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Compare the efficacy and safety of bupivacaine 0.125% and fentanyl 2mcg/ml in comparison with ropivacaine 0.15% and fentanyl 2mcg/ml in intermittent doses for labour epidural analgesia

Dr Prajakta Balasaheb Jadhav[1], Dr Sunita Chandrakant Sankalecha[2], Dr Kashinath Khandu Jadhav[3], Dr Ashok Sampatrao Thorat[4], Dr Sahil Chandrakant Sankalecha[5]

[1]Resident, Department of Anesthesiology, Dr Vasantrao Pawar Medical College, Nashik, Maharashtra, INDIA.

[2]Professor, Department of Anesthesiology, Maharashtra Post Graduate Institute of Medical Education & Research, Nashik, Maharashtra, INDIA.

[3]Associate Professor, Dept of Anesthesiology, Maharashtra Post Graduate Institute of Medical Education & Research, Nashik, Maharashtra, INDIA.

[4]Assistant Professor, Dept of Anesthesiology, Maharashtra Post Graduate Institute of Medical Education & Research, Nashik, Maharashtra, INDIA.

[5]Final MBBS Student, SMBT Medical College, Igatpuri, Nashik, Maharashtra, INDIA.

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ABSTRACT

Background- Labour is a painful process. Since all the parturients suffer with substantial pain of moderate to severe intensity, it is considered as major concern for obstetricians. In previous studies, the efficacies of epidural analgesia for labour with Bupivacaine and Ropivacaine have been reviewed, outcomes were similar, very few studies are based on same properties, actions, doses etc. Therefore, the study was undertaken to compare the efficacy and safety of bupivacaine 0.125% and fentanyl 2mcg/ml in comparison with ropivacaine 0.15% and fentanyl 2mcg/ml in intermittent doses for labour epidural analgesia. **Methodology**-The study was undertaken at Department of Anaesthesiology and Department Obstetrics and Gynaecology at tertiary care centre. Total 78 patients were included in the study which were further divided two equal groups of 39 patients in each group. Group BF received Bupivacaine with Fentanyl and Group RF received Ropivacaine with Fentanyl. Patient was explained about the procedure and was made familiar with 10-point Visual Analogue Scale. Data was recorded and analyzed. **Result-** The onset of action in the RF group was earlier as compared to BF group. Among both the groups, the hemodynamic parameters were more stable in group RF as compared to BF. The VAS score indicated that group RF had more pain relief in patients when comparedwith BF. Patient's satisfaction with pain control was higher with ropivacaine with fentanyl than with bupivacaine with fentanyl. **Conclusion-** Ropivacaine 0.15% and Fentanyl 2mcg/ml in comparison to Bupivacaine 0.125% and Fentanyl 2mcg/ml intermittent doses for labour epidural analgesia produced excellent results.

Keywords-Bupivacaine, fentanyl, ropivacaine, epidural analgesia

Corresponding author: Dr Ashok Sampatrao Thorat, Assistant professor, Dept of Anesthesiology, Maharashtra PostGraduate Institute of Medical Education & Research, Nashik, Maharashtra, INDIA. Email: ashoakthorat@gmail.com

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INTRODUCTION

Labour is a painful process. Since all the parturients suffer with substantial pain of moderate to severe intensity, it is considered as major concern for obstetricians. Labour pain can affect mother and foetus, so adequate analgesia is essential because painful labour can have a significant impact on physiology of both the mother and the foetus. [1]. Epidural analgesia is a central nerve block technique given by injection of a local anaesthetic close to the nerves that transmit pain and is widely used to relieve the labour pain at the time of delivery and enhance maternal satisfaction. It is the most efficient and widespread technique, offers the best effectiveness /safety ratio. [2] With easy availability of epidural analgesia and its advantages has enhanced birthing experience of women for pain relief. [3] Bupivacaine is the most widely used local anaesthetic amide. It provides good analgesia when used in combination with opioid analgesics [4]. The best analgesics should have a long duration of action with little to no perinatal transfer, minimal motor blockage, and no negative effects on the mother or foetus [5]. As a result, it has been demonstrated that combining opiates with local anaesthesia (LA) is more effective than using LA alone. Because of this, LA bupivacaine is frequently used [6]. Levobupivacaine and ropivacaine were used to reduce cardiac risks and CNS toxicity despite bupivacaine's widespread usage and relative safety. For labour analgesia,ropivacaine is most preferable since it is 40% less powerful than bupivacaine and has a propensity for differential blocking [7]. LA is used in conjunction with opioids (fentanyl or sufentanil) to lessen the dosage and side effects of anaesthetic drugs [8]. Ropivacaine, a levorotatory propyl homologue of bupivacaine because of its structural features and physiochemical properties, it is claimed to be less toxic to nervous system and heart in comparison with bupivacaine [9,10]. It is also known to produce ambulatory analgesia [11]. Fentanyl Citrate is lipid soluble synthetic opoid, having higher potency. It used in labour since many decades and produce effective Labour analgesia when used in combination with local anaesthetics [12].

In previous studies, the efficacies of epidural analgesia for labour with Bupivacaine and Ropivacaine have been reviewed, outcomes were similar, very few studies are based on same properties, actions, doses etc. Therefore, the study was undertaken to compare the efficacy and safety of bupivacaine 0.125% and fentanyl 2mcg/ml in comparison with ropivacaine 0.15% and fentanyl 2mcg/ml in intermittent doses for labour epidural analgesia.

MATERIALS AND METHODS

Study place-The study was conducted at Department of Anaesthesiology and Department Obstetrics and Gynaecology at tertiary care centre from October 2020 to December 2022.

Study design- Randomised, Prospective**,** Comparative study.

Inclusion criteria- Patients with ASA Grade I and Grade II, Primigravida and multigravida patients, and those willing to participate and ready to give informed consent.

Exclusion criteria- Patients with previous LSCS, bleeding diathesis, Patients on anticoagulants, unwilling to participate and refusal to give written informed consent.

Sample size- Total 78 patients were included in the study which were further divided two equal groups of 39 patients in each group.

Data analysis- Data was tabulated by EXCEL spread sheet; results were documented in proportions and percentages with appropriate statistical tests by using SPSS 25 statistical software**.**

Ethical considerations- Ethical approval of the study protocol was obtained from the Ethical Committee at the institution before the study was undertaken.

Parturients from the antenatal ward fulfilling the recruitment criteria. The study was divided into two equal groups of 39 patients in each group. Group BF received Bupivacaine with Fentanyl and Group RF received Ropivacaine with Fentanyl. The procedure was commenced when patient landed up in labour with 3 to 5cm of cervical dilatation (Active

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stage of Labour), Patient was explained about the procedure and was made familiar with 10-point Visual Analogue Scale where zero represents no pain, and 10 represents "worst pain". A test dose of 3 mL of 2% lignocaine with epinephrine (1:2 lakh dilution) was administered through the epidural catheter. After 5-10 min of administration of the test dose, In BF group each patient received 5 mL to 10ml of 0.125% bupivacaine and fentanyl 2µg/ml in required doses till adequate pain relief was achieved. This time was defined as T_0 or Time zero. Same was followed in RF group with each patient receiving 5ml to 10ml 0.15% ropivacaine with 2 µg/mL of fentanyl. Additional top-ups of the study drug was given in 3-5 mL titrated doses. Patient's baseline heart rate, blood pressure, respiratory rate and VAS scores was noted after 5mins up to 1hour and thereafter every 30mins, motor blockade by Bromage scale was recorded every 10 min till the next 1 h and then on 30min basis till delivery. Motor blockade was assessed by the modified Bromage scale. At the end of the delivery, the epidural catheter was removed, dressing done and patient shifted to ward.

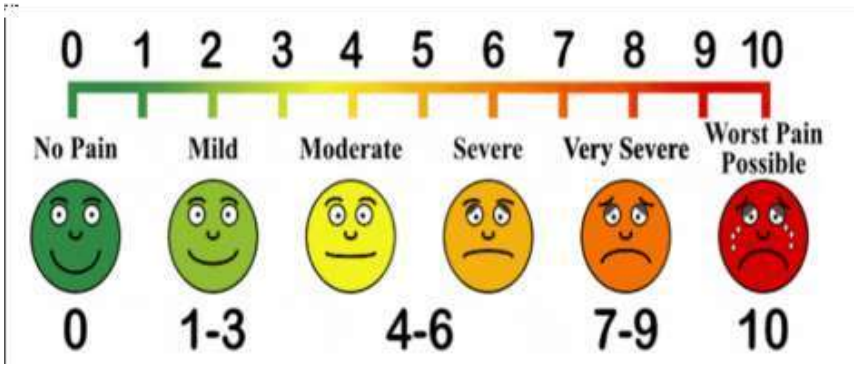

Fig.1 VAS SCORE

Grade	Criteria	Degree of block
0	Free movement of legs and feet	Nil (0%)
I	Just able to flex knee with free movement of feet, ankle	Partial (33%)
II	Unable to flex knee with free movement of ankle, feet	Partial (66%)
III	Unable to flex knee or ankle or move toes	Complete paralysis (100%)

Fig.2 Bromage scale

RESULT

Table 1. Age distribution study

Age in years	Group BF		Group RF		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
< 20	4	10.26	4	10.26	**> 0.999 non – significant)**
21 -40	35	89.74	35	89.74	
Total	39	100	39	100	
Mean	**25.7**		**25.8**		
SD	**4.37**		**4.25**		

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Table 1**.** represents the age distribution of patients in two groups. In both the groups age < 20 years 4 (10.26 %) patients and age 21 -40 years 35 (89.74 %) patients were observed. The independent T- test of statistical analyses showed the differences between the two groups to be statistically insignificant with a p-value > 0.999.

Table 2. Onset of Action

Onset of action in minutes	**Group BF**	**Group RF**	**P- value**
Mean	9.52	6.52	**< 0.001 (significant)**
SD	2.97	2.65	

Table 2. represents the mean time for the onset of action. In group BF the mean time for onset of action was 9.52 minutes with SD 2.97 and in Group RF the mean time taken for onset of action was 6.52 minutes with SD 2.65. The independent T - test is statistically significant in the study of the onset of action in two group with p-value < 0.001.

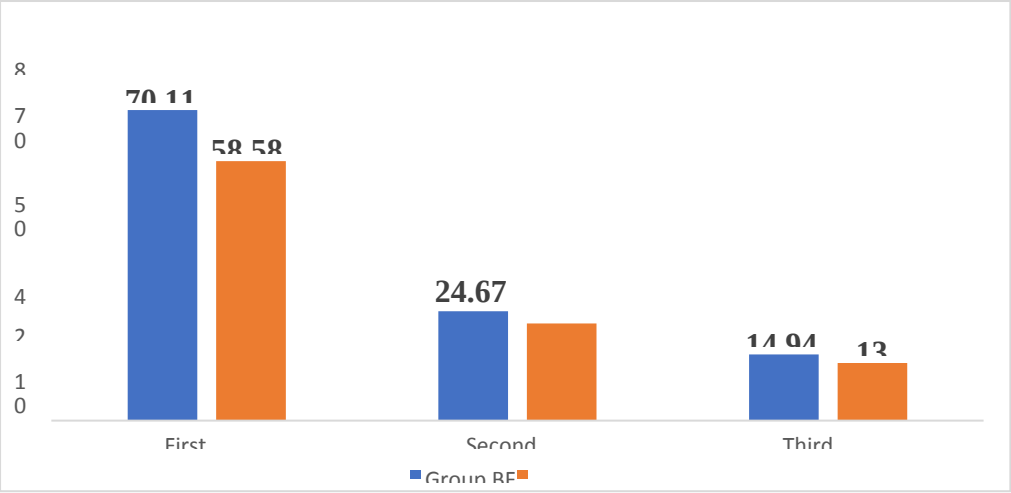

Fig.1 Stages of labour

Figure 1. shows the stages of labour in both the groups**.** Group BF have mean of 70.11 and SD of 31.53 in 1st stage. In group RF have mean of 58.58 and SD 8.86 in 1st stage labour. The chi – square test in first stage of labour in both the groups were statistically significant with P value 0.031.

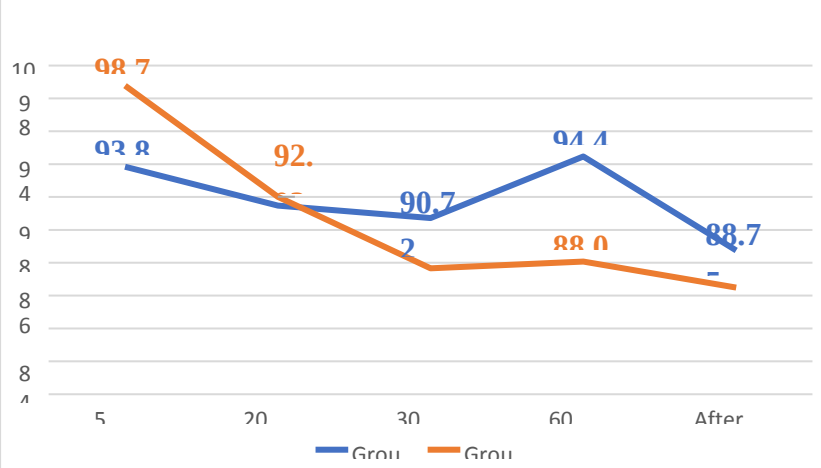

Fig 2. Mean heart rate in two groups

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Fig.2 represents the mean heart rate in five intervals in both groups. The mean heart rate in group BF at five minutes was 93.85 minutes and after delivery, it was 88.75 minutes. The mean heart rate in group RF at five minutes was 98.78 minutes and after delivery, it was 86.49 minutes. The chi square test applied to mean heart rate in both the groups in four intervals was statistically insignificant and at 60 minutes was significant with P value 0.027.

Table 3. Study of Mean Arterial Pressure

Mean Arterial Pressure mmHg	Group BF		Group RF		P-value
	Mean	SD	Mean	SD	
5 minutes	77.63	10.92	75.9	7.95	**0.426 (non -significant)**
20 minutes	77.29	10.21	76.46	7.66	**0.715 (non -significant)**
30 minutes	76.77	10.01	75.25	6.11	**0.421(non - significant)**
60 minutes	75.74	9.54	74.04	6.69	**0.365(non - significant)**
After delivery	76.02	9.12	74.44	6.01	**0.369 (non - significant)**

Table 3. represents the mean of mean arterial pressure (MAP) in five intervals between the two groups. In group BF the mean of mean MAP at five minutes was 77.63 and after delivery, it was76.02. In group RF the mean MAP at five minutes was 75.90 and at the time of delivery, it was74.44. The chi square test applied to mean arterial pressure in the two groups in five intervals is statistically insignificant.

Table 4. Study of mean SpO2

Mean SpO2	Group BF		Group RF		P-value
	Mean	SD	Mean	SD	
5 minutes	99.4	0.68	99.12	0.64	**0.065 (non – significant)**
20 minutes	118.49	1.29	99.22	0.91	**< 0.001 (significant)**
30 minutes	99.51	0.65	99.39	0.7	**0.435 (non – significant)**
After delivery	99.68	0.53	99.61	0.54	**0.565 (non – significant)**

Table 4. represents the mean SpO2 in five intervals. In group BF mean SpO2 at five minutes was 99.40 and at the time of delivery, it was 66.68. The mean SpO2 in group RF at five minutes was 99.12 and after delivery, it was 99.61. In the two groups, the chi square test applied to mean SpO2 at 20 minutes interval was statistically significant with p- value < 0.001.

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Table 5. Study of Motor blockade

Bromage score	Group BF		Group RF		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
1	38	97.44	39	100	**0.314 (non-significant)**
2	1	2.56	0	0	
Total	**39**	**100**	**39**	**100**	

Table 5. was assessed using the Bromage Scale. The group BF has 38(97.44 %) patients with score1 and 1 (2.56 %) patient with score 2. In group RF all 39(110 %) patients reported score of 1. The chi square test in motor blockade Bromage score in both groups was statistically insignificant.

Table 6. Study of Visual Analogue Score

VAS score	Group BF		Group RF		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
1	2	5.13	5	12.82	**0.030 (significant)**
2	13	33.33	24	61.54	
3	16	41.03	6	15.38	
4	7	17.95	3	7.69	
5	0	0.00	0	0.00	
6	1	2.56	1	2.56	
Total	**39**	**100**	**39**	**100**	

Table 6**.** represents the study of VAS score in two groups. The pain perceived by the patients was assessed by showing them a VAS scale. The VAS score was from 1 to 6 score. In group BF maximum of 16 (41.03 %) had a score of 3. In group RF maximum of 24(61.54 %) patients had 2 score. The chi- square test in VAS score in the two groups was statistically significant with a p-value of 0.030.

Table 7. Study of Adverse effects

Adverse effects	Group BF		Group RF		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Baby shifted to NICU	2	5.13	1	2.56	
Bradycardia	1	2.56	0	0.00	

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Hypotension	1	2.56	0	0.00	**0.461 (non – significant)**
Motor blockade	1	2.56	0	0.00	
Shivering	1	2.56	0	0.00	
Ventouse delivery	1	2.56	0	0.00	
Nausea and Vomiting	0	0.00	1	2.56	
Normal	32	82.05	37	94.87	
Total	**39**	**100**	**39**	**100**	

Table 7. represents the adverse effects in two groups. In group BF, 2 (5.13 %) neonates were shifted to NICU,1 (2.56 %) patient had bradycardia, 1 (2.56 %) patient had hypotension, 1 (2.56%) patient had motor blockade, 1 (2.56 %) patient had shivering and 1 (2.56 %) patient hadinstrumental (Ventouse) delivery. In RF only 1 (2.56 %) neonate was shifted to NICU and1 (2.56%) patient had nausea and vomiting respectively. The chi square test applied to side effect in thetwo groups was statistically insignificant.

DISCUSSION

In the present study the of age distribution, the mean age in group BF is 25.70 years with an SD of 4.37 and in group RF 25.80 years with an SD of 4.25. The independent T-test of statistical analysis showed the differences between the two groups to be statistically insignificant with a p-value > 0.999.When correlated with the previous study conducted by Helene Finegold et al. [13] reported a mean age & SD in group B as 24.4 ± 4.12 and group R 24.84 ± 3.47 was statistically insignificant with P - value 0.6849 Another identical study conducted by Shanbin Guo et al.[14] reported a mean age in group B 22.9± 0.6 and in group R 31 ± 4 and found to be statistically insignificant. which is comparable with the present study.
The mean onset of action in group BF is 9.52 minutes with SD 2.97 and in Group RF is 6.52 minutes with SD 2.65. The independent T-test is statistically significant in the study of the onset of action in two groups with p-value < 0.001. This when correlated with the previous study by Helene Finegold et al. [13] where onset time was 10.62+/- 4.9 min in Group B and 11.3 +/- 4.7 min in Group R, the onset of analgesia in bupivacaine was similar when compared with present study but the onset of action of ropivacaine was earlier in the present study. Another comparable study conducted by Robert Gaiser et al. [15] reported in his study that the onset of analgesia in group R is 11.4 +/- 1.6 and in group B 12.4 +/- 2.6.
In the present study, the mean time of the first stage of labour in group BF is 70.11 minutes with an SD of 31.53 and in the group RF, mean time of 58.58 minutes and an SD of 8.86. The chi–square test in the first stage of labour in both groups was statistically significant, findings suggest that there was prolongation of labour in group BF. This correlated with the previous study by Jaime Fernandez et al. [16] wherein there was no prolongation of the first stage of labour between Group B 401+/- 184 min and Group R 365 +/- 186 min with no statistical significance which differed from the present study findings.

In the present study, the mean duration of the second stage of labour was 24.67 +/- 10.48 in Group BF and 21.95 +/- 8.24 in Group RF and the differences were found statistically insignificant. In the comparative study, the results did not correlate with the previous study conducted by Jaime Fernandez et al. [16] wherein the duration of the second stage of labour was 57+/- 47 min in Group B and 47 +/- 38 in Group R groups.

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In the present study, the mean heart rate in group BF at five minutes is 93.85 minutes and after delivery 88.75 minutes. The mean heart rate in group RF at five minutes is 98.78 minutes and after delivery 86.49 minutes. The chi-square test applied to mean heart rate in both the groups in four intervals was statistically insignificant and at 60 minutes was significant.

In group BF, the mean arterial pressure at five minutes is 77.63 and after delivery, it was 76.02. In group RF the mean of mean arterial pressure at five minutes was 75.90 and at the time of delivery, it was 74.44. The chi-square test applied to mean arterial pressure in the two groups in five intervals was statistically insignificant.

In the present study in group BF mean SpO2 at five minutes was 99.40 and at the time of delivery, it was 66.68. The mean SpO2 in group RF at five minutes was 99.12 and after delivery, it was 99.61. The hemodynamic parameters correlated with the previous study by Neel Rana [17] et al. and Fernandez et al. [16] where there was no statistical significance in hemodynamic parameters between the groups. The findings were similar with the present study.

In the present study, the pain perceived by the patients was assessed by showing them a VAS scale. The VAS score was from 1 to 6 score. In group BF maximum of 16 (41.03 %) had a score of 3. In group RF maximum of 24(61.54 %) patients had 2 score The chi- square test in VAS score in the two groups was statistically significant with a p-value of 0.030. Our study results showed that group RF had better pain relief as compared to group BF. The finding correlated with the previous study conducted by Neel Rana et al. [17] the VAS score in the study also reported statistical significance. The study suggested that there was more pain relief in group R as compared to group B. Ropivacaine selectively blocks sensory fibres as compared to motor fibres, so patients get more pain relief with ropivacaine as compared to bupivacaine and patient's satisfaction with pain relief was more in ropivacaine with fentanyl ascompared to bupivacaine with fentanyl.

In the present study in group BF, 2 (5.13 %) neonates were shifted to NICU, and 1 (2.56 %) patient had bradycardia, 1 (2.56 %) patient had hypotension, 1 (2.56 %) patient had motor blockade, 1 (2.56 %) patient had shivering and 1 (2.56 %) patient had Vento use for delivery. In RF only 1 (2.56 %) neonate was shifted to NICU and 1 (2.56 %) patient had nausea and vomiting respectively. The chi-square test applied to a side effect in the two groups was statistically insignificant. The percentage of side effects was less in the RF group than in the BF group. The comparable study by Owen M D et al. [18], Neel Rana et al. [17] reported similar findings with less percentage of side effects with the ropivacaine group.

CONCLUSION

We conclude that in the present comparative study of Bupivacaine 0.125% with Fentanyl 2mcg/ml versus Ropivacaine 0.15% with Fentanyl 2mcg/ml for labour epidural analgesia. Ropivacaine with Fentanyl 2 mcg/ml produced excellent labour analgesia. In terms of safety efficacy and characteristic differential blockade, Ropivacaine is a preferable option to Bupivacaine for labour epidural analgesia.

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