**Clinical Study**

**Comparison of 0.1% Ropivacaine-Fentanyl with 0.1% Bupivacaine-Fentanyl Epidurally for Labour Analgesia**

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Ropivacaine is an alternative to epidural bupivacaine, with greater selectivity for sensory fibres than motor fibres, thus producing less motor blockade as compared to bupivacaine. The purpose of this study was to evaluate the efficacy of Ropivacaine 0.1% when administered epidurally for the relief of labour pain and to compare it with 0.1% bupivacaine, conducted at Rajindra Hospital Patiala, Baba Farid University of Health and Sciences, on 20 parturients after ethical approval from the institutional review board and obtaining written informed consent. Participants were randomly allocated to the two groups (bupivacaine 0.1% (Sensorcaine) + fentanyl 20 μg versus ropivacaine 0.1% (Ropin) + fentanyl 20 μg). It was observed that ropivacaine 0.1% and bupivacaine 0.1%, with fentanyl 20 μg/mL, produced equivalent analgesia for labour. There were no statistically significant differences in the amount of local anaesthetic used, pain scores, sensory levels, motor blockade, labour duration, mode of delivery, and side effects or patient satisfaction amongst the two local anaesthetics using the intermittent top-up technique. We conclude that the combinations of ropivacaine or bupivacaine with fentanyl achieve equally effective and excellent labour analgesia with no motor blockade and without jeopardizing the safety of the mother and foetus and, hence, are recommended for labour analgesia.

1. Introduction

The labour is reported to be one of the most painful experiences in a woman’s life. Epidural bupivacaine provides excellent analgesia for labour and delivery and remains the most widely used local anaesthetic in obstetric analgesia. However, disadvantages include the potential for motor blockage and cardiovascular toxicity. These concerns have prompted the search for alternative agents. Ropivacaine is an alternative and is an amide type local anaesthetic, structurally similar to bupivacaine and mepivacaine. In early animal and human studies, ropivacaine (6-propyl piperidinolide hydrochloride) demonstrated local anaesthetic properties with a potency and duration of action slightly lesser than that of bupivacaine. In addition, the depth and duration of motor block were less with ropivacaine. Low doses of local anaesthetic or opioid combinations are administered to provide a continuous T10-L1 sensory block, during the first stage of labour. Further supplementation may be required, during the late first stage and second stage, to achieve a sacral block [1]. The drugs to be used for this purpose should be quick in onset and long acting with minimum motor blockade and have no significant adverse effects on the mother and fetus. The duration of analgesia may be increased by intermittent top-ups. Commonly used drugs include lidocaine, bupivacaine, ropivacaine, morphine, chlorprocaine, tramadol, fentanyl, and sufentanil. Ropivacaine has a greater selectivity for sensory fibres than motor fibres, thus producing less motor blockade as compared to bupivacaine. Fentanyl is a highly lipid soluble drug, and when placed in the epidural space, peak concentration is reached in about 20 minutes. The low incidence of side effects associated with epidural fentanyl has been explained by the lipid solubility of the agent, which is so great that only low concentration of drug reaches the brain stem. The drug does not impair uterine contractility, which is an essential part of the normal birth process. The purpose of this study was to evaluate the efficacy of ropivacaine 0.1% when administered epidurally for the relief of labour pain and to compare it with 0.1% bupivacaine.
2. Material and Methods

This research was conducted at Rajindra Hospital Patiala, Baba Farid University of Health and Sciences. After ethical approval from the institutional review board and obtaining written informed consent, 20 parturients classified as ASA Grades I and II, who requested epidural labour analgesia, were taken for the study. Participants had singleton pregnancies of greater than 36 weeks of gestation with vertex fetal presentation. All women were in active labour with cervical dilatation of 3–5 cms when epidural catheters were placed. Those who had received opioid or sedative medications were excluded. Other exclusion criteria included patients with breech presentation, multiple pregnancies, APH, aortic stenosis, severe preeclampsia, cephalopelvic disproportion, vertebral deformity, chronic backache, local sepsis, and sensitivity to coagulation defects or anticoagulation therapy, vertebral stenosis, severe preeclampsia, cephalopelvic disproportion, with breech presentation, multiple pregnancies, APH, aortic presentations. All women were in active labour with cervical dilatation of 3–5 cms when epidural catheters were placed. Those who had received opioid or sedative medications were excluded. Other exclusion criteria included patients with breech presentation, multiple pregnancies, APH, aortic stenosis, severe preeclampsia, cephalopelvic disproportion, vertebral deformity, chronic backache, local sepsis, and sensitivity to the drug. Participants were randomly allocated to the two groups. Group I (n = 10) received 10 mL of bupivacaine 0.1% (Sensorcaine) + fentanyl 20 μg and Group II received 10 mL of ropivacaine 0.1% (Ropin) + fentanyl 20 μg, respectively, through the epidural catheter. After intravenous prehydration with 1000 mL lactated ringers solution, patients were placed in flexed sitting position. After raising a midline skin wheal with 2% lidocaine, the epidural space at L2-3 or L3-4 interspace was identified using an 18 G Tuohy needle and by loss of resistance to saline and a multiorifice epidural catheter was inserted about 3–5 cms into the epidural space and secured properly. After the insertion of the catheter, patients were placed in the supine position with left uterine displacement and 30° Reverse Trendelenburg position. The injection was given within 5 minutes. In addition to VAS assessment, other data collected included blood pressure, heart rate, fetal heart rate, and sensory level (as determined by pin prick). Blood pressure and heart rate were recorded every 5 minutes for the first 30 minutes after injecting drug and then every 30 minutes. Fetal heart rate was monitored simultaneously with maternal heart rate. Motor blockage was assessed at regular intervals using modified Bromage scale: 0, no motor block; 1, inability to raise the extended leg and ability to move knees and feet; 2, inability to raise the extended leg and to move knees but ability to move feet; 3, complete motor blockage of lower limbs. To further assess motor block, patients with effective analgesia at 30 minutes were asked to do a partial knee bending from a standing position at the bed side. After initiation of the block, pain relief was assessed using a Verbal Pain Scale after each contraction until they attain grade 3 or grade 4 relief.

Verbal Pain Scale. Onset of pain relief is as follows:

1. no pain relief,
2. little pain relief,
3. a lot of pain relief,
4. complete pain relief.

A Visual Analogue Scale of 0–10 cm was used to determine baseline pain score prior to initiation of block, at the first contraction and after each 15-minute interval until delivery. The time of completion of first stage of labour (full dilatation with urge to push) and second stage (delivery) and the mode of delivery were recorded. Neonatal evaluation included Apgar score at 1 and 5 minutes. All adverse events observed in patients, fetuses, or neonates were recorded.

3. Results

There were no significant obstetric differences in the two groups (Tables I and II).

In Group I, the time of onset of analgesia was 9.40 ± 2.37 minutes, while in Group II, it was 13.20 ± 2.53 minutes (Figure 1(a)). Duration of analgesia observed in Group II was 84.38 ± 49.62 minutes and that in Group I was 76.90 ± 23 minutes (Figure 1(b)).

Rate of cervical dilatation was 2.57 ± 1.44 cm/hr in Group I, while it was 2.88 ± 1.38 cm/hr in Group II which was statistically not significant. The total duration of labour was not prolonged in any of the two groups, being 258.00 ± 137.56 minutes in Group I and 221.50 ± 93.09 minutes in Group II. Nine cases (90%) had excellent analgesia in each of the groups, while 1 case (10%) in Group I and 1 case (10%) in Group II had satisfactory analgesia during first stage of labour.

There were no adverse effects on mother. All the patients were able to get out of the bed during labour. Side effects like nausea and emesis were seen in both groups (20% and 10%, resp.). Retention of urine was not observed in Group I but it was there in Group II in 10% of cases. Incidence of pruritus was 10% and 20% in Group I and Group II, respectively (Figure 2).

All the patients were able to get out of the bed during labour. There was no case of motor blockade in any group. All the patients were able to perform the bed side partial knee bend without difficulty. Review of foetal heart rate tracings did not reveal significant differences between the study

| Table 1: Demographic and obstetric data expressed as mean. |
|---------------------------------|----------------|----------------|
| Age (yr) | Group I | Group II |
| 26.20 | 24.90 |
| Height (cm) | 163.2 | 165.1 |
| Weight (kg) | 73.1 | 87.9 |
| Gestation (wks) | 40.2 | 39.9 |
| Cervical dilatation (cm) | 3.6 | 3.9 |

| Table 2: Hemodynamic data expressed as mean. |
|---------------------------------|----------------|----------------|
| MAP baseline (mmHg) | Group I | Group II |
| 122.80 | 125.00 |
| MAP lowest (mmHg) | 100 | 100 |
| MHR baseline (bpm) | 94.40 | 92.40 |
| MHR lowest (bpm) | 74 | 70 |
| FHR baseline (bpm) | 138.20 | 138.40 |
| FHR lowest (bpm) | 128 | 130 |

MAP: mean arterial pressure; MHR: maternal heart rate; FHR: foetal heart rate.
groups. There were no adverse effects on the foetus and the newborn. No clinical obstetric interventions were needed to be performed in response to foetal heart rate. There were no incidents of Caesarean sections during the study (Figure 3). The Apgar score of all the newborns was within normal range. 90% of the patients did not need local analgesia for stitching of the episiotomy wound after delivery due to persistence of sensory analgesia. 10% of the patients required local anaesthesia for stitching of the episiotomy wound. These patients were given only 1 top-up injection during labour which was sufficient till second stage of labour. So these patients were given active management of the third stage of labour. All patients were followed up after one year telephonically. No patient complained of backache and all patients reported it as a very good experience and all were satisfied with the procedure. Most of them even recommended it to the other parturients of their family and friends as this is a very safe and cost effective technique.

4. Discussion
As a whole, combinations of bupivacaine-fentanyl and ropivacaine-fentanyl have provided rapid, long lasting, and excellent analgesia, with no prolongation of first/second stage of labour. In Group I, the time of onset of analgesia was significantly faster, that is, 9.40 ± 2.37 minutes, as compared to Group II (13.20 ± 2.53 minutes). These results are consistent with studies of Eddleston et al. [2] and Finegold et al. [3]. Duration of analgesia observed in Group II was longer, that is, 84.38 ± 49.62 minutes, when compared with Group I (76.90 ± 23 minutes). These results are comparable with that of Polley et al. [4].

Nine cases (90%) had excellent analgesia in each of the groups, while 1 case (10%) in Group I and 1 case (10%) in Group II had satisfactory analgesia during first stage of labour. The results of the present study are better than that of Stienstra et al. (58% excellent for bupivacaine and for ropivacaine excellent in 64.5% cases and satisfactory in 29% cases) [5], and Muir et al. (52.94% excellent analgesia for bupivacaine and excellent analgesia in 82.35% cases of ropivacaine) [6]. The reason may be the use of bupivacaine only without the addition of opioids. In Group I, 9 cases (90%) had normal vaginal delivery and 1 case was delivered by outlet forceps. While in other studies, rates of NVD are lower
that is, 33% in Girard et al. [7], 50% in Chua et al. [8] due to the use of higher dose of bupivacaine causing some degree of motor blockade and thus, reduced rate of NVD. In Group II, 9 cases (90%) were delivered by NVD and outlet forceps were applied to 1 case (10%), while it is 56.25% in Chua et al. [8]. So, in this study, when bupivacaine and ropivacaine along with low dose of fentanyl were given epidurally, there was high rate of NVD and very low incidence of forceps application.

Side effects like nausea and emesis were seen in both groups (20% and 10%, resp.). Retention of urine was not observed in Group I, but it was there in Group II in 10% cases. Incidence of pruritus was 10% and 20% in Group I and Group II, respectively. These results are consistent with Owen et al. [9] and Chua et al. [8].

Ropivacaine is an amide local anaesthetic with similar physiochemical properties to bupivacaine. Early studies have demonstrated no difference in the pharmacokinetic profiles of the two agents after epidural administration. According to this study, in combination with fentanyl 2 μg/mL, ropivacaine 0.1% was proved to be equivalent to bupivacaine 0.1% regarding time of onset of pain relief, duration of action, quality of analgesia, and extent and duration of sensory block. No difference was observed in the delivery outcome between the two groups. There were no differences in the maternal haemodynamics or foetal heart rate changes in the two groups. All the neonates in both groups had Apgar score > 7.

5. Conclusion

In the present study, ropivacaine 0.1% and bupivacaine 0.1%, with fentanyl 2 μg/mL, produced equivalent analgesia for labour. There were no statistically significant differences in the amount of local anaesthetic used, pain scores, sensory levels, motor blockade, labour duration, mode of delivery, side effects, or patient satisfaction amongst the two local anaesthetics using the intermittent top-up technique.

We conclude that the combinations of 0.1% of ropivacaine with fentanyl (2 μg/mL) and 0.1% of bupivacaine with fentanyl (2 μg/mL) achieve equally effective and excellent labour analgesia with no motor blockade and without jeopardizing the safety of the mother and foetus and, hence, are recommended for labour analgesia.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

References
