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A Comparative Study of 0.15% Bupivacaine with Tramadol and 0.15% Ropivacaine with Tramadol for Epidural Labour Analgesia

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Providing safe and effective pain relief during labor without compromising on the mother and fetus has always been a challenging task for the anaesthetist. The introduction of concept of low concentration of local anaesthetics has allowed ambulation, besides providing pain relief and nonetheless, decreased the incidence of unpleasant side effects such as motor blockade. Ropivacaine is a newer alternative to bupivacaine, with greater sensorimotor differentiation, thus producing less motor blockade in comparison to bupivacaine. The purpose of this study was to evaluate the efficacy of Ropivacaine 0.15% when administered epidurally for the relief of labour pain and to compare it with 0.15% bupivacaine, with tramadol used as an adjunct in both the groups. The study was conducted on 20 healthy parturients after ethical approval from the institutional review board and obtaining written informed consent. Participants were randomly allocated to the two groups (bupivacaine 0.15% + tramadol 2mg/ml versus ropivacaine 0.15% + tramadol 2mg/ml). It was observed that both the local anaesthetic agents provided comparable analgesia without significant side effects at such low concentrations. There were no statistically significant differences in the total amount of local anaesthetic used, pain scores, motor blockade, duration of labor, mode of delivery, side effects and patient satisfaction amongst the two local anaesthetic groups using the intermittent top-up technique. We conclude that the combinations of ropivacaine or bupivacaine with tramadol achieve equally effective labor analgesia without compromising on the margin of safety and, hence, are recommended for labor analgesia.

Introduction

The labor period has been described as one of the most painful experiences in the life of a woman. Epidural analgesia has been the gold standard technique for labor analgesia and Bupivacaine, so far, has remained the most widely used local anaesthetic for this purpose. However, its potential to cause motor blockade and cardiovascular toxicity has led the researchers to look for safer alternatives with better pharmacological profiles (1). Ropivacaine is a newer, long acting amide local anaesthetic agent, with structural similarities to bupivacaine and mepivacaine. In early animal and human studies, ropivacaine (6-propyl pipecoloxylidide hydrochloride) demonstrated lower lipophilicity, thus explaining higher threshold for cardiac and nervous system toxicity (2) . In addition, the depth and duration of motor block are relatively lesser with ropivacaine owing to its lesser potential to penetrate large myelinated motor fibres (3). Low concentrations of local anaesthetics in combination with opioids are used 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.

The drugs to be used for this purpose should be quick in onset and long acting with minimum motor blockade, limited placental transfer and should have no significant adverse effects on the mother as well as the fetus (4). The duration of analgesia may be increased by intermittent top-ups. Commonly used drugs include lignocaine, bupivacaine, ropivacaine, chloroprocaine, tramadol, fentanyl, and sufentanil. Ropivacaine shows differential blockade with greater selectivity for sensory fibres than motor fibres and its analgesic efficacy is almost similar to bupivacaine. Tramadol is a synthetic opiod with multimodal anti nociceptive mechanisms. It has been used as an analgesic adjuvant through different routes, thus providing satisfactory analgesia without

significant adverse effects (5). Many studies have also described weak local anaesthetic properties of tramadol which may explain the effectiveness of adding it to local anaesthetics. 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 0.15% with tramadol 2 mg/ml when administered epidurally for the relief of labour pain and to compare this with ropivacaine 0.15% with tramadol 2mg/ml.

Material and Methods

Following ethical approval from the institutional committee and obtaining written informed consent, 20 parturients classified as ASA Grades I and II, who requested epidural labour analgesia, were enrolled for the study. All the enrolled participants had singleton pregnancies of more than 36 weeks of gestation with vertex fetal presentation. Epidural catheters were inserted on maternal demand. Those who had received opioids or sedatives were not included in the study. Other exclusion criteria included patients with breech presentation, multiple pregnancies, patients with cardiovascular diseases, cephalopelvic disproportion, coagulation disorders or anticoagulation therapy, vertebral deformities, chronic backache, local sepsis or sensitivity to local anaesthetics. Participants were randomly allocated to the two groups. Group I = 10) received 15 mL of bupivacaine 0.15% +tramadol 2 mg /ml and Group II received 15 mL of ropivacaine 0.15% + tramadol 2mg/ml, respectively, through the epidural catheter. Monitors were attached and patients were placed in flexed sitting position. After raising a midline skin wheal with 1% 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 multi orifice 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. Epidural injection was given once the catheter was checked with test dose. Blood pressure and heart rate were recorded every 5 minutes for the first 30 minutes after injecting the 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. After initiation of the block, pain relief was assessed using a Verbal Pain Scale after each contraction until they attained grade 3 or grade 4 relief.

1. 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. Further top ups were given with the same dose as and when demanded by the patient. 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

Table 1: Demographic and obstetric data expressed as ean.

	Group I	Group II
Age (yr)	27.30	26.10
Height (cm)	163.0	164.8
Weight (kg)	72.9	67.9
Gestation (wks)	40.4	38.9
Cervical dilatation (cm)	3.6	3.8

Table 2: Hemodynamic data expressed as mean.

	Group I	Group II
MAP baseline (mmHg)	121.80	125.20
MAP lowest (mmHg)	97	100
MHR baseline (bpm)	92.40	90.60
MHR lowest (bpm)	73	71
FHR baseline (bpm)	138.10	137.40
FHR lowest (bpm)	127	128

MAP: mean arterial pressure; MHR: maternal heart rate; FHR: foetal heart rate.

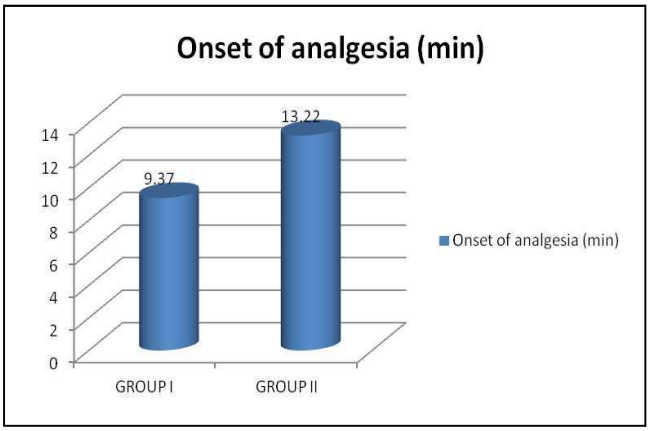


Figure 1: (a) Bar diagram showing time of onset of analgesia.

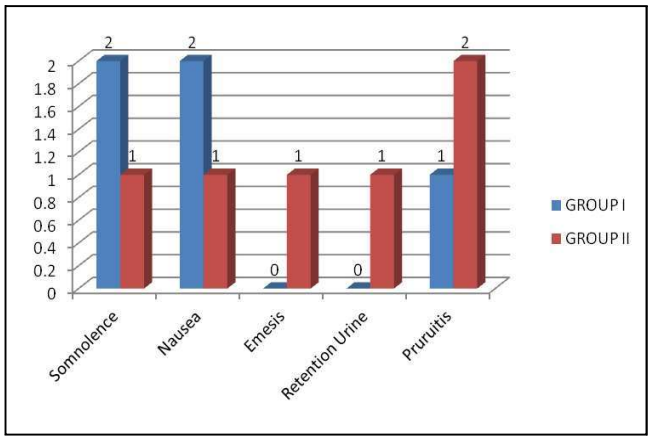


Figure 1: (b) Bar diagram showing time of Duration of analgesia.

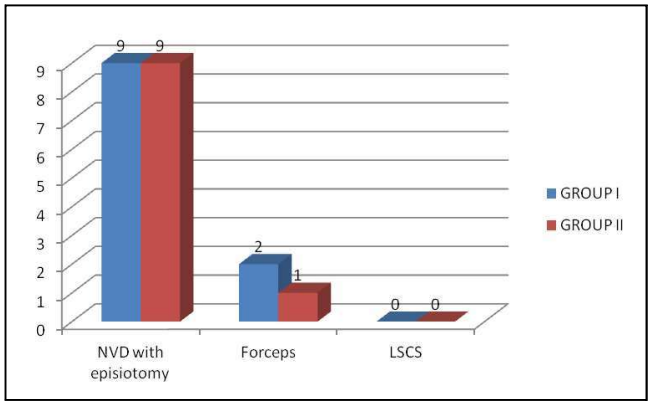


Figure 3: Bar diagram showing distribution of cases according to mode of delivery.

Results :

There were no significant demographic and obstetric differences found between the two groups (Tables 1 and 2). In Group I, the time of onset of analgesia was 9.37 ± 2.37 minutes, while, in Group II, it was 13.22 ± 2.53 minutes (Figure 1(a)). Duration of analgesia observed in Group I was 83.38 ± 49.62 minutes and that in Group II was 77.0 ± 23 minutes (Figure 1(b)). Rate of cervical dilatation was 2.56±1.42 cm/hr in Group I, whereas it was 2.78 ± 1.33 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 257.80±137.41 minutes in Group I and 222.20 ± 93.10 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 partial pain relief during first stage of labour. There were no major complications noted in the parturients. All the patients were able to mobilise with support during labour. Side effects like nausea and pruritus were noted in both the groups (20% and 10%, respectively).Only one case in group II developed urinary retention. Incidence of pruritus was 10% and 20% in Group I and Group II, respectively (Figure 2) .No patient developed motor blockade and all of them could perform the bed side partial knee bend without difficulty. Review of foetal heart rate tracings did not reveal significant differences between the two study groups.

There were no adverse effects on the foetus and the new born. No clinical obstetric interventions were needed to be performed in response to foetal heart rate. There were no conversions to Caesarean sections during the study (Figure 3). The Apgar score of all the newborns was within normal range. No patient developed postpartum haemorrhage as all the patients were given active management of the third stage of labour. A telephonic phone call was done after one year for follow up purpose and to take feedback. No patient complained of any long term complication and all the patients 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.

Discussion:

On the whole, combinations of bupivacaine-tramadol and ropivacaine-tramadol provide fast, long lasting and satisfactory analgesia, and do not prolong the duration of labour. In Group I, the onset

of analgesia was significantly faster, that is, 9.37±2.37 minutes, as compared to Group II (13.22 ± 2.53 minutes). These results are consistent with studies of Finegold et al who compared epidural infusions of ropivacaine 0.1%-fentanyl and bupivacaine 0.125%-fentanyl and found them to be comparable in terms of onset and duration of pain relief [6]. Duration of analgesia as noted in Group I was longer, 83.38 ± 49.62 minutes, while it was 77.0 ± 23 minutes in Group II. Polley et al assessed the minimum local analgesic concentrations of bupivacaine and ropivacaine and found ropivacaine to be significantly less potent than bupivacaine which may explain relatively lesser duration of action of ropivacaine (7). 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 less than satisfactory analgesia during first stage of labour. The results of the present study are better than that of Stienstra et al who compared ropivacaine 0.25% with bupivacaine 0.25% for continuous epidural labor analgesia and found 58% patients in bupivacaine group to have excellent pain relief and while 64.5% patients in ropivacaine group had excellent analgesia(8). Similarly, Muir et al. demonstrated 52.94% excellent analgesia for bupivacaine and excellent analgesia in 82.353% cases of ropivacaine (9). The reason may be the use of local anaesthetic only without the addition of opioids. In our study, in group I, 9 cases (90%) had normal vaginal delivery and 2 case was delivered by outlet forceps. While in other studies, rates of NVD are lower that is, 33% in Girard et al. [10] and 50% in Chua et al (11) 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(11). So, in this study, when bupivacaine and ropivacaine along with low dose of tramadol were given epidurally, there was high rate of NVD and very low incidence of forceps application. Side effects like nausea 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. 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 tramadol 2 mg/ml, ropivacaine 0.15% was found comparable to bupivacaine 0.15% with respect to time of onset of analgesia, duration of action, quality of analgesia, and extent and duration of sensory block. No differences were observed in the neonatal outcomes 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 > 8.

Conclusion:

In the present study, ropivacaine 0.15% and bupivacaine 0.15%, with tramadol 2 mg/mL, provided equivalent analgesia for labour. Tramadol in a dose of 1-2mg/kg body weight does not produce any clinically significant side effects. 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 groups using the intermittent top-ups technique. We conclude that the combinations of 0.15% of ropivacaine with tramadol(2 mg/mL) and 0.15% of bupivacaine with tramadol(2 mg/mL) achieve equally effective and excellent labour analgesia with no motor blockade and without compromising the safety of the mother and foetus and, hence, are recommended for labour analgesia.

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