EPIDURAL ANALGESIA DURING LABOR-0.5% LIDOCAINE WITH FENTANYL VS 0.08% ROPIVACAINE WITH FENTANYL-

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Abstract

Background: Although lidocaine is a cheap and globally available local anesthetic, yet it is not a popular drug for labor analgesia. This is claimed to its higher intensity of motor block, possibility of transient neurological symptoms (TNS) and its placental transfer with probable drawbacks on fetal well-being. However, these effects could be concentration dependent and, the evidence linking them to lidocaine is still lacking. This study was designed to evaluate the efficacy and safety of 0.5% epidural lidocaine plus fentanyl during labor.

Methods

One hundred and twenty healthy full term nulliparous women in early labor with a single fetus presented by the vertex were enrolled in this randomized, double-blind clinical trial. Parturient were assigned to receive epidural analgesia either with lidocaine 0.5% plus fentanyl 2 μg^{-1mL} (LF), or ropivacaine 0.08% plus fentanyl 2 μg^{-1}ml (RF) when their cervix was dilated to 4 centimeters. Analgesia was provided with 20 ml bolus of the study solution and maintained at 10 $ml^{-1}h$. Upper level of sensory loss to cold, Visual Analogue Pain Score (VAPS), motor block (modified Bromage score), the duration of the first and second stages of labor, numbers of instrumental vaginal and cesarean deliveries, the neonatal apgar score, patient satisfaction and side effects, were recorded.

Results

There were no significant differences in sensory level, pain scores, duration of the first and second stages of labor, numbers of instrumental and cesarean deliveries, the neonatal apgar scores, patient satisfaction or side effect between groups. Although motor block was significantly high in lidocaine group compared to ropivacaine group ($p<0.05$), all parturient were moving satisfactorily in bed.

Conclusions

Dilute epidural lidocaine (0.5%) with fentanyl effectively and safely initiates epidural analgesia clinically indistinguishable from 0.08% epidural ropivacaine with fentanyl. Although it induces significant motor block compared to ropivacaine, it still preserves maternal ability to move satisfactorily in bed. Whether further reduction in lidocaine concentration could trim down the motor block, remains to be investigated.

Keywords: Anesthesia: Obstetric Technique: Epidural Drug: Lidocaine.

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Introduction

Lidocaine can be used to provide complete analgesia during labor, yet it has been frequently accused with higher intensity of motor blockade that is frequently linked to bad obstetric and fetal outcome as well as decreased maternal satisfaction. As with other local anesthetics[1-3], lowering lidocaine concentration and addition of fentanyl, could minimize the intensity of the motor block while maintaining effective analgesia.

Although TNS usually occur after spinal anesthesia, likely with hyperbaric lidocaine[4], they are uncommon after epidural anesthesia with different types of local anesthetics[5,6]. Despite clear evidence of placental transfer of lidocaine at rate of 0.5/0.7[7], reported effects on the newborn have been subtle and probably not clinically significant.

Our purpose of this study is to evaluate the efficacy and safety of 0.5% lidocaine plus fentanyl 2 $\mu g^{-1}ml$ for epidural analgesia during labor, in comparison to, ropivacaine 0.08% plus fentanyl $2\mu g^{-1}ml$.

Methods

This prospective, double-blind, randomized study protocol was developed in collaboration with obstetricians. After approval of the local Ethics Committee and patients' written informed consent, one hundred and twenty parturients were en rolled in this study. Inclusion criteria included: request for analgesia, nulliparity, age18-35 years, body weight <90 kg, ASA physical status I or II, gestational age 37 >weeks, single fetus in cephalic presentation, normal fetal heart rate and cervical dilatation of 3-5 cm. Exclusion criteria included: patients receiving analgesia prior to enrollment, presence of complicated hypertension, diabetes mellitus, neurological disease, recent hemorrhage, preeclampsia, eclampsia, suspicion of fetal malformation or intrauterine growth retardation, fever of more than°38 C or history of allergy to local anesthetics.

Parturients were randomized by using a computer-generated randomization table to receive epidural analgesia of either 0.5% lidocaine with fentanyl $2\mu g^{-1}ml$ (LF), or 0.08% ropivacaine with fentanyl $2\mu g^{-1}ml$ (RF). The LF solution was attained by adding 62.5 ml lidocaine 1% (625 mg) and 5 ml of fentanyl (250 µg) to a 57.5 ml of preservative-free 0.9% saline. The while RF solution was attained by adding 20 ml of 0.5% ropivacaine (100 mg) and 5 ml of fentanyl (250 µg) to a 100 ml of preservative-free 0.9% saline. Twenty ml was then removed from the resultant 125 ml of either LF or RF solutions to be given to an anesthesiologist not directly involved in the patient's care or data collection to initiate epidural analgesia. The remaining 105 ml of each study solution was used for continuous epidural analgesia ($10\ ml^{-1}\ hr$).

Maternal oxygen saturation (SpO_2), heart rate and automated noninvasive blood pressure were monitored throughout labour.

Upon request of epidural analgesia, each parturient was preloaded with 500 ml of lactated Ringer>s solution before the initiation of epidural analgesia. A 20-gauge epidural catheter (SIMS Portex LTD, UK) was inserted under aseptic precautions in the lateral position at L3-L4 or L4-L5 interspaces with the loss of resistance to saline technique. The epidural catheter was then secured and the parturient placed in the supine position with left uterine displacement with the head of the bed elevated 20-30 degrees. Labor analgesia was initiated by the blinded anesthesiologist with a total volume of 20 ml of one of the study solutions given as four fractionated boluses (5 ml-each) within 4 minutes to achieve a bilateral block at ≥T 10-sensory level. Once the epidural analgesia is established, continuous infusion of 10 ml per hour of the analgesic solution was delivered to the laboring women to maintain labor analgesia. Further boluses of 5-10 ml of lidocaine 0.5% or ropivacaine 0.08% were given from the allocated randomized syringes for breaking through pain. Each fractionated dose was managed as a test dose (aspirating the catheter to detect accidental intravascular injection while unintended intrathecal administration of the epidural analgesic was recognized by the observation of a rapid onset of profound analgesia similar to that observed with intrathecally administered analgesics). Hypotension (systolic blood pressure below 100 mmHg or a 20% reduction from baseline) was treated with additional left uterine displacement, maternal oxygen administration, IV fluid bolus, or ephedrine as indicated.

The visual analogue pain scale (VAPS) [0-100

mm scale: 0 = no pain, 100 = worst pain ever] was measured at the peak of contractions before and 5, 10, 20, 30 min after the administration of the epidural analgesia and then at hourly intervals.

Sensory level to cold, a Modified Bromage Score (1 = complete block; unable to move feet or knee, 2 = almost complete block; able to move feet only, 3 = partial block; just able to move knee, 4 = detectable weakness of hip flexion, 5 = no detectable weakness of hip flexion while supine with full flexion of knees) were obtained 30 min after epidural injection and again at hourly intervals. Side effects including nausea/vomiting, pruritis, backache, shivering, urinary retention, and respiratory depression, were reported.

The duration of the first and second stages of labor, mode of delivery (spontaneous vaginal, instrumental vaginal vacuum-assisted and cesarean deliveries), and 1, 5-min neonatal apgar scores were recorded in each patient. Parturient satisfaction was assessed immediately after delivery as excellent (score 4), good (score 3), fair (score 2), or poor (score 1).

Routine intrapartum monitoring was documented by the obstetrician which included; electronic continuous fetal heart rate monitoring (CFHM), hourly progress of labor, cervical dilation, station, and position of the fetal head, and the degree of caput and molding.

The progress of labor is considered abnormal if it is two or more hours beyond the normal rate of progress (defined as 1 cm or more dilation per hour during the active phase of labor). Abnormal progress of labor was managed by artificial rupture of membranes, oxytocin infusion or cesarean delivery according to the obstetrician clinical judgment. Patients are allowed to push when cervical dilation is confirmed and when they have the desire to bear down. If maternal effort was judged to be inadequate by the attending obstetrician, epidural infusion rate was halved or stopped. Prolonged second stage (failure to deliver the fetus after the start of pushing for 1 h) was managed with either ventouse extraction, obstetric forceps or by cesarean delivery. The possibility of Transient Neural Symptoms (TNS) [symmetric pain and/or dysesthesia in the buttocks, lower lumbar region and/or legs] were investigated in all parturients during the first three days after delivery.

Statistical analysis was performed using unpaired t test to compare parametric data whereas the Fisher>s exact test was used to compare data expressed as percentages. $P<0.05$ was considered significant.

Results

One hundred twenty four women were initially included in the study. Four patients (two in each group) were excluded due to accidental dural puncture. The demographic, labor and delivery characteristics of the parturients were similar in each group (Table1).

Table 1
Maternal Demographic Data and Labor Characteristics

	LF (n = 60)	RF (n = 60)	p
Age (yr)	26 ± 4.92	25 ± 4.39	0.311
Height (cm)	165.6 ± 3.59	166.367 ± 2.16	0.156
Weight (kg)	75.07 ± 2.25	77.13 ± 2.14	1.01
Gestational age (wk)	38.20 ± 1.18	38.28 ± 0.94	0.67
Duration of 1st stage (min)	539.67± 25.61	545.33 ± 26.13	0.23
Duration of 2nd stage (min)	61.33 ± 6.76	63 ± 6.59	0.17
Oxytocin use (n) %	36 (60%)	34 (56.66%)	0.85
Mode of delivery (n):			
Spontaneous vaginal	56(93.33%)	55(91.66%)	1.00
Instrumental vaginal	1(1.66%)	1(1.66%)	1.00
C/S (dystocia)	2(3.33%)	3(5%)	1.00
C/S (fetal distress)	1(1.66%)	1(1.66%)	1.00

Both solutions produced effective analgesia during labor without significant differences in VAPS at any observation time for the first 30 min (Fig. 1). VAPS was then maintained at zero level throughout the study as was measured at hourly intervals.

The upper level of sensory loss to cold was similar in both groups after 30 min (Fig. 2). The epidural infusion was maintained at a rate of 10ml $^{l-}$h in both groups without affecting the maternal effort. No patient in either groups requested supplementary analgesia.

The differences in motor block between groups became noticeable within 60 min of the initiation of epidural analgesia and persisted throughout labor. Patients in LF group developed significantly more motor block (85% of patients had modified Bromage score of 4 and 15% had score of 3) than patients in RF group (85% of patients had modified Bromage score of 5 and 15% had score of 4). No patient in either group developed profound motor block (modified Bromage score of 1 or 2) (Fig. 3). Resolution of the sensory and motor block was complete within 2 hours after delivery and discontinuing the epidural infusion.

The number of neonates that presented with Apgar scores below 7 at one and five minutes were not significantly different between both groups. None of the neonates needed naloxone or NICU admission. Maternal satisfaction was similar in both groups (Table 2).

No significant differences were detected in the incidence of side effects or complications between the two groups (Table 3). Twelve hours postoperatively, three patients (2 in RF group and 1 in LF group) developed TNS that persisted for two days.

Fig. 1
VAPS at each observation time for the first 30 min. VAPS was maintained at zero level throughout the study as was measured at hourly intervals

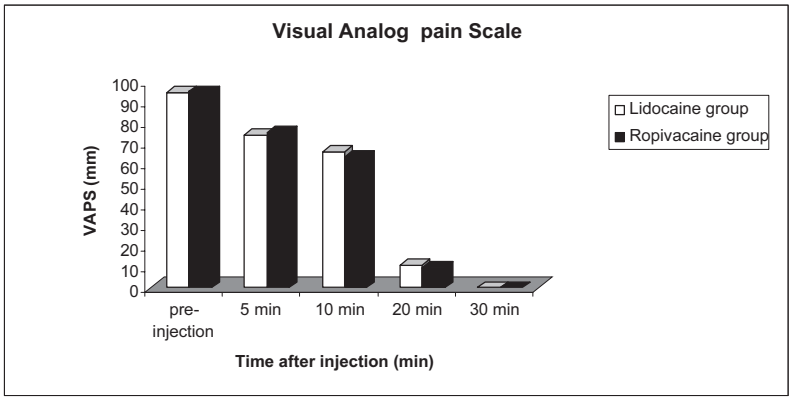

Fig. 2
Distribution of the upper level of sensory loss to cold at 30 min

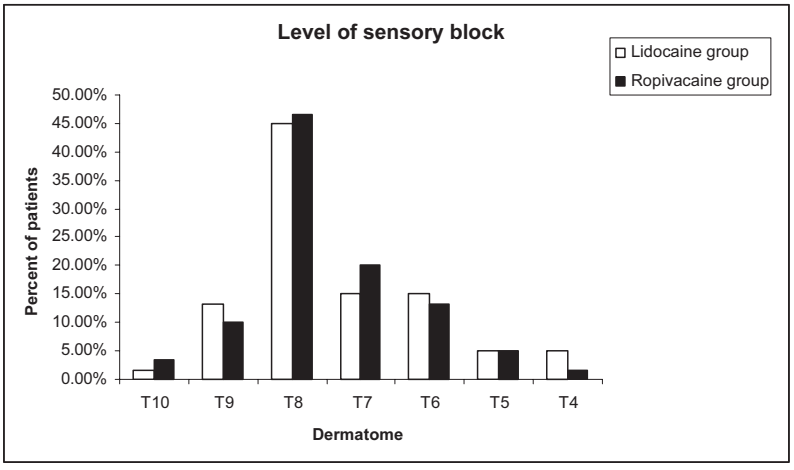

Fig. 3
The most intense motor block experienced by each patient at any assessment interval throughout labour is presented

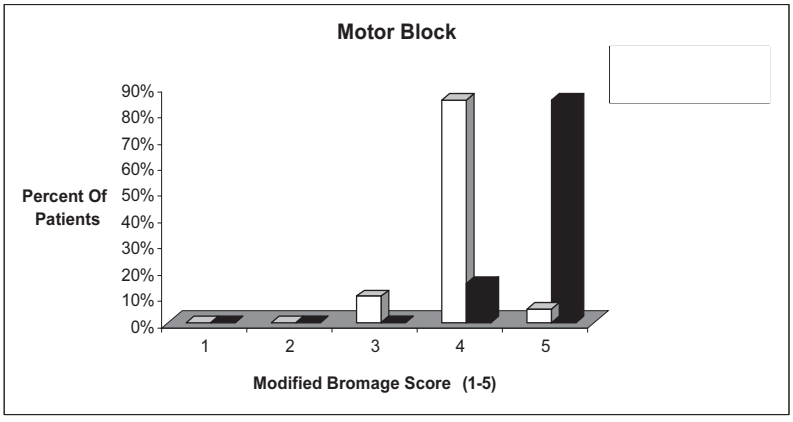

Table 2
Apgar scores and Maternal Satisfaction

	LF (n = 60)	RF (n = 60)	*p*
Apgar scores First minute <7 (%)	2(3.33%)	2(3.33%)	1.00
Apgar scores Fifth minute <7 (%)	2(3.33%)	1(1.66%)	1.00
Maternal Satisfaction (%)			
Excellent (4)	42(70%)	39(65%)	0.70
Good (3)	18(30%)	21(35%)	0.70
Fair (2)	0	0	
Poor (1)	0	0	

Table 3
Side Effects and Complications

	LF (n = 60)	RF (n = 60)	*p*
Hypotension	2(3.33%)	1(1.66%)	1
Nausea/Vomiting	2(0.03%)	1(1.66%)	1
Pruritis	25(42%)	27(45%)	0.85
Backache	5(8%)	4(7%)	1
Shivering	3(5%)	3(5%)	1
Urinary retention	1(1.66%)	0	1
Respiratory depression	0	0	
Pain, dysesthesia	1(1.66%)	2(3.33%)	1

Discussion

This study showed that continuous epidural 0.5% lidocaine with fentanyl effectively provides labor analgesia comparable to epidural 0.08% ropivacaine with fentanyl without significant adverse maternal or fetal outcomes. Albeit, this low concentration of lidocaine continues to be associated with significant more motor block compared to ropivacaine, parturients were able to ambulate adequately in bed with improved maternal satisfaction. We chose that dilution of ropivacaine/fentanyl for comparison because it became the mainstay of routine painless labour in clinical practice in many centers and it appears to provide a true walking epidural[8].

In recent years there has been a steady decline in the concentrations of local anesthetics used for epidural analgesia in labor[1-3,8]. Previous reports[9,10] using higher concentrations of continuous epidural lidocaine for labor analgesia concluded that; associated high intensity of motor block was not accompanied with any detrimental effects in terms of obstetric outcomes, duration of the second stage of labor, or the mode of delivery. Our study using low lidocaine concentration (0.5%) confirmed the previously mentioned studies with the advantage of less motor block.

In the present study, the use of low concentrations of epidural lidocaine (0.5%) continued to be associated with sufficient motor block that precluded true «walking epidural» (observed in ropivacaine group). Despite the belief that links motor blocking properties of epidurally administered analgesics to prolonged second stage and increased instrumental delivery rate, there are some studies, in which least concentrated doses of local anesthetic were used for epidural labor analgesia, and patients were able to walk, yet, instrumentation delivery rate was increased[11-13]. Also, Evron et al[14] in their prospective, randomized double blinded study showed that the lower intensity of the motor block is not associated with any benefit in terms of obstetric outcomes, duration of the second stage of labor, and obstetric intervention. Moreover, the clinical benefits of an ambulating parturient on the progress of labour and labour outcome, other than improved patient satisfaction, remain controversial[15,16]. In addition Nafisi[10] suggested that a pain free mother can cooperate more fully and can push more effectively and this may neutralize the left over motor blocking effect of lidocaine observed in our study.

In our study, neonatal Apgar score values were similar in both lidocaine and ropivacaine groups. Lidocaine is frequently chosen for epidural anesthesia for Cesarean delivery due to its rapid onset when compared to bupivacaine. Epidural injection of large dose of lidocaine during Cesarean section may result in a greater accumulation of the drug in newborn[17,18], however, reported effects on newborns are probably not clinically significant because the term fetus is able to biotransform lidocaine by hepatic enzymatic activity[7].

Our results showed that transient neurologic toxicity (TNS) could occur after continuous epidural analgesia with either lidocaine or ropivacaine with no statistical differences between both groups. Other studies described the occurrence of TNS after epidural

analgesia during labor with bupivacaine, ropivacaine and lidocaine[5,6,19]. Recently, Shifman et al[5] investigated the incidence of TNS in puerperas after epidural analgesia during labor using either 1% lidocaine or 0.2% ropivacaine infusion compared to control. They concluded that epidural analgesia during labor is not a cause of TNS and the type of a local anesthetic (lidocaine, ropivacaine) does not affect its incidence. The incidence of TNS in our study is lower compared to the previously mentioned study (2% versus 25% for lidocaine and 3% versus 27% for ropivacaine). This lower incidence could be credited to the use of lower local anesthetic concentrations in our study.

Local anesthetics were first implicated as potentially neurotoxic drugs after reporting cauda equina syndrome following continuous spinal anesthesia[20]. The Food and Drug Administration issued a safety alert in May of 1992[21] warning practitioners about the association of cauda equina syndrome with continuous spinal anesthesia. Later in 1993, Schneider et al[22] reported a new syndrome of possible transient neurologic toxicity (currently referred to as TNS) after hyperbaric subarachnoid anesthesia with 5% lidocaine. It was postulated by the authors that the stretching of the cauda equina by the lithotomy position stretched some of the nerve fibers within the cauda equina, rendering them vulnerable to toxic potential of a 5% solution of lidocaine. Wong et al. in 1996[23] reported the first case of TNS after epidural anesthesia. In that case, the patient received a total of 600 mg of 2% lidocaine (preceded by 45 mg of 1% lidocaine as a test dose) over a period of 20 minutes, to provide a level of T7. In view of the large-dose of local anesthetic injected (645 mg) and the large concentration used, the transdural transfer of lidocaine would have resulted in a fairly large concentration of the anesthetic, probably sufficient to cause TNS by a mechanism similar to that produced by 0.5% lidocaine injected intrathecally, especially when administered for surgery performed on patients in the lithotomy position[24].

It was postulated that continuous infusions of a local anesthetic will result in elevated intrathecal concentrations in the spinal fluid. This factor combined with the fact that most deliveries are performed with the parturient in the lithotomy position, could result in TNS after epidural injections of local anesthetics for delivery[25].

In our study, we did not give a test dose of high lidocaine concentration with epinephrine as in addition, it might affect our clinical end results, there is increasing evidence that this practice is neither sensitive nor specific to detect either vascular or intrathecally catheter misplacement[26,27]. Instead, we used the “fractionated bolus” technique that considers every dose administered via the catheter as a test dose to safeguard against the possibility of intrathecal or intravascular catheter migration[28].

In conclusion, epidural lidocaine (0.5%) with fentanyl effectively and safely initiates epidural analgesia clinically indistinguishable from 0.08% epidural ropivacaine with fentanyl. Although it induces significant motor block compared to ropivacaine, it still preserves maternal ability to move satisfactorily in bed. For our knowledge, this is the first study to use low lidocaine concentration (0.5%) for epidural analgesia. Whether further reduction in lidocaine concentration could trim down the motor block, remains to be investigated.

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