

EFFICACY OF EPIDURAL ANALGESIA DURING LABOUR

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Summary

Although labour is considered as a normal physiological process, it can produce significant pain, requiring appropriate pain management. A painful labour also had detrimental effects on the mother and fetus. Ideal labour analgesia technique should dramatically reduce the pain of labour, while allowing the parturient to actively participate in birthing experience and have minimal adverse effects on the fetus and progress of labour. Epidural analgesia and opioids are often used for management of labour pain. Epidural analgesia is an effective method for managing labour pain. Studies have indicated that the procedure has few contraindications and few side-effects. The study was done to see the efficacy and safety of epidural analgesia with conventional analgesia (Inj. Pethidine and phenergan) during labour. In this study, pregnant women with active labour (Cervical dilation 4cm) were grouped into two A & B. Group A received epidural analgesia (0.125% Bupivacaine & 50 microgram Fentanyl) & group B received conventional analgesia (Inj. Pethidine & phenergan). Then the subjects were followed up and outcomes were recorded in a preformed data collection sheet. All data were analyzed by computer based software SPSS version 15. The study demonstrated a significantly earlier onset of effective analgesia in epidural group than that in the conventional

group. The pain score at onset of analgesia and at different time intervals following induction and at the time of delivery were appreciably lower in women receiving epidural analgesia than those receiving conventional analgesia ($p < 0.001$). There was no significant difference between epidural and conventional groups in terms of complications like nausea and/or vomiting ($p = 0.431$), prolonged 2nd stage of labour ($p = 0.127$), mode of delivery (Normal / Instrumental / Cesarean) ($p = 0.455$). Neonatal outcome was evaluated in terms of APGAR score at 1 & 5 minutes of birth in both groups which showed no significant differences ($p = 0.401$ and $p = 0.536$ respectively). So, epidural analgesia is an effective analgesia during labour.

Key words

Epidural analgesia; Labour pain; Active labour; Prolonged labour; Instrumental delivery.

Introduction

Labour is a normal physiological process but is usually associated with pain and discomfort. Pain relief is an integral part of labour management. Obstetric analgesia is essential not only for patient's comfort but also for fetomaternal safety, as pain associated physiological responses are potentially harmful for the fetus [1]. Numerous methods are used to relieve labour pain. These include pharmacological and non-pharmacological methods of pain management. Of the pharmacological agents, epidural analgesia and opioids are commonly used. However, controversy surrounds about these two methods regarding the maternal and perinatal outcome following analgesia [2].

Epidural analgesia is the most effective method for the control of labour pain, remains the patient to be fully awake and participating in all aspects of the birthing process [3]. It allows emergency caesarean section to be performed without recourse to spinal or general anesthesia [4]. It did not have any adverse effects on the foetal outcome. But irregularities of analgesia, toxicity of Local Anesthetics (LA) are the major limitations.

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Some retrospective studies have demonstrated that epidural analgesia impedes the progress of labour and increasing operative delivery rates [5,6,7]. Evidence is unclear as previous reviews have included disparate regimens for epidural analgesia and women of mixed parity [8,9,10]. On the other hand, studies have suggested that intramuscular pethidine provides little pain relief in labour and has a number of side effects affecting mother and neonate. It can cause nausea, vomiting in mothers, reduced fetal heart rate variability and accelerations and neonatal respiratory depression. There is few study comparing the relative side effects and efficacy of epidural analgesia and conventional analgesia with Inj pethidine-phenergan for labour pain management in our country and there is no study in Chittagong Medical College Hospital, although the number of primi patients delivered there in 2012 were 7369[11]. So the present study is deemed essential to popularize the epidural analgesia among the obstetrician in our country for the management of labour pain.

Materials and methods

It was a Randomized Controlled Trial done in Obstetrics and Gynaecology Department of Chittagong Medical College Hospital in one year from October 2012 to September 2013. Total 80 Pregnant women with labour pain admitted in the Department of Obstetrics and Gynaecology were included in the study who were primigravida, Gestational age of greater than 37 weeks (Confirmed by ultrasound), having no obstetric risk factors, spontaneous onset of labour, established labour (Cervical dilation >4cm with regular uterine contraction) and with cephalic presentation. The pregnant women in labour with active maternal hemorrhage or coagulopathy, maternal septicemia or febrile illness, infection at or near needle insertion site were excluded from the study.

The sample size was determined using formula for hypothesis testing for two proportions. Assumed that epidural analgesia would cause a significant reduction of labour pain intensity in 80% of the patients, while the conventional (Inj. Pethidine- phenergan) method would cause reduction of pain intensity in 60% of the patients [12]. Randomization was done by the rule of odds and even i.e. all odds cases were given epidural analgesia and even cases received conventional analgesia.

To prepare for the administration of epidural analgesia informed consent was obtained from the selected women. An intravenous line was inserted. Each patient was positioned on her side or in a sitting position and was connected to a blood pressure monitoring device. Then the area was cleaned with an antiseptic solution, lumbar epidural punctures were performed at the L₃₋₄ interspace using a midline approach with an 18-gauge Tuohy needle. Once the needle was appropriately placed in the epidural space, a 20-gauge multi-orifice epidural catheter (Minipack, Portex Ltd, Kent, UK) was threaded 3 cm into the space through the cranially directed tip of the needle. Having confirmed a negative aspiration test for blood or cerebrospinal fluid, 3 mL of 2% Lidocaine with epinephrine 5ug/mL was injected through the needle as a test dose. The patients were observed for any increase in heart rate and were questioned about dizziness, tinnitus, metallic taste in the mouth or sudden warmth or numbness in the legs. If these response were negative after 5 minutes, 10mL of 0.125% Bupivacaine and 50 g Fentanyl was injected via the epidural catheter. The catheter was taped in place along the patient's back with the end over her shoulder for easy retrieval when further doses (5ml) were required. To prepare for the administration of conventional analgesia informed written consent was obtained from the selected women. Inj. Pethidine is available in our country in ampoule containing 100mg (2ml), Inj. Phenergan is available in ampoule containing 50mg (2ml) and Pethidine antidote (Inj. Naloxone) is also available in ampoule containing 0.4mg (1ml). The area (upper & outer aspect of arm –the Deltoid muscle) was cleaned with an antiseptic solution. Though the standard dose of pethidine is 1mg /kg body wt but this study used 75mg of pethidine and 25mg of phenergan for patient weight <70kg and 100mg of pethidine and 25mg of phenergan for patient weight >70kg which was administered through a 5cc disposable syringe as a single dose during active labour. The effectiveness of epidural and conventional analgesia were assessed at 5,10,15,20 &30 minutes interval for onset of analgesia and then assessed hourly till delivery with Visual Analog Scale (VAS). All the variables were recorded on data collection sheet.

Visual Analog Scale (VAS) is a simple and efficient method for measuring intensity of pain which is used in this study. The VAS is a 10 Cm horizontal line where 0 means no pain and 10 mean worst pain and 1 to 9 indicates progressive severity. The selected women of this study were informed about the VAS scale and asked to point her pain on the scale based on severity and the score was recorded on data-sheet.

Data processed and analysed by using statistical software SPSS (Statistical Package for Social Sciences) version 15 (Chicago, Illinois). The test statistics used to analyze data were Student's t-test (For comparison of data presented in quantitative scale-age, parity, gestational age), Chi-square Test or Fisher's Exact Probability Test (For comparison of data presented in categorical scale- outcome in both groups). Statistical significance was set at p-value < 0.05 and confidence interval set at 95% level.

Results

The present study intended to assess the efficacy and safety of epidural analgesia with conventional analgesia during labour. The main purpose of the study was to compare the efficacy of the two modalities in reducing intensity of labour pain. The findings of the study derived from data analysis are documented below:

Table I shows the comparison of baseline characteristics between epidural and conventional analgesia groups. The two groups were almost identical with respect to maternal and gestational age (p = 0.127 and p = 0.454 respective).

Pain was monitored hourly after onset of analgesia and it was recorded in the data-sheet Pain score from onset of analgesia up to delivery was observed to be significantly lower in epidural group than the conventional group. (Fig 1).

There was no significant difference between the epidural and Conventional analgesia groups in term of complications like Nausea /Vomiting (p=0.431) Prolonged 2nd stage of labour (p=0.127). Hypotension and Duration of 1st stage of labour were not affected in either group (Table II).

Majority of the patients in either group have had normal delivery. The difference between the two groups in terms of their mode of delivery was insignificant. (p=0.455) (Table III).

Neonatal outcome was evaluated in terms of APGAR score at 1 and 5 minutes of birth in both groups which showed no significant differences (p = 0.401 and p = 0.536 respectively) (Table IV).

Table I : Comparison of baseline characteristics between the study groups

Baseline characteristics	Group		p-Value
	Epidural (n=40)	Conventional (n=40)	
Maternal Age (Years)	24.1 ± 2.3	24.4± 1.6	0.127
Gestational Age (Weeks)	38.9 ± 4.9	39.5 ± 1.3	0.454

Data were analysed using Student's t-Test and were presented as mean ± SD.

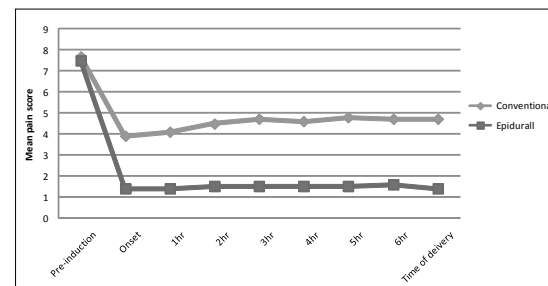


Figure 1 : Changes in pain score following epidural and conventional analgesia

Table II : Comparison of maternal complications between the study groups

Complications	Group		p-Value
	Epidural (n=40)	Conventional (n=40)	
Nausea/Vomiting*	0 (0.0)	3 (7.5)	0.431
Prolonged 2 nd stage of labour*	4 (10.0)	0 (0.0)	0.127

Figures in the parentheses denote corresponding percentage.

*Data were analysed using Fisher's Exact Test.

Table III : Comparison of mode of delivery between the study groups

Mode of delivery	Group		RR	P value
	Epidural (n=40)	Conventional (n=40)		
Normal	34 (85.0)	34 (85.0)	1	
Caesarean	2 (5.0)	5 (12.5)	0.4	0.455
Instrumental (Forceps/Ventouse)	4 (10.0)	1 (2.5)	0.86	

Figures in the parentheses denote corresponding percentage.

Data were analysed using χ^2 Test.

Table IV : Comparison between foetal outcome with epidural and conventional groups

Fetal outcome	Group		p-Value
	Epidural (n=40)	Conventional (n=40)	
APGAR score at 1 minute	7.9 \pm 0.7	7.8 \pm 0.8	0.401
APGAR score at 5 minutes	8.5 \pm 0.6	8.3 \pm 0.6	0.536

Figures in the parentheses denote corresponding percentage.

Data were analysed using Fisher's Exact Test.

Discussion

The present study intended to assess and compare the efficacy and safety of epidural and conventional analgesia on primigravidae women with established labour demonstrated a significantly earlier onset of analgesia in epidural group than that in the conventional group. The pain score at onset of analgesia and at different time intervals after induction of analgesia and at the time of delivery were appreciably lower in women receiving epidural analgesia indicating that drastic reduction of pain intensity and maintenance of the low intensity of pain up to delivery were successfully achieved in epidural group, where as conventional analgesia group failed to reduce the pain intensity to a tolerable level.

Thus, the primary objective of managing labour pain was achieved with epidural analgesia. Consistent with findings of our study, Sharma and colleagues reported that women who received epidural analgesia had lower pain scores during labour and delivery compared to women who received intravenous meperidine analgesia [13].

In terms of secondary objective like maternal and neonatal complications, the epidural analgesia was considered safe and favourable. None of the women receiving epidural analgesia experienced nausea and/or vomiting, where as 3 (7.5%) of the conventional group have had the condition. Ullman and associates reported pethidine provides little pain relief in labour and had a number of side effects affecting mothers and neonates [14]. It can cause nausea, vomiting, drowsiness in mothers and reduce foetal heart rate variability and accelerations. Neonatal effects include respiratory depression and impaired feeding.

In our study Prolonged 2nd stage of labour was observed in 4 (10.0%) cases of epidural analgesia group compared to none in the conventional group (p=0.127). Rate of caesarean section 2(5.0%) in epidural and 5(12.5%) in conventional group (RR 0.4) instrumental delivery (Forceps/Ventouse) were 4 (10.0%) in epidural group & one (2.5%) in conventional group (RR 0.86) which is insignificant in terms of their mode of delivery (p=0.455). Sharma and associates reported that a significantly higher proportion of women randomized to epidural analgesia encountered forceps deliveries due to prolonged 2nd stage of labour compared to meperidine analgesia (13% vs 7%) with adjusted odds ratio being 1.86 (p< 0.001) which was not consistent with our findings where instrumental delivery due to prolong 2nd stage of labour were more in epidural group than conventional group but not significant [13]. Epidural analgesia may increase the risk of instrumental delivery by several mechanisms. Maternal efforts at expulsion can be impaired, causing foetal malposition during descent. Sharma did not find any difference in the rate of cesarean deliveries between epidural and intravenous meperidine analgesia (10.5% vs 10.3%) with adjusted odds ratio being 1.04 (p=0.920) which is also consistent with our findings [13]. The causes of cesarean deliveries in both groups in our study were foetal distress. The

causes of foetal distress in epidural group were due to obstetrical ones like cord around the neck or strong uterine contractions but not as a direct result of epidural like maternal hypotension etc. In pethidine group the causes of foetal distress were not only the obstetrical ones but also associated with pain related physiological responses. Liao and associates when compared with placebo or opioids, women receiving epidural analgesia had more instrumental vaginal births and caesarean sections for foetal distress, although there was no difference in the rates of caesarean section overall [15].

In Jone's study it was observed that women receiving epidural analgesia were more likely to experience hypotension and fever although none of these side-effects was evident in the present study [16]. Finally, a recent study conducted in Pakistan reported that epidural analgesia did not have any adverse effects on the neonatal outcome which was also consistent with our study [17].

The investigators, in general, are of the opinion that epidural analgesia is effective in reducing pain during labour. Epidural analgesia had maternal satisfaction with pain relief and no statistically significant impact on the risk of prolonged 2nd stage of labour, instrumental delivery rate, caesarean section rate and did not appear to have an immediate effect on neonatal status. Further research may be helpful to evaluate rare but potentially severe adverse effects of epidural analgesia on women in labour and long-term neonatal outcomes.

Conclusions

From the findings of the study, it can be concluded that epidural analgesia with Bupivacaine plus fentanyl induces a much earlier onset of analgesia than does the conventional analgesia with pethidine-phenergan injection.

The intensity of pain is dramatically reduced to a tolerable level following epidural analgesia and is maintained at this level up to delivery which in the conventional analgesia is not attained.

There was no significant difference between the epidural and conventional analgesia in terms of maternal complications (Nausea / Vomiting / Hypotension, Prolonged 2nd stage of labour, Caesarean section rate and rate of Instrumental delivery) and neonatal outcome.

Recommendation

In the light of the findings of the present study and discussion thereof, the recommendations are put forward.

- 1) Further trials with large sample-size should be undertaken to come to a unanimous conclusion about the two modalities of pain management in labour.
- 2) Long term follow up studies are also needed to assess maternal and fetal well being.

Disclosure

All the authors declared no competing interest.

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