

A COMPARATIVE STUDY OF 0.125% ROPIVACAINE WITH FENTANYL 2 MCG/ML VERSUS 0.125% BUPIVACAINE WITH FENTANYL 2MCG/ML FOR LABOUR EPIDURAL ANALGESIA

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ABSTRACT

BACKGROUND

This study was undertaken to determine whether epidural analgesia is superior to all methods of pain relief for labour. Previous studies compared different concentrations of local anaesthetics epidurally with or without additives. Here ropivacaine is compared because, it is a new long acting amide local anaesthetic agent which is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in relatively reduced motor blockade. The reduced lipophilicity is associated with decreased potential of central nervous system toxicity and cardiotoxicity. Because of its favourable pharmacokinetic profile, the ropivacaine is chosen for labour epidural in comparison with bupivacaine.

Aims and Objectives- to compare smaller concentration of epidural ropivacaine with bupivacaine in intermittent doses for obstetric analgesia by adding fentanyl to ropivacaine and bupivacaine solutions.

MATERIALS AND METHODS

In this prospective randomised double-blind study, sixty women in labour were randomly allocated to receive either bupivacaine 0.125% with fentanyl 2 mcg/ml or ropivacaine 0.125% with fentanyl 2mcg/ml. visual analogue scale was used to test sensory block and pain respectively. Bromage scale was used to test motor block. Haemodynamic parameters, duration of labour, APGAR score for 1 and 5 minutes, dose requirement of drug to produce analgesia, incidence of side effects were also recorded. Data was expressed as mean \pm standard deviation and analysed using students unpaired t test, chi square test at p-value <0.05.

RESULTS

Regarding haemodynamic stability, onset of analgesia, quality of analgesia, sensory blockade, neonatal outcome, requirement of drugs, duration of labour and incidence of side effects both drugs showing similar results. Five parturients in bupivacaine group had a motor block of Bromage score 2 and were delivered with assistance. None of the parturients in ropivacaine group had any motor block and all had spontaneous vaginal delivery, but this difference was not statistically significant.

CONCLUSION

Ropivacaine 0.125% with fentanyl 2mcg/ml produces similar analgesia with significantly less motor block than a similar concentration of bupivacaine with fentanyl during labour.

KEYWORDS

ropivacaine, bupivacaine, epidural analgesia.

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BACKGROUND

Epidural blockade is the ideal analgesic technique in labour.¹ It has the advantage of being able to provide continuous analgesia for an unpredictable period of time and to convert analgesia to anaesthesia if an operative intervention becomes necessary. Epidural injection of a local anaesthetic combined with an opioid provides a more rapid onset of

analgesia with little motor blockade. The pain relief starts sooner and also lasts longer than either drug alone. It allows both the drugs to be used in lower concentration, thereby reducing the risk of local anaesthetic systemic toxicity, motor blockade as well as opioid side effects.^{2,3,4}

Bupivacaine and Ropivacaine are widely used to provide efficient epidural analgesia in labour. The value of bupivacaine is limited by the risks of motor blockade and cardiac toxicity. Ropivacaine has the advantage of more sensory motor differential blockade as well as decreased risk of systemic toxicity.

We therefore undertook this comparative, prospective, double-blind study using epidural bupivacaine 0.125% with fentanyl 2 μ cg/mL and epidural ropivacaine 0.125% with fentanyl 2 μ cg/mL with respect to onset of analgesia, quality of analgesia, incidence of motor block, sensory level

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achieved, requirement of local anaesthetic drug, incidence of instrumental delivery, duration of labour, and incidence of side effect.

MATERIALS AND METHODS

Institutional scientific and ethical committee approval was obtained for the study. Sixty American Society of Anesthesiologists (ASA) physical Status I or II parturients in active labour with a cervical dilation of more than 3 cm, having full term live foetus without any obstetric complication and requesting epidural analgesia were prospectively randomized ($n = 30$ in each group) using a computer-generated table of random numbers. The study was carried out from January 2017 to September 2017. In this double-blind study, parturients received 10 ml bolus dose of either 0.125% bupivacaine with fentanyl 2mcg/ml (BF) or 10ml bolus dose of 0.125% ropivacaine with fentanyl 2 mcg/ml (RF), followed by intermittent top up dose of study drugs.

Exclusion criteria included, body mass index more than 30, parturient's height <150 cm, age <18 years, anticipated difficult intubation, contraindication for epidural catheter placement, sensitivity to study drug, administration of intravenous (IV) analgesics within 1h of epidural request. Parturients were explained about the study and written informed consent was obtained. They were explained and demonstrated the use of visual analogue scale (VAS) for quantification of their pain at the peak of uterine contraction. Study solution was prepared by a qualified anaesthesiologist who was not involved in patient management or data collection and handed over to the investigator. Code number was put on parturient record sheet, and decoding was done at the end of the study for statistical analysis. The study was done by another qualified anaesthesiologist.

All resuscitation equipment and multi-channel monitor were kept ready. IV access was secured when parturient requested epidural analgesia and thus enrolled in the study. Parturients were rehydrated with 500 mL of Ringer Lactate solution and intermittent oral sips of clear fluid were allowed. Epidural catheter was inserted under strict aseptic precautions, when cervical dilatation reached ≥ 3 cm with active labour.⁴ The procedure was performed using 18 G Touhy's needle (Epidural Minipack System 1, Portex, Smiths Medical India Pvt Ltd). A multi orifice catheter with micro bacterial filter was placed in L3-L4 or L4-L5 inter vertebral space using loss of resistance technique and advancing the catheter tip 4 cm cephalad. The parturient was placed in the supine position with left uterine displacement. A test dose of 3 mL of lignocaine (2%) with 15 mcg epinephrine was administered through the epidural catheter after careful aspiration to rule out subarachnoid or IV placement of the catheter. Once negative test dose was established, then initial dose of 10 mL of study drug was administered via epidural catheter in two incremental boluses of 5 mL over 10 min. Pain was assessed during peak of each uterine contraction by VAS.

If VAS ≥ 4 after 15 min of epidural bolus, further study solution was administered in aliquots of 5 mL every 5 min till

VAS <4. If VAS remained ≥ 4 after 30 min or after 30 ml of epidural drug, rescue analgesia with 10 mL of 0.25% study drug was given in aliquots of 5 mL over 10 min. If VAS remained ≥ 4 in spite of rescue analgesia, then labour analgesia was considered inadequate, and other mode of analgesia or reinsertion of the epidural catheter was considered, such parturients were excluded from the study. Initial dose of study solution required to reduce VAS ≤ 4 was considered as "loading dose" and time required for same was considered as "onset of analgesia."⁵ Later during labour, whenever parturient had VAS ≥ 3 , parturient were given intermittent bolus top up of 5 mL of study solution. Minimum time between top up was decided to be 5 min, with hourly limit of 30 ml. Rescue analgesia was given if VAS persisted ≥ 4 even after giving 30 mL of top up in an hour. Total number of top ups required, and total amount of drug required were noted. Every top up was given after confirming negative aspiration for blood and cerebrospinal fluid.

Visual analog scale score was recorded every 5 min for first 30 min, then at every 30 min till the end of labour. VAS at the end of the first stage and second stage was also noted.

Parturients were excluded from data analysis in case of a positive epidural test dose, persistent inadequate analgesia in spite of rescue analgesia, delivery within 2 h of epidural catheter placement, accidental epidural catheter removal, or inadequate data collection.

In the second stage of labour, drug was administered with parturient in semi-recumbent position and was asked to bear down with contraction. Vital parameters of mother such as blood pressure, heart rate, respiratory rate, and maternal saturation were recorded throughout the study. Blood pressure was recorded in the supine position with left lateral tilt by sphygmomanometer.⁶

Maternal sedation was assessed using modified Ramsay sedation score.⁷ Motor block was assessed by Bromage scale and peak motor block achieved during study was noted. Sensory block was assessed by loss of cold sensation to ether swab in midclavicular line, every 30 min and peak sensory level achieved during the study was noted down. Analgesic effect was measured using VAS score for pain (0 = no pain and 10 = worst pain).⁸

Foetal heart rate was recorded throughout the study; neonatal welfare was assessed by Apgar score. Incidence of instrumental deliveries, total dose and hourly requirement of bupivacaine/ropivacaine and fentanyl used, was recorded. Maternal side effects like nausea, vomiting, pruritus, and hypotension, respiratory depression (respiratory <8/min) were noted treated. Fall in blood pressure of more than 20% of the baseline value or systolic blood pressure <90 mm/Hg was considered as hypotension and treated with fast infusion of IV fluid and vasopressor like Ephedrine if required.

Respiratory rate <8 or fall in SaO₂ <95% was considered as respiratory depression and was treated with supplemental oxygen with Venti mask, Ambu bag was also kept available as a resuscitative measure. Parturient and

newborn were followed-up for 24hrs for any late complications.

At study termination, parturients were asked to rate overall epidural analgesia as either excellent, good, fair, poor or absent, to know the quality of analgesia. Parturients were asked whether they were satisfied or not with labour analgesia.

Statistical Analysis

With power of study 80% and Type 1 error of 5% (level of significance (α) = 0.05), the sample size required was calculated as 25 in each group and to compensate for dropouts a sample size of 30 subjects per group was chosen. All statistical analysis were performed using SPSS (Statistical package for social sciences) version 20 for windows. The profile of the cases were compared with the treatment allocation in order to check if there was any significant imbalance. Descriptive statistics are presented as mean \pm 1SD. Chi-square test for association was used to compare categorical variables between treatment allocations. Data was expressed as mean and SD and analysed using Student's unpaired t-test. For categorical data like adverse events, Chi-square test was used. In this study, P <0.05 was considered to be statistically significant.

RESULTS

Sixty patients completed the study. Thirty patients received 0.125% Bupivacaine with Fentanyl 2 mg/ml and the remaining 30 received 0.125% Ropivacaine with Fentanyl 2 mg/ml. Demographic and obstetric variables in both the groups were comparable (Table 1).

	Group	N	Mean	Standard Deviation	Standard Error of Mean
Age (years)	R	30	22.53	2.129	0.389
	B	30	23.23	2.329	0.425
Height	R	30	154.183	2.8207	0.5150
	B	30	154.983	2.9139	0.5320
Weight (kg)	R	30	62.100	3.7541	0.6854
	B	30	62.050	6.1073	1.1150

Table 1. Comparison of age and anthropometric variables of mothers between the two groups

The statistical difference between the two groups was insignificant. Duration of stages I and II of labor and total duration in both the groups were comparable and showed no statistical significance; P value was >0.01 by independent t-test with equal variance (Table 2).

Duration (Min)	Group	n	Mean	Standard Deviation	Standard Error of Mean	P Value	Difference
Stage 1	R	30	162.80	43.234	7.893	0.710	Not significant
	B	30	158.83	39.021	7.124		
Stage 2	R	30	33.33	12.391	2.262	0.125	Not significant
	B	30	27.57	16.085	2.937		
Total duration of labour	R	30	196.07	42.329	7.728	0.380	Not significant
	B	30	186.23	43.675	7.974		

Table 2. Comparison of Duration of Labour Between Two Groups

The mean duration of first stage of labour was 162.8 \pm 43.23 min in the Ropivacaine group and 158.4 \pm 39.02 min in the Bupivacaine group. As the P value was 0.710, it was statistically insignificant. The mean duration of second stage of labour in the Ropivacaine group was 33.33 \pm 12.39 min and in the Bupivacaine, group was 27.57 \pm 16.08 min. This was statistically insignificant as the P value was 0.125. There was no statistically significant difference in the total duration of labour between the two groups, which was 196.07 \pm 42.32 min and 186.33 \pm 43.67 min in the Ropivacaine and Bupivacaine groups, respectively (P value 0.380).

Maternal heart rate, blood pressure (Table 3), (Table 4) and foetal heart rate were comparable in both the groups. None of the patients had hypotension, bradycardia, and foetal bradycardia. 60 patients had their haemodynamics monitored continuously starting at baseline (before epidural), 15min, 30min, 45min, 1, 1.5, 2, 3, 4, 5, 6, 7 hours. The minimum monitoring time was around 3 hrs in both the groups.

The following table shows the heart rate variations in both groups.

Comparison of Heart Rate (Heart rate in beats per minute).

Time	Group R Heart rate (bpm)	Group B Heart rate (bpm)	t-value	p-value
Baseline	92.23 \pm 4.60	92.33 \pm 4.07	0.089	0.929
15 mins	78.80 \pm 3.09	78.53 \pm 3.01	0.338	0.736
30 Mins	79.10 \pm 3.39	78.50 \pm 3.22	0.703	0.485
45 Mins	77.83 \pm 2.81	76.87 \pm 3.25	1.234	0.222
1 Hour	77.77 \pm 2.78	76.87 \pm 3.25	1.154	0.253
1.5 Hr	77.77 \pm 2.78	76.87 \pm 3.25	1.154	0.253
2 Hr	77.76 \pm 2.82	76.87 \pm 3.25	1.125	0.265
3 Hr	77.76 \pm 2.82	76.87 \pm 3.25	1.125	0.265
4 Hr	77.96 \pm 2.81	76.96 \pm 3.34	1.166	0.249
5 Hr	77.96 \pm 2.99	76.95 \pm 3.48	1.036	0.306
6 Hr	79.00 \pm 3.464	76.63 \pm 2.67	1.323	0.215
7 Hr	82.00 \pm 2.828	81.20 \pm 1.79	0.469	0.659

Table 3. Comparison of Heart Rate

There was no statistical significance between the two groups. p value not significant.

The following table shows the comparison of Systolic blood pressure between the two groups during their labour.

Systolic blood pressure in millimeters of mercury.

Time	Group R Systolic Blood pressure (mm of Hg)	Group B Systolic Blood pressure (mm of Hg)	t-Value	p-Value
Baseline	119.47±7.95	120.07±6.27	0.325	0.747
15 mins	119.47±7.10	119.67±6.99	0.110	0.913
30 Mins	119.47±7.10	119.67±6.99	0.110	0.913
45 Mins	119.47±7.10	119.67±6.99	0.110	0.913
1 Hour	119.13±7.31	119.67±6.99	0.289	0.774
1.5 Hr	119.13±7.31	119.67±6.99	0.289	0.774
2 Hr	119.45±7.23	119.67±6.99	0.118	0.906
3 Hr	119.45±7.23	119.67±6.99	0.118	0.906
4 Hr	119.41±7.31	120.58±6.89	0.589	0.559
5 Hr	118.87±7.13	120.27±7.13	0.660	0.513
6 Hr	127.50±2.52	122.50±6.48	1.459	0.175
7 Hr	120.00±14.14	125.60±5.18	0.854	0.432

Table 4. Comparison of Systolic Blood pressure

There was no statistical significance between the systolic blood pressures between the two groups at any period of time.

The mean baseline VAS score in group R was 9.60 ± 0.968, whereas in group B, it was 9.17 ± 0.98 (P value 0.09, which was not significant). At 20 min, all the patients in both the groups were pain free with a VAS score of 0-2. Distribution of VAS at various intervals in both the groups was comparable and showed no statistical significance (P >0.01) (figure 1).

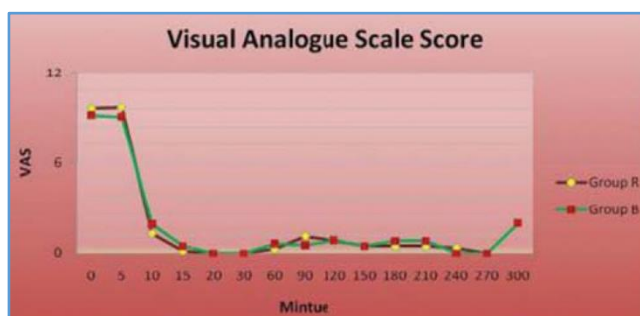


Figure 1. Comparison of VAS at Various Intervals between Two Groups

Motor Block

No patient out of 30 patients in group R developed motor block, whereas 5 patients in group B developed grade 2

(mild) motor block, which means the ability to weakly flex the knees (Bromage Scale) (Table 5). This was statistically significant as the p value was 0.018. (p value<0.05).

		Bromage 1	Bromage 2	Total
Group	R	30	0	30
	B	25	5	30
Total		55	5	60

Table 5. Patient Distribution As Per Bromage Scores Between Group R And B

Twenty-three patients in group R desired to ambulate and were allowed to walk with assistance satisfactorily. Twenty-one patients in group B desired to ambulate and, hence, were made to walk satisfactorily. Distribution of Bromage scoring in both the groups showed statistical significance (P <0.05). No patient in group R required either forceps delivery or caesarean section. In group B, there was one delivery by outlet forceps (3.33%) due to prolonged second stage. One patient required caesarean section in group B. Pattern of mode of delivery in both the groups was comparable and showed no statistical significance (P >0.05). The mean total dose of drug required for group R was 31.83 ± 0.52 mg and for group B was 33.25 ± 7.66 mg (P = 0.444). The statistical difference between the two groups was insignificant. The mean total dose of Fentanyl in group R was 50.87 ± 10.35 µg, whereas it was 53.20 ± 12.26 µg in group B (P value 0.429, not significant).

There were two patients, one from each group, who had vomiting. One patient from group B had pruritis. Two neonates, one from each group, were admitted to Neonatal Intensive Care Unit for observation, but both were discharged after 2 h. Adverse events in both the groups (Table 6) were comparable and showed no statistical significance (P > 0.05 by chi-square test).

Augmentation of labour in both the groups was comparable and was done as per the obstetrician's protocol for active labour management.

Neonatal Outcome

The neonatal outcome was rated with Apgar score at 1 & 5 minutes. The average Apgar score during 1st minute assessment was 7.87 ± 0.346 and 7.80 ±0.484 in group-R and group-B respectively. At 5 minutes, the Apgar score was 10.00 ± 0.001 and 10.00 ± 0.001 in group-R & B respectively. The difference in mean values were not statistically significant at both 1 minute (p=0.542) and 5 minutes (0.000).

	No Adverse Events	Baby Admitted in NICU	DTA	Prolonged Second Stage	Pruritus	Vomiting	Total
Group B	25	1	1	1	1	1	30
Group R	28	1	0	0	0	1	30
Total	53	2	1	1	2	1	60

Table 6. Comparison of Adverse Events Between Two Groups

DISCUSSION

In the present study Bupivacaine and Ropivacaine for labour epidural analgesia are compared. We decided to compare Bupivacaine with Ropivacaine with fentanyl. The recommended dose of bupivacaine in labour epidural analgesia is 0.0625%-0.125% and that of ropivacaine is 0.08%-0.2% at the rate of 8-15 ml/hour.⁹ Neuraxial local anaesthetics and opioids act synergistically to provide neuraxial analgesia. This combination decreases the MLAC of local anaesthetics used.¹⁰ We used fentanyl in a concentration of 2 µg/ml as it was used most commonly in previous studies. Motor block from local anaesthetic can be minimized either by reducing the concentration of the local anaesthetic or by choosing a local anaesthetic with a high differential sensory: motor block ratio, such as Ropivacaine¹¹ The advantage of using a low concentration of local anaesthetic was well demonstrated in Comparative Obstetric Mobile Epidural Trial (COMET).¹² This showed that the instrumental vaginal delivery rate was less frequent when a low dose epidural regimen (Bupivacaine 0.1% with Fentanyl 0.0002%) was compared with a traditional epidural regimen (Bupivacaine 0.25%). In the present study 10 ml of 0.125% of Ropivacaine and 10 ml of 0.125% Bupivacaine with 2 mcg/ml of fentanyl are used for initiation and then 6-8 ml of the study drugs are used for maintenance. The parturients were comparable in regards to age, weight, gravida, parity, vaginal dilatation in both groups. In another study done by Paddalwar S et al 0.125% Ropivacaine with Fentanyl 2 mcg/ml produced excellent labour analgesia, which was clinically indistinguishable from a similar concentration of Bupivacaine and Fentanyl.¹³ In a study conducted by Choudhary et al, comparing 0.2% epidural ropivacaine with parenteral opioid, there was significant decrease in pain scores by using VAS (visual analogue scale) as compared to opioid group. Hence establishing the importance of epidural ropivacaine as an effective labour analgesic agent.¹⁴

Motor Block

In the present study, 5 patients in bupivacaine group had demonstrable Bromage score- 2 motor block. There was no clinically demonstrable motor block in the ropivacaine group. This difference was statistically significant p value - 0.018 (significant at p < 0.05). Capogna et al and Linda et al¹⁵ have found ropivacaine less potent than Bupivacaine by a factor of 0.4. Some clinical studies have shown that Ropivacaine provided analgesia with less motor block compared with similar concentrations of Bupivacaine, similar to the findings of our study.¹⁶ In a study conducted by Paddalwar S et al the incidence of motor block was more in the Bupivacaine Group when comparing equi-potent concentrations of bupivacaine and ropivacaine both with concentrations of 0.125% and with fentanyl of 2 mcg/ ml. They concluded that ropivacaine should be a agent of preference because of its advantage of less incidence of motor block, longer duration of analgesia, less propensity to cause cardiotoxicity, when used as intermittent doses.¹³

Heart Rate

The heart rate in the present study after administration of the study drugs varied from 77.76±2.82 to 82.00 ± 2.828 in the ropivacaine group and from 76.63±2.67 to 81.20±1.79 in the bupivacaine group. The difference in the heart rates in the two groups were statistically insignificant. Similar results were seen in a study done by Finegold et al.

Blood Pressure

In the present study the Systolic Blood Pressure decreased to 119.47±7.10 mmHg in the ropivacaine group and to 119.67±6.99 mmHg. In the bupivacaine group (P = 0.913) 15 min after administration of the drug. No other subsequent SBP measurements differed between the two groups at any of the measurement points. The study results were similar to another study done by Finegold et al.¹⁷

Duration of Labour

Duration of 1st Stage of Labour-

A meta-analysis by Halpern et al (1998)¹⁸ concluded that epidural analgesia produced prolonged 1st stage of labour by 42 minutes. In a study done by Choudhary et al the duration of first stage of labour was shorted in epidural group where 0.2% ropivacaine with fentanyl is used as compared to control group.¹⁹

In the present study the duration of first stage of labour was 295.30 ± 54.464 minutes in ropivacaine group and 303.20±65.653 minutes in the bupivacaine group. There was no statistically significant difference in the mean duration. (p value - 0.614)

Duration of 2nd Stage of Labour

In the present study there was no difference in the duration of second stage of labour in both groups. The mean duration was 35.57±6.44 min in ropivacaine group and 35.60±5.80 min in bupivacaine group. This difference was not statistically significant (p value - 0.983).

Instrumental Vaginal Delivery

Writer et al,²⁰ found that instrumental vaginal delivery was less frequent in women who received Ropivacaine compared with those who received Bupivacaine(27% vs. 40%; P <0.01).

In our study, where we used smaller concentration of the study drugs, there was no significant difference in the mode of delivery in both the groups probably because the degree of motor block developed in Bupivacaine was not significant and did not affect the progress and mode of delivery, which is similar to the findings of Campbell et al.²¹

Foetal and Neonatal Outcome

The APGAR scores at 5 min were also statistically similar in both groups (p value = 0.569). Hence asserting the point that epidural analgesia has no difference in the neonatal outcome as compared to the control group by comparing the APGAR scores at 1 and 5 minutes.¹⁴

In the present study the foetal heart rate during the process of labour analgesia was within normal limits. There

was no incidence of post epidural foetal bradycardia. The mean APGAR score was 7.87 ± 0.346 & 7.80 ± 0.484 in ropivacaine and bupivacaine groups respectively at 1 min. At 5 minutes it averaged to 10.00 ± 0.001 & 10.00 ± 0.001 respectively. There was no significant difference in NICU admission in both groups.

Beilin and Halpern in 2010²² 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. Contrary to the popular belief that epidural analgesia causes prolongation of duration of labour, we found statistically significant reduction in the duration of labour in both the study groups, which was also observed by our obstetricians. Similar findings were reported by Khan et al and Nafisi et al.^{23,24} Reduction in duration of first stage of labour by 2 h was also observed by Lee et al., in the Ropivacaine group.²³ Adverse maternal events and foetal effects were statistically insignificant. we selected intermittent top ups in our study, As per various other studies,²⁵ drug consumption is less in intermittent top-up doses, which certainly affects the development of motor block, Besides, close monitoring also develops confidence between the patient and the physician, and provides opportunity to recognize the complications immediately.

CONCLUSION

We found that 0.125% Ropivacaine with Fentanyl 2 µg/ml produced excellent labour analgesia, which was clinically indistinguishable from a similar concentration of Bupivacaine and Fentanyl, with the advantage of less incidence of motor block and slightly longer duration of analgesia, apart from its lesser propensity to cause cardiotoxicity, when used as intermittent doses.

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