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A Study on Combined Spinal Epidural Labour Analgesia a Comparison between 0.125% Bupivacaine with Fentanyl Versus 0.1% Ropivacaine with Fentanyl

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Abstract

Introduction: The responsibility of the Anaesthesiologist in obstetrics is arguably greater than in any other fields of anaesthesia. *Aim:* To compare the quality of epidural analgesia of 0.125% bupivacaine with 0.1% ropivacaine after intrathecal administration of fentanyl 25 µg in combined spinal epidural labour analgesia. *Methodology:* After obtaining ethical committee approval and written consent 60 term healthy primi gravida with cephalic singleton pregnancy were selected. Intrathecal fentanyl 25 µg initiated in all parturients. Group B receives epidural 0.125% bupivacaine 10 ml with 2 µg of fentanyl/mL agroup R receives epidural 0.1% ropivacaine 10 ml with 2 µg of fentanyl/mL two groups were compared in terms of quality of analgesia, vitals & fetal outcome. *Results:* Quality of analgesia was excellent in both the groups. Maximum motor blockade (grade 1 Bromage) has occurred during the first stage of labour and doesn't affect the progression of labour or fetal outcome. *Conclusion:* We had concluded that both epidural bupivacaine 0.125% and ropivacaine 0.1% provides equal

Keywords: Combined spinal epidural labour analgesia; Intrathecal fentanyl; Bupivacaine; Ropivacaine.

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Introduction

Labour is defined as events that occur serially in female genital tract in order to expel the products of conception out of the womb into outer world through the vagina [1].

History of obstetric anaesthesia began with James Young Simpson, who administered Ether to a woman with deformed rachitic pelvis in 1847. She survived the complicated delivery absolutely free of pain [2]. John Snow administered chloroform to Queen Victoria during hereighth child birth, Prince Leopold In 1950 [3]. Labour pain leads to cortisol, epinephrine and nor epinephrine release into maternal circulation which may affect the uterine blood flow Neuraxial techniques especially combined spinal epidural technique provides rapid onset of analgesia and better maternal satisfaction [4].

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In this study, we compared the quality of labour analgesia of epidural 0.125% bupivacaine with fentanyl µg/mL and 0.1% ropivacaine with fentanyl 2 µg/mL following intrathecal fentanyl 25 mcg.

Aim of the study

The aim of the study is to compare the quality of epidural analgesia of 0.125% bupivacaine with fentanyl µg/mL and 0.1% ropivacaine with fentanyl 2 µg/mL after intrathecal administration of fentanyl 25 mcg in combined spinal epidural labour analgesia.

Objectives

Primary Objective

To compare the quality of analgesia during the labour in both the groups.

Secondary Objective

To compare duration and progression of of labour.

To compare newborn evaluation with APGAR score.

To study the side effects of the drugs and procedure.

Methodology

This comparative clinical study of combined spinal epidural labour analgesia for vaginal delivery with intrathecal fentanyl 25 µg +epidural 0.125% bupivacaine 10 mL with 2 µg of fentanyl/ mL versus intra thecal fentanyl 25 µg+ epidural 0.1% ropivacaine 10 mL with 2 µg of fentanyl/mL was conducted in 60 parturients, who consented for painless labour in Kilpauk Medical College and Hospital, Chennai after obtaining permission from the Institutional Ethical committee. After taking a written informed consent, only those who fulfilled the selection criteria were included in this study.

Inclusion criteria

1) Pregnant women with singleton pregnancy, term gestation, cephalic presentation, in active first stage of labour, the mothers who are booked and all antenatal investigations are within normal limits.

2) Cervical dilation >3 cm and <5 cm.

3) Age 18-35 years, Height >150 cm.

4) BMI 18-25

5) Primi gravida

Exclusion criteria

1) Mothers with co-existing diseases like diabetes, hypertension, PIH, bronchial asthma, epilepsy, thyroid disorders, IHD, valvular heart disease, previous LSCS

2) Spine abnormalities and local skin infections.

3) Coagulopathies.

4) Cephalo pelvic disproportion.

5) Preterm gestation.

6) Fetal distress.

Antenatal mothers in antenatal wards and those who attended outpatient department were counselled about labour analgesia. Thorough assessment of mothers including investigation, systemic examination was done. Those mothers who fulfilled inclusion criteria when enters the active stage of labour was enrolled in our study.

The study population consisted of 60 parturients allocated into two groups, 30 in each group. The parturients satisfying the selection criterianwere randomized by computer generated randomization table into two groups of thirty each - Group B and Group R. The randomization sequence was prepared in double-blinded manner. The study blinding was broken after the statistical analysis.

(1) Group B (Bupivacaine): received intrathecal fentanyl 25 µg + epidural 0.125% Bupivacaine 10 mL with 2 µg of fentanyl/mL.

(2) Group R (Ropivacaine): received intrathecal fentanyl 25 µg + epidural 0.1% Ropivacaine 10 mL with 2 µg of fentanyl/mL.

Preparation of the Parturient

She was prepared as per the routine preparation done for delivery, in addition to preparation of back to perform epidural block.

The onset of active labour, degree of cervical dilatation and the adequacy of pelvis for vaginal delivery were assessed by attending obstetrician, before performing the block.

Monitors (NIBP, pulse oximeter, ECG and CTG) connected and base line vitals were recorded.

An IV line was started on the non dominant and with an 18 G cannula.

The parturient was preloaded with 500- 1000 mL 0f Ringer lactate solution.

Anti aspiration prophylaxis (Inj. Ranitidine 50 mg and Ondansetron 4 mg IV) was given.

All equipments needed for airway management and resuscitation of the mother and baby was kept ready before performing the block.

Preparation of epidural bupivacaine and ropivacaine

The epidural drug preparation (including top up doses) was done by the duty assistant professor who prepared it according to the group allocation. 2 mL of 100 mcg fentanyl (50 µg/mL) diluted with 3 mL of normal salinewhich gives 20 mcg /mL fentanyl. For group B-2.5 mL of 0.5% bupivacaine mixed with 20 mcg of prepared inj. fentanyl (1 mL) and 6.5 mL of normal saline which gives 0.125% bupivacaine with fentanyl 2 mcg/mL. For group R- 5 mL of 0.2% ropivacaine mixed with 20 mcg of prepared inj. fentanyl (1 mL) and 4 mL of normal saline which gives 0.1% ropivacaine with fentanyl 2 mcg/mL.

Performing the Block

Block was performed after shifting patient to operation theatre. We used separate needle CSE technique for this study. Subartachnoid block was performed under aspesis and local analgesia at L 4-5 AND 25 µg Fentanyl given after confirming free flow of CSF. Epidural space was located at L3-4 L2-3 using loss of resiistance technique using 18G Tuohy needle with bevel directed upwards Catheter was placed 3-5 cm in the epidural space. After negative aspiration for blood and CSF, the epidural catheter was secured. Two mL of prepared solution was given as epidural test dose. Each increment of the therapeutic dose was considered the test dose. These precautions were followed in all bolus injections of local anaesthetic through an epidural catheter. With patient in supine position, left uterine displacement was done by placing a wedge under the right buttock. Remaining 8 mL of 0.125% bupivacaine with 2 µg/mL fentanyl for group B or 8 mL of 0.1% ropivacaine with 2µg/ mL fentanyl for group R was given epidurally and patient was shifted back to labour room. After 60 minutes or when pain recurred or after two segments was regressed whichever was earlier, 5 mL (0.125% bupivacaine or 0.1% ropivacaine with fentanyl µg/mL) was given epidurally in presence of duty assistant professor. Left uterine displacement was maintained throughout the labour. Intermittent bladder catheterisation was done. At the time of onset of second stage of labour; she may feel pain over perineum, inner thigh, anus or vagina.

Full dose of 10 mL of (bupivacaine 0.125%/ ropivacaine 0.1%) was administered regardless of previous dose at second stage, relieves the pain without affecting course of labour and this avoids further analgesia for episiotomy also. Obstetric management was decided by obstetricians.

Continuous maternal and fetal monitoring was done and epidural catheter was removed six hours after delivery.

Monitoring

1) Time of onset of analgesia (Time taken for achieving visual analogue scale to become less than 3).

2) Assessment of sensory blockade (every 15 minutes using spirit cotton for loss of cold sensation in the midclavicular line bilaterally from the nipple to the pubic symphysis).

3) Assessment of motor blockade (Modified Bromage Scale)

4) Assessment of sedation (5- point scale).

5) Duration of analgesia (Time interval from the onset of analgesia till the return of painful contraction (VAS more than 3) or till regression of sensory level to below T12)

6) Hemodynamics.

7) Complications or side-effects if any.

8) Obstetric progress by partograph.

9) Fetus monitoring by fetoscope, cardio tocograph.

At birth, the APGAR score of the neonate at 1 and the 5th minute was used to assess the neonatal well being. Any neonate with an APGAR score of less than 7 was resuscitated with suctioning, mask ventilation and intubation if needed and ventilated with 100% oxygen.

Patient Satisfaction Score

1-excellent

2-good

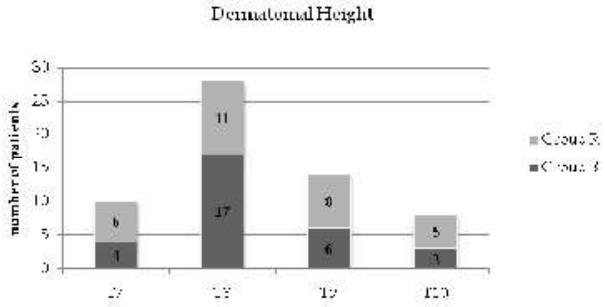
3-poor

Statistical Analysis

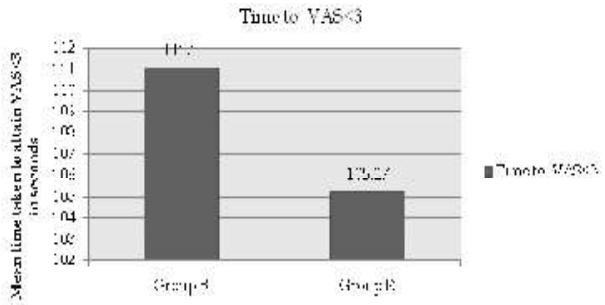
The statistical analysis were done using SPSS

(Statistical package for social sciences) version 17 for windows. Descriptive statistics are presented as mean±SD. Two sided independent student's t tests to analyze continuous data and Chi-square test for association was used to compare categorical variables between treatment allocations. $p<0.05$ was considered as statistically significant

Result



Graph 1: Dermatomal Height



Graph 2: Time to VAS<3

Table 1: Demoography

	Group B	Group B	P value
Age	21.97 ± 2.356	22.63 ± 2.484	0.291
Weight (mean±S.D)(kg)	71.30 ± 5.484	71.53 ± 5.941	0.875
Height (mean±S.D)(cm)	160.23 ± 4.400	158.77 ± 5.117	0.239

	Group B	Group B	P value
Cervical dilatation(cm)	4.23±0.430	4.23±0.430	1.0
Active phase of first stage of labour	171.97±19.089	172.03±25.926	0.991
Second stage of Labour	31.30±5.240	31.10±5.762	0.889
Total duration	203.77±19.856	203.13±22.793	0.909

	Group B	Group B	P value
Total number of epidural bolus	4.33±0.547	4.00±0.947	0.1
Total Volume of Epidural Drug(mL)	33.33±4.011	32.17±4.676	0.991
Total Dose of Fentanyl(µg)	66.67±8.023	64.33±9.353	0.304

Table 2: Dermatomal Height (Chi-square test)

	T7	T8	T9	T10	P Value
Group B	4(13.3%)	17(56.7%)	6(20.0%)	3(10.0%)	0.48
Group R	6(20.0%)	11(36.7%)	8(26.7%)	5(16.7%)	

	Group B	Group B	P value
Baseline VAS(student's t test)	9.70±0.466	9.53±0.507	0.19
Time to VAS<3 (in seconds)	111.10±17.197	105.27±8.828	0.104
Total Dose of Fentanyl(µg)	66.67±8.023	64.33±9.353	0.304

Table 3: Motor blockade

Motor blockade	0	1	2	3
Group B	20(66.7%)	10(33.3%)	0	0
Group R	26(86.7%)	4(13.3%)	0	0
P value	0.67			

Table 4: Outcome

Outcome	Group B	Group B	P value
Vaginal delivery	29(96.7%)	29(96.7%)	
Forceps	1(3.3%)	1(3.3%)	1.0
Emergency LSCS	0	0	

Table 5: APGAR Score

APGAR Score	Group B	Group B	P value
1 Min	7.57±0.504	7.57±.0504	1.000
5 Min	8.57±0.504	8.87±0.346	.009

Table 6: Complications

Complications	Group B	Group B	P value
Pruritus	22(73.3%)	20(66.7%)	0.5
None	8(44.4%)	10(55.6%)	

Table 7: Patient satisfaction

Patient satisfaction score	Group B	Group B
1	30(100%)	30(100%)
2	0	0
3	0	0

Discussion

Neuraxial method provides excellent and satisfactory analgesia without compromising maternal and fetal safety hence it is considered till now as a gold standard technique for providing labour analgesia [5].

Many studies showed that ropivacaine is 60% as potent as that of bupivacaine. There have been many studies compared equal concentration of drugs [14,17], (0.125% bupivacaine vs 0.125% ropivacaine) and equi-potent concentration [18,19]

of both drugs (0.1% bupivacaine vs. 0.15% ropivacaine).

In our study, there were no difference between two groups with respect to age, height and weight.

Mean baseline VAS in group B was 9.7 with S.D of 0.466 and in group R mean baseline VAS was 9.53 with S.D of 0.507. p value of 0.19 and it was statistically insignificant.

Labour analgesia was initiated in both groups between 4-5 cms of cervical dilatation. Mean cervical dilatation in both groups was 4.23 cm with S.D of 0.430. P value of 1.0 which was statistically insignificant.

CSE analgesia often initiated with intrathecal opioid (fentanyl 25 μg or sufentanyl 5 μg) in early latent phase with cervical dilatation less 4-5 cm followed by epidural catheter placement in healthy nulliparous women. Addition of local anesthetics to opioid intrathecally is unnecessary for achieving complete spinal analgesia especially in early stage will result in hypotension and profound motor blockade particularly if it is followed by an epidural injection of local anesthetics [12,13].

In our study, we initiated labour analgesia with intrathecal fentanyl 25 μg followed by epidural catheter placement in L3-L4/L2-L3 space and catheter tip fixed at T12/L1. Ten min after spinal analgesia group B received ten mL of 0.125% bupivacaine with fentanyl 2 μg/mL and group R received ten mL of 0.1% ropivacaine with fentanyl 2 μg/mL.

Mean onset of analgesia (time to VAS <3) was 111.10 sec with S. D of 17.197 in group B and mean onset of analgesia was 105.27 sec with S.D of 8.828. P value of 0.104 was statistically insignificant. There is no significan difference between two groups with respect to onset of analgesia.

Maximum dermatomal level of sensory blockade achieved in both groups was T7. 13.3% in group B and 20.0% in group R had T7 level. 56.7% in group B and 36.7% in group R had T8 level.10.0% in group B and 16.7% in group R achieved T10 level .20% in group B and 26.7% in group R achieved T9 level. P value was 0.48 and statistically insignificant.

This was comparable to the level achieved by Owen et al. [14] and Guisasola [18] et al. Incidence of motor block was less in many studies and it was statistically significant in many studies (Gautier et al, Fischer et al, Meister et al, Campbell et al., Fine gold et al.) [14,17]. In our study, 20(66.7%) of patients in group B and 26(86.7%) of patients in group R had no motor blockade. 10 patients (33.3%) in group B and 4 (13.3%) patients in Group R had grade 1 Bromage (minimal) motor blockade. No patient in any groups was developed grade 2 or 3 motor blockade P value of 0.67, which is statistically insignificant. Maximum motor blockade (grade 1 Bromage) has occurred during first stage of labour and was seen immediately following bolus dose. There were no statistically significant differences in blood pressure, pulse rate, saturation in both the groups.

No statistically significant differences in Sedation score of both groups. Some patients showed mild drowsiness (score 1) mainly due to effective pain relief. Fetal heart rate changes in both groups were within normal limits. Pvalue of both the groups shows no statistically significant changes.

In both the groups VAS was maintained with less than 3. In most cases VAS 3 usually coincide with the onset of 2nd stage of labour. Repeating the 10 mL of bupivacaine maintained the analgesia.

Mean duration of active phase of 1st stage of labour in group B was 171.9±19.089 minutes and 172.03 ± 25.926 minutes in group R. Mean duration of 2nd stage of labour in group B was 31.30±5.240 minutes and i n group R it was 31.10 ±5.762 minutes. Mean total duration of labour in group B was 203.77 ±19.856 minutes and in group R it was 203.13± 22.793 minutes. All durations were statistically insignificant

Our results were correlated well with many studies (Feranandez 2001, Owen 20024, Boselli 2003, Halpern 2003) [18,14]. In contrast Lee et al. 2002, found that the bupivacaine group had longer first stage of labour than ropivacaine group. However they concluded that the difference may be of limited clinical significance.

In our study CSE is associated with more rapid cervical dilatation and shorter duration of labour. This result was consistent with studies conducted by Amit. G. Bhagwat et al. [9] and Lawrence C Tsen et al. [8].

Mean of total number of epidural bolus doses used in group B was 4.33 with SD of 0.547. In group R Mean of total number of epidural bolus doses used was 4.00 with SD of 0.947. P value of0.100 and was statistically insignificant.

Mean of total volume used for epidural analgesia in group B was 33.33 mL with SD of 4.011. In group R mean of total volume used for epidural analgesia used was 32.17 mL and SD of 4.676. p value of 0.102 and was statistically insignificant. There was no difference between two groups in volume

requirements.

During second stage, all parturients in our study required ten mL of local anaesthetic bolus for effective pain relief during episiotomy. This was not influenced by position of patient and mainly depends on volume Merry AF et al., Park WY et al., Erdemir HA et al studies showed that inconsistent results with position of patient during drug administration but by increasing the volume of drug [22,23,24] during second stage of labour.

Mean of total dosage of fentanyl used in group B was 66.67 µg with SD of 8.023. In group R mean of total dosage of fentanyl used was 64.33 µg with SD of 9.353. p value of 0.304 and was statistically insignificant.

Most studies showed that incidence of emergency caesarean delivery were less with CSE technique when compared to conventional epidural [9,10] Risk of caesarean delivery does not increased by neuraxial techniques and also by time of initiation of labour analgesia in latent phase (cervical dilatation 4 cm).

In both groups all babies delivered by normal vaginal delivery except two babies were delivered by forceps delivery. Both of them were secondary to poor maternal efforts. No other case underwent caesarean section.

The recent Cochrane review [20] which compared epidural analgesia with inhalational and intravenous analgesia (mainly opioid) and observed that there was less fetal acidosis and less nalaxone administration in babies born to mothers having labour epidural analgesia.

Beilin and Halpern in 2010 [16,21] did a focused review with various studies that compared bupivacaine and ropivacaine and concluded that there was no evidence that neonatal outcome is adversely affected when ropivacaine or bupivacaine is used for labour analgesia. In our study, at 1 minute in group B mean of APGAR score was 7.57 and SD was 0.504. In group R mean was APGAR score 7.57 and SD was 0.504. P value of 1.0 and was statistically insignificant.

At 5 minutes in group B mean of APGAR score was 8.57 and SD was 0504. In group R mean was APGAR score 8.87 and SD 0.346. p value of 0.009 and was statistically insignificant.

In our study, Pruritus was seen in both the group B (73.3%) and group R (66.7%). In most of womens it was self limiting and got settled within hour of fentanyl administration. Some responded well to Ondansetron 4 mg IV. No other complications were seen during labour analgesia RE Collis, DWL Davies concluded that overall satisfaction was greater in CSE group than conventional epidural because of CSE produces rapid onset of analgesia [4,7]. In our study, all parturients in both the group experience and gave satisfaction score of (=1) excellent analgesia during labour till delivery.

Conclusion

The observation of this study shows that both bupivacaine 0.125% and ropivacaine 0.1% administered epidurally as a part of combined spinal epidural technique following intrathecal 25 µg provides equal and effective analgesia. Duration of labour was not prolonged rather combined spinal epidural analgesia decreases the duration of labour. Patient satisfaction, level of sensory blockade, mode of delivery, duration of labour, neonatal outcome and complications are comparable between both the groups. Bupivacaine group had relatively more motor blockade which was grade 1 Bromage when compared to ropivacaine group but that was not statistically significant. Maximum motor blockade of grade 1 Bromage was seen during first stage of labour especially immediately after first epidural bolus dose which doesn't affect the progress of labour. But the observation of this study with respect to motor blockade was not statistically significant which needs further future studies in large scale.

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