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Research Article

A clinical study of the effectiveness of continuous epidural labour analgesia for vaginal delivery with 0.0625% bupivacaine with 0.0002% fentanyl

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ABSTRACT

Background: Pain in labour is an extremely agonising experience for most women. Unrelieved labour pain produces many physiological changes which are detrimental to both the mother and the foetus. Various methods have been used to alleviate this pain. It is now well recognized that the only consistently effective method of pain in labour is lumbar epidural analgesia. Using a higher concentration of local anaesthetic agent to produce analgesia can be associated with undesirable side effects such as motor block, haemodynamic disturbances or interference with the progress of labour. Hence, various adjutants like adrenaline, clonidine and particularly opioids have been used to reduce the amount of local anaesthetics used and yet provide satisfactory analgesia. In view of the above, the present study assesses the clinical effectiveness of continuous lumbar epidural analgesia for vaginal delivery by using 0.0625% bupivacaine with 2µg/ml of fentanyl.
Methods: Forty parturient admitted to Chennai Medical College and Hospital, Trichy, for vaginal delivery and who were in active labor was given 8 ml of 0.0625% bupivacaine with 2µg/ml of fentanyl. The parturient were assessed with respect to onset and duration of analgesia, maximum level of analgesia, pain scores, homodynamic parameters, motor block, side effects, mode of delivery and neonatal outcome.
Results: The onset of analgesia was significantly faster in 0.0625% bupivacaine with 0.0002% fentanyl (9.7 minutes). A greater proportion of parturient achieved a maximum level of analgesia unto T8. The duration of analgesia was also significantly longer. The effectiveness of analgesia was better. There were no significant cardiovascular changes or any motor blockade. The side effects were mild sedation and in the parturient who received fentanyl. The mode of delivery and the Apgar scores of the neonates at 1 and 5 minutes were comparable.
Conclusions: It was concluded that continuous lumbar epidural analgesia with 8 ml of 0.0625% bupivacaine with 2 µg of fentanyl improved the quality and duration of analgesia without producing any adverse effects on the mother or on the neonate.

Keywords: Epidural analgesia, Obstetric analgesia, Bupivacaine, Fentanyl, Labour pain

INTRODUCTION

Pain in labour is an extremely agonising experience for most women. Various methods have been tried since time immemorial to alleviate this pain. However, this endeavor did not receive much support till the late 19th century, with analgesia for labour being opposed for both medical and religious reasons. It was also believed that

pain had a biological value and attempts to abolish it would be detrimental to both the mother and the foetus. However, the recognition of various physiological disturbances that can occur due to unrelieved labour pain brought about a change in this thinking. In view of this, the concept of labour analgesia came to be widely accepted.

Objectives

1. To assess the effectiveness of lumbar epidural analgesia for vaginal delivery using 0.0625% bupivacaine and 0.0002% fentanyl.
2. To assess the maternal hemodynamic status, pain scores and neonatal outcome.

METHODS

This clinical study of epidural labour analgesia for vaginal delivery with 0.0625% bupivacaine with 2µg/ml of fentanyl using continuous lumbar epidural technique was conducted on 40 parturients in Chennai Medical College & research centre, Trichy, after obtaining permission from the Ethical Committee. Only those parturient who fulfilled the following criteria were chosen for the study

Inclusion criteria:

1. All mothers had undergone routine antenatal checkups and all antenatal investigations were within normal limits.
2. They were aged 18 years or above and were more than 150 cm tall.
3. They were either primigravida or gravida 2.
4. The presentation was a singleton, term foetus with vertex presentation.
5. They were in active labour with a cervical dilatation between 4-6 cm.
6. Effacement >50%.
7. Willingness of epidural.
8. ASA I-ASA II.
9. Weight up to 80Kg

Exclusion criteria:

1. The mothers had co-existing diseases like gestational diabetes, pregnancy induced hypertension, bronchial asthma, epilepsy, ischemic or valvular heart disease or previous Caesarean section.
2. Patient refusal
3. Mutiparous
4. Short stature
5. Weight >85Kg
6. Obstetric complication
7. Coagulation abnormality

Performing the block

The parturient was placed in left lateral position. The back was cleaned with spirit and excess spirit was removed with a dry sponge. The back was then draped with a sterile towel.

The L3-L4 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 1ml of 2% lignocaine using a 23G hypodermic needle. The epidural space was then identified with an 18G Tuohy needle by loss of resistance technique using a 20ml glass syringe with a freely moving plunger.

After confirming the position of the needle in the epidural space by loss of resistance technique, catheter introduced 5cm into space and gently aspirated for blood or C.S.F .test dose of 3ml of lignocaine 2% with 15 mcg adrenalin was injected through the catheter. After negative observation for intravascular or subarachnoid placement the catheter was secured and the patient then shifted to labour room.

The initial bolus of 8 ml of study solution containing of 0.0625% bupivacaine with 2mcg /ml fentanyl was administered followed by continuous infusion of the same drug combination at a rate of 6 ml per hour. Vitals monitored and hypotension defined as a decrease of 20% from the base line was treated with ephedrine.

Bradycardia is treated with inj. atropine 0.6 mg i.v if require. After the injection, the parturient was turned to her back and left uterine displacement was provided using a wedge under the right buttock.

The following observations were recorded:

1. Time of onset of analgesia.
2. Level of sensory blockade.
3. Assessment of motor blockade.
4. Assessment of sedation.
5. Effectiveness of pain relief.
6. Duration of analgesia.
7. Assessment of cardiovascular status.
8. Complications/side-effects, if any.

Onset of analgesia

This was defined as the time interval from the time of epidural injection till the time when a sensory level of T12 was achieved.

Level of sensory blockade

The level of sensory blockade was assessed every 15 minutes using loss of sensation to pinprick in the midclavicular line bilaterally from the nipple to the pubic symphysis.

Assessment of motor blockade

Motor blockade was assessed after the epidural block as per the modified Bromage scale.

Score Description

- No motor blockade
- Unable to lift leg straight
- Unable to flex knees
- Unable to flex ankles.

Assessment of sedation

Sedation was assessed using a 5-point scale.

Score Description

- Wide awake
- Drowsy
- Dozing, eyes shut intermittently
- Asleep
- Unarousable

Effectiveness of pain relief

The effectiveness of pain relief was assessed using a verbal rating score.

Score Description

1. No relief When there was no relief of pain at all
2. Little relief when there was some relief but the parturient was still uncomfortable.
3. Much relief When there was only slight discomfort
4. Complete relief When there was no pain at all

Duration of analgesia

This was taken as the time interval from the onset of analgesia till the return of painful contractions or till regression of sensory level to below T12. The parturient were observed for 15 minutes after delivery to assess pain relief.

Assessment of cardiovascular status

Baseline values of maternal pulse rate and blood pressure were recorded. These parameters were again recorded after the epidural block, at every 2 minutes interval up to 20 minutes, then at the 30th minute and every 15 minutes thereafter till delivery or termination of the study. Foetal heart rate was continuously monitored using a cardiotocograph.

Side-effects of drugs/procedure

Incidence of hypotension, bradycardia, nausea, vomiting, pruritis, and drowsiness were observed and recorded. The progress of labour was observed closely after instituting epidural block.

The frequency and intensity of uterine contractions, dilation and effacement of the cervix, descent of the presenting part and foetal heart rate were assessed periodically by the obstetrician.

The requirement for instrumental deliveries or Caesarean section and the indications for the same were also noted. The foetal heart rate was monitored periodically. A rate of less than 100/minute was taken as bradycardia and a rate of more than 160/minute was taken as tachycardia.

At birth, the Apgar score of the neonate at 1 minute and 5 minutes was used to assess the neonatal well-being. Any neonate with an Apgar score of less than 7 was resuscitated with suctioning, mask ventilation and, if needed, intubation and ventilation with 100% oxygen and intravenous atropine and dextrose.

RESULTS

Forty parturients who were admitted to Chennai Medical College Hospital for expected vaginal delivery were studied. They received 0.0625% bupivacaine with 0.0002% fentanyl using a continuous lumbar epidural technique. They were then observed till the delivery of the foetus and the following observations were recorded.

Quality of analgesia

Quality of analgesia was assessed on the overall assessment of qualify of anaesthesia, the duration analgesia and the onset of analgesia.

Table 1: Maternal characteristic.

Age	**21.65 ± 3.42 (years)**
Height	152 ± 8.61 (cms)
Weight	54.15 ± 2.78 (kg)
Gestational age	38.45 ± 2.05 (weeks)
Cervical dilatation	3.3 ± 0.98 (cm)
Baseline VAS	8.05 ± 1.4

Table 2: Onset of analgesia.

Variable	Time in sec
Time of loss of sensation to pin prick	9.35 ± 1.72
Time of first painless contractions	10.81 ± 2.1

Mean time of onset of loss of sensation by pinprick was 9.35 ± 0.72 very much comparable to studies which used 0.0625 % bupivacaine with 0.0002% fentanyl for epidural labour analgesia.

Table 3: VAS score.

First stage	**2.4 ± 0.49**
Second stage	4.3 ± 0.37

The mean VAS score for the labouring parturient was 3.61 ± 0.66 where as for the 1st stage it was 2.4 ± 0.49 and for 2nd stage 4.3 ± 0.37.

Table 4: Episiotomy pain relief.

Grades	No of parturient	Percentage
0	30	75
1	6	15
2	4	10

75% of parturient experience no pain during labour and only 10% of parturient had unbearable pain that were supplemented with local infiltration for episiotomy.

Table 4: Global quality of analgesia.

Grades	No of parturients	Percentage
0	36	90
1	4	10
2	0	0

90 % of the parturient subjectively felt that they had better relief than expected. None of the patients experienced worst pain than expected.

Table 5: Height of sensory blockade.

Level	No of parturient	Percentage
> T 7	12	2.5
T 7 – T 10	39	97.5
< T 10	0	0

Average height of sensory blockade was between T_7-T_{10} in 97.5 % of the parturient. Only 1 parturient developed a sensory level higher than T_7.

Table 6: Ambulation /motor blockade.

Motor blockade	No of Parturient	Percentage
0 / ambulation	39	97.5
1	0	0
2	0	0
3	1	2.5

Only 1 parturient (2.5%) developed motor blockade of grade 3 bromage scale. 97.5 % of the parturient were able to successfully ambulate during their labour.

Maternal vital signs

Hemodynamically all the parturient were stable and changes in hemodynamic variables were not significant.

The mean total duration of the Labour was 247.5 ± 16.8 min and mean duration for First stage was 206 ± 23 min. the Second stage had a mean duration of 41.5 ± 10.8 min (Table 7).

Table 6: Maternal vital signs.

Variables	Mean
Pulse rate (per min)	106 ± 9.2
Respiratory rate (per min)	21.2 ± 1.8
SpO_2 (%)	98.8 ± 1.8
Systolic BP (mmHg)	119.5 ± 21
Diastolic BP (mmHg)	78.88 ± 7.9
MAP (mmHg)	81.6 ± 11.1

Table 7: Duration of labour (min).

First stage	**206 ± 23**
Second stage	41.5 ± 10.8
Total duration	247.5 ± 16.8

Table 8: Mode of delivery.

Mode	No of Parturient	Percentage
Natural	34	85
Outlet forceps	3	7.5
Low midcavity forceps	1	2.5
Caesarean section	2	5

85 % of parturient delivered naturally. 3 parturient (7.5 %) required assistance for delivery of child of these 3 parturient forceps assistance for delivery and 2 patients (5 %) had to undergo caesarean section.

Table 9: Maternal side effect.

Side effects	No of Parturient	Percentage
Dural puncture	1	2.5
Venous puncture	5	12.5
Pruritus	0	0
Nausea / Vomiting	0	0
Rigor	0	0
Sedation	3	7.5
Hypotension	0	0
Urinary retention	0	0
Respiratory depression	0	0

Venous puncture was common side effect seen in 5 (12.5%) parturient, next was sedation seen in 3 parturient (7.5%), Dural puncture seen in 1 parturient (2.5%).none of them developed hypotension or respiratory depression as a side effect.

2 neonates had an Apgar of <8 at 1 minute. Of these 2 neonates only one had an Apgar of <8 at 5 minutes.

Table 10: Fetal vital signs (min).

Fetal heart rate (per minute)	132.41

Table 11: Apgar score.

Time	Apgar Score	No of Babies
	8 to 10	38
5 minutes	< 8	1
	8 to 10	39

Table 12: Fetal complications.

Complication	No of babies
Bradycardia	0
Respiratory depression	0

Neither of these complications was noted in the neonates.

DISCUSSION

The ideal labour analgesic technique should be effective, safe for the mother and the foetus, should be easy to administer, should provide consistent, predictable and rapid onset of analgesia in all stages of labour, should be devoid of motor blockade and should preserve the stimulus for expulsive efforts during the second stage of labour.[1] It is now well recognized that the only consistently effective method of pain relief in labour is lumbar epidural analgesia.[1]

Previously, the local anesthetics bupivacaine, lidocaine and 2-chloroprocaine were used to provide epidural labour analgesia.[1] Administration of local anaesthetics was by intermittent boluses or continuous infusions set at predetermined rates. However, some of the patients studied received larger doses of local anaesthetic than was needed for maternal comfort.[2] More local anaesthetic can produce more motor and sympathetic blockade. Impairment of uterine blood flow during labour is an important cause for foetal asphyxia and neonatal morbidity.[3] The current study was undertaken to assess the efficacy of continuous lumbar epidural technique using a 0.0625% bupivacaine with 0.0002% fentanyl in a low concentration.

Bupivacaine still remains the most often used local anaesthetic in labour analgesia.[4] Various workers have used varying concentrations of bupivacaine. Undiluted bupivacaine (0.5%) was popular for initiation and maintenance of labour analgesia.[5] However, it caused dense motor blockade and interference with maternal awareness of contractions.[5] Despite providing excellent pain relief in labour, epidural analgesia using local anaesthetics alone produces 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.[6] 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 0.0625% bupivacaine have noticed:

- Avoidance of significant motor blockade.[7]
- Duration of second stage of labour was not prolonged.[7,8]
- No difference in the mode of delivery.[9]

However, the use of low concentrations of bupivacaine provides sub-optimal, short-lived analgesia when used alone.[4] Epidural opioids offer the possibility of analgesia without motor block, but when used alone, do not provide satisfactory analgesia throughout labour.[10] Addition of an opioid to local anaesthetic solutions can provide effective analgesia with bupivacaine sparing and a reduction in motor block.[10] Addition of fentanyl, sufentanil and adjuvants like adrenaline for extradural analgesia along with very dilute concentration of local anaesthetics has allowed greater mobility and near normal somatic sensation.[4]

Lyons et al. demonstrated that the optimal dose of fentanyl may be 3µg/ml for labour analgesia.11 Most workers have used 2µg/ml of fentanyl with a local anaesthetic.[7,8,10]

Commencing epidural analgesia during early labour can cause:

- Slowing or arrest of labour necessitating the use of oxytocin.
- Motor paralysis of the pelvic and abdominal muscles resulting in lack of internal rotation and insufficient bearing down force.
- Absence of Ferguson reflexes.
- Increased risk of hypotension.
- Accumulation of local anaesthetic in the maternal and foetal blood.
- Unpleasant subjective awareness of numbness and paralysis by the mother.[8]

Most workers have commenced epidural analgesia when the cervical dilation was 3 cm or more. In the present study, the epidural analgesia was instituted with cervical dilation being between 4- 6cm.

All parturients were preloaded with 500ml of Ringer's lactate solution before establishing the block, in order to decrease the incidence of hypotension following sympathetic blockade.

Dosage-concentration in the present study

Bupivacaine 0.0625% with 0.0002% fentanyl was used for this study. The reason behind using this concentration was based on following studies.

With the above concentration, 97% were ambulant as per the study of David H. Chestnut et al & 93% were ambulate as per study of Jaime Fernandez-Guisasola et al.[7,12]

Onset of analgesia

Onset of analgesia has been defined by various authors as:

- time taken for achieving a verbal rating score of 3 or 4.7
- time taken for 50% reduction in VAS score.4
- time taken to achieve a dermatomal level of T12.

In our study time of onset of analgesia was taken as the time interval from time of epidural injection till the time when a sensory level of T12 was achieved.

In the present study, the mean onset of analgesia time was 9.35 ± 1.72 minutes. The average onset time of 6 minutes noticed by Mc Morland et al.[13]

Level of sensory blockade

The upper level of sensory block was assessed by using loss of sensation to pinprick in the midclavicular line, bilaterally from the nipple downwards. Adequate epidural analgesia in the first stage of labour requires afferent sympathetic block to the level of tenth thoracic dermatome. In the present study, the upper level of sensory block in most of the parturients was T7-T10 (97.5%) in these groups. Jaime Fernandez-Guisasola et al. shows upper level of sensory block in most of the parturient as T8 (T7-T9).[12]

This was comparable to the level achieved by Owen et al.[14] This concurs with the studies of Bleyaert et al. and James et al. who have used 0.125% and 0.1% bupivacaine respectively in their studies.[10,15]

Quality of analgesia

Most workers have used a 10cm visual analogue scale to assess the quality of pain relief.

In the present study, verbal rating score has been used to assess the quality of pain relief. 85% of parturients experienced complete pain relief. None of the parturient experienced worst pain than expected. The parturient that experienced some pain were those in whom Labour progressed so fast that adequate blockade of sacral analgesia hadn't occurred by them.

K. S. James et al. observed 69% of parturient experienced pain free contraction by using 0.1% bupivacaine with fentanyl 50 µg/ml by 30mins.[10] Khan et al. observed pain relief in first stage is 91.3% and second stage is 69.6%.[16] The study of Eddleston et al. who used 0.25% bupivacaine and found satisfactory analgesia in 95.4% of parturients.[17]

Episiotomy pain relief

In this study 75% had no pain at all during episiotomy and only 10% patient had intolerable pain.

David H. Chestnut et al. in their study demonstrated that 20-30% of the patient needed additional local infiltration for pain relief during episiotomy while using 0.0625% bupivacaine with 0.0002% fentanyl.[8]

Motor blockade

Motor blockade was assessed using the modified Bromage scale. In the present study only one parturient developed motor block was accidental dural puncture had occurred so 97.5% of parturient were allowed to ambulate after epidural performed.

This concurs with the studies of Cohen et al. (who found minimal or absent motor block in all groups). Mild motor blocked (grade 0 to 1) was observed by David H. Chestnut et al in their study where they used an infusion of 0.0625% bupivacaine with 0.0002% fentanyl. Russel and Reynolds et al. in their study parturient who received an infusion of 0.0625% bupivacaine with 0.0002% fentanyl, twenty Percentage of parturient were unable to raise their leg. Mild motor blockade (grade 0 to 1) was observed by Owen et al. in their study where they used an infusion of 0.125% bupivacaine. Elliott observed motor blockade in 50% of parturient with the use of 0.25% bupivacaine.[7-9,14,18,19]

The use of a small volume of a low concentration of bupivacaine has probably prevented motor block in any parturient in this study.

Sedation

Sedation was assessed using a 5 point scale from wide awake to unarousable. In the present study, 7.5% of parturient experienced mild sedation i.e. scores of 1. Gautier et al observed that pain relief was associated with light sedation in 35% of patients.[20]

Cardiovascular status assessment

Cardiovascular assessment included monitoring of maternal heart rate and blood pressure. The values were recorded prior to the institution of the epidural block (i.e. baseline value) and then at every 2 minute interval for the first 20 minutes, at the 30th minute and every 15 minutes thereafter till delivery or the termination of the study.

Hypotension after epidural analgesia depends on:

- Total dose and concentration of bupivacaine.
- Maximum level of sympathetic blockade.

- Presence or absence of preloading.
- Position of the patient

In the present study, hypotension has been taken as systolic blood pressure less than 90 mm Hg. No parturient in this group experienced any hypotension. Using continuous epidural analgesia with 0.0625% bupivacaine -0.0002% fentanyl David H. Chestnut shows no patients had hypotension. Jaime Fernandez-Guisaola et al. observed the incidence of hypotension to be 4% by using 0.0625% bupivacaine with 0.0002% fentanyl. Using continuous epidural analgesia with 0.125% bupivacaine, Bleyaert et al. observed the incidence of hypotension to be 10%. Owen et al. found hypotension in 25% of parturient receiving bupivacaine, which responded well to treatment. Cohen et al. found hypotension in 5-11% of patients receiving fentanyl along with bupivacaine. [7,12,14,15,18]

There was no incidence of bradycardia in the present study. The maternal heart rate ranged from 79±12 to 98±13 beats per minute as observed by Finegold et al.[21]

Side effects

In the present study, parturient experienced dural puncture 2.5% & venous puncture 12.5%. Chestnut et al found common side effect nausea/vomiting an incidence of 18% and 24% in the bupivacaine alone and combination groups respectively. David H C. Chestnut et al shows incidence of side effect pruritus (22%), nausea (27%), and emesis (7%).[7,8]

Various studies by Cohen et al. (26-32%) and Chestnut et al (7-12%) have observed a higher incidence of pruritus. Lyonset al. have observed that the incidence of pruritis is not significant with 1 µg/ml, 2 µg/ml and 3 µg/ml of fentanyl.[8,11,18]

Mode of delivery

In the present study the mode of delivery was about 85% of the parturient (35 patients) was delivered spontaneously, 10% of parturient (4 patients) underwent instrumental delivery in the form of outlet forceps application & 5 % (2 patients) of the parturient needed cesarean section.

This is similar to the observations of David H. Chestnut who observed spontaneous delivery 59%, instrumental delivery 29% & cesarean section 10%, in his study. James et al. observed 5.7% rate of instrumental delivery, 17%cesarean section in this groups. David H. Chestnut et al shows 60% of spontaneous delivery, 15% cesarean section. Khan et al. shows 8% of cesarean section. Jaime Fernandez-Guisasola et al. shows 5.8% cesarean delivery, 11.8% of forceps delivery.[7,8,10,12,16]

Neonatal outcome

The mean APGAR score in the present study was 8 at 1 minute and 10 at 5 minutes. This is similar to the study of Meister et al. who found that 84% of neonates at 1 minute had scores >8 and 96% of neonates at 5 minutes had scores more than 9 while using a combination of bupivacaine and fentanyl.[22] Elliott found that addition of 4µg/ml of fentanyl did not affect the neonatal outcome and that 90% of neonates at 1 minute and 100% at 5 minutes had scores >7.9.

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