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A COMPARATIVE STUDY OF LOW CONCENTRATION OF LEVOBUPIVACAINE VERSUS ROPIVACAINE WITH FENTANYL FOR PATIENT-CONTROLLED EPIDURAL LABOUR ANALGESIA

Anaesthesiology

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ABSTRACT

Background- This study was designed to evaluate the efficacy of low concentrations of local anaesthetics (0.1% ropivacaine and 0.1% levobupivacaine) with 2 µg/ml fentanyl

Methods-In this prospective study, 60 labouring parturients were randomly allocated into two equal groups to receive either 0.1% ropivacaine (group-B) with 2 µg/ml fentanyl or 0.1% levobupivacaine (group-A) with 2 µg/ml fentanyl as epidural solutions via PCEA pump infusions (4 ml/h) after 15 ml loading dose of the respective solutions.

Results- Mean hourly drug consumption (mg) was 12.69 ± 2.48 and 13.64 ± 5.98 in groups A and B, respectively. Only one parturient in Group A had duration of labour extending beyond 11 hours 30 minutes. Mean total drug consumption in milligrams (calculated by including loading dose, demand boluses, background infusion and manual rescue boluses) was found to be 56.78 ± 31.20 mg and 64.25 ± 39.20 mg in groups A and B, respectively. There were no observed statistically significant differences in hourly and total drug consumption among both the groups.

Conclusion- The use of newer local anaesthetics (levobupivacaine and ropivacaine) in low concentrations with opioids (fentanyl) as a PCEA (patient-controlled epidural analgesia) technique may offer high maternal satisfaction in terms of quality of pain relief with fewer adverse events like instrumental assisted vaginal delivery (AVD) and adverse foetal outcomes.

KEYWORDS

Levobupivacaine, ropivacaine, opiods

INTRODUCTION:

The pain of childbirth is often rated by women as being most painful experience of their lives. It is estimated that about two third of normal healthy pregnant women, suffer severe intolerable pain during labour and only 2% describe it as little or no discomfort. There are several factors which influence parturition pain and its severity varies widely. It is influenced by parity, primiparous women experience more pain during early labour while multiparous women feel greater pain in the second stage. [1,2]

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, chloroprocaine, 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. [3]

MATERIALS AND METHODS:

Place of study: Department of Anaesthesia**,** Government Medical College, Kota and attached group of hospitals

Time of study: From Nov.-2019 to March-2019

Design of the Study: The present study was a prospective observational study.

INCLUSION CRITERIA-

After informed consent, 60 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.

EXCLUSION CRITERIA-

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, coagulation defects or anticoagulation therapy, vertebral deformity, chronic backache, local sepsis, and sensitivity to the drug.

60 Participants were randomized using sealed envelope allocation to receive a loading dose of 15 ml of 0.1% levobupivacaine with 2mcg/ml fentanyl (group A) or 0.1% ropivacaine with 2 mcg/ml fentanyl (group B) delivered over 10 mins using a PCEA pump. This initial loading dose served as the test dose, which was given gradually under monitoring for any signs of inadvertent intrathecal or intravascular placement.

If the onset of analgesia did not occur within 30 minutes, a further 10 ml of study solution was delivered over 10 minutes via PCEA pump. Subsequently if the onset of analgesia did not occur within 60 minutes, 10 ml of bupivacaine 0.25% solution was administered (rescue analgesia) and the parturient was withdrawn from the study. Subsequent maintenance of labour analgesia was achieved using a PCEA pump programmed to deliver 5 ml of study solution as per parturient demand with a lock out interval of 15 minutes along with a background infusion (BI) of 4 ml/hour in both groups. Breakthrough pain [visual analog scale (VAS) >30 mm], defined as a parturient requesting additional analgesia irrespective of PCEA use was treated with additional 5 ml rescue boluses of study solution given manually by the anaesthesiologist and recorded. All parturients were nursed in either left lateral position or were given a 30° wedge under her right hip throughout labour.

DATA ANALYSIS-

Data was recorded as per Performa. The data analysis was computer based; SPSS-22 will be used for analysis. For categoric variables chi-square test was used. For continuous variables independent samples *t*-test was used. *p*-value <0.05 was considered as significant.

RESULTS:

Table 1. Socio-demographic variable

Variable	Group-A	Group-B	p-value
Age in Yrs	25.36±2.16	25.36±2.16	0.69
Weight in Kg	51.23±6.44	53.69±7.42	0.769
ASA grade(I:II)	22:8	21:9	0.236

The two groups were statistically comparable in terms of obstetric parameters like gravida and cervical dilatation since p >0.5.

Median pre-epidural VAS (out of 10) was 8 and 8 in groups A and B, respectively, with no statistically significant difference.

No statistically differences were found in terms of pre-epidural parameters (PR, SBP, DBP, and SpO2) between both the groups.

Median onset of analgesia was 10 minutes and 11 minutes in groups A and B, respectively (*P* >0.05).

Mean of total duration of epidural analgesia was 296.32 ± 192.69 minutes in group A and 352.69 ± 263.11 minutes in group B. This was not statisticallysignificant.

Quality of pain relief was adequate with VAS of ≤3 at most of the time intervals in both the groups. Median VAS at all times was not significant among both the groups except at 8 hours 3. Statistically significant differences were noted in VAS between both groups at 8 hours 30 minutes (*P* value = 0.011) and the median was 3 mm in group A and 5mm in group B.

Mean number of demand boluses per hour at all times were statistically insignificant among both groups except at ninth hour, which were 0.08 ± 0.21 in group A and 0.21± 0.19 in group B. Therefore, the number of demand boluses per hour showed statistically significant difference at ninth hour between both groups.

Mean total number of manual rescue boluses of study solution in group A and B were found to be 0.98± 2.67 and 0.61 ± 1.48, respectively. The difference was not statistically significant.

Mean time of first requirement of manual rescue bolus (hours) was 3.42 ± 0.72 and 2.14 ± 1.68 in groups A and B, respectively. Time of first requirement of manual rescue bolus did not vary statistically significantly among the two groups.

Mean hourly drug consumption (mg) was 12.69 ± 2.48 and 13.64 ± 5.98 in groups A and B, respectively. Only one parturient in Group A had duration of labour extending beyond 11 hours 30 minutes. Mean total drug consumption in milligrams (calculated by including loading dose, demand boluses, background infusion and manual rescue boluses) was found to be 56.78 ± 31.20 mg and 64.25 ± 39.20 mg in groups A and B, respectively. There were no observed statistically significant differences in hourly and total drug consumption among both the groups.

The median highest level of sensory block was T8, thus attaining adequate level of analgesia in both the groups.

Motor block did not occur in 26 parturients in each group. One parturient in group A developed Modified Bromage Grade I motor block, and two parturients in group B developed grade I motor block. Only one parturient in group A had grade II motor block. Grade III motor block was not observed in any parturient. Hence, there were no statistically significant differences in terms of intensity and incidence of motor block among both groups.

DISCUUSION:

Multiple factors like station and position of the foetal head, maternal pain and the urge to bear down, and epidural analgesia-induced motor block contribute to the outcome of second stage of labour.Among these factors leading to instrumental AVD, motor block of perineal or abdominal muscles resulting in impairment of Fergusson-Harris reflex (needed for bearing down efforts in the second stage) and abnormal internal rotation of foetal head have been proposed to be a major determinant in increasing instrumental AVD rates.[4] Studies using ropivacaine in higher concentrations especially ≥0.2% have been found to be associated with greater motor blockade.[5] This can be eliminated by using these local anaesthetic agents in a lower concentration (0.05–0.15%). However this curtails effective analgesia.[6] Using an opioid along with local anaesthetics improves the analgesia while causing less motor blockade, thus reducing the incidence of AVD. The reason for choosing 0.1% concentration of local anaesthetic in this study was to achieve minimal motor blockade thereby targeting to decrease the incidence of instrumental AVD. Though ropivacaine is considered 40% less potent than levobupivacaine, we chose to evaluate equipotent lower concentrations based on the studies of Wang and Purdie *et al*., which demonstrate nearly similar clinical potencies of levobupivacaine and ropivacaine when used at concentrations ≤0.1%.[7,8]

Newer drugs (levobupivacaine and ropivacaine) have high differential sensory-motor block ratio, less potential for cardio and neurotoxicity thereby offering better safety profile as compared to bupivacaine.[9,10] PCEA, a well accepted technique of administering epidural labour analgesia, improves maternal analgesia and enhances parturient satisfaction with the use of lowest possible effective doses of local anaesthetics, thereby reducing the total drug consumption.[11] This leads to minimal motor block and probable favourable effect on mode of delivery.[12] This formed the basis of the use the PCEA technique along with background infusion of 4 ml/h in this study.

None of the parturients were excluded from the study as all the parturients achieved onset of analgesia within 30 minutes of administration of initial loading dose of study solutions. A uniform analgesia initiation and maintenance technique was used in all the subjects.

The confounding factors which can affect the progress and outcome of labour such as duration of all stages of labour, total duration of epidural analgesia, oxytocin consumption throughout labour, onset of analgesia, the highest level of sensory block (T_8) and total local anaesthetic drug consumption among both groups varied insignificantly thus making the two groups comparably similar.

CONCLUSION:

The use of newer local anaesthetics (levobupivacaine and ropivacaine) in low concentrations with opioids (fentanyl) as a PCEA technique may offer high maternal satisfaction in terms of quality of pain relief with fewer adverse events like instrumental AVD and adverse foetal outcomes.

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