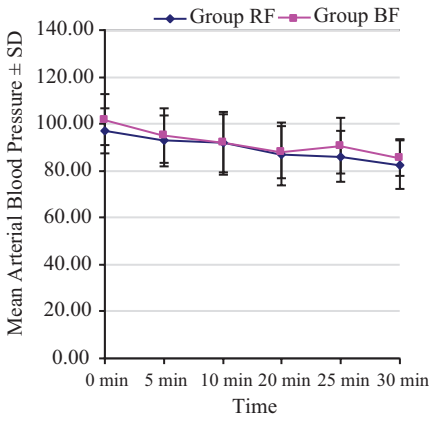

Figure-3: Mean Arterial Pressure ± SD (mm of Hg)

DISCUSSION

In our study we compared low dose epidural infusion of ropivacaine (0.075%) with fentanyl (2µg/ml) and bupivacaine (0.05%) with fentanyl (2µg/ml) for labour analgesia that were thought to be equipotent.[9,17]

The study showed that in both the groups there is a decline in VAS score after the start of bolus dose and reached a value of VAS score <3 in 25 minutes in Group RF and in 30 minutes in Group BF. VAS at 20, 25, 30 minutes had significant p value ($p > 0.05$), showing earlier onset of analgesia in Group RF as compared to Group BF. However once the analgesia was established both the groups provide equally effective analgesia throughout the labour. The reason for this statistically significant difference at 20, 25, 30 min could be due to the fact that smaller increments of bolus doses as given in our study produce minimum local anaesthetic concentration which may lead to different onset of action due to different dose response curves.[10] The study conducted by Bolukbasi D et al (2005), showed that continuous epidural infusion of ropivacaine 0.0625% with fentanyl (2µg/ml) and bupivacaine 0.0625% with fentanyl (2µg/ml) produces good analgesia with similar pain scores all of labour.[18]

Haemodynamic parameters (Heart Rate and mean arterial

pressure) remained stable in all parturients in the study through the course of labour except 6 patients in Group RF and 3 patients in Group BF who experienced hypotension and were treated with single dose of intravenous 6mg ephedrine. Medge DO et al (2002) compared ropivacaine 0.075% with fentanyl (2µg/ml) with bupivacaine 0.075% with fentanyl (2µg/ml) through patient controlled epidural analgesia and found haemodynamics were stable and comparable throughout the study. Hypotension was seen in 40% of patients in Group RF and 20% in Group BF.[10]

In our study motor block was not found in any of the patient in both the groups, that is, motor block was Bromage Degree 0 in all the patients throughout the study. This is comparable with the study conducted by Dave NM et al (2004), in which no motor block was found in group with continuous infusion of 0.0625% bupivacaine with fentanyl (0.0001%) as compared to group with 0.125% bupivacaine.[19] Another study conducted by Rhonda MZ states that ambulation was demonstrated in 75% patients of group bupivacaine 0.08% with fentanyl (2µg/ml) and 100% ambulation was seen in group ropivacaine 0.08% with fentanyl (2µg/ml).[20]

The normal vaginal delivery was 90% in Group RF and 100% in Group BF. 10% of patients in Group RF had instrumental delivery (2 forceps, 1 vacuum). None of the patient in either group had Caesarean delivery. Medge DO et al (2002) found 32% instrumental delivery in Group ropivacaine 0.075% with fentanyl (2µg/ml) as compared to 8% in Group bupivacaine 0.075% with fentanyl (2µg/ml) given through patient controlled epidural infusion.[10]

Similar study by Writer W D et al (1998) on 403 labouring women and compared 0.25% ropivacaine and bupivacaine through intermittent bolus dose and found incidence of instrumental delivery more in ropivacaine group.[21]

Incidence of urine retention was not reported in any of the patients in both the groups. Rhonda M et al (2000) concluded that ropivacaine .08% with fentanyl 2mcg/ml effectively initiates epidural analgesia, established labor while preserving their ability to ambulate and micturate, spontaneous micturation was seen in 100% of patients.[20]

Supplemental dose was not required in both the groups after the start of infusion till delivery of the foetus as break through pain was not reported by any of the patient, after the start of infusion. This could be explained by the fact that slow rise in total concentration of the drug in continuous infusion technique increases the duration of action.[22]

Mean total duration of epidural infusion was 2.8 hours in Group RF and 2.6 hours in Group BF (not significant). Mean total dose of anaesthetic drug used was 45ml in Group RF and 44ml in Group BF (not significant). Medge DO et al (2002) compared ropivacaine 0.075% with fentanyl µg/ml) with bupivacaine 0.075% with fentanyl (2µg/ml) through patient controlled epidural analgesia and found no difference in local anaesthetic used in between the groups.[10]

Foetal Heart Rate variations were within physiological limits. No evidence of foetal bradycardia was found. Neonatal outcome as assessed by APGAR scores and umbilical cord blood gas analysis was satisfactory and comparable in both the groups ($p > 0.05$). This is comparable with the study conducted by Guisasola JF with continuous infusion of 0.0625% bupivacaine with fentanyl (2µg/ml) and 0.1% ropivacaine with fentanyl (2µg/ml) which states that labour analgesia had no effect on neonatal outcome with similar result in both the groups.[9] Another study conducted by Manuel C et al (2001) also found similar result and states that no adverse effect on neonatal well being was found with continuous infusion of 0.07% ropivacaine with fentanyl (2µg/ml).[23] Capogna G et al (2004) found that the use of very diluted or low concentrations of local anaesthetic solutions may reduce their placental passage and does not affect the well being of the neonate at birth.[24] Bader AM et al (1995) concluded that even when maintained for many hours, continuous infusion labour analgesia does not appear to result in significant foetal drug accumulation.[25]

No incidence of dural puncture, vomiting, pruritis, bradycardia was seen in any of the patient in both the groups. Patient's and Gynaecologist's satisfaction score was >80% excellent in Group RF and >70% in Group BF. Robinson JO et al (1980) compared epidural analgesia with bupivacaine 0.5% with pethidine and inhalational analgesia and found epidural block to be more satisfying and effective method of pain relief for labour.[26] The limitations of our study were the smaller sample size and secondly we have not mobilize the patient, which would have given better assessment of motor block at low-dose infusion.

CONCLUSION

We conclude that the onset of analgesia is faster in Group Ropivacaine 0.075% with fentanyl as compared to group Bupivacaine 0.05% with fentanyl. However once the analgesia was established both the groups had safe and effective analgesia throughout the labour. Both the groups were comparable in terms of maternal haemodynamics, motor block, foetal outcome, maternal and obstetrician satisfaction. However the incidence of instrumental delivery was higher in Ropivacine group.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 16-03-2019; **Accepted:** 20-04-2019; **Published:** 13-05-2019