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Original Research Article

The effects of epidural analgesia in normal labour

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ABSTRACT

Background: Epidural analgesia is considered to be gold standard technique for labour analgesia but is claimed to prolong labour. Previous studies have evaluated epidural analgesia versus systemic opioids to no analgesia. The present study evaluated the effect of epidural analgesia on duration of labour compared to no analgesia.
Methods: Sixty primigravida with full term-singleton, vertex presentation in spontaneous labour were included in the study. Parturient willing for epidural analgesia were allocated as epidural group (n=30), rest served as control. The intervention in active stage of labour included 10 ml of Inj. Bupivacaine 0.125% and Inj. Fentanyl 100µg and maintenance with infusion of Inj. Bupivacaine 0.125% and Inj. Fentanyl 2µg/ml added at a rate of 6-8 ml/hr. Duration of the first two stages of labour, patient satisfaction, side effects, number of instrumental vaginal/ vacuum-assisted deliveries, and neonatal APGAR score were recorded.
Results: The mean duration of first stage of labour was shorter in epidural group (250.17±106.33 minutes) compared with control (302.00±111.99 minutes), (p= 0.071). The mean duration of second stage in epidural group was (18.73±6.82 minutes) compared with control (18.33±14.53 minutes) was not significant (p= 0.892). Although instrumental vaginal delivery rate was greater in the epidural group (6.7%) as compared to control (3.3%), (p=1.000). Pain score (VAPS) varied between1-3 and 4-10 in epidural group and control respectively (p< 0.001). The APGAR scores at 5 min and neonatal ICU admissions were statistically comparable.
Conclusions: Epidural analgesia with Bupivacaine and Fentanyl results in good pain relief with undue prolongation of labour.

Keywords: Bupivacaine, Epidural analgesia, Fentanyl, Labour, Nulliparous, Parturient

INTRODUCTION

The pain of child birth is the most severe pain, most women will undergo in their lifetimes. The American college of obstetricians and gynecologists (ACOG) states: 'Labour results in severe pain for many women. There is no other circumstance where it is considered acceptable for a person to experience untreated severe pain, amenable to safe intervention, while under a physician's care'. In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labour.[1]

Safe fetal outcome without any adverse maternal effect is the chief goal of pain relief during labour, and epidural analgesia is the most efficient and widely employed modality for this.[2]

Numerous strategies, both pharmacologic and non-pharmacologic, have been used as treatment of labour pain.[3] Neuraxial blockade techniques are accepted as the gold standard for intrapartum labour analgesia. Multiple randomized controlled trials comparing epidural analgesia with systemic opioids, nitrous oxide, or both

have demonstrated lower maternal pain scores and higher maternal satisfaction with neuraxial analgesia.[4]

The management of epidural analgesia during labour has changed over the past two decades. The addition of neuraxial opioids (such as fentanyl) to local anesthetics allow adequate labour analgesia with very dilute solutions of local anesthetics, thus minimizing potential adverse effects on the progress of labour and lower extremity motor block.[5]

The present study evaluated the effect of epidural analgesia on duration of labour compared to no analgesia in normal labour.

METHODS

A prospective clinical comparative observational study with convenient sampling study protocol was developed in collaboration with anesthesiologists at Department of Obstetrics and Gynecology, P.E.S. Institute of Medical Sciences and Research, Kuppam and approved by the Institutional Human Ethics Committee (IHEC). Sixty parturients who presented in spontaneous labour were enrolled in the study after a written informed consent was signed.

Inclusion criteria

- Pregnant women consenting for participating in the study
- Singleton pregnancy with vertex presentation
- Gestational age from 37 - 41 weeks
- Hb% ≥ 9gm/dl
- Women in active stage of labour (cervical dilatation >4cm)
- Normal fetal heart rate pattern status
- American Society of Anesthesiologists (ASA) physical Status I or II, and request for analgesia.

Exclusion criteria

- Patient refusal
- Multiparity
- Gestational age of <37 weeks or >42 weeks
- Cervical dilatation of <4cm
- Pregnancy with other co-morbid conditions
- Patients with any evidence of fetal distress or abnormal heart rate pattern
- ASA status >II
- Medical disorders complicating pregnancy like diabetes, hypertensive disorders of pregnancy etc.
- Untreated coagulopathy or patient on any anticoagulant therapy, Neurologic or neuromuscular diseases
- Infection at the injection site or systemic sepsis
- Allergy to local anesthetics
- Defective haemostasis imposing an increased risk of epidural or spinal haematoma e.g. severe thrombocytopenia; coagulopathy; blood factor disorders; recent Enoxaparin (Clexane)
- Suspicion of fetal malformation or intrauterine fetal growth retardation
- Fever of more than 38°C
- Patients who underwent caesarean section (e.g., descent arrest) for any reason during delivery were excluded from the study.

Parturients (n=30) who desired epidural analgesia were allocated in the first group (epidural group), whereas those (n=30) who were not enthusiastic to labour analgesia were allocated in the second group (control). Maternal oxygen saturation (SpO2), heart rate, automated non-invasive blood pressure and continuous fetal heart rate were monitored throughout the course of labour. The obstetric management was similar in both groups.

The progress of labour was recorded on WHO Modified Partograph. Routine intrapartum management of all women included intravenous fluid management and continuous external electronic fetal heart-rate monitoring. The frequency and duration of uterine contractions were assessed with the cardiotocographic monitoring. Pelvic examination was performed every 2nd hourly to evaluate the progress of labour. The aim was to produce a rate of cervical dilation of at least 1 cm/hour. The decision to proceed to operative delivery was made according to maternal or fetal indications.

Epidural solution preparation

Loading dose was prepared using a 10 ml syringe with 2.5 ml of 0.5% Inj. Bupivacaine, 100µg (2ml) of Inj. Fentanyl and diluted to 10 ml using 0.9% NaCl (Normal saline). This preparation results in 0.125% Inj. Bupivacaine and 100µg of Inj. Fentanyl added. Epidural infusion was prepared using a 50 ml syringe with 12.5 ml of 0.5% Inj. Bupivacaine, 100 µg (2 ml) of Inj. Fentanyl added and diluted to 50 ml using 0.9% NaCl.

In the epidural group, patients were preloaded with 500 ml of lactated Ringer's solution. Under a strict aseptic precaution with patient in the left lateral decubitus position, L1-L2 space was identified. Skin was infiltrated with 3ml of 2% Inj. Lignocaine. Epidural space was approached with 18G epidural needle by loss of resistance to saline technique. An 18-gauge epidural catheter was threaded and placed 5cms in the epidural space and secured appropriately.

The parturient was then positioned supine with left uterine displacement. At 4 cm cervical dilatation and upon request for labour analgesia, 10 ml of Inj. Bupivacaine 0.125% with Inj. Fentanyl 100 µg was injected as bolus to achieve a bilateral block at ≥T10 sensory level. Once the epidural analgesia was established, continuous infusion of 0.125% Inj. Bupivacaine with Inj. Fentanyl 2µg/ml added at a rate of 6-8 ml/hour of the analgesic solution was started to

maintain labour analgesia. Further bolus of 5 ml of the analgesic solution was administered for break through pain.

Hypotension (SBP <100 mmHg or a 20% reduction from baseline) was treated with additional left uterine displacement, maternal oxygen administration, IV fluid bolus, or IV ephedrine as indicated. The visual analogue pain scale (VAPS) [0–10 mm scale: 0=no pain, 10=worst pain ever] 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.

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 the knee, 4=detectable weakness of hip flexion, 5=no detectable weakness of hip flexion while supine with full flexion of knees) were recorded after administering epidural drug preparation and at 30 minutes and again at hourly intervals. In the control group, if any parturient requested analgesia, 100 mg of I.M. Inj. Tramadol was administered.

The primary outcome of the study included pain management, satisfaction with birth experience, duration of labour, adverse effects associated with the use of epidural for the management of labour pain. The secondary outcome included the mode of delivery (spontaneous, instrumental or vacuum), 1-min and 5-min neonatal APGAR scores. The study ended at the time of vaginal delivery (spontaneous, instrumental, or with vacuum extraction), or when the decision was made to perform a caesarean delivery for any reason.

Statistical analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven1s test to assess the homogeneity of variance has been used. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small. The Statistical software namely SPSS 18.0, and R environment version 3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

Sixty term nulliparous women in spontaneous labour were enrolled in this study (30 patients in each group). Parturients in both groups showed similarity in demographic and obstetric data.

No parturient in either group was initially included and later excluded because of pain or any other reason and they continued to stay in the study group.

Table 1: Mean scores of age (years) distribution in two groups of patients studied.

Age in yea	Group I	Group II	Total
18-20	12 (40%)	14 (46.7%)	26 (43.3%)
21-25	14 (46.7%)	14 (46.7%)	28 (46.7%)
26-30	3 (10%)	1 (3.3%)	4 (6.7%)
>30	1 (3.3%)	1 (3.3%)	2 (3.3%)
Total	30 (100%)	30 (100%)	60 (100%)
Mean±SD	21.73±3.20	21.53±3.01	21.63±3.09

The study group comprised 60 nulliparous parturients. Age of the patient varied between 18 and 32 years in epidural group and between 18 and 33 years in control group with mean age of 21.73±3.20 and 21.53±3.01 years respectively (Table 1).

Gestational age of the patient varied between 37- 41 weeks in epidural group and between 38 - 40 weeks in control group with mean gestational age of 39.19±1.01and 39.56±0.81 weeks respectively (Table 2). Both groups were similar in obstetric and maternal demographic character like age and gestational age.

Table 2: Mean scores of Gestation Age (weeks) distribution in two groups of patients studied.

Gestation Age (weeks)	Group I	Group II	Total
37-39	16 (53.3%)	7 (23.3%)	23 (38.3%)
39-40	8 (26.7%)	15 (50%)	23 (38.3%)
>40	6 (20%)	8 (26.7%)	14 (23.3%)
Total	30 (100%)	30 (100%)	60 (100%)
Mean±SD	39.19±1.01	39.56±0.81	39.37±0.93

The mean duration from the time of 4cm to full dilatation (Active stage of labour) was significantly shorter in epidural group (250.17±106.33 min) compared with control group (302.00±111.99 min) (P = 0.071) (Table 3).

Table 3: Mean scores of gestation age (weeks) distribution in two groups of patients studied.

Active stage (minutes)	Group I	Group II	Total
<200	10 (33.3%)	3 (10%)	13 (21.7%)
200-400	17 (56.7%)	21 (70%)	38 (63.3%)
>400	3 (10%)	6 (20%)	9 (15%)
Total	30 (100%)	30 (100%)	60 (100%)

P=0.071*, Significant, Fisher Exact Test

There was no statistically significant difference in the mean duration of second stage of labour in epidural group (18.73±6.82 min) compared with control group (18.33±14.53 min) (P= 0.892) (Table 4).

Table 4: Mean scores of second stage (minutes) distribution in two groups of patients studied.

Second stage (minutes)	Group I	Group II	Total
<15	8(26.7%)	15(50%)	23(38.3%)
15-30	21(70%)	11(36.7%)	32(53.3%)
>30	1(3.3%)	4(13.3%)	5(8.3%)
Total	30(100%)	30(100%)	60(100%)

P=0.033*, Significant, Fisher Exact Test

The mean duration of first stage of labour was shorter in epidural group (250.17±106.33 minutes) compared with control group (302.00±111.99 minutes) (p=0.071), while there was no significant prolonged duration of second stage of labour (18.73±6.82 minutes) as compared to control (18.33±14.53 minutes) (p=0.892) 6z (Table 5).

Table 5: Comparison of duration of active stage/Second stage in two groups of patients studied.

In minutes	Group I	Group II	Total	P value
Active stage	250.17 ±106.33	302.00 ±111.99	276.08 ±111.7	0.071
Second stage	18.73 ±6.82	18.33 ±14.53	18.53 ±11.25	0.892

Although, the number of instrumental deliveries (forceps or vacuum assisted deliveries) looked to be greater in epidural group (6.7% patients in the epidural group versus 3.3% in the control) but it was not statistically significant (P= 1.000). Administration of epidural analgesia with 0.125% Inj. Bupivacaine with Inj. Fentanyl 2 µg/ml during labour did not significantly prolong the active or second stages of labour (P=0.071 and 0.892 respectively). The rates of instrumental or vacuum-assisted deliveries were not statistically different between the two groups (Table 6).

Table 6: Comparison of mode of delivery in two groups of patients studied.

Mode of delivery	Group I	Group II	Total
Forceps	2 (6.7%)	1 (3.3%)	3 (5%)
Vaginal	28 (93.3%)	29 (96.7%)	57 (95%)
Total	30 (100%)	30 (100%)	60 (100%)

P=1.000, Not Significant, Fisher Exact Test

Although, there was motor block in two patients (6.7% with modified Bromage score of 3) in epidural group. Resolution of the sensory and motor block was complete within 1 hour after delivery and discontinuing the epidural infusion and was not statistically significant (P= 0.492). No other side effects were seen (Table 7).

Table 7: Comparison of Side effects in two groups of patients studied.

Side effects	Group I	Group II	Total
Nil	28 (93.3%)	30 (100%)	58 (96.7%)
Motor block	2 (6.7%)	0 (0%)	2 (3.3%)
Total	30 (100%)	30 (100%)	60 (100%)

Epidural infusion with 0.125% Inj. Bupivacaine and Inj. Fentanyl 2 µg/ml produced effective analgesia during labour. VAPS reached between level 0-3 within 5 minutes and then maintained at the same level throughout the study as was measured at hourly intervals. The epidural infusion was maintained at a rate of 6-8 ml/hour. No patient in the epidural group requested supplementary analgesia. Two patients in the epidural group developed motor block (6.7% of patients had modified Bromage score of 3).

Resolution of the sensory and motor block was complete within 1 hour after delivery and discontinuing the epidural infusion. No other significant differences were detected regarding other side effects between the two groups. Pain score of the patient varies between 1 to 3 in epidural group and between 4 to 10 in control group, which is highly significant showing good pain relief (P <0.001) (Table 8).

Table 8: Comparison of pain score in two groups of patients studied.

Pain Score (VAPS)	Group I	Group II	Total
0	0 (0%)	0 (0%)	0 (0%)
1-3	30 (100%)	0 (0%)	30 (50%)
4-6	0 (0%)	25 (83.3%)	25 (41.7%)
7-10	0 (0%)	5 (16.7%)	5 (8.3%)
Total	30 (100%)	30 (100%)	60 (100%)

P<0.001**, Significant, Fisher Exact Test

Patient satisfaction is good to excellent with epidural group showing good satisfaction with birth experience, which will not be achieved without analgesia (Table 9).

The number of neonates that presented with APGAR scores below 7 at 1 and 5 min (P=0.306, P=1.000 respectively) were not statistically different between the two groups (Table 10).

Birth weight of the baby varies between 2.2 - 3.7 kg in epidural group and between 2.2 - 3.8 kg in control group with mean birth weight of 2.85±0.39 and 2.75±0.38 kg respectively (P=0.295) (Table11).

The rate of neonatal ICU admissions was lower in epidural group (13.3%) compared to control group (16.7%) (P=0.143) (Table 12).

Table 9: Comparison of pain score in two groups of patients studied.

Patient satisfaction	No. of patients	%
Fair	4	13.3
Good	11	36.7
Excellent	15	50.0
Total	30	100.0

Table 10: Comparison of baby APGAR scores (1 and 5 minute) in two groups of patients studied.

Baby APGAR	Group I (n=30)	Group II (n=30)	Total (n=60)	P value
1 min				
1-3	2 (6.7%)	0 (0%)	2 (3.3%)	0.306
4-6	3 (10%)	6 (20%)	9 (15%)	
7-10	25 (83.3%)	24 (80%)	49 (81.7%)	
5 min				
1-3	0 (0%)	0 (0%)	0 (0%)	1.000
4-6	2 (6.7%)	2 (6.7%)	4 (6.7%)	
7-10	28(93.3%)	28(93.3%)	56(93.3%)	

Table 11: Comparison of mean birth weight (kg) distribution in two groups of patients studied.

Birth weight (kg)	Group I	Group II	Total
<2.5	4 (13.3%)	5 (16.7%)	9 (15%)
2.5-3.5	25 (83.3%)	24 (80%)	49 (81.7%)
>3.5	1 (3.3%)	1 (3.3%)	2 (3.3%)
Total	30 (100%)	30 (100%)	60 (100%)
Mean±SD	2.85±0.39	2.75±0.38	2.80±0.38

P=0.295, Not Significant, Student t test

Table 12: Comparison of admission in NICU distribution in two groups of patients studied.

NICU	Group I	Group II	Total
Nil	26 (86.7%)	25 (83.3%)	51 (85%)
Perinatal asphyxia	3 (10%)	0 (0%)	3 (5%)
Perinatal depression	1 (3.3%)	2 (6.7%)	3 (5%)
Respiratory distress	0 (0%)	3 (10%)	3 (5%)
Total	30 (100%)	30 (100%)	60 (100%)

P=0.143, Not Significant, Fisher Exact Test

DISCUSSION

Epidural analgesia provides significantly analgesia, as measured by VAS in both the first and second stage of labour than parenteral opioid.[6]

In current study, epidural analgesia was given in active stage of labour (when cervical dilatation is 4 cm). ACOG recommends that "when feasible obstetrician should delay the administration of epidural analgesia in nulliparous parturients until the cervical dilatation reaches at least 4 cm.[7]

Short duration of first stage may be because of better analgesia with epidural resulting to decrease inhibitory effect of catecholamines on uterine contractility hence faster cervical dilatation. With combined spinal-epidural (CSE), and its resultant benefits of decreased motor block, a study demonstrated a decreased duration of first-stage labour with CSE compared to conventional epidural analgesia.[8]

Prolonged labour seems to occur more frequently when a higher dose of local anesthetic agent is used.[9] 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 negligible.[10-12]

The instrumental delivery rate is yet another important outcome measure, as the procedure increases the risk of maternal perineal trauma, and adverse neonatal outcomes in cases of difficult delivery. It must be noted that results are often affected by multiple confounding factors, such as the neuraxial analgesic technique, method of epidural analgesia maintenance, local anesthetic concentration, degree of analgesia during second stage of labour and obstetric factors.[13] Instrumental births declined over time (Table 13), this indicate the strength of association between epidural analgesia and instrumental birth may reflect improved epidural techniques and management of epidural labour.[14]

However, authors found that the incidence of instrumental delivery was not significantly different (Epidural, 6.7% versus without epidural, 3.3%). This was in contrast to earlier studies which reported higher rates of instrumental delivery in epidural compared to parenteral opioids or entonox. It is doubtful whether local anesthetic epidural analgesia would harm neonates. Our results demonstrated no significant difference in neonatal outcome between the epidural and the control groups.15 This was indicated by the normal APGAR score for the neonates. This was in agreement with the results of Liu et al, who performed meta-analysis of 7 randomized controlled trials comparing low concentration epidural

infusions with parenteral opioids.[15] Controversially, other studies demonstrated abnormal neonatal outcome after local anesthetic epidural analgesia, which could be explained by the use of higher equipotent anesthetic concentrations than present study.[16]

Table 13: Effect of epidural analgesia on duration of first and second stages of labour and on mode of delivery in other studies.

Author	No. of patients	First stage with epidural	Second stage with epidural	Instrumental delivery with epidural	Conclusion
Anwer et al	100	Prolong	Prolong	-	Epidural analgesia does prolong the duration of second stage of labour and increases the instrumental delivery rate. Neonatal outcome is satisfactory, with few intra-partum complications
Agrawal D et al	120	Short	Prolong	No difference	No increase in instrumental vaginal or caesarean delivery rate in the epidural group. Patient satisfaction is good to excellent. The APGAR scores at 5 min were comparable
Anim-Somuah et al	9658	-	Prolong	Higher	Epidural analgesia reduces pain during labour, but there is increased need for instrumental delivery. There was no statistically significant impact on the risk of caesarean section, maternal satisfaction with pain relief and long-term backache and did not appear to have an immediate effect on neonatal status as determined by APGAR scores.
Mousa et al	160	No effect	No effect	No difference	Epidural analgesia does not prolong labour compared with parturients without analgesia
Fyneface-Ogan et al	50	Short	Short	-	The epidural analgesia group was satisfied with the experience of labor than those who did not receive analgesia or those who received parenteral opioids/sedative.
Nafisi S et al	395	No effect	No effect	No difference	Epidural analgesia with 1% lidocaine does not prolong the first and second stages of labor and does not increase vacuum-assisted or cesarean delivery rate.
Wong et al	750	Short	No effect	-	Neuraxial analgesia in early labor did not increase the rate of cesarean delivery, and it provided better analgesia and resulted in a shorter duration of labor than systemic analgesia.

Although many studies, have compared two different methods of labor analgesia with regard to maternal, obstetric, and neonatal outcomes, there is only one trial done by Morgan et al, that compared epidural with no form of analgesia.[17] It was designed for primiparous women who underwent early obstetric analgesia using concentrate anesthetics that have affected, to a great extent, the motor power with its possible drawbacks on labour outcomes.[18] To authors knowledge, this is the first controlled trial conducted to evaluate the effect of dilute epidural analgesia on the duration of labour and maternal and neonatal outcome, compared with a group not receiving any sort of analgesia.

In the current study, epidural analgesia by bupivacaine with fentanyl is associated with shorter duration of first stage of labour in epidural group as compared to control group. There is no significant difference in second stage of labour in epidural group as compared to control.

Many studies have found that epidural analgesia as compared with systemic opioid analgesia or no analgesia is associated with a prolonged first stage of labour while some studies showed no effect on first stage. Several retrospective studies consistently demonstrated an association between epidural analgesia and increased durations of second stages of labour, but few randomized, prospective studies could not find any significant relation regarding the effects of epidural analgesia on the duration of labour as compared to non-epidural analgesia (Table 13).

Present study lacked the double blinding methodology, as it was impossible to blind the clinician or the parturient. However, we would not expect the results to be biased, as there was tremendous consistency with the protocols. Other criticism could be the ethical conduct of labour without any sort of analgesia. However, this was

completely left to the patient to decide without any persuasion on the need of analgesia.

CONCLUSION

In conclusion, the mean duration of first stage of labour was shorter in epidural group (250.17±106.33 minutes) compared with control group (302.00±111.99 minutes) while there was no significant prolongation of second stage of labour (18.73±6.82 minutes) as compared to control (18.33±14.53 minutes). Although, the number of instrumental deliveries (forceps or vacuum assisted deliveries) looked to be greater in epidural group (6.7% patients in the epidural group versus 3.3% in the control) but it was not statistically significant (P= 1.000). Pain score of the patient varies between 1 to 3 in epidural group and between 4 to 10 (VAPS) in control group, which is highly significant showing good pain relief (P <0.001). The number of neonates that presented with APGAR scores below 7 at 1 and 5 min were statistically similar between the two groups. Epidural analgesia during labour using Bupivacaine (0.125%) with Fentanyl 2 μg/ml is not associated with prolongation of the first two stages of labour and has good pain relief and good patient satisfaction with birth experience.

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