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A Comparative Study to Evaluate the Effect of 0.2% Ropivacaine With Fentanyl Compared to 0.125% Bupivacaine With Fentanyl for Labor Analgesia
- A Prospective, Randomised,Double Blinded and Controlled Study

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Abstract

Background: *Pain less labor, a complete freedom from labor pains, is a dreamto every parturient woman . Lumbar epidural analgesia offers a safe and effective method of pain relief during labor.The benefits include effective pain relief without appreciable motor block, reduction in maternal catecholamines, and a means to rapidly achieve surgical anesthesia. Bupiacaine is commonly used but Ropivacane is considered as good alternative.*[1]

Material and Methods: *This study was undertaken from April to September2012.The aim of this study was to evaluate the effect of 0.2% Ropivacaine with 25 mcg Fentanyl compared to 0.125% Bupivacaine with 25 mcg Fentanyl for labor analgesia. 50 pregnant woman of American Society of Anesthesiologists grading I&II ,nulliparous, singleton pregnancy, vertex presentation were taken up for the study.They were randomly divided into two groups (each comprising of 25), Group R(Ropivacaine group) and Group B(Bupivacaine group). The results were statistically analysed by student's t- test. The demographic data were comparable in both groups.*

Results: *There was no significant difference among two groups in the total duration and second stage oflabor, the volume of local anesthetic, onset and duration of analgesia, neonatal outcome as far as Apgar scores at 1 and 5 minutes. But the incidence of spontaneous vaginal delivery are more and Cesarean delivery & Forceps delivery are less in Ropivacaine group compared to bupivacaine group.*

Conclusion: *We conclude that 0.2% Ropivacaine with 25 mcg Fentanyl is preferred to 0.125% Bupivacaine with 25mcg Fentanyl for labor analgesia as it is associated with less number of instrumentation and caesarean sections, while maintaining same degree of sensory blockade.*

Keywords: *Bupivacaine, labor analgesia, Ropivacaine.*

INTRODUCTION

Obstetric analgesia is the achievement of modern anaesthesia. A variety of labour analgesia options are available, including psycho-prophylaxis, Transcutaneous electrical nerve stimulation (TENS)[2], systemic medication, inhalational techniques, and neuraxial blocks. Contemporary regional analgesic techniques provide rapid, almostcomplete analgesia while minimizing risk to the mother and foetus.Continuous epidural techniques allow analgesia to be maintained for prolonged periods of time; the presence of the catheter also allows the quality of the analgesia to be varied should conditions change, or instrumental or operative delivery be required. In the first stage of labour, T-10 to L-1 segments are to be blocked. In the second stage of labour, S-2,3,4 segments are to be blocked. Initially 2-catheter technique was used, where one catheter was kept in Lumbar region and second catheter was kept in sacral region. Local anaesthetics were administrated separately through them basing on the stage of labour. Presently, single catheter is placed in the Lumbar region and it provides a safe and effective method of pain relief during labour.The benefits include effective pain relief without appreciable motor block, reduction in maternal catecholamines, and a means to rapidly achieve surgical anaesthesia.

A combination of epidural and spinal analgesia also is available. This technique combines the rapid pain relief from the spinal regional block with the constant and consistent effects from the epidural block.[3] It allows sufficient motor function for patients to ambulate. In Patient controlled Epidural Analgesia Technique (PCEA), PCA (Patient controlled analgesia pump) is connected to the epidural catheter and patient can use the pump, whenever she gets contractions and pain.[3,4] Complications with regional analgesia are uncommon, but may include postdural puncture headache Rare serious complications include neurologic injury, epidural hematoma, or deep epidural infection.

Our study evaluated the effect of 0.2% Ropivacaine with 25 mcg Fentanyl compared to 0.125% Bupivacaine with 25 mcg Fentanyl for labor analgesia.

MATERIAL AND METHODS

- After obtaining the institutional ethical committee approval and informed consent from the patients, this study was undertaken from March-June 2012 at Government General Hospital, Kakinada, India. Sample size was calculated with SPSS with Sample Power.50 pregnant woman of ASA I &II, nulliparous, singleton pregnancy, vertex presentation were taken up for the study. They were randomly divided into two groups (each comprising of 25), Group R (Ropivacaine group) and Group B (Bupivacaine group).
- **Inclusion criteria:**1. Pregnant woman of ASA I &II, 2. Nulliparous parturients,3. Singleton pregnancy and 4. Vertex presentation.
- **Exclusion criteria:** 1. Patient refusal, 2 Allergy to amide local anaesthetics,

3.Multiparous parturients, 4.Multiple-foetal gestations, 5.Pre-term pregnancy, 6.Overt maternal coagulopathy ,7.Infection at the needle site, 8.Maternal hemodynamic instability and 9.Accidentaldural puncture.

- After attaining 3cm of cervical dilatation, two 18G IV cannulae are secured, Patient was kept in left lateral position and under aseptic conditions epidural L3/4 or L2/3 space was identified by loss of resistance technique with 16G Tuohy needle and epidural catheter 16 G is placed. Patients in group R were given 0.2% Ropivacaine with Fentanyl 25 mcg made to 10ml.Patients in group B were given 0.125% Bupivacaine with Fentanyl 25mcg made to 10ml.If first stage is prolonged same dose of drug is repeated. After attaining second stage of labor, in sitting position, Patients in group R were given 0.2% Ropivacaine with Fentanyl 25 mcg made to 10ml.Patients in group II(B) were given 0.125% Bupivacaine with Fentanyl 25mcg made to 10 ml.

Monitoring: Heart Rate, Non Invasive Blood Pressure Monitoring (Systolic Blood Pressure, Diastolic Blood Pressure and Mean Arterial Pressure), SPO_2(continuous)&ECG(continuous) were monitored..All baseline parameters were recorded.

PARAMETERS OBSERVED

1) Obstetrical outcomes,

2)Analgesia outcomes and neonatal outcomes were observed.

Obstetrical outcomes

- Spontaneous vaginal delivery
- Caesarean delivery
- Forceps delivery
- Total length of labor (min)
- Duration of second stage of labor (min)

Analgesia outcomes

- Onset of analgesia (min)
- Duration of analgesia (min)
- Degree of motor blockade.

Neonatal outcomes

- Apgar at 1 min
- Apgar at 5 min
- Motor blockade was assessed by Bromage Scale(Table 1)

BromageScale(Table 1)

SCALE	
0	No block
1	Inability to raise extended leg
2	Inability to flex Knee
3	Inability to flex ankle and foot

- Assessment of pain is by VAS scale .
- At the end of study, all the data was compiled systematically and analyzed using student's t-test.
- Value of $p > 0.05$ was considered not significant

$p < 0.05$ was considered significant and $p < 0.0001$ as highly significant

STATISTICAL ANALYSIS: Student's t-test

RESULTS

Demographic data(Table 2)

Demographiccharacter	R(n:25)	B(n:25)	P value
Age (yrs)	22.2±1.8	23.3±1.06	0.0114
Height (cm)	158±4.6	156±4.25	0.1169
Weight (kg)	55±4	56±5	0.4387
ASA (I/II)	13/12	12/13	-

The demographic profiles in both the groups (Table 2) were comparable with regards to age, height and weight and are statistically not significant (p value >0.05 by student's t-test)

Obstetrical Outcome (Table 3)

Obstetrical outcomes	R(n:25)	B(n:25)	P value
Spontaneous vaginal delivery	22	14	0.008
Cesarean delivery	2	8	0.0279
Forceps delivery	1	5	0.0424
Total length of labor (min)	404±28.4	421±27.7	0.1081
Length of second stage of labor (min)	153±18	158±20	0.4777

When Obstetric outcome (Table 3) was compared between the two groups, incidence of spontaneous vaginal delivery was more in Ropivacaine group (p value was 0.008 –student's t-test) and incidence of caesarean deliveries and instrumentation are more in Bupivacaine group(p values 0.0279 & 0.0424 respectively and both are <0.05 and statistically significant)

Analgesia Outcome(Table 4)

Analgesia outcomes	R(n:25)	B(n:25)	P value
Onset of analgesia (min)	15±2.33	16±2.57	0.253
Duration of analgesia (hrs)	6.5±0.22	6.3±0.18	0.222
Incremental dose of drug in the first stage	5	6	0.186
Motor blockade (bromage score)	R(n:25)	B(n:25)	P Value
0	24	14	0.0004
1	1	8	0.0167

2	0	3	0.0019
3	0	0	

When analgesia outcome was compared (Table 4), there was no statistic all significant difference between the two groups (p value > 0.05). When motor blockade was compared in between the two groups by Bromage Scale (Table 4), there was less motor blockade in Ropivacaine group (p value <0.05 - statistically significant).

Neonatal Outcome(Table 5)

Neonatal outcomes	R(n:25)	B(n:25)
Apgar(8-10) at 1 min	25	25
Apgar(8-10) at 5 min	25	25

Side Effects (Table 6)

	P(n:25)	B(n:25)
Hypotension	6	8
Nausea	4	4
Vomiting	0	0
Pruritus	0	0
Respiratory depression	0	0

There was no difference between the two groups as far as Noenatal outcome (Table 5) and side-effects(Table 6) are concerned.

DISCUSSION

Pain is a subjective and varied phenomenon.In the first stage of labour, pain arises primarily from nociceptors in uterine and perineal structures. Nerve fiberstransmitting pain sensation during the first stage of labour travel with sympathetic

fibersand enter at the T10-L1 spinal segments. In the second stage, fetal descent withsubsequent distention of the pelvic floor results in somatic pain impulses primarily rough the pudenda nerve. Pain less labour is a dream for all the parturient women. Different measures are tried to alleviate the suffering of thepregnant women. Non-pharmacological measures are not very effective. There are typically three pharmacological choices for labour analgesia-epidural, intravenous or intramuscular opioids and inhaled nitrous oxide. Epidural analgesia has become the mainstay in labour pain management, especially in tertiary care facilities. It involves lumbar access (L2-3, L3-4, L4-5) into the epidural space .Bupivacaine has been used in low doses with Fentanyl or Sufentanil by epidural route to produce selectively sensory blockade without any motor blockade to facilitate normal vaginal delivery. Ropivacaine is supposed to have lesser motor blockade, when compared to Bupivacaine and levo-Bupivacaine.[5,6,7]

This present study was undertaken to compare the effect of 0.2% Ropivacaine with 25mcg Fentanyl compared to 0.125% Bupivacaine with 25mcg Fentanyl for labor analgesia.

In this study ,The demographic profileswere statistically not significant.

The incidence of spontaneous vaginal delivery are more in Ropivacaine group andare statistically significant.

The requirement of Cesarean delivery & Forceps delivery are more in Bupivacaine group and also statistically significant. There were more parturients without motor block in the Ropivacaine group than in the Bupivacaine group and was statistically significant and our results correspond to the results of study by Hughes D, Hill D, Fee H .[8],Lacassie, H. J., Columb, M. O., Lacassie, H. P., Lantadilla, R. A.,[9]& Campbell DC and Nunn RT.[10]

- There was no significant difference in the total duration and second stage of labor .There was no significant difference in the volume of local anesthetic used by each group.
- Onset and duration of analgesia in both groups are not significantAnd our results correspond to the findings in the studies by Polley LS, Columb MO & Naughton NN[5]&Lee, B. B., NganKee, W. D., Ng, F. F., Lau, T. K., Wong,E. L.,[11]

  Studies byGatt S, Crooke D, Lockley S, et al,[12] Writer, W. D., Stienstra, R., Eddleston, J. M., Gatt, S. P.,Griffin, R., Gutsche, B. B., Joyce, T. H., Hedlund, C.,Heeroma, K., Selander, D. et al [13]and by Bolukbasi, D., Sener, E. B., Sarihasan, B., Kocamanoglu,S and Tur A[14] showed no difference in neonatal out come in both Ropivacainegroup and Bupivacaine group. According to Evron, S., Glezerman, M., Sadan, O., Boaz, M., Ezri, T [15]also there was no difference in the neonatal outcome in both Bupivacaine and Ropivacaine groups .In our study also there were no differences in neonatal outcome as far as Apgar scores at 1 and 5 minutes.
- When side effects in both the groups are compared and analysed statistically the P

value (>0.05) is not statistically significant.

CONCLUSION

We conclude that 0.2% Ropivacaine with 25 mcg Fentanyl is preferred to 0.125% Bupivacaine with 25mcg Fentanyl for labor analgesia as it is associated with less number of instrumentation and caesarean sections, while maintaining same degree of sensory blockade.

REFERENCES

1. Meister GC, D'Angelo R, Owen M, et al. A comparison of epidural analgesia with 0.125% ropivacaine with fentanyl versus 0.125% bupivacaine with fentanyl during labor. AnesthAnalg 2000; 90: 632–7.
2. Simkin P, Bolding A. Update on non - pharmacologic approaches torelieve labor pain and prevent suffering. J Midwifery WomensHealth 2004; 49:489-504.
3. D'Angelo R . New Techniques for labor analgesia: PCEA and CSE .ClinObstet Gynecol. 2003 ; 46 : 623 - 632 .
4. Chua, N. P., Sia, A. T., Ocampo, C. E., Parturient-con-trolled epidural analgesia during labour bupivacaine vs. ropivacaine. ANAESTHESIA 56, 1169-1173, 2001
5. Polley LS, Columb MO, Naughton NN, et al. Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes. Anesthesiology 1999; 90: 944–50.
6. Capogna G, Celleno D, Fusco P, et al. Relative potencies of bupivacaine and ropivacaine for analgesia in labour. Br J Anaesth 1999; 82: 371–3.
7. Alahuhta, S., Ala-Kokko, T. I.,Ropivacaine : a new agentfor epidural labour analgesia ACTAANAESTHESIO-LSCAND,42, 887-889, 1998.
8. Hughes D, Hill D, Fee H. A comparison of bupivacaine-fentanyl with ropivacaine-fentanyl by epidural infusion for labor analgesia.Anesthesiology 2000; 93: A1051
9. Lacassie, H. J., Columb, M. O., Lacassie, H. P., Lantadilla, R. A., The relative motor blocking potencies of epidural bupivacaine and ropivacaine in labor. ANESTH ANALG, 95, 204-208, 2002.
10. Campbell DC, Nunn RT, et al. Epidural ropivacaine vs. bupivacaine: obstetric outcomes. Anesthesiology 2001; 94:A16
11. Lee, B. B., NganKee, W. D., Ng, F. F., Lau, T. K., Wong,E. L., Epidural infusions of ropivacaine and bupivacaine for labor analgesia : a randomized, double-blind study of obstetric outcome.ANESTHA-NALG,98, 1145-1152, 2004.
12. Gatt S, Crooke D, Lockley S, et al. A double-blind, randomized parallel investigation into the neurobehavioral status and outcome of infants born to mothers receiving epidural ropivacaine 0.25% and bupivacaine 0.25% for analgesia in labor. Anesth Intensive Care 1996; 24:108–9

13. Writer, W. D., Stienstra, R., Eddleston, J. M., Gatt, S. P.,Griffin, R., Gutsche, B. B., Joyce, T. H., Hedlund, C.,Heeroma, K., Selander, D., Neonatal outcome and mode of delivery after epidural analgesia for labour with ropivacaine and bupivacaine : a prospective meta-analysis. BR J ANAESTH, 81, 713-717, 199
14. Bolukbasi, D., Sener, E. B., Sarihasan, B., Kocamanoglu S., Tur, A., Comparison of maternal and neonatal out-comes with epidural bupivacaine plus fentanyl and ropivacaine plus fentanyl for labor analgesia. INT J OBSTET ANESTH, 14, 288-293, 2005.
15. Evron, S., Glezerman, M., Sadan, O., Boaz, M., Ezri, T.,Patient-controlled epidural analgesia for laborpain : effecton labor, delivery and neonatal outcome of 0.125% bupivacaine vs 0.2% ropivacaine. INTJ OBSTETANESTH,13, 5-10,2004.
16. Norris MC, Grieco WM, Borkowski M, et al. Complications of laboranalgesia: Epidural versus combined spinal-epidural techniques.AnesthAnalg 1994; 79:529-37.