EPIDURAL VERSUS OPIOID ANALGESIA FOR PAIN RELIEF IN LABOUR : A COMPERATIVE STUDY

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Abstract

Backgroud : Pain management is an universal concern for women during labour. Ideal labour analgesia should effectively reduce the pain and have minimal adverse effects on the fetus and progress of labour. **Materials and methods :** The present cross sectional comparative study was carried out in the Department of Obstetrics and Gynecology, Chittagong Medical College Hospital (CMC&H) between January 2014 and July 2014 to compare the efficacy and safety between epidural analgesia and opioid analgesia on nulliparous women in labour. In this study, study population were Pregnant women with labour pain admitted in the Department of Obstetrics and Gynaecology, CMC&H. Samples were selected following inclusion and exclusion criteria. Then randomization was done to divide them in groups, group A & B each having 40 patient. Group A received epidural analgesia at the L3-4 interspace with 0.125% Bupivacaine 10 ml and Fentanyl 50 mg & group B received opioid analgesia (Inj. Pethidine and Phenargon). Then the subjects were followed up and outcome were recorded in a preformed data collection sheet. All data were analyzed by computer based software SPSS version 15. Quantitative data was analyzed by Student's t- test. Categorical variables were analyzed by Chi square (χ^2) test & Fisher's Exact Test. **Results :** Statistical significance was set at P value less than <0.05 and confidence interval set at 95% level. The two groups were almost identical with respect to maternal age, gestational age and pre-induction pain score (p = 0.127, p = 0.454 and p = 0.186 respectively). The onset of analgesia in epidural group was significantly earlier than that in the opioid group. The pain score at onset and at different time intervals following induction and at the time of delivery were appreciably lower in women receiving epidural analgesia with Bupivacaine 0.125% and Fentanyl than those receiving opioid analgesia with Pethidine & Phenargon injection (p < 0.001). In terms of the complications like nausea and/or vomiting there was no significant difference between the epidural and the opioid groups (p = 0.431). Four (10.0%) patients in the epidural group experienced prolonged 2nd stage of labour compared to none in the opioid group (p = 0.027). Majority of the patients in either group have had normal delivery. Only 2 (5%) patients in the epidural group and 5 (12.5%) in the opioid group required caesarean delivery and 4 (10.0%) patient in the former group and 1 (2.5%) patient in later group required instrumental delivery (p = 0.455). Fetal distress was primarily the indication for caesarean delivery in either group (p = 0.310). Instrumental delivery in the epidural group was required due to prolonged 2nd stage of labour and in opioid group due to fetal distress in 2nd stage of labour (p = 0.027). No significant differences was observed between the epidural and opioid analgesia groups in terms of APGAR scores at 1 and 5 minutes of birth (p = 0.401 and p = 0.536 respectively). **Conclusion :** The study concluded that epidural analgesia with Bupivacaine induces a much earlier onset of analgesia than does the opioid analgesia with Pethidine & Phenargon injection. The intensity of pain

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was dramatically reduced to a tolerable level following epidural analgesia and was maintained at this level up to delivery. There was no significant difference in complications between the epidural and opioid groups.

Keywords
Labour Pain; Epidural analgesia; Opioid analgesia; VAS pain scale.

Introduction

Labour analgesia is an integral part of labour management. Ideal labour analgesia should effectively reduce the pain of labour as well as ensure feto-meternal safety[1]. There are many methods to serve this purpose. These include pharmacological and non-pharmacological methods. Of the pharmacological agents, epidural analgesia and opioids are commonly used.

Epidural analgesia is a central nerve block technique achieved by injection of a local anesthetic close to the nerves that transmit pain and is widely used as a form of pain relief in labour. This procedure makes the woman more comfortable during labour keeping fully awake and participating in all aspects of the birthing process[2]. Epidural anesthesia done by a team of an experienced anesthetist, a dedicated obstetrician and a trained mid-wife can convert the painful labour into a less stressful event[3]. It allows emergency caesarean section to be performed under same setting without further spinal or general anesthesia[4]. Though it is one of the most effective lobour analgesia method irregularity of analgesia, toxicity of Local Anesthetics (LA) are the major limitations. However some authors reported that epidural analgesia impedes the progress of labour and increase operative delivery as well as cesarean section rates[5-7]. But evidence is unclear as previous reviews have included disparate regimens for epidural analgesia and women of mixed parity[8-10]. Epidural dose is often reduced in the second stage of labour with the intention of improving maternal expulsive efforts and decreasing the need for Instrumental Vaginal Delivery (IVD)[11].

On the contrary, intramuscular Pethidine provides insufficient pain relief in labour and has a number of side effects affecting mother and neonate. It causes nausea, vomiting in mothers and reduced fetal heart rate variability and accelerations. Neonatal effects include respiratory depression[12].

In Chittagong Medical College Hospital the number of prime patient delivered in 2013 were 7369[13]. And labour pain management was widely performed with inj. Pethedine & Phenargon. Epidural analgesia was also used as a technique of providing pain relief in labour in some cases. But there are few studies evaluating the side effects and efficacy of epidural analgesia in pain management in labour. So the present study is to find whether epidural analgesia is safe and effective during labour. This study will facilitate a better understanding about the management of labour pain. The data generated from the proposed study might help the obstetrician to decide which modality of labour pain management will be appropriate in a particular case of pregnant woman in labour.

Materials and methods

This cross sectional comparative study was carried out in the Department of Obstetrics and Gynecology, Chittagong Medical College Hospital (CMCH) over a period of six month between January 2014 to June 2014. The study population were all pregnant women with labour pain admitted in the Department of Obstetrics and Gynaecology, CMCH.

Inclusion criteria

i) Primigravida patients
ii) Gestational age of greater than 37 weeks (Confirmed by ultrasound)
iii) Having no obstetric risk factors
iv) Established labour (Cervical dilation > 3 cm with regular uterine contraction) and with cephalic presentation.

Exclusion criteria

i) Active maternal hemorrhage or coagulopathy
ii) Maternal septicemia or febrile illness
iii) Infection at or near needle insertion site

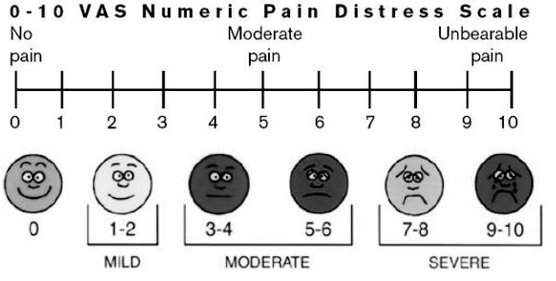
A total of 80 patients were recruited to test the hypothesis. These patients were then divided equally into two groups (Each group comprising with 40 patients) using random allocation procedure (Lottery method). A written informed consent was obtained from all the patients.

The selected women for the administration of epidural analgesia after securing an intravenous line was positioned on her side or in a sitting position and the area was cleaned with an antiseptic solution, lumbar epidural punctures were performed at the L_{3-4} 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 following equipments were available, a blood pressure monitoring device, oxygen, epidural insertion equipment, fetal monitor and additional intravenous fluid. The patients were also mounted for heart rate & was assessed 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 50µg 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 were required. The effect of epidural analgesia was assessed at half an hour interval till delivery additional doses of anesthetic were injected if needed.

The women selected for giving opioid analgesia got 75mg of Pethidine and 25mg of Phenergan for patient weighing <70kg and 100mg of pethidine and 25mg of Phenergan for patient weighing >70kg. A single dose of drug was given intramuscularly during active labour.

Intensity of pain was measured on a 0 – 10 Visual Analogue Scale (VAS), where 0 means no pain and 10 means worst pain, while 1 to 9 indicates progressive severity. A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure amount of pain. Operationally a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end, as illustrated in Figure. The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in millimeters from the left hand en d of the line to the point that the patient marks.



The patient was asked to point her pain on the scale based on severity and the score was recorded on data-sheet. The pain was monitored at half-hourly interval up to the time of delivery.

Data were processed and analyzed using statistical software SPSS (Statistical Package for Social Sciences) version 16 (Chicago, Illinois). The test statistics used to analyses 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). For all analytical tests the level of significance was 0.05 and p-value < 0.05 was considered significant.

Results

In this study a total of 80 term, primigraviada women with established labour and were included and were randomly assigned to epidural analgesia group (Receiving Bupivacaine 0.125% and fentanyl) and opioid analgesia group (Receiving pethidine-phenargon injection). The findings of the study derived from data analysis are documented below:-

Table I : Comparison of baseline characteristics between the study groups

Baseline characteristics#	Group Epidural (n = 40)	Opioid (n =40)	p-value
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.

Table II : Comparison of analgesia between the study groups

Analgesia	Group Epidural (n = 40)	Opioid (n =40)	p-value
Time to onset of analgesia# (min)	12.3 ± 2.5	26.5 ± 4.0	< 0.001
Effective analgesia* VAS (0-2cm)	37(92.5)	4(10.0)	< 0.001

* Data were analyzed using c^2 Test figures in the parentheses denote percentage
#Data were analyzed using Student's t-Test and were presented as mean ± SD.

Table III : Changes in pain score following epidural and opioid analgesia

Intensity of pain[#] (VAS 0-10 cm) Pain score	Group Epidural (n = 40)	Opioid (n =40)	p-value
Pre-induction	7.5 ± 1.7	7.7 ± 1.5	0.186
At onset of analgesia	1.4 ± 0.2	3.9 ± 0.6	< 0.001
0.5 hr after induction	1.4 ± 0.1	4.1 ± 0.9	< 0.001
1 hrs after induction	1.5 ± 0.3	4.5 ± 0.6	< 0.001
1.5 hrs after induction	1.5 ± 0.2	4.7 ± 0.7	< 0.001
2 hrs after induction	1.5 ± 0.1	4.6 ± 1.1	< 0.001
2.5 hrs after induction	1.5 ± 0.4	4.8 ± 2.4	< 0.001
3 hr after induction	1.5 ± 0.1	4.7 ± 2.9	< 0.001
3.5 hrs after induction	2.0 ± 0.3	4.7 ± 2.9	< 0.001
4 hrs after induction	1.4 ± 0.4	4.7 ± 2.9	< 0.001
4.5 hrs after induction	1.5 ± 0.3	4.8 ± 2.8	< 0.001
5 hrs after induction	1.5 ± 0.2	5.1 ± 2.8	< 0.001
5.5 hrs after induction	1.5 ± 0.3	5.1 ± 2.8	< 0.001
6 hrs after induction	1.5 ± 0.2	5.3 ± 2.7	< 0.001
At the time of delivery	1.5 ± 0.2	5.3 ± 2.7	< 0.001

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

Table IV : Comparison of maternal complications between the study groups

Complications	Group Epidural (n = 40)	Opioid (n =40)	p-value
Nausea/Vomiting*	0(0.0)	3(7.5)	0.431
Prolonged 2nd stage of labour*	5(12.5)	0(0.0)	0.027

Figures in the parentheses denote corresponding percentage;
*Data were analysed using Fisher's Exact Test.

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

Mode of delivery	Group Epidural (n = 40)	Opioid (n = 40)	p-value
Normal	34 (85.0)	34 (85.0)	
Caesarean	2 (5.0)	5 (12.5)	0.455
Instrumental (forceps/Ventouse)	4 (10.0)	1 (2.5)	

Figures in the parentheses denote corresponding percentage;
Data were analyzed using χ^2 Test.

Table VI : Comparison between fetal outcome with epidural and Opioid

Fetal outcome	Group Epidural (n = 40)	Opioid (n =40)	p-value
APGAR score at 1 minute	7.9 ± 0.7	7.8 ± 0.8	0.401
APGAR score at 5 minute	8.5 ± 0.6	8.3 ± 0.6	0.536

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

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

Table II shows Maternal outcome in terms of analgesia demonstrates that a significantly earlier onset of analgesia was observed in epidural group than that in the opioid group (p < 0.001). Majority (92.5%) of the epidural group exhibited effective analgesia throughout the period of labour as compared to only 10% of the opioid group (p < 0.001).

TableIII shows Pain score at onset of analgesia was lower in the epidural group than that in the opioid group (p < 0.001). Pain score at different time intervals from onset of analgesia up to delivery was observed to be appreciably lower in the former group than those in the latter group (p < 0.001) at all level of evaluation.

Table IV shows complications like nausea and/or vomiting were completely absent in the epidural group as opposed to 7.5% in the opioid group (p = 0.431). Duration of Ist stage of labour was not affected in either group. Five (12.5%) patients in the epidural group and none in opioid group experienced prolonged 2nd stage of labour (p = 0.027).

Table V shows majority of the patients in either group have had normal delivery. Only 2 (5.0) patients in the epidural group and 5 (12.5) in the opioid groups required caesarean delivery. Five patients in the epidural group (12.5%) and one (2.5) in the opioid group required instrumental delivery (Forceps/Ventouse). The difference between the two groups in terms of their mode of delivery was insignificant (p=0.455).

Table VI shows neonatal outcome was evaluated in terms of APGAR score at 1 and 5 minutes of birth. There were no significant differences between the epidural and opioid analgesia groups in terms of APGAR scores at 1 and 5 minutes of birth ($p = 0.401$ and $p = 0.536$ respectively).

Discussion

Among 80 patients the two groups were almost identical in respect to maternal age, gestational age and pre-induction pain score ($p = 0.127$, $p = 0.454$ and $p = 0.186$ respectively). The onset of analgesia in epidural group was significantly earlier than that of opioid group which is similar to observations in Cochrane Database Systemetic Review 2000 by Howell CJ[10]. The pain score at onset and at different time intervals after induction and at the time of delivery were appreciably lower in women receiving epidural analgesia than those receiving opioid analgesia (With Inj. pethidine-phenargon). 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[14]. Another large trial with 992 nulliparous women, Dickinson JE and colleagues reported that epidural analgesia had lower pain score than continuous midwifery support (Supplemented by intramuscular meperidine, nitrous oxide inhalation, or nonpharmacologic methods of pain relief)[15].

Epidural analgesia was considered safe and favorable in terms of maternal and neonatal complications . None of the women receiving epidural analgesia experienced nausea and/or vomiting, where as 3 (7.5%) of the opioid 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[16]. It can cause nausea, vomiting and dysphoria in mothers and reduce fetal heart rate variability and accelerations. Neonatal effects include respiratory depression and impaired feeding. In the opioid group respiratory depression (In terms of low APGAR score) was not observed in our study. However, a recent study conducted in the United Kingdom with Intramuscular Diamorphine demonstrates that diamorphine provides better analgesia with fewer side effects in mothers and neonates[12].

In the present study Prolonged 2nd stage of labour was observed in 4(10.0%) cases of epidural analgesia group compared to one in the opioid group ($p=0.027$). Rate of caesarean section 2(5.0%) in epidural and 5(12.5%) in opioid group instrumental delivery (Forceps/Ventouse) were 4 (10.0%) in epidural group to one (2.5%) in the opioid group which is statistically insignificant. Sharama also 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 ($p = 0.920$)[14]. Sharma and associates reported that a significantly higher proportion of women randomized to epidural analgesia encountered forceps deliveries compared to meperidine analgesia (13% vs 7%) with adjusted odds ratio being 1.86 ($p < 0.001$) and epidural women had prolonged second stage of labour which was not consistent with our findings where instrumental delivery due to prolong 2nd stage of labour were more in epidural group than opioid group but not significant[14]. Liao and associates when compared with placebo or opioids, women receiving epidural analgesia had more instrumental vaginal births and caesarean sections for fetal distress, although there was no difference in the rates of caesarean section overall[17]. 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[18]. A recent study conducted in Pakistan reported that epidural anesthesia did not have any adverse effects on the fetal outcome[19].

Conclusion

The key findings of the study is that epidural analgesia with Fentanyl plus B-Bupivacaine induces a much earlier onset of analgesia, reduces the intensity of pain to a tolerable level and maintains at this level up to delivery with fewer side effects like maternal nausea and or vomiting .

Recommendation

Further study in more centers with large sample-size should be undertaken. 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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