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Original Research Article

Epidural labor analgesia: a comparison of mixture of ropivacaine 0.125% with fentanyl versus ropivacaine 0.2% with fentanyl

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ABSTRACT

Background: Ropivacaine is more selective for sensory fibers when compared to other local anesthetics, producing less motor block. This permits better maternal ambulation and also allows for normal progression of labor, which translates into lesser instrumental deliveries and higher vaginal deliveries. Objective was to evaluate 0.125% versus 0.2% ropivacaine, with 2 µg/ml of fentanyl in epidural labor analgesia, regarding their sensory and motor block characteristics.
Methods: This prospective study was conducted among 40 patients, 20 in each group [group A (0.125% ropivacaine with 2 µg/ml fentanyl), group B (0.2% ropivacaine with 2 µg/ml fentanyl)], for epidural labor analgesia in obstetrics and gynecology department (labor room). The efficacy of the drugs was tested by comparing the onset of analgesia, duration of labor analgesia, dose requirement, pulse, BP, sensory effect, motor effect, FHR, APGAR score and side effects.
Results: Total duration of labor analgesia was 230.25 minutes with 55.68 SD and 186.25 minutes with 57.7 SD in group A and group B respectively ($p<0.05$). The total dose of ropivacaine used was 81.00 mg and 68.50 mg in group A and B respectively ($p<0.05$). Total dose of fentanyl required was 94.50 µg and 73.50 µg in group A and group B respectively ($p<0.05$). There was no significant difference found in hemodynamic parameters in both groups.
Conclusions: Both the concentrations are effective in producing epidural labor analgesia. However, onset of analgesia was significantly faster with 0.2% ropivacaine. The required dose of ropivacaine was significantly higher in 0.125% ropivacaine. 0.2% ropivacaine shorten the duration of labor compared to 0.125% ropivacaine.

Keywords: Epidural, Fentanyl, Labor analgesia, Local anesthetics, Ropivacaine

INTRODUCTION

Myths and controversies are always attached with pain relief during labor.[1] Epidural local anaesthetics and opioids are used with local analgesia during labor for pain relief since long time.[2,3]

Ropivacaine, an amide local anesthetic is fewer cardiotoxic in animals as well as it may also be more selective for sensory fibers when compared to other local anesthetics, producing less motor block.[4,5] This permits for raise maternal ambulation and also allows for normal progression of labor, which translates into lesser instrumental deliveries and higher vaginal deliveries6although this is controversial. These factors indicate that ropivacaine may be superior to bupivacaine in obstetric analgesia. Side effects of ropivacaine are hypotension, hypersensitivity reactions, nausea, vomiting, paresthesia, dizziness, arrhythmia, urinary retention, foetal bradycardia.

So, the present study was conducted with the objective to evaluate 0.125% versus 0.2% ropivacaine, with 2 µg/ml of fentanyl in epidural labor analgesia, regarding their sensory and motor block characteristics.

METHODS

Study setting and duration

The study was conducted in obstetrics and gynecology department (labor room) during 2016-2017 SMIMER Medical College, Surat, Gujarat.

Study design and study population

This prospective study enrolled 40 patients, 20 in each group [group A (0.125% ropivacaine with 2 µg/ml fentanyl) =20, group B (0.2% Ropivacaine with 2 µg/ml fentanyl) =20], for epidural labor analgesia.

Inclusion criteria

Inclusion criteria was age 18 to 35 years, nullipara or primigravida patients of ASA class 1 or 2 physical status who were in active phase of labor with cervical dilatation 3-4 cm with single fetus and vertex presentation.

Exclusion criteria

Exclusion criteria was patients with complicated obstetric history like pre-eclampsia, multiple pregnancy, abnormal lie, placenta previae, previous LSCS. Parturients with associated medical history like morbid obesity, bleeding disorder, patient on anticoagulant therapy, severe anaemia, skeleton deformity, psychiatric disorder, infection on local site.

Anaesthesia technique

Detailed pre-anaesthetic evaluation was carried out. Obstetric examination was carried out by on duty obstetrician regarding per-abdomen examination for presentation and position of the fetus, per vaginal examination to assess dilatation of cervix, station, position of head, effacement and presenting part.

After explaining the procedure, intavenous access was secured and 500 ml of Ringer lactate was started for preload. Patients were pre-medicated with injection glycopyrrolate 0.2 mg i.v. and injection ondansetron 4 mg i.v. Pre procedure pulse, blood pressure, VAS score, fetal heart rate and obstetric parameters like cervical dilatation, station and effacement were noted. Patients were placed in the left lateral position. Under aseptic precaution, lumber epidural needle was inserted at L_2-L_3 or L_3-L_4 interspinous space with sterile 18G Tuohy's needle and epidural space identified by using loss of resistance technique. The multi-orifice epidural catheter was inspected for its patency and threaded through the needle cephalad gently till 3-4 cm length of the catheter in the epidural space.

For group A, 15 ml of 0.125% ropivacaine was prepared by taking 2.5 ml of 0.75% isobaric ropivacaine and diluting it with 12.5 ml of distilled water. After negative aspiration, test dose of 3 ml of 0.125% ropivacaine with 2 µg/ml fentanyl was given. 12 ml of 0.125% ropivacaine with 2 µg/ml fentanyl was given.

For group B, 15 ml of ropivacaine (0.2%) was taken directly from a 20 ml ampoule. After negative aspiration, test dose of 3 ml of 0.2% ropivacaine with 2 µg/ml fentanyl given. 12 ml of 0.2% ropivacaine with 2 µg/ml fentanyl was given

1st top up dose (in both groups)

After the bolus dose when patient complained of pain and VAS>3 then after 15 minutes of bolus dose an additional top up dose of 15 ml of study medication was administered.

2nd top up dose (in both groups)

An additional dose of ropivacaine 15 ml was given as a top up dose on patient request with a gap of 15 minutes between two subsequent top-up doses.

Measurement tools

Till the delivery of baby all the patients were monitored. Any time during the labor if patient complains of pain and VAS score >3 then rescue analgesia with same concentration as top up dose was given. All patients were monitored for pulse, BP, sensory effect, motor effect at 5 minutes, 10 minutes, 15 minutes, 20 minutes, 30 minutes, 45 minutes, 60 minutes, 90 minutes, 120 minutes, 150 minutes, 180 minutes, 210 minutes till delivery of baby. Fetal heart rate was monitored continuously by anaesthesiologist and obstetrician by stethoscope and cardio topography machine. Progress of labor was monitored by on duty obstetrician and labor was managed by the protocol of obstetric department. Monitoring of patient in post-operative room for adverse effects or side effects during post-operative period till baseline hemodynamic value achieved.

Data analysis

Qualitative data were expressed as percentages and proportions. Quantitative data were expressed as mean and standard deviation. The differences between two groups with respect to continuous variables were analysed using unpaired t-test while categorical variables were analysed using chi-square test. All the statistical tests were performed in Epi Info 3.5.1 software by CDC, USA. P value <0.05 was considered as statistically significant while p value<0.01 was considered as statistically highly significant.

Ethical consent

Before proceeding with study, appropriate ethical clearance was obtained from medical college Ethics Committee. Each patient was included in the study only after informed consent.

RESULTS

Table 1 shows that the mean age in 0.125% ropivacaine group was 21.7 years with 2.73 SD and in 0.2% ropivacaine group was 22.1 years with 2.59 SD (p>0.05). The mean weight in 0.125% ropivacaine group was 63.95 kg with 4.24 SD and in 0.2% ropivacaine group was 62.3 kg with 2.90 SD (p>0.05). The mean height in 0.125% ropivacaine group was 155.25 cm with 2.69 SD and in 0.2% ropivacaine group was 155.75 cm with 2.42 SD (p>0.05). The mean cervical dilatation in 0.125% ropivacaine group was 3.8 cm with 0.75 SD and in 0.2% ropivacaine group was 3.7 cm with 0.74 SD (p>0.05). The mean effacement in 0.125% ropivacaine group was 45.5% with 5.10 SD and in 0.2% ropivacaine group was 46% with 5.02 SD (p>0.05). The mean station of vertex in 0.125% ropivacaine group was 2.1 cm with 1.2 SD and in 0.2% ropivacaine group was 2.4 cm with 0.76 SD (p>0.05).

Table 1: Demographic and obstetrics data of study participants (n=40).

Variables	Group A (n=20) (mean±SD)	Group B (n=20) (mean±SD)	P value
Age (year)	21.7±2.73	22.1±2.59	0.63*
Weight (kg)	63.95±4.24	62.3±2.90	0.16*
Height (cm)	155.25±2.69	155.75±2.42	0.54*
Cervical dilation (cm)	3.8±0.75	3.7±0.74	0.60*
Effacement (%)	45.5±5.10	46±5.02	0.78*
Station of vertex	2.1±1.2	2.4±0.76	0.62*
Mode of delivery			
Spontaneous	16 (80)	14 (70)	0.76**
Instrumental	2 (10)	3 (15)	
LSCS	2 (10)	3 (15)	

*- Student 't' test, **- Chi-square test

Table 2: Dose requirement, onset and block characteristics (n=40).

Variables	Group A (n=20)	Group B (n=20)	P value
Onset of analgesia (minutes)			
0-5	5 (25)	18 (90)	<0. 001**
>5-15	10 (50)	2 (10)	
>15-30	5 (25)	0 (00)	
Onset of analgesia (mean±SD)	11.25±5.59	5.50±1.53	
Motor block (bromage scale)			
Grade 3	0 (00)	0 (00)	0.18**
Grade 2	0 (00)	0 (00)	
Grade 1	1 (5)	5 (25)	
Grade 0	19 (95)	15 (75)	
Mean time range until which patient didn't require 1st top-up dose (minutes)			
60-90	17 (85)	11 (55)	0.17**
91-120	1 (5)	3 (15)	
121-150	2 (10)	4 (20)	
>150	0 (00)	2 (10)	
Total duration of labor analgesia (minutes)	230.25±55.68	186.25±57.7	0. 01*
Total dose of ropivacaine (mg)	81.00±15.64	68.00±21.42	0.035
Total dose of fentanyl (µg)	94.50±31.20	73.50±28.33	0.032*

*- Student 't' test, **- Chi-square test

Table 2 shows that After giving 1st dose of local anaesthetic that is drug through epidural catheter, patients were assessed for onset of pain relief at pre-determine interval. Within 0-5 minutes 90% patients in 0.2% ropivacaine group had VAS<3 whereas only 25% patients had achieved VAS<3 in 0.125% ropivacaine group. When mean of time to achieve VAS<3 in 0.125% ropivacaine group and 0.2% ropivacaine group was calculated, it was 11.25 minutes with 5.59 SD and 5.50 minutes with 1.53 SD respectively (p<0.05). Not a single patient in either group had grade 3 or grade 2 motor block. Almost 5% patients in 0.125% ropivacaine group and 25% patients in 0.2% ropivacaine group had grade 1 motor block. 95% patients in 0.125% ropivacaine group and 75% patients in

0.2% ropivacaine group did not develops any motor blockade after labor analgesia (p>0.05). Almost 85% patients in 0.125% ropivacaine group and 55% patients in 0.2% ropivacaine group required 1st top up dose after 60-90 minutes of bolus dose of analgesia. Duration of bolus dose was lasted upto 91-120 minutes in 5% patients of 0.125% ropivacaine group and 15% patients in 0.2% ropivacaine group (p>0.05). Total duration of labor analgesia was 230.25 minutes with 55.68 SD and 186.25 minutes with 57.7 SD in group A and group B respectively (p<0.05). The mean total dose of ropivacaine used in 0.125% ropivacaine group was 81.00 mg with 15.64 SD and in 0.2% ropivacaine group was 68.50 mg with 21.42 SD (p<0.05). Total dose of fentanyl required was 94.50 µg with 31.2 SD and 73.50 µg with 28.33 SD in group A and group B respectively (p<0.05).

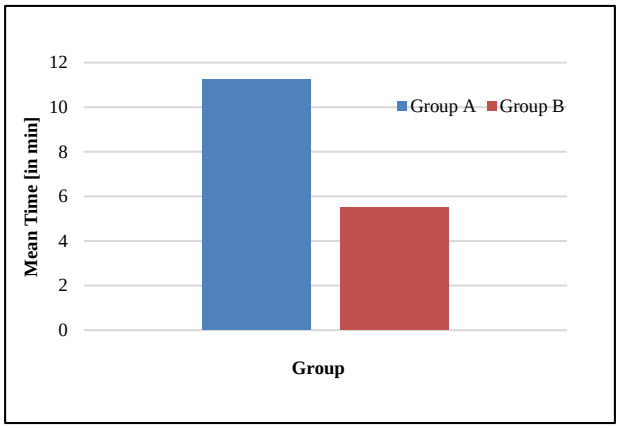

Figure 1: Onset of analgesia.

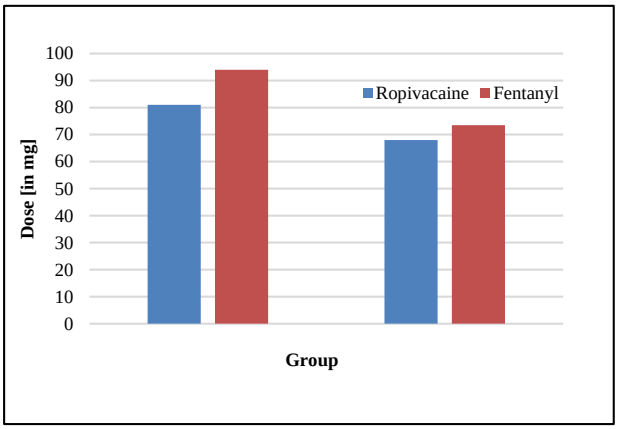

Figure 2: Total dose of ropivacaine and fentanyl.

Figure 3 shows that mean pulse rate was 89.9 per minutes with 6.82 SD in 0.125% ropivacine group and 86.80 per minutes with 8.85 SD in 0.2% ropivacaine group before initiation of labor analgesia. Pulse rate was monitored throughout the course of labor and intra-group and inter-group comparison was done to find out any difference. When mean pulse rate in 0.125% ropivacaine group was compared with baseline no significant difference was observed (p>0.05).

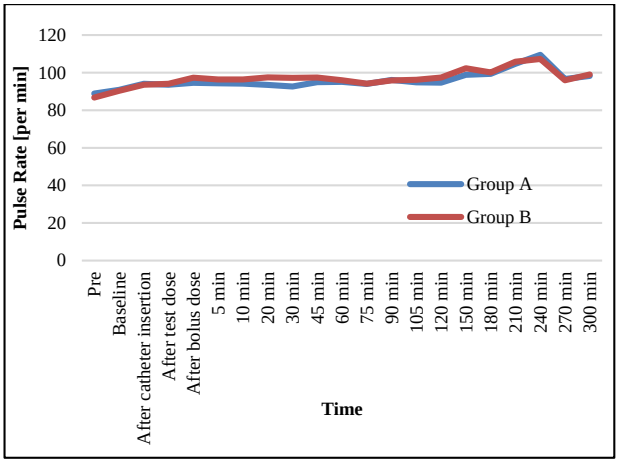

Figure 3: Pulse rate.

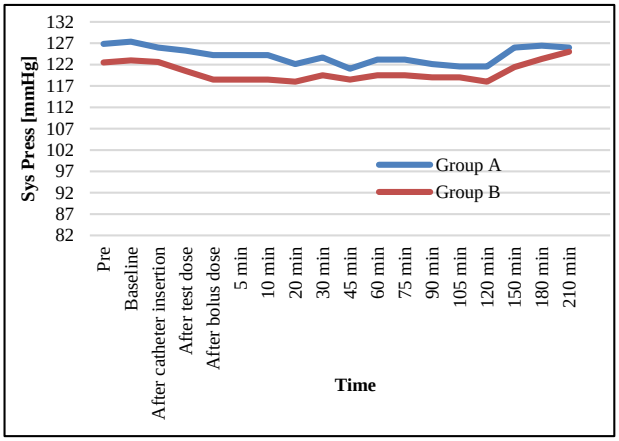

Figure 4: Systolic pressure.

Figure 4 shows that systolic blood pressure in 0.125% Ropivacaine group after giving epidural analgesia was compared to baseline the difference was statistically insignificant after 10 minutes till 180 minutes (p>0.05). In 0.2% ropivacaine group also mean systolic blood pressure was insignificant from baseline from 5 minutes after initiation of labor analgesia till the end of study.

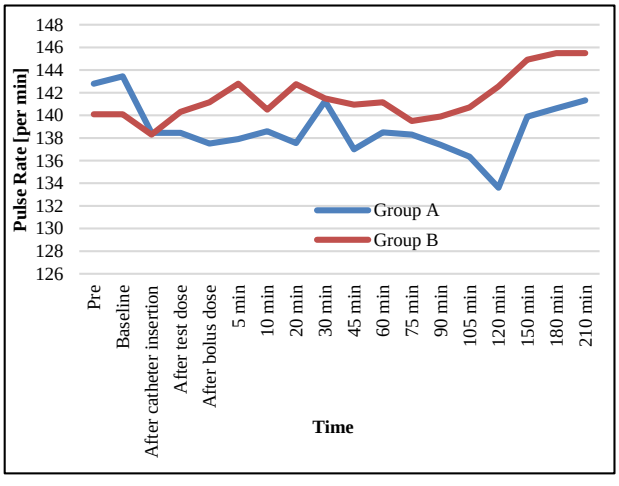

Figure 5: Fetal heart rate.

Figure 5 shows that there was no statistically significant difference present between fetal heart rate in both groups at various durations.

The mean APGAR score at 1min was 8.05 with 1.09 SD in group A and 7.85 with 0.67 SD in group B. The mean APGAR score at 5 minutes was 10.0 in group A and 10.0 in group B. Only one patient in group A and two patients in group B were developed nausea.

High block was considered when the sensory level was T_4 or above. No patient in both groups had high block. There wasn't any episode of hypoxia in any patient in both groups. Only 1 patient from 0.2% ropivacaine group had convulsion and LSCS done.

DISCUSSION

Ropivacaine and levobupivacaine reduced systemic toxicity and a better preservation of motor function.[8] Ideal obstetric analgesia technique should produce effective pain relief with minimal side effects for both mother and baby and it should not affect the progress of labor.[1]

The two groups were similar demographically. Spontaneous delivery was most common mode of delivery in both the groups. Onset of analgesia was earlier in 0.2% ropivacaine group compared to 0.125% ropivacaine group which is significant statistically. Average duration of onset of analgesia was statistically significantly almost doubled in 0.125% ropivacaine group compare to 0.2% ropivacaine group.

This finding is correlated with the study done by Chhetty et al, Handley et al and Duggan et al which reported that a decrease in time for onset occurs with increasing concentrations of epidural ropivacaine.[9-11]

Present study didn't observe any cases in grade 3 and 4 motor block (bromage scale) in both the group. Higher number of cases was observed in grade 1 motor block in 0.125% ropivacaine group compare to 0.2% ropivacaine group but the difference was statistically not significant.

Study done by Lee et al, Ngan Kee et al and Debon et al observed no motor block.[12-14] However, higher incidence of motor block in previous studies could be attributed to higher concentrations of ropivacaine (0.25%, 0.275%, 0.5%).[15,16]

Total duration of labor analgesia was statistically significantly higher in 0.125% ropivacaine group compared to 0.2% ropivacaine group. total required doses of fentanyl and ropivacaine was also significantly higher in 0.125% ropivacaine group than 0.2% ropivacaine group.

Duration of analgesia of initial bolus dose was also significantly more with 0.2% ropivacaine in our study as observed by others.[17] Addition of adjuvant opioids leads to further increase in duration of analgesia.[18]

Purdie et al had studied total 60 patients with controlled epidural bolus administration of 0.1% ropivacaine and 0.1% levobupivacaine, both with 0.0002% fentanyl, for analgesia during labor.[19] Mean cervical dilatation was 2.7 cm in R group and 2.8 cm in L group.

Our study observed that mean pulse rate per minute was not significantly lower in 0.125% ropivacaine group compared to 0.2% ropivacaine group. Study observed that mean systolic blood pressure per minute was statistically not significantly higher in 0.125% ropivacaine group compare to 0.2% ropivacaine group. Study observed that diastolic blood pressure per minute was similar in 0.125% ropivacaine group and 0.2% ropivacaine group. Present study observed no significant changes in maternal pulse rate and blood pressure which shows that changes in maternal pulse rate (PR) and blood pressure are not related to change in the dose of local anesthetic. Similar observation was also noted in the study done by Chhetty et al.[9]

Study observed equal APGAR score at 1 minute, 5 minutes after birth in both groups. Also, least side effect was observed in both the groups. The main undesirable side-effects with ropivacaine analgesia are hypotension, bradycardia, nausea, paresthesia, and urinary retention, which are mild and transient.

CONCLUSION

Present study concludes that both the concentrations are effective in producing labor analgesia. However, onset of analgesia was significantly faster with 0.2% ropivacaine than 0.125% ropivacaine. The required dose of ropivacaine was statistically significantly higher in 0.125% ropivacaine group compared to 0.2% ropivacaine group. There was no significant motor blockade observed with both concentrations. First top-up dose required was significantly earlier in 0.125% R group than in 0.2% R group. Total dose of ropivacaine and fentanyl consumed in both groups were comparable. The consumption of fentanyl was more with 0.125% ropivacaine. 0.2% ropivacaine shortens the duration of labor compared to 0.125% ropivacaine. No significant difference in haemodynamic changes, mode of delivery, side effects, APGAR score was observed in both groups.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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