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Comparative Study of 0.125% Bupivacaine and 0.2% Ropivacaine by Combined Spinal-Epidural Technique for Labour Analgesia

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Abstract: ***Introduction**: Intrathecal fentanyl is useful in a distressed parturient to facilitate fast pain relief and better positioning for epidural catheter placement. Many pharmacologic studies claim that Epidural ropivacaine has prolonged duration of sensory block and less motor block compared to bupivacaine and hence we hereby design study to compare 0.125% bupivacaine and 0.2 % ropivacaine for efficacy of analgesia in terms of maximum duration of analgesia, top - up requirements and to look for any associated complications. **Aims and objectives**: To compare efficacy between epidural bupivacaine and ropivacaine, top - up requirements in labor analgesia. **Materials and methods**: A total of 60 patients belonging to ASA I and II aged 18 - 35 years were randomized into two groups. Group B received intrathecal 25 mcg fentanyl + 10ml of 0.125% Bupivacaine epidurally (2.5ml of 0.5 % Bupivacaine with 7.5 ml NS). Group R received intrathecal 25mcg fentanyl + 10ml of 0.2 % Ropivacaine epidurally (3ml of 0.75 % with 7ml NS). Pain was assessed using Numeric rating score (NRS) and top - up doses are repeated when numerical pain score is ≥ 5. **Results**: Group R had prolonged effective analgesia and require lesser number of epidural doses in 24hrs as compared to Group B (P value 0.002 and 0.011 respectively). There were no significant differences between groups considering time to reach maximum analgesia and NRS after Combined Spinal Epidural Analgesia (CSEA). None of the subjects in Group B and R had Maternal Hypotension, Maternal Paraesthesia and Fetal bradycardia. There was slight increase in instrumentation for delivery.*

Keywords: Anesthetics, Local; Analgesics, Opioid; Analgesia, Obstetrical; Analgesia, Epidural

1. Introduction

According to Scriptures, pain during childbirth originated when God punished Eve and her descendants for Eve's disobedience in the Garden of Eden. History of labor analgesia dates back to 1847 and the first woman to be anaesthetized for childbirth in the United States was Fanny Longfellow, wife of the American poet Henry Wadsworth and was administered ether. The most widely publicized labor analgesia was of Queen Victoria who in 1853 with the strong encouragement of her husband Prince Albert, chloroform administered to her by Dr. John Snow for her 8th confinement of Prince Leopold. Dr. Snow wrote afterwards, **—Her Majesty expressed great relief from the application, the pains being trifling during the uterine contractions, and whilst between the periods of contraction there was complete ease‖.** Queen Victoria's enthusiastic acceptance of Chloroform subsequently popularized its use. Indeed, for her 9th and last confinement of her daughter Princess Beatrice, Dr. Snow administered the Chloroform again.[1]

Childbirth is painful experience in lifetime but still it is considered routine event in life. Labor pain is excruciating and it adds a spectrum of adverse psychological and physical stress to mother and fetus. Many factors influence to cope with the labor pain and most determining factors are parity, fear, educational status, previous experience of labor, culture, motivation[2]. Painful uterine contractions causes high catecholamine levels and hyperpnea resulting into maternal and fetal hypoxemia.3The delivery of a newborn into the arms of a conscious and pain - free mother is one of the most exciting and rewarding moments in obstetric practice.

History of labor analgesia after inhalational agents, introduced pudendal, caudal, and paracervical blocks. Continuous caudal analgesia for labor was popularized from 1942; it was superseded by the lumbar epidural approach in the 1960's. In 1990s Combined spinal - epidural analgesia (CSEA) and patient - controlled epidural analgesia (PCEA) were introduced.[4]

There, have been various non - pharmacological and pharmacological efforts to alleviate the agony with the labor and the evidence supports the Epidural and CSEA remains gold standard[5]. CSEA aims to provide rapid and effective pain relief to the parturient mother with minimal side effects in mother and the fetus.

Pharmacologically both Bupivacaine and Ropivacaine are long actingamide local anesthetics but ropivacaine is less lipophilic [6]and there by resulting in reduced motor blockade and has more selective action over pain transmitting A - delta (δ) and C fiberover motor function A - beta (β) fibers [6]. Ropivacaine due to its shorter carbon chain on the amine portion without demonstrated stereoselectivity, ropivacaine is claimed to have higher threshold for cardiotoxicity and CNS toxicity than Bupivacaine[7, 8]. We designed this study to compare 0.125% Bupivacaine and 0.2% Ropivacaine for their clinical effects of efficacy in terms of onset and duration of analgesia, motor blockade, complications if any.

Aims and objectives

The aim of this study is to evaluate and compare the efficacy between epidural bupivacaine and ropivacainein labor analgesia by CSEA technique.

2. Materials and methods

This study was conducted after approval by Institutional ethics committee. An informed written consent was obtained from all the patients for participation in this study. This randomized double blind prospective study included total of 60 parturients randomized by computer generated table of random numbers into 2 groups of 30 each (n=30) to compare efficacy between epidural Bupivacaine and Ropivacaine in Labor analgesia using CSE technique and was conducted in Department of Anesthesiology and Critical care in Tertiary care hospital from Jan 2015 – May 2016. Both the participant and investigator are not aware of the drug given to reduce bias. Parturients in both groups had cervical dilatation 3 - 5 cm at the time of administration of CSEA. The American College of Obstetricians and Gynecologists (ACOG) statement had suggested that epidural analgesia is to be delayed until 4–5 cm cervical dilatation based on the study published by Thorpe et al.9. Later ACOG revised along with American Society of Anesthesiologists (ASA) emphasizing that there is no need to wait till the cervical dilation has reached 4–5 cm and endorsed a statement that "Maternal request is a sufficient indication for pain relief in labour"[10] In our study we gave analgesia on maternal request.

Pandya et al concludes that early labor analgesia is not associated with increase in cesarean deliveries. Rather it increases maternal satisfaction.[11]

Inclusion criteria:
1) ASA I and II grade Parturients.
2) Uncomplicated pregnancy scheduled for normal vaginal delivery
3) Vertex presentation not in fetal distress
4) Singleton fetus
5) Age between18 and 35 years.

Exclusion criteria:
1) Patient refusal
2) History of blood clotting disorders
3) Local infection of the back
4) Pregnancy induced hypertension with Coagulopathy & Antepartum hemorrhage.
5) Maternal valvular heart disease or anticoagulant therapy.
6) Previous Caesarean section for contracted pelvis.
7) Pre - existing neurological disease & severe deformity of spine.

Parameters studied:
Both groups B and R were given intrathecal injection of 25mcg Fentanyl (0.5ml). Group B received 10ml of 0.125% Bupivacaine epidurally and Group R received 10ml of 0.2% Ropivacaine. Top - up doses were given when NRS is ≥5. Top - ups not given during bearing down.
Various parameters studied were
a) Onset of action
b) Time to reach maximum analgesia
c) Duration of analgesia and Requirement of Top - ups
d) NRS during active contractions and after giving spinal and epidural drugs
e) Motor weakness
f) Systolic Blood pressure (BP) / Mean BP/ Diastolic BP
g) Maternal and Fetal Heart rate
h) Requirement of Top - ups

Fetal and maternal complications if any and instrumentation assistance for delivery were also noted.

Pre anesthetic assessment was performed and informed consent was taken. All demographic parameters of parturients including age, height, weight, gestational age, cervical dilatation and parity were recorded. After securing intravenous (IV) line for pre - loading with Ringer's lactate (10ml/kg body weight). Patient is placed in left lateral position. Under strict sepsis 2ml of 0.2% lignocaine was infiltrated into skin at L3 - L4 and L4 – L5 level. In L4 - L5 space 26G Qunicke's needle placed, after free flow of CSF, 25mcg of fentanyl is injected. With 18G Tuohy needle using loss of resistance (LOR) to airtechnique epidural space was identified and epidural catheter was inserted and secured to skin. After securing, negative pressure is applied at the hub of catheter and after confirming absence of CSF and blood, 10ml of study drug was injected. Analgesia was considered adequate if pain score on NRS ≤ 3. (Table 1) NRS score and hemodynamic monitoring of mother and fetal HR monitoring was done every 5mins for 10mins; every 10mins for 30 mins; every 30mins till the delivery. A change on the NRS of two numbers (20%) during assessment is regarded as being clinically significant.[12]

Parameters studied are Time of onset of analgesia until maximum analgesia, duration of analgesia, requirement of top - ups and side effects are assured. The study ended at the time of delivery after giving 10ml bolus dose of test drug for post - partum analgesia and catheter was removed.

Statistical analysis
The data was analyzed using Software SPSS version 20 to draw conclusions.

The patient characteristics (non – parametric data) were analyzed using the "Chi – square test". For parametric data were analyzed using T - test.

$P < 0.05$ was considered statistically significant and $P < 0.001$ was considered as highly significant.

Power of the study was calculated by taking error 0.05 i. e., P value < 0.05, considered as significant.

3. Results

No statistical difference was seen in demographic and baseline parameters in both groups. The difference between two groups for mean age, height, weight, cervical dilatation, Baseline NRS and time to reach maximum analgesia was found to be statistically non - significant (P>0.05).

Duration of analgesia was statistically significant with P value of 0.002 and is in favor of Ropivacaine. B group was 123.5 min (SD = 55.39) R group was 168 min (SD = 49.91). (Table 2)

Mean NRS score after CSE were significantly lesser with both Bupivacaine and Ropivacaine and is statistically not significant (P = 0.593). NRS score after CSE in B group was 2.33 (SD=0.92) and in R group was 2.2 (SD = 1.0). (Table 3)

Top up requirement was less for Ropivacaine group due to its longer duration of action and is statistically significant. (P value = 0.011) (Table 4)

All the parturients had normal vaginal delivery. Instrumentation increased in both the groups (13.33 % in B group and 16.67 % in R group) and is statistically not significant. (Table 5)

Incidence of pruritus was present in both groups and is statistically not significant. (76.6% in B group and 70% in R group).

No significant nausea and vomiting were observed in both the groups. No significant hypotension was observed in both the groups.

No incidence of paraesthesias and motor weakness in both the groups. Motor level block was assessed by Modified Bromage scale.[13] (Table 6)

There was no incidence of fetal bradycardia in both the groups.

Maternal satisfaction was measured by scale in which 5 was given for excellent, 4 for very good, 3 for good, 2 for fair and 1 for poor. It was Very good in 24 parturients in group B and 25 parturients in group R and the difference was found to be statistically non - significant (P >0.05).

Table 1: NRS Scoring

Before giving CSEA

0	1	2	3	4	5	6	7	8	9	10

After Maximum Sensory Block

0	1	2	3	4	5	6	7	8	9	10

Table 2: Onset and Duration of analgesia: Duration of analgesia is longer in R group.

Parameters	Group B		Group R		P value
	Mean	SD	Mean	SD	
Onset of Analgesia (min)	80.67	29.7	79.67	30.23	0.89 Not significant (NS)
Max Analgesia (min)	223	93.11	227	93.78	0.869 (NS)
Duration of Analgesia (min)	123.5	55.39	168	49.91	0.002 (Significant)

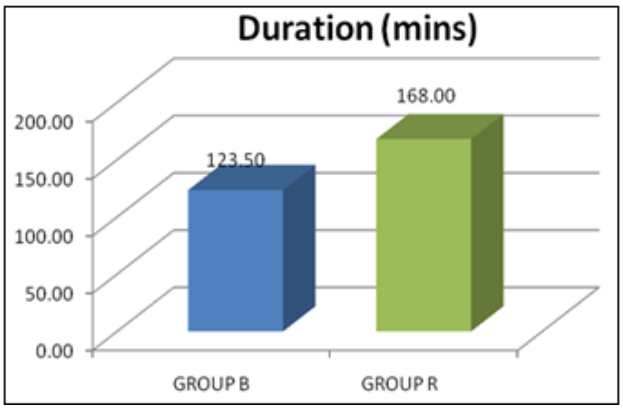

Figure 1: Duration of analgesia: Analgesia is prolonged in R group

Table 3: Baseline NRS and NRS after block: There is no difference between B and R groups

NRS	Group B		Group R		P value
	Mean	SD	Mean	SD	
Baseline NRS	7.4	0.89	7.47	0.9	0.774 (NS)
NRS after block	2.33	0.92	2.2 ± 1	1	0.593 (NS)

Pain was assessed with the NRS of 10 points, after the administration of the epidural analgesia. A decrease in the NRS >50% at was taken as a successful epidural analgesia.

Table 4: Requirement of Top - ups: Requirement of top - up is less in R group

Parameters		Group B No. of patients (%)	Group R No. of patients (%)	Total No. of patients (%)	P value	Significance
Top – up doses	0	9 (30)	16 (53.33)	25 (41.67)	0.011	Significant
	1	12 (40)	14 (46.67)	26 (43.33)		
	2	7 (23.33)	0 (0)	7 (11.67)		
	3	2 (6.67)	0 (0)	2 (3.33)		
Total		30	30	60		

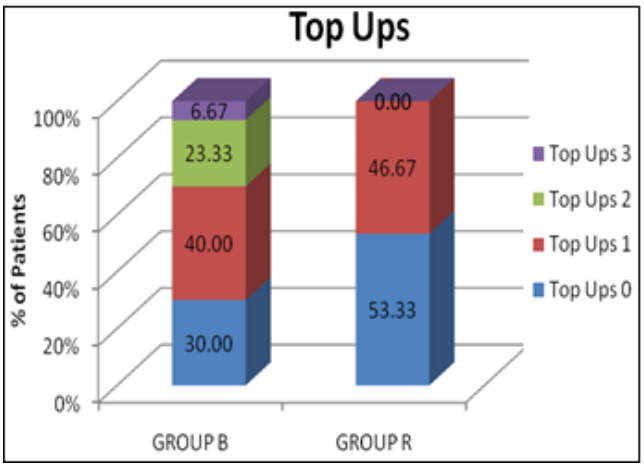

Figure 2: Requirement of Top - ups: 53.3 % of parturients did not require top - up dose in R group compared to 30% in B group. In R group remaining 46.67% of parturients required only one top - up dose. There were no (0.00) second and third top - up doses required in R group due to prolonged duration of analgesia.

Table 5: Mode of delivery: Instrumentation (vacuum assistance) was increased in both the groups

Mode of delivery	Group B	Group R	Total	P value	Significance
ND	26 (86.67)	25 (83.33)	51 (85)	0.718	Not significant
Vacuum	4 (13.33)	5 (16.67)	9 (15)		
Total	30 (100)	30 (100)	60 (100)		

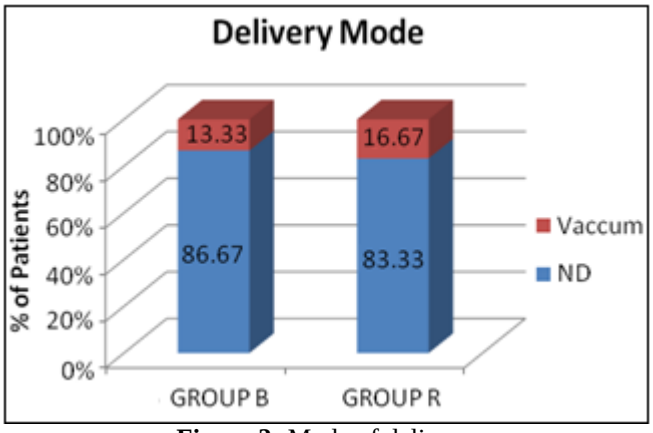

Figure 3: Mode of delivery

Table 6: Modified bromage scale

Score	Criteria	Degree of block
1	No motor block	None
2	Inability to raise extended leg; able to move knees and feet	33%
3	Inability to raise extended leg and move knee; able to move feet	66%
4	Complete block of motor limb	Total

Pain relief and motor blockade were assessed at soon after giving epidural, then maximal loss of pain sensation in every minute and every 15 minutes thereafter till vaginal delivery.

4. Discussion

Labor pain is excruciating and it adds a spectrum of adverse psychological and physical stress to mother and fetus. Many factors influence to cope with the labor pain and most determining factors are parity, fear, educational status, previous experience of labor, culture, motivation1. Culturally in few places parturients are humiliated if couldn't able to bear labor pain and treated as mentally weak. Culture should be considered as parturients are socialized to be stoic and therefore labor pain will be assessed by treating gynecologistaccordingly and CSEA will be advised.[14]

There, have been various non - pharmacological and pharmacological efforts to alleviate the agony with the labor and CSEA remains gold standard. CSEA combines the advantages of the epidural analgesia with that of spinal analgesia with rapid onset and consistency. The epidural catheter can be used for providing anesthesia for lower segment caesarean section if required. CSEA includes intra - thecal injection of lipophilic opioids (Fentanyl) followed by introduction of catheter into epidural space for maintenance of analgesia by extradural route. After initial bolus dose of local anesthetic by extradural route, bolus doses of 10ml are repeated when NRS is above 5.

In our study intermittent bolus of drug is preferred over continuous drug infusion. Patkar, et al. found that intermittent bolus of epidural top - up had lesser total requirement of drug and lesser break through pain.[15]

There have been many studies showing Ropivacaine causes lesser motor blockade due to its selective action on A - δ and C fibers (involved in pain transmission) rather than on A - β fibers (involved in motor function). Ropivacaine offered favorable sensory motor differentiation. Ropivacaine has higher cardiovascular collapse/CNS ratio and thereby greater safety margin than Bupivacaine.[16]

The minimum local anesthetic concentration (MLAC) of ropivacaine is higher than bupivacaine demonstrating ropivacaine is less potent than bupivacaine[17.] This indicates higher concentration of ropivacainerequired to provide analgesia equipotent to 0.125% bupivacaine. Many studies conclude that ropivacaine 0.2% produces the same clinical effects as levobupivacaine 0.125%.[18, 19]

Many authors concluded that ropivacaine 0.2% offers adequate analgesia, better than 0.15% or 0.1% concentration with minimal motor block and hemodynamic sideeffects[20]. From these studies we come to know that 0.2% ropivacaine and 0.125% bupivacaine analgesic potencies are comparable and thereby we used these concentrations of bupivacaine and ropivacaine in our study.

Shenvi et al. compared 0.1% bupivacaine and 0.15% ropivacaine and concludes that both the drugs produce equivalent analgesia in terms of duration and quality. Incidence of motor blockade and instrumental delivery was higher in bupivacaine group but the difference was not statistically significant[21].

Chetty et al. compared epidural 0.125% ropivacaine and 0.2% ropivacaine in labor analgesia. It concludes that 0.2% ropivacaine group has faster onset, longer duration of analgesia and lesser top - ups. Both the groups did not show any motor block.[22]

Gündüz et al. comparedepidural 0.125% bupivacaine with fentanyl and epidural 0.125% ropivacaine with fentanyl in labor analgesia and concludes that both the drugs provided equivalent analgesia with high maternal satisfaction and tolerable side effect[23].

Bawdane, et al. compared epidural 0.1% ropivacaine with fentanyl and 0.1% bupivacaine with fentanyl in labor and found that both the drugs are comparable in terms of onset, quality of analgesia, incidence of motor block and requirement of local anesthetic drug [24].

Wassen et al. compared routine labor analgesia versus labor analgesia on request contradicts against the routine epidural analgesia. They found that routine epidural analgesia is associated with increase instrumentation of delivery, unplanned cesarean section, and maternal hypotension[25].

Our study is different from these studies in relation to addition of intrathecal fentanyl before placing epidural for making parturient more co - operative for epidural. Based on

the previous studies we selected 0.2% ropivacaine and 0.125% bupivacaine in labor analgesia to compare onset, duration of analgesia which were not studied previously.

5. Conclusion

Our study demonstrated that both B and R groups provided equivalent and comparable analgesia in terms of onset and maximum analgesia. Analgesia in R group was found to be superior in terms of lesser breakthrough pain, lessneed of rescue top - up bolus requirement and thereby better quality of analgesia. Incidence of motor blockade is absent with both the groups.

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