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Original Article

Comparative Evaluation of 0.2% Ropivacaine versus 0.125% Ropivacaine under Combined Spinal-epidural Technique for Labor Analgesia

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Abstract

Background: Both pharmacological and non-pharmacological strategies for pain relief in labor have been tried and tested since long. Combined spinal-epidural analgesia (CSEA) satisfies the basic requisites of labor analgesia. Various concentrations of local anesthetics along with the addition of opioids can be used. The objective of this study is to compare the quality of labor analgesia with two different concentrations of ropivacaine (0.2% vs. 0.125%) and assess fetomaternal outcome.

Materials and Methods: A total of 60 primipara women with a singleton pregnancy in active labor were given CSEA after randomly allocating them in two groups of 30 each. Both Group A and Group B received intrathecal injection of 4 mg (2 ml) 0.2% ropivacaine + 25 μg (0.5 ml) fentanyl: Group A - epidural dose of 15 ml of 0.2% ropivacaine solution + 2 μg/ml fentanyl and Group B - epidural dose of 15 ml of 0.125% ropivacaine + 2 μg/ml fentanyl. Then, continuous epidural infusion was started at the rate of 10 ml/h which was continued until the end of delivery.

Results: Group A showed better maintenance of analgesia and better maternal satisfaction while parturients in Group B needed rescue top-up analgesia due to breakthrough pain.

Conclusions: It was concluded that ropivacaine in both concentrations (0.2% and 0.125%) with fentanyl is effective for initiation of labor analgesia. However, quality of analgesia with 0.2% ropivacaine concentration is superior to 0.125% concentration.

Key words: Combined spinal-epidural, Fentanyl, Labor analgesia, Ropivacaine

INTRODUCTION

Childbirth is a major lifetime event in the life of a woman. Labor pain has higher score on pain scale when compared to other painful life experiences.[1] Labor pain results in maternal stress response which is harmful to the mother and fetus.[2] It leads to maternal stress-related release of catecholamines which affect both maternal and fetal hemodynamics. Pain relief can obtund all stress responses.

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With advancing times, labor analgesia is becoming more popular, but providing safe and effective analgesia has been a challenge.[3] Combined spinal-epidural analgesia (CSEA) technique has become more popular and favored in recent years.[4] Low-dose local anesthetics and opioids lead to rapid onset of analgesia, and also, the duration of analgesia can be extended through the use of epidural catheter.

Local anesthetics alone or with adjuvants can be used for pain relief in regional techniques. Ropivacaine, a homolog of bupivacaine, has been associated with reduced incidence of cardiotoxicity and motor blockade.[5] It provides better sensory motor differentiation so useful when motor blockade is not needed, has a better neonatal outcome, and allows for normal progression of labor and maternal ambulation.[6] For providing optimal labor epidural analgesia, minimal concentrations of local anesthetics

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are continuously in the search. Studies comparing the efficacy of continuous infusion of 0.2% versus 0.125% ropivacaine for labor analgesia have not been done in our institution, which leads us to undertake this study. The primary outcome of the study was the onset and quality of labor analgesia. The secondary outcome was fetomaternal outcome, complications, and maternal satisfaction score.

MATERIALS AND METHODS

Approval from the institutional ethical committee was taken, and this study was conducted in our hospital on 60 term primiparous women who were in the age group of 20–35 years with ASA Grade I and II status, having uncomplicated pregnancy in vertex presentation and scheduled for normal vaginal delivery. Parturients in active labor and on request were included in this study. Exclusion criteria included coagulation/bleeding disorder, sepsis, cephalopelvic disproportion, vertebral column deformity, or infection at the site.

It was a prospective and randomized double-blind study. The power analysis was used for a sample size of a minimum of 30 subjects per group. Sixty parturients were randomly allotted to two groups of 30 each, using computed-generated table of random numbers. Double blinding was done to remove any bias, and the drugs were made by an anesthesiologist or person who was not involved in the study.

Both the Groups A and B were given intrathecal injection of 4 mg of 0.2% ropivacaine (2 ml) +25 μg fentanyl (0.5 ml). Group A received epidural dose of 15 ml of 0.2% ropivacaine + 2 μg/ml fentanyl (30 μg), 0.2% ropivacaine from a 20 ml ampoule (Ropin®, Neon). Group B received epidural dose of 15 ml of 0.125% ropivacaine + 2 μg/ml fentanyl (30 μg), 0.125% ropivacaine made by taking 2.5 ml of 0.75% isobaric ropivacaine and diluting it with 12.5 ml of normal saline. 30 μg of fentanyl (Trofentanyl®) was made by taking six parts from a tuberculin syringe to divide 1 ml (50 μg/ml) into 10 parts and then added to ropivacaine in both the groups. The total volume of both the solutions was made up to 16 ml with normal saline. The continuous epidural infusion was set at 10 ml/h after the epidural dose and continued until the end of delivery.

Informed consent and pre-anesthetic evaluation were done, and demographic data of the parturients including age, height, weight, gestational age, cervical dilatation, and parity were recorded. Baseline visual analog scale (VAS) score and baseline vitals, i.e., heart rate (HR), non-invasive blood pressure, respiratory rate, and oxygen saturation were recorded. After securing intravenous (i/v) line for preloading with ringer lactate (10 ml/kg body weight) and in left lateral decubitus position and strict asepsis, 2 ml of 2% lignocaine was infiltrated at L3–L4 or L4–L5 level. With 18G Tuohy needle using the loss of resistance technique, epidural space was identified. A 27G Whitacre spinal needle introduced through the lateral eye of Tuohy's needle, and after free flow of cerebrospinal fluid (CSF), the study drug was injected for subarachnoid block and epidural catheter was inserted and secured up to the depth of 3–4 cm into the epidural space. The catheter was aspirated for the presence of blood or CSF. The clinical signs of i/v injection were checked whether parturient felt dizzy or had tinnitus, and parturient was kept in supine position with left lateral tilt. An epidural bolus of the study solution was given when the parturient reported two consecutive contractions as painful (VAS >3) or regression of the effect of spinal analgesia until T10 level. Continuous epidural infusion of the study drug was started through the catheter at the rate of 10 ml/h and maintained at constant rate until the end of delivery. Analgesia was considered adequate if pain score on VAS ≤3. The rescue bolus dose of 5 ml of the study solution in respective groups was given to the parturient on demand at any time during labor.

VAS score and continuous hemodynamic monitoring of mother and also fetal HR monitoring were done. All the readings were recorded every 2 min for 10 min, every 5 min for 30 min, and every 15 min until 300 min or the end of study or whichever was earlier. Bradycardia (defined as HR <60 bpm) was treated with injection atropine i/v and hypotension (fall in systolic blood pressure below 90 mmHg or reduction of >20% from baseline value) was treated with i/v fluid bolus and if necessary with i/v injection ephedrine. Time of onset until complete analgesia was noted. Highest sensory level and motor blockade, requirement of rescue epidural top-up, and side effects were assessed. Maternal satisfaction score was assessed after 24 h of delivery with a scale of 5 - excellent, 4 very good, 3 - good, 2 - fair, and 1 - poor. The study ended at the time of delivery and catheter was removed.

Statistical Analysis

The data from the present study were compiled and analyzed using software IBM SPSS 23.0 (Armonk, NY: IBM Corp.) to draw relevant conclusions. The patient characteristics (non-parametric data) were analyzed using the "Chi-square test," and the "Unpaired *t*-test" was used for intergroup comparison (parametric data). $P < 0.05$ was considered as statistically significant and $P < 0.001$ was considered as highly significant. Power analysis was used to calculate the power of the study by taking α error 0.05. The power achieved was well above 90%. The results were then analyzed and compared to previous studies.

RESULTS

No statistical difference was seen in demographic and baseline hemodynamic parameters in both the groups. The difference between the two groups for mean age, height, weight, and ASA grade was found to be statistically non-significant ($P > 0.05$). Parturients in both the groups had cervical dilatation of 3–4 cm at the time of administration of CSEA. $P = 0.605$ was observed which was statistically non-significant [Table 1].

The mean VAS was statistically significant at 135 min ($P < 0.05$) and 180 min ($P < 0.05$) and statistically non-significant at all other measured intervals ($P > 0.05$) [Figure 1]. The mean number of epidural top-ups required was 0 in Group A and 1.40 ± 0.55 in Group B. The difference between the two groups was statistically highly significant ($P < 0.001$) [Figures 2 and 3].

No significant hypotension was observed in parturients in both the groups. Pruritus was present in both the groups (66.67% - Group A and 63.33% - Group B). No significant nausea, vomiting, and shivering were observed in the parturients in both the groups. No case of respiratory depression and dural puncture was seen ($P > 0.05$) [Table 2].

APGAR score was noted at 1, 5, and 10 min in both the groups after the birth of the baby. Two babies in Group A had a score of 7 at 1 min and no baby had an Apgar score of <8 at 5 and 10 min in both the groups. The difference between both the groups was statistically non-significant ($P > 0.05$) [Table 3].

Maternal satisfaction score 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 excellent in 24 parturients in Group A and was very good in 26 parturients in Group B. The difference was found to be statistically significant ($P < 0.05$) [Table 4].

DISCUSSION

In previous years, higher concentrations of local anesthetics were used which were associated with motor blockade, resulting in limited ambulation during labor and decreased pelvic tone which impairs the bearing down efforts in the second stage of labor. At present times, low-dose local anesthetics are being used which block the painful stimuli and preserve the motor functions.[7] It is intriguing to strike a balance between parturients' satisfaction score with good analgesia and reduce the motor block, thus making the parturient participate in labor and reducing the rate of instrumental deliveries.[8]

The use of opioids prolongs the duration of analgesia but with side effects of pruritus, nausea, vomiting,

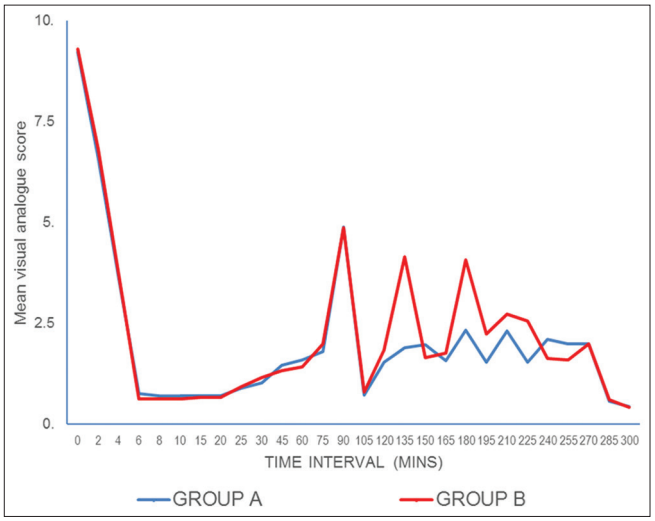

Figure 1: Mean visual analog scale score. *Showing significant difference at 135 min and 180 min

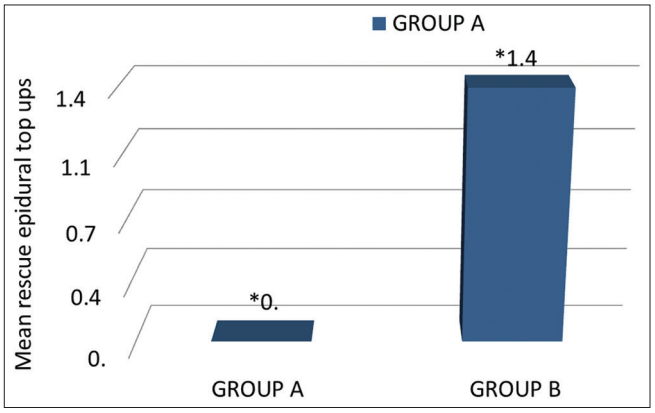

Figure 2: Mean rescue epidural top-up doses. *Showing significant difference between the two groups

Table 1: Demographic data and obstetric data

Parameters	Group A		Group B		*P* value
	Mean	SD	Mean	SD	
Age (years)	25.67	3.93	27.40	5.19	>0.05 (NS)
Height (cm)	152.73	2.91	153.80	8.06	>0.05 (NS)
Weight (kg)	64.47	6.11	65.40	7.83	>0.05 (NS)
Cervical dilation (cm)	3 (50%)	4 (50%)	3 (43.33%)	4 (56.67%)	>0.05 (NS)
VAS score (pre-block)	9.23	0.57	9.30	0.53	0.05 (NS)

Data are displayed as mean±SD or ratio. VAS: Visual analog scale, SD: Standard deviation

Table 2: Side effects and complications

Side effects and complications	Group A		Group B		*P* value	Significance
	Number of cases	% age	Number of cases	% age		
Maternal hypotension	2	6.67	1	3.33	2	>0.05 (NS)
Pruritus	20	66.67	19	63.33	20	>0.05 (NS)
Nausea/vomiting	2	6.67	1	3.33	2	>0.05 (NS)
Respiratory depression	0	0.00	0	0.00	-	-
Shivering	3	10.00	2	6.67	3	>0.05 (NS)
Dural puncture	0	0.00	0	0.00	-	-
Urinary retention	1	3.33	0	0.00	1	>0.05 (NS)
Post-dural puncture headache	0	0.00	0	0.00	-	-

Table 3: Apgar score

Groups	Apgar score		
	At 1 min	At 5 min	At 10 min
Group A			
<7	2	0	0
8	11	6	2
9	16	18	20
10	1	6	8
Group B			
<7	0	0	0
8	16	11	2
9	14	18	25
10	0	1	3
χ^2 value	4.06	5.04	2.83
P value	0.25	0.10	0.24
Significance	>0.05 (NS)	>0.05 (NS)	>0.05 (NS)

Table 4: Maternal satisfaction score

Score	Group A		Group B	
	Number of cases	% age	Number of cases	% age
5	24	80.00	-	-
4	6	20.00	26	86.66
3	-	-	4	13.34
2	-	-	-	-
1	-	-	-	-
LSCS	-	-	-	-
Total	30	100.00	30	100.00

Scale of 5 - excellent, 4 - very good, 3 - good, 2 - fair, 1 - poor. LSCS: Lower segment cesarean section

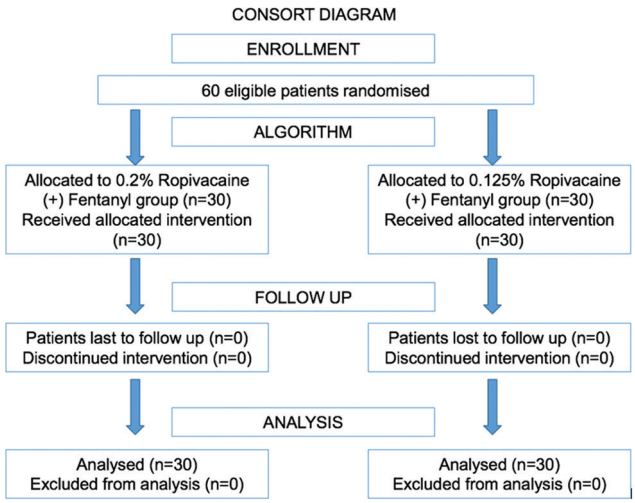

Figure 3: Consort diagram

respiratory depression, fetal HR abnormalities, and urinary retention.[9] Ropivacaine causes lesser motor blockade due to its selective action on Aδ and C fibers (involved in pain transmission) rather than on Aβ fibers (involved in motor function) and is lesser cardiotoxic. There are a relatively fewer number of studies depicting the role of different concentrations of ropivacaine for labor analgesia. Many authors concluded that ropivacaine 0.2% offers adequate analgesia, better than 0.15% or 0.1% concentration with minimal motor block and hemodynamic side effects.[10]

Both the groups were comparable in mean age, weight, height, and ASA grade and cervical dilatation. The mean cervical dilatation was 3.2 ± 0.52 cm in Group A and 3.53 ± 0.6 cm in Group B (P > 0.5). Previously, it was believed that a higher rate of cesarean was observed with epidural being started early in labor (<2 cm).[11] The 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.*[12] Current ASA guidelines recommend that maternal request for labor pain relief is sufficient justification for intervention and the decision should not depend on arbitrary cervical dilation.

The mean onset of analgesia was 5.58 ± 0.5 min in Group A and 5.53 ± 0.48 min in Group B. Hughes *et al.*,[13] in their study, compared 2.5 mg ropivacaine and 2.5 mg bupivacaine and observed the onset of analgesia to be 6.5 ± 2.3 min in ropivacaine group. The mean duration of analgesia after subarachnoid block was 90.17 ± 8.96 min in Group A and 90.00 ± 10.12 min in Group B. In a study done by Kim *et al.*,[14] it was concluded that intrathecal ropivacaine offered shorter duration of analgesia (87 ± 47 min) as compared to levobupivacaine (122 ± 56 min). However, ropivacaine offered a greater margin of safety in systemic toxicity and favorable sensory motor differentiation. Low-dose anesthetics reduce the incidence of motor blockade. 83.34% of parturients in Group A and 86.66%

of parturients in Group B had no motor blockade. Motor block of Grade 2 or 3 was not seen in the parturients in any of the groups. Higher incidence of motor block in older studies could be due to the use of higher concentrations of ropivacaine (0.75%[15] and 0.5%[16]).

The mean VAS 15 min after the first epidural dose was 0.73 ± 0.68 in Group A and 0.80 ± 0.79 in Group B. The mean VAS scores were significantly higher in Group B at 135 and 180 min. Thus, breakthrough pain leads to the use of rescue top-up bolus doses (5 ml bolus of study solution) in Group B. Mean number of rescue epidural top-up in Group B was 1.40 ± 0.35 and 0 in Group A until the end of delivery ($P < 0.001$, highly significant). A study was conducted in a total of 60 term parturients by Chuttani *et al*., for comparison of low concentrations of levobupivacaine (0.1%) versus ropivacaine (0.1%) with fentanyl, for which background infusion and on-demand bolus of the study solutions were used with patient-controlled epidural analgesia pump. It was observed that the number of manual rescue bolus doses was found to be more in ropivacaine group.[17]

Hemodynamic parameters were also compared. All the parturients had spontaneous vaginal delivery. No statistical significance was observed in side effects and complications in both the groups. Hypotension was observed which responded to i/v fluids. Most common side effect observed was pruritus in both the groups. All cases of pruritus were mild and required no treatment. Postulated mechanism of pruritus due to fentanyl is the modulation of serotonergic pathways and medullary dorsal horn activation. In a study done by Fan *et al*., in 60 parturients comparing tramadol and fentanyl with ropivacaine, it was found that pruritus was present in 13% of parturients in the fentanyl group alone.[18] Nausea, vomiting, and shivering were also noted. No case of dural puncture, PDPH, and respiratory depression was observed.

There was no fetal HR abnormality detected. Apgar score was favorable at 1, 5, and 10 min and fetal outcome was good. Maternal satisfaction score was significantly better in Group A.

Our study demonstrated that 0.2% ropivacaine offered superior quality of analgesia than 0.125% ropivacaine. More breakthrough pain leading to the use of rescue epidural analgesia was observed in 0.125% ropivacaine group (Group B).

Limitations

A large sample size could give a better outlook on maternal and neonatal outcome. Furthermore, limited parturients were willing for labor analgesia in our institution. Cord blood sampling is important for the interpretation of blood gases and pH and gives an objective idea of fetal exposure to hypoxia during labor, but it was not done in our setup (technical issues). Besides, the comparison of intermittent bolus technique with continuous infusion could give a better measure of local anesthetic and opioid consumption.

CONCLUSIONS

Our study demonstrated that both 0.2% and 0.125% ropivacaine concentrations provided effective analgesia at the onset of labor. Analgesia in 0.2% ropivacaine group was found to be superior in terms of lesser breakthrough pain that leads to significantly better quality of analgesia and no need of rescue top-up bolus requirement.

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