Comparative Study of 0.1% Ropivacaine-Fentanyl with 0.1% Bupivacaine-Fentanyl Given Epidurally for Labour Analgesia

Neel Rana¹, Asit Kothari², Priyal Shah³, Henal Jethi⁴, Devarsh Thakkar⁵

ABSTRACT
Introduction: Addition of fentanyl to bupivacaine or ropivacaine in epidural space will increase duration and quality of analgesia with similar safety profile. Study aimed to compare epidural Inj. Bupivacaine 0.1% + Inj. Fentanyl and Inj. Ropivacaine 0.1% + Inj. Fentanyl for onset, effectiveness and duration of analgesia, to study motor blockade intensity, to study hemodynamic parameters, to study technical and drug related complications in mother and baby and to study acceptability of technique by patient.

Material and methods: A prospective interventional study was conducted on 50 adult females with primigravida / multigravida full term pregnancy for epidural analgesia under ASA 1 & 2. Unpaired Student t test was used to interpret the results.

Results: Patients got more pain relief and satisfaction with ropivacaine+fentanyl as compare to bupivacaine+fentanyl.

Conclusions: Addition of fentanyl to bupivacaine or ropivacaine in epidural space increase duration and quality of analgesia with similar safety profile and reduce the requirement of local anesthetic drugs during labour. It did not hamper ambulation and bearing down of patient and had similar incidence of maternal and fetal outcome, with good patient satisfaction.

Keywords: Bupivacaine, Epidural, Fentanyl, Labour, Ropivacaine

INTRODUCTION
Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage”. It is influenced by parity, being primiparous women experiences more pain during early labor while multiparous women feel greater pain in the second stage. In the recent era, there are many pharmacological and nonpharmacological methods available for labour analgesia. Pharmacological methods include inhalational agents, systemic analgesia and various regional techniques. Nonpharmacological methods include psychoprophylaxis, breathing exercises, immersion in water during active labour, touch and massage, hypnosis, yoga, acupuncture, Transcutaneous Electrical Nerve Stimulation (TENS), intradermal sterile water injection, electroanalgesia, and audioanalgesia. According to the literature available, to control labour pain popular method is epidural administration of opioids with local anesthetic agent since both acts synergistically and reduces the dose of local anesthetic agent, provides excellent analgesia and has less/ minimal side effects. To be with the current era of technical advancement, out of all the techniques we selected most popular and widely accepted option of epidural administration of 0.1% Bupivacaine + Fentanyl or 0.1% Ropivacaine + Fentanyl for the labour pain. Study aimed to compare epidural Inj. Bupivacaine 0.1% + Inj. Fentanyl and Inj. Ropivacaine 0.1% + Inj. Fentanyl for onset, effectiveness and duration of analgesia, to study motor blockade intensity, to study hemodynamic parameters, to study technical and drug related complications in mother and baby and to study acceptability of technique by patient.

MATERIAL AND METHODS
After Institute’s ethical committee approval, the study was conducted at BJMC and Civil Hospital, Ahmedabad. Written and informed consent from all the patients was obtained. It is a prospective interventional study of 50 adult females with primigravida/multigravida full term pregnancy for epidural analgesia was selected into two groups. First group received Inj. Bupivacaine 0.1% 10 ml + Fentanyl 40µg followed by top up dose with 0.1% Bupivacaine 8ml + Inj. Fentanyl 20µg, and second group received Inj. Ropivacaine 0.1% 10 ml + Fentanyl 40µg followed by top up dose with 0.1% Ropivacaine 8ml + Inj. Fentanyl 20µg through epidural catheter. Level of analgesia was checked. Sensory level was checked by touch and pressure. Motor block was assessed by modified bromage scale. VAS pain scale was used for assessment of pain. Sedation score was observed throughout the process of labour and delivery.

RESULTS
This study was planned to compare potency and efficacy of bupivacaine with fentanyl and ropivacaine with fentanyl during process of labour analgesia. All the patients were divided in 2 groups. Group B (n=25) received 0.1 % Inj. Bupivacaine 10ml + Inj. Fentanyl 40 µg followed by top up dose with 0.1% Bupivacaine 8ml + Inj. Fentanyl 20µg, while Group R (n=25) received 0.1% Ropivacaine 10ml.

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<table>
<thead>
<tr>
<th></th>
<th>Group B</th>
<th>Group R</th>
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<tbody>
<tr>
<td>Normal</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td>Normal / episiotomy</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
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<td>0</td>
</tr>
<tr>
<td>Force outlet</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vaccum</td>
<td>1</td>
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</tr>
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Table-1: Mode of delivery

Figure-1: Sedation score after 45 minutes

Sedation score after 45 minutes (fig-1):
Group B (Mean ± S.D.) = 0.28 ± 0.46
Group R (Mean ± S.D.) = 0.2 ± 0.41
P value = 0.5177
Sedation score between two groups was statistically not significant (P > 0.05).

VAS (Pain score)
As shown in fig. 2 pain score were greatly reduced from 8.36 ± 1.35 to 1 ± 1.26 in Group B (statistically significant, P < 0.05) while in Group R 8 ± 1.41 to 0.2 ± 0.41 (statistically significant, P < 0.05), after 30 minutes. Between the groups VAS (Pain score) was statistically not significant most of time except at 15 min. (P= 0.003), 30 min. (P= 0.004), 90 min. (P= 0.0151), 120 min. (P= 0.0133), 150 min. (P = 0.0117), 270 min. (P = 0.0274).

Duration of analgesia after 1st dose
Group B (Mean ± S.D.) = 162 ± 23.8
Group R (Mean ± S.D.) = 171.6 ± 13.13
P value = 0.0838
Duration of analgesia after 1st dose in minutes with Group R (171.6 ± 13.13) was more as compared to Group B (162 ± 23.8), but (P = 0.0838) so it is statistically not significant (P > 0.05) (fig-3).

Fetal heart rate changes
As shown in fig. 4 fetal heart rate changes in group B and group R not statistically significant most of time (P value > 0.05) except at 510 minutes P value = 0.048, statistically significant (P value < 0.05) (fig-4).

Mode of delivery
Incidences of instrumental delivery were more in Group B as compare to Group R (table-1).

DISCUSSION
Pain relief in labour has always been surrounded with myths and controversies and providing effective and safe analgesia during labour has remained an ongoing challenge. Modern neuraxial labour analgesia reflects a shift in obstetrical anesthesia, thinking away from a simple focus on pain relief towards a focus on the overall quality of analgesia. Central neuraxial analgesia is the most versatile method of...
labour analgesia and the gold standard technique for pain control in obstetrics that is currently available. Epidural blockade is an effective means of providing analgesia during labour.\textsuperscript{2} 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 toxicity. There have been conflicting comparisons of ropivacaine and bupivacaine for labour analgesia.\textsuperscript{3-5} Dilute solutions of epidural local anesthetics combined with opioids may be used to minimize unwanted motor block. The requirement of local anesthetic drug dose depends upon the dose of fentanyl added.\textsuperscript{6}

We carried out this study for comparison of potency and efficacy of 0.1% bupivacaine with fentanyl and 0.1% ropivacaine with fentanyl epidurally in a women undergoing process of normal labour belonging to ASA 1 and II at the time of cervical dilatation of 3 to 5 cm. Both groups were comparable in the terms of age, weight, height, parity, mean duration of labour, mean duration of sensory analgesia, incidence of motor block and incidence of instrumental deliveries and LSCS. The dose of bupivacaine and ropivacaine used in our study was 0.1% 10ml below the central nervous system or cardio toxic threshold. It provides satisfactory analgesia for labour.

There are evidences that diluted large volume is more effective than concentrated small volume with less motor effects which reduce operative deliveries. There are evidences suggesting that low concentration of local anesthetics used alone may provide incomplete analgesia in 2nd stage of labour.

We performed our study in normal patients with age group between 18 to 30 years. As we compare two groups then age distribution in group B (Mean ± S.D. = 24.4 ± 4.12) and group R (Mean ± S.D. = 24.84 ± 3.47) was statistically not significant as P = 0.6849 (P > 0.05, NS). There was no any significant fluctuation of heart rate, systolic blood pressure and diastolic blood pressure in both groups after administration of drugs.

After giving epidural drug in both groups patient remained fully conscious. If we compare sedation score after 45 minutes, in group B (Mean ± S.D. = 0.28 ± 0.46) and in group R (Mean ± S.D. = 0.2 ± 0.41) and P = 0.5177. So, it was statistically not significant (P > 0.05, NS).

As compare to the previous studies of various authors who used bupivacaine + fentanyl combination and our findings were almost similar, regarding duration of analgesia in minutes (Mean ± S.D. = 162 ± 23.8). Sedation score was not significant but VAS score reduced from 8.36 ± 1.35 to 1 ± 1.26 after first 30 minutes. VAS (pain score) was statistically significantly reduced (p < 0.05) from the baseline till the delivery of baby.\textsuperscript{7-13}

As compare to the previous studies of various authors who used ropivacaine + fentanyl combination and our findings were almost similar, regarding duration of analgesia in minutes (Mean ± S.D. = 171.6 ± 13.13). Sedation score was not significant but VAS score reduced from 8 ± 1.41 to 0.2 ± 0.41 after first 30 minutes. VAS (pain score) was statistically significant (p < 0.05) from the baseline till the delivery of baby.\textsuperscript{7-13}

Duration of analgesia after 1st dose in minutes in group B (Mean ± S.D. = 162 ± 23.8) and in group R (Mean ± S.D. = 171.6 ± 13.13) and P = 0.0838. So P > 0.05, it was statistically not significant. But onset of action was earlier with ropivacaine as compare to bupivacaine. Duration of analgesia was almost similar with both drugs.

In our study, VAS (Pain score) was assessed every 15 minutes in 1st hour and then was assessed subsequently for every 30 minutes. If we compare VAS (pain score) of both groups then it shows significance at 15 minutes (p = 0.003), 30 minutes (p = 0.004), 90 minutes (p = 0.0151), 120 minutes (p = 0.0133), 150 minutes (p = 0.0117), 270 minutes (p = 0.0274). It was statistically significant (p <0.05). So it suggests there was more pain relief in group R as compare to group B. Ropivacaine selectively blocks sensory fibers as compare to motor fibers, so patient get more pain relief with ropivacaine as compare to bupivacaine. And patients’ satisfaction of getting pain relief was more this ropivacaine with fentanyl as compare to bupivacaine with fentanyl. Mode of delivery, incidence of instrumental delivery was more in group B as compare to group R. With bupivacaine with fentanyl out of 25 patients, 3 patients required instrumental delivery (2- LSCS, 1- Vacucox) as compare to ropivacaine with fentanyl there was no need of any instrumentation required for delivery.

Fetal heart rate change in both groups were statistically not significant except at 510 minute (P = 0.048), which was statistically significant as P < 0.05. In both groups there was no significant change in fetal heart rate.

In our study, APGAR score at 1 minute, in group B (Mean ± S.D. = 5.4 ± 0.7) and in group R (Mean ± S.D. = 6 ± 0.58) and P = 0.002. So, it’s statistically significant (P < 0.05). APGAR score at 5 minute, in group B (Mean ± S.D. = 7.2 ± 0.5) and in group R (Mean ± S.D. = 7.68 ± 0.85) and P = 0.0189. So, it’s statistically significant (P < 0.05). Outcome of new born was better with ropivacaine with fentanyl as compare to bupivacaine with fentanyl.

CONCLUSION

We conclude from our study results and confirm the previous study results that epidural administration of 0.1% bupivacaine 10 ml + fentanyl 40 µg and 0.1% ropivacaine 10 ml + fentanyl 40 µg provides sufficient pain free period during the process of labour, requires less top ups, without much side effects on mother or baby.

REFERENCES