Original Research Paper

Volume - 13 | Issue - 11 | November - 2023 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

A CLINICAL STUDY OF COMPARISION BETWEEN EPIDURAL BUPIVACAINE 0.125 % WITH FENTANYL 2MCG/CC AND LIGNOCAINE 0.5 % WITH FENTANYL 2 MCG/CC IN LABOR ANALGESIA BY INTERMITTENT BOLUS TECHNIQUE

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ABSTRACT **Background And Objective:** Severe labor pain affects physiological and psychological status. Hence epidural analgesia is a gold standard to provide effective and safe labor pain relief. The present study aimed to assess the maternal analgesia, complications and outcome of labor and neonatal outcome following lumbar epidural analgesia with intermittent boluses of 0.125 % bupivacaine and 0.5 % lignocaine in combination with inj Fentanyl 2mcg/cc. **Methods:** The present prospective comparative study was conducted among patients in age group of 18-30 years with gravida 1 and 2 belonging to ASA grade 2 are selected at Bapuji Hospital and Chigateri General Hospital, Teaching Hospitals Attached to J.J.M. Medical College, Davangere, undergoing normal delivery were randomly allocated into two groups comprising of 25 patients in each group. Informed consent was taken. Patients with gravida 3 or more, multiple pregnancy, severe anemia, pregnancy induced hypertension, bleeding disorders and nor willing to be part of study were excluded from the study. Patients were randomly grouped as group A - 25 patients receiving 8-10ml of 0.125 % bupivacaine with inj Fentanyl 2mcg/cc for epidural analgesia and group B - 25 patients receiving 8-10ml of 0.5 % lignocaine with inj Fentanyl 2mcg/cc for epidural analgesia. After intrathecal drug administration, the following parameters are noted in the patients. Maternal blood pressure is recorded at 5, 10, 20, 30, 60 minutes respectively. Continuous maternal and fetal HR monitoring is done. The efficacy of analgesia is assessed by visual analog scale (VAS). The data were collected in proforma and entered in excel sheet and analysed using SPSS v21 operating on windows 10. A P value of & <0.05 was considered statistically significant. **Results:** A total of 50 patients with mean age of 24.72±3.60yrs. The vital parameters like pulse rate, blood pressure and oxygen saturation were comparable between the group, with no significant difference noted between the groups (p>0.05). Study documented a significant longer duration of analgesia in group A compared to the patients in group B. The mean duration of analgesia in group A was 57mins and in group B was 49.20 mins (p<0.05). The Maternal outcome and the fetal outcome between the groups were comparable with no significant difference, however the bupivacaine showed better outcome compared to lignocaine combination with fentanyl. **Conclusion:** The present study highlights the findings that the duration of analgesia in patients administered with bupivacaine showed a significant longer duration compared to lignocaine. The neonatal outcome and the maternal outcome of labor was comparable between the groups with no significant difference noted.

KEYWORDS : Bupivacaine, Labor, Lignocaine, Fentanyl, Analgesia, Visual analogue score

INTRODUCTION

Labour is characterised by regular, painful uterine contractions which increase in frequency and intensity involving the active process of delivering a foetus. [1] Labor pain is associated with both a visceral and somatic component. Uterine contractions and cervical dilatation result in visceral pain. These pain impulses are transmitted by A delta and C fibers and enter spinal cord at T10 and L1 level. As the fetal descends downwards somatic pain is transmitted through pudendal nerve (S2-S4).[2] Labor analgesia aims to produce a selective sensory block from T10 to L1 while at the same time sparing motor supply to the lower limbs (L2 -L5) and it is called MOBILE EPIDURAL or WALKING EPIDURAL analgesia.[2]

In 1901, two Frenchmen, Jean-Anthanase Sicard and Fernand Cathelin, independently documented the first epidural anaesthesia via a caudal route. Fidel Pagés Miravé, a Spanish military surgeon, successfully accomplished the lumbar approach in 1921. [3] The ideal local anesthetic for labor analgesia should produce a reliable sensory block, no motor block. [2]

This can be achieved by giving low dose local anesthetics.[4] Bupivacaine, the amide local anesthetic is highly protein bound, a feature that limits transplacental transfer. After epidural administration of bupivacine during labor, The patient perceives pain relief within 8 to 10 minutes, but approximately 20 minutes are required to achieve the peak effect. Duration of analgesia is approximately 90 minutes.

Lignocaine is an amide type of local anesthetic with a duration of action intermediate between those of bupivacaine and 2 chloroprocaine. Lignocaine is less protein bound, the umblical vein to maternal vein lignocaine concentration ratio is approximately twice that of bupivacaine.5

The VAS measures a patient's subjective pain perception. It's a 100-mm solid line on which the subject marks the intensity of pain or discomfort. One end is marked with adjectives indicating no pain or complete pain relief, while the other end is marked with the worst suffering imaginable or no pain relief.[6]

The VAS is a one-dimensional tool that does not take into account culture, communication, situations, mood states, or other elements that may influence pain perception or reporting (McCool et al., 2004). Despite this, the VAS is frequently used since it is simple to apply, fast to assess, and avoids inaccurate terminology (Breivik et al., 2001; Good et al., 2001). The VAS is sensitive to acute pain at mild, moderate, and severe intensity levels and has adequate reliability in a wide range of acute pain sufferers.[6]

The present study aimed to assess the neonatal outcome and maternal analgesia, complications and outcome of labor following lumbar epidural analgesia with intermittent boluses of 0.125 % bupivacaine and 0.5 % lignocaine in combination with fentanyl 2mcg per cc.

METHODOLOGY

The present study is a Prospective comparative study conducted from March 2021 – June 2022. Patients in age group of 18-30 years with gravida 1 and 2 belonging to ASA grade 2 are selected at Bapuji Hospital and Chigateri General Hospital, Teaching Hospitals Attached to J.J.M. Medical College, Davangere.

Inclusion Criteria

- Age-18 yrs to 30 yrs.
- Gender- female.
- Gravida 1 and 2.
- ASA 2.

Exclusion Criteria

- Patients unwilling for the procedure.
- Parturients gravida 3 or above.
- Parturients with multiple pregnancies

50 adults in age group of 18 to 30 years who are undergoing normal delivery were randomly divided into Group A or Group B after taking written informed consent for the same from parent/guardia.

Group A: comprising of 25 patients receiving 8-10ml of 0.125 % bupivacaine with inj Fentanyl 2mcg/cc for epidural analgesia.

Group B: comprising of 25 patients receiving 8-10ml of 0.5 % lignocaine with inj Fentanyl 2mcg/cc for epidural analgesia.

On admission a full medical, anesthetic and obstetric history followed by a detailed general and obstetric examination was done.

Patient shifted to labor room and intravenous access established with 18 or 20 gauze IV cannula and lactated Ringer's solution 8- 10 ml/kg infused intravenously before the procedure. The monitors (pulse oximeter, non invasive blood pressure, ECG) are connected to the patient on arrival to labor room and baseline parameters were recorded (Pulse rate, B P, Respiratory rate, Oxygen saturation, ECG. Fetal Heart Rate.

A 18-gauge epidural catheter 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.

The study solution used are 0.125 % bupivacaine and 0.5 % lignocaine with 2mcg/cc Fentanyl are prepared by diluting 2 cc of 0.5 % of bupivacaine to 8cc with fentanyl 2mcg/cc and Lignocaine 0.5% with 8-10cc with fentanyl 2mcg/cc.

An initial dose of 10-15 ml of the study solution is injected slowly through the epidural catheter by intermittent epidural bolus technique with the patient in supine position with left lateral tilt. Once the epidural analgesia is established, intermittent bolus dose of 8-10cc of drug will be given to respective groups. Each fractionated dose was managed as a test dose. Hypotension was treated with additional left uterine displacement, maternal oxygen administration, IV fluid bolus, or ephedrine a indicated.

Routine intrapartum monitoring was documented by the obstetrician. The progress of labor is considered abnormal if it is two or more hours beyond the normal rate of progress.

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 following parameters are noted in the patients. Maternal blood pressure is recorded at 5, 10, 20, 30, 60 minutes respectively. Continuous maternal and fetal HR monitoring is done. The efficacy of analgesia is assessed by visual analog scale (VAS).

Assessment Of Analgesia

Duration Of Action: It is defined as the time interval between administration of drug epidurally to achieve its peak effect and the time when patient complains of break through pain in the intralabor period.

Pain Assessment: was done through VISUAL ANALOGUE SCALE First advocated by Revill and Robinson (1976). It consists of a 10 cm line which states "no pain" at one end and at the other end has "worst pain". The patient simply marks the line to indicate pain intensity. Patients are instructed about the VAS and to point out the intensity of pain as 0-no pain, 10-worst pain.

Assessment Of Sensory Block

Onset of sensory Block: Is defined as the time interval from administration of local anaesthetic into epidural space to the loss of pin prick sensation corresponding to the dermatome. Highest level of sensory block is noted.

Duration of sensory block: is the time taken from the maximum level of sensory block till the patient feels pain.

Intensity of motor blockade is assessed by Modified Bromage scale. 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.

The same bolus dose is repeated if the patient complaints of pain. A maximum of five top up doses are allowed which would provide analgesia for about 8 hour. The outcome of labor is assessed in terms of normal vaginal delivery, assisted vaginal delivery, or cesarean section. Fetal well-being is assessed by Apgar score at 1 and 5 min. The following maternal complications such as maternal hypotension, unintentional dural puncture, unexpected high block, motor blockade, pruritus, and headache are looked for. When the patient began to experience recurrent pain, the anesthesia provider assess the pain relative to the stage of labor and the extent of sensory blockade and then administer another epidural bolus of local anaesthetic.

Analgesia is usually re-established with the bolus injection of 8 to 10 ml of local anaesthetic solution. The spread and quality may change with repeated lumbar epidural injections of local anaesthetic. After several injections, blockade of the sacral segments, intense motor blockade, or both may develop. The sensory level and the intensity of motor blockade should be assessed and recorded before and after each bolus injection of local anaesthetic.

Statistical Analysis

The data were collected in proforma and entered in excel sheet and analysed using SPSS v21 operating on windows 10. Categorical data were represented in the form of frequency and percentage. Association between variables was assessed with Chi Square Test Quantitative data was represented as Mean & Sd. Comparison of variables was done with Un-paired t- test. A P value of & <0.05 was considered statistically significant.

Sample Size Estimation

Sample Size Calculation:

$s = (r + 1)(Sd2 \times (Z_{\beta} + Z\alpha)2) / d2$

r = Ratio between groups, Z_{β} Std normal variate for power , 80% power = 0.84, Zα 1.96, d= mean difference between groups

Sample size: 50

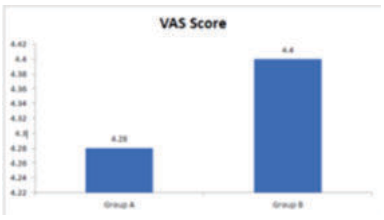
RESULTS

In present study total of 50 patients fulfilling inclusion criteria are included with mean age of 24.72±3.60yrs. The patients were randomly allotted into two groups as group A and group B with 25 patients in each group.

Among the patients, the mean age between the group were comparable with no significant difference noted between the groups. The vital parameters like pulse rate, blood pressure and oxygen saturation were comparable between the group, with no significant difference noted between the groups (p>0.05).

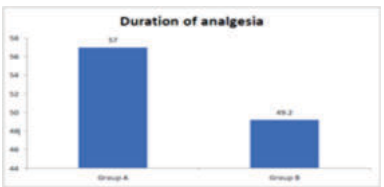
Comparison of the mean VAS score, there is no significant difference was noted with mean VAS score between the groups. However the mean level of the VAS pain score was lower in group A compared to group B. (p>0.05).

Graph 1: Comparison Of Mean VAS Score Of Analgesia Between The Groups.



On comparison of the duration of analgesia, the study documented a significant longer duration of analgesia in group A compared to the patients in group B. The mean duration of analgesia in group A was 57 mins and in group B was 49.20 mins (p<0.05).

Graph 2: Comparison Of Mean Duration Of Analgesia Between The Groups



On comparison of the outcome of labor, the outcome was comparable between the group A and group B with no significant difference with incidence of caesarean, instrumental delivery and normal delivery. (p>0.05).

On comparison of the mean APGAR score, there is no significant difference in the mean score between the group A and group B. However, the mean APGAR score was found the higher in group A compared to group B.(p>0.05)

DISCUSSION

Severe labor pain affects physiological and psychological status.2 Hence epidural analgesia is a gold standard to provide effective and safe labor pain relief.[7]

The present study aimed to assess the maternal analgesia, complications and outcome of labor and neonatal outcome following lumbar epidural analgesia with intermittent boluses of 0.125 % bupivacaine and 0.5 % lignocaine in combination with inj Fentanyl 2mcg/cc.

The patients were randomly allotted into two groups as group A and group B with 25 patients in each group. In present study total of 50 patients fulfilling inclusion criteria are included with mean age of 24.72±3.60yrs. Among the patients, the mean age between the group were comparable with no significant difference noted between the groups. The vital parameters like pulse rate, blood pressure and oxygen saturation were comparable between the group, with no significant difference noted between the groups. (p>0.05). Similar to present study Wesam F, et al., documented the mean age between the group were comparable with no significant difference and also the vitals of the patients were comparable between the groups.[8]

Comparison of the mean VAS score, there is no significant difference was noted with mean VAS score between the groups. However the mean level of the VAS pain score was lower in group A compared to group B.(p>0.05) On comparison of the duration of analgesia, the study documented a significant longer duration of analgesia in group A compared to the patients in group B. The mean duration of analgesia in group A was 57mins and in group B was 49.20mins. (p<0.05)

Similar study by Pooja M, et al., documented that single shot intrathecal analgesia using fentanyl 25 µg and bupivacaine 2.5 mg when given in the active phase of first stage of labor had rapid onset with satisfactory pain relief and minimal motor block.[4]

In another study by Syal K, et al., documented the duration of analgesia was statistically significantly prolonged, but there was no change in the length of labour, ambulation, frequency of instrumentation and caesarean sections, or the result for the foetus.[9]

On comparison of the outcome of labor, the outcome was comparable between the group A and group B with no significant difference with incidence of caesarean, instrumental delivery and normal delivery.(p>0.05) On comparison of the mean APGAR score, there is no significant difference in the mean score between the group A and group B. However, the mean APGAR score was found the higher in group A compared to group B.(p>0.05)

Lakshmi R, et al., found combination of a small amount of 0.2% ropivacaine and 2 mcg/mL fentanyl was successful in reducing labour discomfort. Both methods were equally successful and might be advised for labour analgesia[10]

CONCLUSION

The present study highlights the findings that the duration of analgesia in patients administered with bupivacaine showed a significant longer duration compared to lignocaine. The neonatal outcome and the maternal outcome of labor was comparable between the groups with no significant difference noted. However, overall superior results were found with the 0.125 % bupivacaine with fentanyl compared to the 0.5% lignocaine with fentanyl combination. Both bupivacaine and lignocaine in combination with fentanyl was found safe and effective as epidural analgesia during normal delivery.

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