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Research Article

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Effect of Epidural Labor Analgesia on Maternal Physiology of Labor Using 0.125% Bupivacaine with 2 µg/mL Fentanyl

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Abstract: The pain in labor is arguably the most severe pain most women will endure in their lifetimes. Unrelieved labor pain produces many physiological changes which are detrimental to mother. Various methods have been used to alleviate this pain. It is now well recognized that the only consistently effective method of pain relief in labor is lumbar epidural analgesia. However, there are concerns regarding unintended adverse effects on the mother. Objective of the study was to assess the effects of epidural analgesia when compared with no pain relief during labor. 120 nulliparous women in term labor were assigned to the study and allocated into two groups. Parturients who request epidural analgesia were allocated in the epidural group, whereas those not, in non-epidural group. Epidural analgesia was provided with 0.125% bupivacaine with 2 mcg/ml of fentanyl using a top up dosage technique. Quality of pain relief by VAPS score, duration of the first and second stages of labor, usage of oxytocin, mode of delivery and maternal side effects if any were recorded. Epidural analgesia was found to offer better pain relief with good maternal satisfaction. However, it was associated with an increased risk of assisted vaginal birth and oxytocin administration with no significant variation in duration of labor and cesarean delivery. Epidural analgesia appears to be effective in reducing pain during labor and highest maternal satisfaction with pain relief. However, women who use this form of pain relief are at increased risk of having an instrumental delivery with no statistically significant impact on the risk of cesarean delivery.

Keywords: Epidural analgesia, Bupivacaine, Fentanyl.

INTRODUCTION

Labor pain ranks amongst the most severe form of pain, described as intolerable by a third of women .The ability to produce pain relief is desirable enough in its own right. Various methods have been tried since time immemorial to alleviate this pain. Pain during labor releases catecholamines & increased levels of catecholamine can also relax the uterus & prolong the duration of labor. Pain will produce maternal hyperventilation leading to hypocarbia & respiratory alkalosis. Hence an effective form of pain relief will help to hasten the stages of labor.

The lumbar approach to the epidural space for analgesia in labor was first used by Graffagnino and Seyler in 1938. In the next decade, Flowers and collegues recommended using continuous lumbar epidural analgesia with a catheter [1].

Among all the techniques available, the epidural method comes closest to the ideal in being effective in alleviating labor pain and in being safe for both mother and the foetus [2]. The concentrations of local anaesthetics initially used were high enough to cause motor blockade [3]. Concerns about this motor blockade and its effect in delaying the progress of labor has led to the use of low concentrations of local anaesthetics [5] which produce selective sensory blockade [6], thereby sparing the motor fibres. But the duration and quality of analgesia produced by only low concentrations of local anaesthetics was unsatisfactory. So their effect was potentiated by the use of adjuvant like adrenaline [6], clonidine [7] and opioids [6]. Among these, opioids are the most commonly used [6]. Formerly long acting opioids like morphine [2], pethidine [3], buprenorphine etc were used. As they were associated with significant respiratory depression and other complications, safer agents were investigated. The short-acting, lipophilic drugs like fentanyl and sufentanyl have lowered the incidence of these complications.

Epidurally administered fentanyl, in concentrations ranging from 2-4 mcg/ml, along with local anaesthetic agents, has been found to be effective in relieving the pain of labor for prolonged periods with good patient satisfaction and without any side effects like respiratory depression in the mother and fetus [7-11]. Fentanyl significantly reduces levobupivacaine requirements for epidural analgesia in labor [4]. But the use of more than 4 mcg/ml of fentanyl as an adjuvant to epidural local anaesthetics has been associated with significant side effects like pruritis and possible respiratory depression [12]. In view of this, the present study was undertaken to compare the clinical usefulness of a low concentration 0.125% bupivacaine with 2mcg/ml of fentanyl vs. no analgesia at all.

The present study was done with following objectives

- To study the incidence of instrumental or cesarean delivery and duration of first and second stage of labor.
- To assess the effect of pain relief by using epidural analgesia during labor.

EXPERIMENTAL SECTION

This comparative clinical study of epidural labor analgesia with 0.125% bupivacaine with 2mcg/ml fentanyl versus no analgesia was conducted in Department of Obstetrics and Gynecology in association with Department of Anesthesiology at Vani Vilas & Bowring and Lady Curzon hospital attached to BMCRI, Bangalore. Clearance was obtained from hospital ethics committee for the study, written informed consent was obtained from all the parturients. The study of 120 parturients in labor was included in the study.

Inclusion criteria

- Pregnant woman with regular antenatal visits (registered cases).
- Healthy primigravida at term with singleton pregnancy with vertex presentation.
- ASA I and ASA II.
- Maternal request for epidural analgesia.
- Age group 18-35 years.
- Women in active labor with cervical dilatation 3-4cm.

Exclusion criteria

- The woman refusing or withdrawing of consent.
- Parturient with gravid 2 or more.
- Parturients with multiple pregnancies
- Medical complications associated with pregnancy.
- Medical disorders complicating pregnancy.
- Cephalopelvic disproportion.
- History of ante partum hemorrhage.
- Defective hemostasis imposing an increased risk of epidural or spinal hematoma e.g. severe thrombocytopenia; coagulopathy; blood factor disorders; recent Heparin or Clexane.
- Parturients with spinal deformity, skin infections.
- History of allergy to local anesthetic.

A detailed history, complete physical examination and routine investigations were done for all parturients. Parturients were randomly selected and divided into 2 groups of 60 each.

Epidural group received Inj. Bupivacaine 0.125% and Inj. Fentanyl 2 μ g/ml. Non-epidural group received no analgesia at all.

The obstetric management was similar in both groups. Routine intra-partum management of all women included intravenous fluid management and continuous external electronic fetal heart-rate monitoring. Amniotomy is performed at admission as a part of active labor management if the fetal membranes were intact. The frequency and duration of uterine contractions were assessed with the cardiotocographic monitoring. Pelvic examination was performed every hour to evaluate the progress of labor. The aim was to produce a rate of cervical dilation of at least 1 cm/h. When the rate of dilation fell below this, coincidental with hypotonic uterine contractions, oxytocin is infused in a protocol starting at the equivalent of 6 mIU/min and increasing by 4 mIU/min every 15 min up to a maximum of 40 mIU/min until there are 7 contractions per 15 min. For accurate administration of oxytocin, we diluted 3 IU of oxytocin to 50 mL with 0.9% sodium chloride. This gives a solution containing 60 mIU/mL which, when infused at a rate of 1 mL/h, gives the patient 1 mIU/min of oxytocin. Oxytocin infusion is given through a separate line using a motor driven syringe pump. The decision to proceed to operative delivery was made according to maternal or fetal indications. The visual analogue pain scale (VAPS) [0-10scale: \leq =no pain, 4-6=moderate pain, >7 severe pain] was measured at the peak of contractions before and 5, 10, 20, and 30 min after the administration of the epidural analgesia and then at hourly intervals.

Labor analgesia technique

The parturient was positioned in a left lateral position with the help of an assistant. Under aseptic conditions the back was prepared with 5% povidine iodine solution, spirit and the area was draped. L2-L3 interspace was identified; skin was infiltrated with 1ml of 1% xylocaine. After preparation of the parturient and ensuring the necessary equipments the L2-3 interspace was chosen to perform the block. A skin wheal was raised in the midline over this space and the subcutaneous tissues were infiltrated with 1 ml of 2% lignocaine using a 23 G hypodermic needle. The epidural space was then identified with an 18G Touhy needle by loss of resistance technique using a 10 ml glass syringe with a freely moving plunger and appropriate epidural catheter was placed and catheter was secured in place by adhesive dressing. Test dose was given using 3ml of 1% lignocaine with adrenaline after confirming the position of the catheter in the epidural space, after 3min of observation, study drug-10ml of 0.125% bupivacaine with 2 mcg/ml of fentanyl

were injected through the catheter slowly.0.125% bupivacaine was prepared by diluting 5ml of 0.25% bupivacaine with 5ml of normal saline and to which 2 mcg/ml of fentanyl was added. After the injection, the parturient was turned on her back and left uterine displacement was provided using a wedge under the right buttock. Further boluses of 5 mL of the analgesic solution were given for breaking through pain.

Our primary outcome included the duration of labor, pain relief, mode of delivery whereas our secondary outcome included number of parturients receiving oxytocin and maternal satisfaction. The study ended at the time of vaginal delivery (spontaneous, instrumental, or with vacuum extraction), or when the decision was made to perform a cesarean delivery for any reason.

Statistical analysis

The observations recorded in each group were compared using statistical analysis. The raw data collected using the protocol was converted into grouped data by selecting appropriate class intervals meeting the objectives of the study. Percentages were calculated for the purpose of comparison between epidural and nonepidural group. The mean values and standard deviation were calculated by using the appropriate formulae both for grouped and ungrouped data. The difference in the mean values between epidural and non-epidural group was tested by t-test to find the statistical significance. Proportion test was also used for the purpose of analysis. The calculated values were compared with the table values for the corresponding degrees of freedom (n1+n2-2=30+30-2=58) at 5% or 0.05 level of significance (p values). p<0.05 was significant and p> 0.05 was not significant.

RESULTS

One hundred and twenty term nulliparous women in spontaneous labor were enrolled in this study (60 patients in each group). Parturients in both groups were comparable in terms of age, weeks of pregnancy, parity and stage of cervical dilatation at the time of entry into study (Table 1). All parturients included in the study were included in data analysis.

	Epidural group	Non-epidural group	P value
Age in yrs	25 (20-31)	26 (20-37)	NS
Height in cms	156 (5)	154(6)	NS
Weight at term	63 (8)	60 (7)	NS
Nulliparous	-	-	NS
Gestational age in weeks	37.99 ±0.68	38.01 ±0.77	0.82

 Table 1: Patient's demographic data (mean (SD or range) or number of patients)

Table 2: Labor characteristics (mean (SD or range) or number of patients):

	Epidural group	Non-epidural group	P value
Cervical dilatation in cms	3.4(0.9)	3.2(0.9)	NS
Oxytocin usage	80 (66.6%)	48(40%)	$X^2 = 13 P < 0.05 S$
First stage	81.3 (6.43)	83.4 (5.97)	p>0.10 NS
Second stage	38.76(14.47)	36.03(17.56)	p>0.10 NS
Total duration of labor	122.76(42.82)	119.43(42.14)	p=0.07 NS
Normal delivery	80(67%)	100(83.3%)	NS
Instrumental delivery	40(33.3%)	12(10%)	p<0.05

Administration of epidural analgesia with Inj. Bupivacaine 0.125% and Inj. Fentanyl 2 μ g/ml during labor did not significantly prolong the first or second stages of labor (p>0.10 NS) including total duration of labor (p=0.07 NS). There was a significant differences in percentages of subjects who received oxytocin $(p<0.05 X^2 = 13 S)$ with the maximal rate of oxytocin infusion being significantly higher in the epidural group compared with the non-epidural group. The rate of instrumental or vaccum-assisted deliveries were statistically high in epidural group (p<0.05) (Table 2).



Fig. 1: Pain rating by visual analogue scale



Fig. 2: Distribution based on maternal satisfaction after epidural labor analgesia

Epidural analgesia of Bupivacaine 0.125% with fentanyl 2 µg/mL produced effective analgesia during labor. The pain relief during labor assessed by parturients feedback method using visual analogue pain scale. VAPS reached zero level after 30 min and then was maintained at the same level throughout the study as was measured at hourly intervals. The upper level of sensory loss to cold was \geq T10. In epidural group 100% of women showed excellent analgesia. Whereas in non-epidural group 83.7% experienced severe pain and 16.3% experienced moderate pain.(X2 = 6.7 P=0.01 S) which was statistically significant (Fig. 1). 100% maternal satisfaction was seen for labor pain relief in epidural group (Fig. 2).



Fig. 3: Distribution based on complications/side effects to the parturient

Fig. 3 shows the complications/ side effects observed in epidural group of parturients. No complications or side effects were observed in the majority of parturients in both groups. However 26.67% of parturients in epidural group had nausea or vomiting. One parturient

in epidural group had pruritis which subsided spontaneously.

DISCUSSION

"Divine is the task of relieving pain" - Hippocrates

The ideal labor analgesic technique should be effective, safe for the mother and fetus, should be easy to administer, should provide consistent, predictable and rapid onset of analgesia in all stages of labor, should be devoid of motor blockade and should preserve the stimulus for expulsive efforts during the second stage of labor. It is now well recognized that the only consistently effective method of pain relief in labor is lumbar epidural analgesia [3]. Bupivacaine still remains the most often used local anesthetic in labor analgesia [16], various workers have used varying concentrations of bupivacaine. Undiluted bupivacaine(0.5%) was popular for initiation and maintenance of labor analgesia [3]. However, it caused dense motor blockade and interference with maternal awareness of contractions [3]. Despite providing excellent pain relief in labor, epidural analgesia using local anesthetics alone produce motor block in up to 85% of patients reduces maternal satisfaction with analgesia and is associated with a prolonged second stage and an increased incidence of instrumental delivery [7]. In an attempt to reduce the adverse effects of high concentrations of bupivacaine, adjuvants like fentanyl were added so as to decrease the maintenance concentration of bupivacaine from 0.5% to as low as 0.0625%.

Workers using 0.125% bupivacaine have noticed:

- Avoidance of significant motor blockade [13].
- Duration of second stage of labor was not prolonged [13, 17]
- No difference in the mode of delivery [18].

However, the use of low concentrations of bupivacaine provides sub-optimal, short-lived analgesia when used alone [15]. Epidural opioids offer the possibility of analgesia without motor block, but when used alone, do not provide satisfactory analgesia throughout labor. Addition of an opioid to local anesthetic solutions can provide effective analgesia with bupivacaine sparing and a reduction in motor block [7]. Addition of fentanyl, sufentanyl and adjuvants like adrenaline for extradural analgesia along with very dilute concentration of local anesthetics has allowed greater mobility and near normal somatic sensation [15].

The present study was undertaken to compare the effectiveness of epidural labor analgesia provided by using 0.125% bupivacaine with 2 mcg/ml of fentanyl.

Many workers have studied labor analgesia in latent phase at 3cm cervical dilatation. Here we included only parturients in active phase of labor at 3-4cm cervical dilatation. The effect of epidural analgesia on the duration of labor has been extensively studied in primiparous parturients with inconsistent results. Wideranging, it appears that it has no clear effect on the duration of the first stage, whereas the second stage is more constantly prolonged. The claimed association of epidural analgesia with prolonged delivery has long been attributed to motor blockade with concomitant weakness of pelvic floor muscles that reduces the effective maternal pushing and the involuntary bearing down reflex, however this is not the case when dilute anesthetics are used where motor blockade is minimal. Conversely, there is evidence to demonstrate that epidural analgesia may accelerate labor as the provision of effective analgesia reduces maternal catecholamines, and hence minimizing its inhibitory effect on uterine contractility [20]. In present study we studied duration of labor progress using partograph and did not find significant difference in first and second stage and of labor. However, the duration of second stage of labor was not allowed to prolong as oxytocin was used. In 10% of cases instrumental delivery was needed due to poor maternal bearing efforts due to lack of pain. Whereas Anim et al observed significant prolongation of second stage of labor [19].

The mode of delivery was spontaneous vaginal in most of the parturients i.e. 83.3% in epidural group, whereas 16.7% of parturients underwent instrumental delivery in the form of outlet forceps or ventouse application. None of the parturients needed cesarean section. This is similar to observations of Elliot who observed instrumental delivery in 60% and 8% in the bupivacaine alone and combination groups respectively [9]. James *et al.* [7] observed 25.7% and 5.7% rate of instrumental delivery in the bupivacaine alone and combination groups respectively used a 10cm or 100mm visual analogue scale to assess the quality of pain relief. In the present study we used visual analogue scale to assess pain rating.

Celleno et al. [21] seen complete pain relief (22.8% to 3.3%) which is similar to our study finding where all the patients had complete pain relief after epidural analgesia. Also we found significant association between epidural analgesia and the number of patients who required oxytocin augmentation during labor. Our results are supported by the findings of Anim *et al.* [19]. 70% of the parturients in epidural group did not experience any side effects. The most common side effect was nausea and/or vomiting with an incidence of 26.67% in the epidural group which is statistically significant (p<0.05). This concurs with the study by chestnut *et al.* [8] where they found an incidence of 18% and 24% in the bupivacaine alone and combination groups respectively.

Only one parturient experienced pruritis which subsided spontaneously. This is in contrast to various studies by Cohen *et al.* [14]. 26-32% and Chestnut *et al.* [8] (7-12%) who have observed a higher incidence of pruritis. Lyons et al have observed incidence of pruritis is not significant with 1, 2 and 3 mcg/ml of fentanyl [12]. And all parturients in epidural group experienced labor being more pleasant than terrified with epidural analgesia which concurs with various studies [9, 13, 19].

CONCLUSION

"The delivery of the infant into the arms of a conscious and pain free mother is one of the most exciting and rewarding moments in medicine" - Moir DD

A comparative study of lumbar epidural analgesia in labor using 0.125% bupivacaine with 2 mcg/ml Fentanyl showed that superior pain relief was one of the major advantages of epidural analgesia and was associated with increased maternal satisfaction. The onset of analgesia was rapid and duration of analgesia was longer in majority of parturients and few parturients needed top-up dosage. With significant increase in assisted vaginal births. The epidural analgesia appears to alter the dynamics of labor necessitating the use of oxytocin needs to be applied in practice. None of the included parturients reported any rare but serious adverse effects. There was no evidence of immediate effects on the baby; however, long-term consequences are still not known.

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