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A Comparative Study of Labour Analgesia between Ropivacaine with Fentanyl versus Bupivacaine with Fentanyl by Combined Spinal Epidural Technique

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Abstract: Introduction: *Labor pain is excruciating and a significant contributor of stress and anxiety. Painful uterine contractions cause maternal hyperventilation and increased catecholamine release resulting in maternal and fetal hypoxemia. Providing labor analgesia takes away the disadvantage and result in better maternal and fetal outcome.*
Materials and methods: *This study was conducted in tertiary care hospital, Kolkata, India. Booked antenatal cases term, singleton pregnancy with the vertex as presenting part were excluded in this study. The design of the study was, randomly the patients were devided into 2 groups of each using a computer allocated random chart. Both groups (B and R) received 20 micro gram fentanyl intra thecally. One group (Group B) was given epidural bupivacaine 0.125% (in 12 ml) and the second group (group R) received epidural ropivacaine 0.2% (in 12 ml).*
Results: *The average age of the patient in group B was 23.87±3.43 years and in group R was 25 ± 2.21 years. The age difference between the two groups was not statistically significant (p=0.134) by students unpaired t test (p>0.05). The average weight of the patient in group B was 61.53 ± 6.39 kg and in group R was 61.13 ± 4.93 kg. There was no statistically significant difference in weight distribution between groups (0.787) by student's unpaired test (p>0.05). The table shows ASA grade distribution in both the study group. Both the groups were comparable. There was no statistically distribution in parity between two group (p=0.688) by fischer's exact test 2 tailed (p>0.05).*
Conclusion: *There is significant difference in duration of analgesia between both the study groups, favouring ropivacaine for its longer duration. Top up requirement is less for Ropivacaine group due to its longer duration of action. The profile of block with low doses of Ropivacaine in terms of its greater sensory-motor separation and higher Clearance than bupivacaine make it suitable for use. Feto-maternal complications are negligible with Ropivacaine, no feto-maternal complications noted in this study. Ropivacaine-because of its effective and longer duration of analgesia, profile of block in terms of its greater sensory-motor separation and higher clearance than bupivacaine make it suitable for use. Hence clinical place of Ropivacaine in extradural analgesia during labour offers distinct advantages over bupivacaine-the current local anaesthetic drug of choice.*
Key Words: *Labor pain, anxiety, singleton pregnancy, fentanyl, ropivacaine*.

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I. Introduction

Labor pain is excruciating and a significant contributor of stress and anxiety. Painful uterine contractions cause maternal hyperventilation and increased catecholamine release resulting in maternal and fetal hypoxemia. Providing labor analgesia takes away the disadvantage and result in better maternal and fetal outcome. 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. Even though combined spinal epidural analgesia (CSEA) is considered as a safe technique with greater maternal satisfaction, there were no differences in maternal satisfaction, mode of delivery, and ability to ambulate between CSEA and epidural techniques.

With the emerging concept of low dose and minimal local anesthetic (LA) dose and volumes, all present day labor epidurals are low-dose epidurals. In the last decade, the concentration of LA used to maintain labor epidural analgesia has been decreasing (0.0625%–0.125%) in an attempt to reduce the total dose of LA used as well as to avoid motor blockade.

Epidural bupivacaine provides excellent sensory block and has been used for labor analgesia for many years. However, concern about its cardiac toxicity and the intensity of motor block has led to the investigation of other agents. Ropivacaine has been associated with reduced incidence of operative vaginal delivery and less motor block when compared to bupivacaine. Recently, it has been shown that ropivacaine appears equipotent to bupivacaine, less cardiotoxic and neurotoxic and seem to be more suitable agent for pain relief in laboring women.

In the randomized study comparing levobupivacaine, ropivacaine and bupivacaine with fentanyl for labor analgesia concluded that all three regimens were effective during the first stage of labor although pain scores were higher in those receiving levobupivacaine. Motor block was greater with bupivacaine than with levobupivacaine.

The quality of analgesia is excellent when highly lipid-soluble opioids are added. The addition of opioids to LA reduces its requirement by synergistic effect of opioid receptors in the spinal cord. This reduces the chances of motor blockade and the hemodynamic perturbations.

The aim of this study is to evaluate and compare the clinical efficacy between epidural bupivacaine and ropivacaine with intra thecal fentanyl by CSEA and to study their efficacy to establish rapid analgesia and avoid motor paralysis with minimal side effect to the fetus.

II. Materials And Methods

Study area: This study was conducted in tertiary care hospital, Kolkata, India.

Study Population: Booked antenatal cases term, singleton pregnancy with the vertex as presenting part were excluded in this study.

Inclusion criteria:

- ASA I and ASA II grade parturients.
- Uncomplicated pregnancy scheduled for normal vaginal delivery.
- Vertex presentation not in fetal distress.
- Singleton fetus.
- Age between 18 and 35 years.

Exclusion criteria:

- Patient refusal.
- Local infection of the neck.
- Pregnancy induced hypertension with coagulopathy and antepartum haemorrahge.
- Maternal vascular heart disease or anticoagulant therapy.
- Previous caesarian section for contracted pelvis.
- Pre existing neurological disease and severe deformity of the spine.

Study Period: Jan 2015 to May 2016

Sample Size: 60

Sample Design: The design of the study was, randomly the patients were devided into 2 groups of each using a computer allocated random chart. Both groups (B and R) received 20 micro gram fentanyl intra thecally. One group (Group B) was given epidural bupivacaine 0.125% (in 12 ml) and the second group (group R) received epidural ropivacaine 0.2% (in 12 ml).

Group B: Patients receiving 20 microgram of fentanyl intra thecally plus 12 ml of 0.125% bupivacaine epidurally I combined spinal epidural analgesia.

Group R: patients receiving 20 micro gram of fentanyl intra thecally plus 12 ml of 0.2% ropivacaine epidurally in combined spinal epidural analgesia.

In both the groups all the study parameters were noted and analyzed. The results were compiled under each group of the drugs and compared.

Study Procedure: Permission of the hospital ethical committee was obtained before proceeding on the study.

The mother was explained about procedure and its benefits. If possible she was familiarized with another mother who has delivered the baby under the procedure.

Obstetrician colleagues were discussed about the case and their concurrence was obtained. Informed consent from the patient was obtained for labour analgesia technique as routine for any other anesthesia and surgical procedure.

Labour analgesia was made available to any women who requested for pain-relief and did not exhibit any specific contra indication. Maternal BP, pulse, cervical dilation and stage of labour, fetal heart rate are recorded. An intravenous access was established with 18G intravenous analgesia was administered when patient was in active labour with cervical dilatation of 3-4 cm.

After taking proper aseptic precaution and giving local infiltration, 25/26G Quincke's spinal needle was inserted into subarachnoid space at L2-3/L3-4 inter vertebral space. After return of clear CSF, patient was given a single

intra thecal injection of 20 micrograms fentanyl. The time of the intra thecal injection was noted and the monitoring of clinical parameters for analgesia and side effects according to the study protocol was initiated. As soon as the patient becomes comfortable and more co-operative, tuohy needle was inserted into epidural space at the same space via midline approach using the loss of resistance technique and an epidural catheter was inserted 3-5 cm into the epidural space and was secured for administration of 12 ml of 0.125% bupivacaine or 12 ml of 0.2% ropivacaine as stat and it was repeated when required till the delivery of baby.

Statistical Methods: categorical variables are expressed as number of patients and percentage of patients and compared across the groups using Pearson's chi square test for independence of attributes. Continuous variables are expressed as mean ± SD and compared across the 2 groups using unpaired t test. The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e if any p value less than 0.05 it has been considered as significant.

III. Results

Following are the observations made during the study between the two groups of 30 patients each based on the drugs used on them.

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**Significance**
Age	23.87 ± 3.43	25 ± 2.21	0.134	Not significant

Table 1: Maternal age profile of study groups

Table 1 shows maternal age in years. The average age of the patient in group B was 23.87±3.43 years and in group R was 25 ± 2.21 years. The age difference between the two groups was not statistically significant (p=0.134) by students unpaired t test (p>0.05).

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**Significance**
Weight	61.53 ± 6.39	61.13 ± 4.93	0.787	Not significant

Table 2: Body weight profile of study groups

The average weight of the patient in group B was 61.53 ± 6.39 kg and in group R was 61.13 ± 4.93 kg. There was no statistically significant difference in weight distribution between groups (0.787) by student's unpaired test (p>0.05).

		Group		**Total**		
		Group B	**Group R**		**P Value**	**Significance**
Gravida	**Primi**	27(90)	25(83.33)	52(86.67)	0.448	Not significant
	Multi	3(10)	5(16.67)	8(13.33)		
Total		30(100)	30(100)	60(100)		

Table 3: Status of parity in study groups

Table 3 shows status of parity in two study group. The two groups were comparable with respect to parity (p=0.448) by fisher's exact test 2 tailed (p>0.005).

		Group		**Total**		
		Group B	Group R		P Value	Significance
ASA Grade	I	26(86.67)	27(90)	53(88.33)	0.688	Not significant
	II	4(13.33)	3(10)	7(11.67)		
Total		30(100)	30(100)	60(100)		

Table 4: ASA grade in study group

The table shows ASA grade distribution in both the study group. Both the groups were comparable. There was no statistically distribution in parity between two group (p=0.688) by fischer's exact test 2 tailed (p>0.05).

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**significance**
Baseline VAS	7.4 ± 0.89	7.47 ± 0.9	0.774	Not significant

Table 5: Baseline VAS Score

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**significance**
Onset of analgesia	8.67 ± 29.7	79.67 ± 30.23	0.898	Not significant

Table 6: Onset time of analgesia

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**significance**
Max analgesia (sec)	223 ± 93.11	227 ± 93.78	0.869	Not significant

Table 7: Time to reach maximum analgesia

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**significance**
Duration (mins)	123.5 ± 55.39	168 ± 49.91	0.002	Not significant

Table 8: Duration of analgesia

	Group			
	Group B	**Group R**		
	Mean ± SD	**Mean ± SD**	**P Value**	**significance**
VAS after block	2.33 ± 0.92	2.2 ± 1	0.593	Not significant

Table 9: VAS After CSEA

		Group		Total		
		Group B	**Group R**		**P Value**	**Significance**
Itch	ABSENT	7(23.33)	9(30)	16(26.7)	0.559	Not significant
	PRESENT	23(76.67)	21(70)	44(73.3)		
Total		30(100)	30(100)	60(100)		

Table 10: Incidence of pruritus in both study groups

		Group		Total		
		Group B	**Group R**		**P Value**	**Significance**
Nausea/vomiting	absent	28(93.33)	29(96.67)	57(95)	0.554	Not significant
	Present	2(6.67)	1(3.33)	3(5)		
Total		30(100)	30(100)	60(100)		

Table 11: Nausea and vomiting in both groups

		Group		Total		
		Group B	**Group R**		**P Value**	**Significance**
Hypotension	Absent	30(100)	30(100)	60(100)	NA	NA
Total		30(100)	30(100)	60(100)		

None of the group showed hypotension.

Table 12: Incidence of hypotension in both study groups

		Group		Total		
		Group B	**Group R**		**P Value**	**Significance**
Paraesthesia	Absent	30(100)	30(100)	60(100)	NA	NA
Total		30(100)	30(100)	60(100)		

None of the group showed Paraesthesia.

Table 13: Incidence of Paraesthesia in both study groups

		Group		Total		
		Group B	**Group R**		**P Value**	**Significance**
Delivery Mode	ND	26(86.67)	25(83.33)	51(85)	0.718	Not Significant
	Vaccum	4(13.33)	5(16.67)	9(15)		
Total		30(100)	30(100)	60(100)		

Instrumentation is increased in both groups but it is statistically not significant.

Table 14: Mode of delivery in both study groups

		Group		Total		
		Group B	**Group R**		**P Value**	**Significance**
Fetal bradycardia	Absent	30(100)	30(100)	60(100)	NA	NA
Total		30(100)	30(100)	60(100)		

None of the group showed fetal bradycardia.

Table 15: Incidence of fetal bradycardia in both study groups

IV. Discussion

Labour analgesia techniques, in the present time are one of the widely practiced procedures performed by an anesthesiologist and are requested by the obstetrician colleagues as well as the parturient mothers from the labour room. The newer methods of pain relief have not only brought in the joy and pleasure to the mother but also bring in a host of advantages and safety to her as well as to her offspring. The environment inside the labour rooms is no longer a place of agony and apprehension but a place full of assurances and co-operation between the mother and the assisting persons during the delivery process. This has become possible because of the most modern technique of combined spinal epidural analgesia and using very minute dose of potent drugs by which some of the drawbacks are avoided while taking the advantages of their analgesic properties appropriate to the duration and the situation for the delivery process to complete.

Early onset of analgesia has a great clinical significance. The CSE technique stands superior to the conventional simple epidural technique for labour analgesia as far as rapidity and reliability of the technique is concerned. The spinal component of CSE technique is responsible for the definite and early onset of analgesia. Drug distribution becomes more uniform and predictable because of mixing of the drug in the CSF medium to reach the target receptors easily and generally utilizing a lesser quantity of the drug establishing the analgesia procedure faster than the conventional epidural analgesia technique. Early onset of action leads to better patient co-operation for placement of epidural catheter.

The most popular among the drug groups used now a days for the purpose of labour analgesia are the potent lipophilic mu agonist narcotics like fentanyl/sufentanyl and long acting amino amide local anaesthetics like bupivacaine/Ropivacaine. Both these group of drugs are known to produce rapid onset of analgesic action. But their inherent side effects are the matter of concern. A lot of studies are available in the literature which have used either the narcotics alone or combining narcotic with the local anaesthetic drugs to achieve the goal of rapid and define labour analgesia in the initial spinal component of CSE technique. Various studies have been conducted in the past and have recorded the side effects of fentanyl. Their incidences have been brought down by reducing the doses which are still capable of providing sufficient analgesic action to counter the labour pain and thereby alleviating the unwanted effects of pain on the mother and the fetus.

Loss of muscle power makes a mother handicapped by losing strength in the lower limbs and abdominal wall to facilities expulsion of fetus in the second stage of labour or to move out of bed to evacuate her bowel/bladder herself. This defeats the present day's concept of walking epidural. Hypotension when severe may jeopardize the safety of the mother as well as the fetus.

Nausea vomiting normally make a mother uncomfortable and may be severe enough to cause hypotension. Similarly itching brings in discomfort but is never life threatening. However, respiratory depression to either the mother or the new born in dangerous. Occurrence of these side effects and their severity in this study, if any, were recorded and were used as the yard stick for the comparison between the two drugs. The mother was monitored closely using multi para monitor and cardiotocograph for fetal monitoring.

So this study was done to note the onset of analgesia by intra-thecal fentanyl and compare the duration and quality of analgesic effect and top-ups required between the epidural bupivacaine and Ropivacaine during CSE labour analgesia. It also compares the incidence of unwanted effects like muscle weakness, hypotension, nausea-vomiting, pruritus, fetal respiratory depression by the individual drugs.

The basic references for this study were previous studies done by Eddleston Et al, owen et al, polly et al, Finegold H which compared bupivacaine versus Ropivacaine in labour analgesia.

The sample size in each group (Group B and group R) was 30. Demographic characteristics of patients were comparable to each other in both the groups in respect of age, weight, ASA grade and parity.

V. Conclusion

The main focus of this study is to provide adequate pain relief with minimal effects on the maternal power (uterine activity and progress of labour), passage (birth canal) and passenger (fetus).

There is distinct advantage of combined spinal epidural over only epidural technique because giving intra thecal opioid leads to rapid onset of action and makes the mother cooperate for epidural.

There is significant difference in duration of analgesia between both the study groups, favouring ropivacaine for its longer duration.

Top up requirement is less for Ropivacaine group due to its longer duration of action.

The profile of block with low doses of Ropivacaine in terms of its greater sensory-motor separation and higher Clearance than bupivacaine make it suitable for use.

Feto-maternal complications are negligible with Ropivacaine, no feto-maternal complications noted in this study.

Ropivacaine-because of its effective and longer duration of analgesia, profile of block in terms of its greater sensory-motor separation and higher clearance than bupivacaine make it suitable for use. Hence clinical place of Ropivacaine in extradural analgesia during labour offers distinct advantages over bupivacaine-the current local anaesthetic drug of choice.

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