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Original Research Article.

A Study to Assess the Effects of Epidural Analgesia and Parenteral Analgesia on Maternal and Neonatal Outcomes Among Parturients Experiencing Slow Progression of Labour: A Comparative Study

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ABSTRACT

Introduction: Epidural analgesia however has been shown to be associated with maternal side effects like hypotension, hyperthermia and prolonged labour which are likely to have adverse effects on the fetal outcome, thus discouraging its use in clinical practice. Neonatal/fetal effect should be one of the most important determinants for choosing ideal analgesia. As there is no study which specifically has looked into the effects of labour analgesia on neonatal outcomes on augmentation of labour, it would be prudent to measure the impact of epidural analgesia in parturients requiring augmentation of labour and its effects on maternal and neonatal outcomes.

Materials and Methods: The present study was carried among 60 labouring women with partographic evidence of slow progress of labour requiring augmentation in active phase of labour. The enrolled women were randomly allocated into group 1 in which epidural analgesia was established according to guidelines of department of Anesthesia and intensive care, PGIMER. Patients in group 2 received IM tramadol hydrochloride 1 mg/kg (with max. dose 400 mg / 24 hours) every 4 hours. All the women were monitored for 24 to 48 hours postpartum period for complication like hypotension, motor weakness, urinary retention, sedation, nausea or vomiting, allergy fever. The neonates were followed up till discharge from hospital.

Results: Most common maternal complication in epidural group was numbness and in tramadol group was vomiting. All most all (93%) of women in epidural group were satisfied with type of analgesia and more than 77% of women reported it to be excellent. In tramadol group only 41% reported analgesia as fair and good but rest of them were dissatisfied with type of analgesia (p-0.001). Ninety three percent of women in epidural group desired to use it again in next pregnancy as compared to 20% in tramadol group. Urinary retention needing catheterization was similar in both groups. Most of neonates in both the groups had established breast feeding with in 12hrs. There was no difference between the groups in the incidence of neonatal jaundice requiring phototherapy. No neonates in either group required NICU or nursery care.

Conclusion: To conclude, our study results suggest epidural analgesia might have edge over narcotic analgesics in dystocia. Neonates are more likely to get benefit. However epidural analgesia might increase second stage complications and vigilant care whenever mother on epidural analgesia is mandatory.

Keywords: Dystocia; Epidural Analgesia; Tramadol Hydrochloride.

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INTRODUCTION

The unrelieved pain of dystocia and its augmentation not only leave lasting psychic scars, but also increases the incidence of post-traumatic stress disorder and significant postpartum depression.[1]

Due to these chain of events culminating in deleterious effects on both maternal and fetal outcome it is believed that some form of labour analgesia should be offered to all the mother particularly in difficult labour.

Commonly used pharmacological methods in labour analgesia include injectable opioids and epidural analgesia. Systemic analgesia mostly used during labour does not effectively reduce the pain, anxiety and hyperventilation in mother. It may exert deleterious effect in fetus as it crosses placental barrier and likely to cause neonatal respiratory depression.

An ideal analgesia for labour blocks only those nerves sub serving pain leaving all other functions intact. No current drugs or technique has that degree of selectivity. However, among the available methods a properly managed epidural analgesia stands closest. Compared to opioids epidural analgesia not only produces far superior pain reliefs it relieves hyperventilation as well.[2] It has also been seen that sympathectomy induced by epidural analgesia reduces uterine and umbilical arterial vascular resistance and hence improves inter-villous blood flow.[3] The improved utero-placental perfusion leads to better fetal oxygenation and acid base balance.

Epidural analgesia however has been shown to be associated with maternal side effects like hypotension, hyperthermia and prolonged labour which are likely to have adverse effects on the fetal outcome, thus discouraging its use in clinical practice. Earlier studies suggested that epidural analgesia increased the risk of caesarean delivery by upto 12-fold, however recent clinical trials and observational studies have failed to confirm this finding. A recent meta-analysis conducted by Zhang et al had found that epidural analgesia during labour did not increase the risk of caesarean delivery, nor did it necessarily increase oxytocin use or instrumental delivery caused by dystocia. The duration of the active phase of labour appeared unchanged, though the second stage of labour was prolonged. This meta-analysis however did not comment upon neonatal effects.[4]

Neonatal/fetal effect should be one of the most important determinant for choosing ideal analgesia. Unfortunately, scanty reports are available on such an important issue. The recent modification in the area of epidural usage has reduced the maternal complication like hypotension, hyperthermia, prolonged second stage.[5] As there is no study which specifically has looked into the effects of labour analgesia on neonatal outcomes on augmentation of labour, it would be prudent to measure the impact of epidural analgesia in parturients requiring augmentation of labour and its effects on maternal and neonatal outcomes.

MATERIALS AND METHODS

The present prospective randomized controlled study was carried among 60 labouring women with partographic evidence of slow progress of labour requiring augmentation in active phase of labour. A written informed consent was taken from all participating women before intervention. Inclusion criteria comprised of women in spontaneous and/or induced labour, vertex presentation, gestational age 36 to 41 weeks and patients who had slow progress in cervical dilatation (1cm/hrs) or arrest in cervical dilatation over 4 hours in active phase of labour and decision was taken to augment labour or to continue oxytocin in escalated dose in induced labour. Exclusion Criteria comprised of patient's refusal, any contraindication to regional technique or iv analgesia, congenital malformation of fetus, abruptio placentae or placenta previa i.e. antepartum hemorrhage, coagulopathy/ thrombocytopenia (platelets count < 75000/uL), fetal distress, intrauterine infection, any allergy to bupivacaine or tramadol, multiple pregnancy, intrauterine fetal death, severe intrauterine growth restriction, severe preeclampsia, antepartum eclampsia, severe maternal medical disorder like heart diseases, insulin dependent diabetes, severe anemia cervical dilatation > 9 cm, women who had received opioid analgesia within 4 hours, women who had already received epidural analgesia before start of study, malpresentation, women with evidence of obstructed labour or cephalo-pelvic disproportion. The enrolled women were randomly allocated into two groups; group 1 or group 2 to receive analgesia using a computer-generated random number table. The sequentially numbered sealed envelopes containing random number were opened just before initiation of analgesia by an investigator not further involved in the study.

Information regarding maternal history of present pregnancy, relevant past history, family history, obstetric history and routine investigations was taken and recorded. Onset of labour was defined as presence of regular painful uterine contractions i.e. 3 regular painful contractions over 10 min, together with at least one of the following features: mucoid or blood show, cervical dilatation of ≥3cm, or spontaneous rupture of membrane.

Slow progress of first stage was defined as < 1cm of dilatation of cervix per hour after 3 cm dilatation of cervix. Maternal vitals were checked, and every woman received intravenous infusion of 500ml of lactated Ringer solution 20 minutes before the start of the study in both groups. Afterwards intravenous maintenance fluid was given at the rate of 8-10 drops per minute in both groups. Oxytocin augmentation was done with similar oxytocin augmentation protocol in both groups as per PGIMER, labour room protocol. Low dose protocol was used using infusion pump. Thirty units of oxytocin was dissolved in 500 ml of normal saline. Infusion was started as the rate of 3 mU per minute(mU/min) and was increased at the rate of 3mU/min every 30min reaching maximum dose till moderate uterine contraction (3-4 contraction in 10-minute lasting 30-40 second each) or maximum dose of 72mU/min was achieved.

Group 1 (Epidural Group): Epidural analgesia was established according to guidelines of department of Anesthesia and intensive care, PGIMER. Epidural analgesia was initiated by a 10 ml bolus of mixture of 15 mg bupivacaine (0.15%) and 30 ug fentanyl given through an 18 G epidural catheter inserted at the level of the L-Ls space. Proper positioning of the catheter was confirmed by using a test dose of 3ml of 0.25% bupivacaine with 1:200000 (15g) adrenaline, given before the administration of drugs to rule out inadvertent subarachnoid or intravenous access. If demand of further analgesia was made after 3 hours of the initial bolus, top ups of same drugs mixture was repeated. However, if it was made within 2-3 hours, fentanyl dose was reduced to 30 ug and if demand was made in less than 2 hours, fentanyl dose was reduced to 20 ug in a 10 ml bolus of 0.15% bupivacaine respectively. If women required more than two top-ups, a continuous infusion of 0.1% bupivacaine + 2 ug fentanyl per ml was started at the rate of 10 ml that was titrated to desire analgesic effect (VAS less than 3). Motor power was assessed intermittently by the modified Bromage score. (Appendices) Concentration of local anaesthetics was adjusted in subsequent top-ups so as to keep motor power in lower limb more than 4/6. All the epidurals were given and monitored by similar protocol. Epidural top-ups and infusions were stopped once women in second stage.

Group 2 (Intramuscular Tramadol Group): Patients in group 2 received IM tramadol hydrochloride 1 mg/kg (with max. dose 400 mg / 24 hours) every 4 hours. If additional doses were required, half of the initial dose was given. However, if required after 4 hours the same dose as the initial bolus was given with a maximum dose not exceeding 400 mg in 24 hours. Tramadol was discontinued when cervical dilatation was >8 cm. If patients complain of nausca or vomiting, antiemetic Ondansetron 4mg IV was given and recorded. Total dose of tramadol was recorded.

Monitoring and Assessment:

At the time of establishment of epidural analgesia maternal monitoring was done using electrocardiography (ECG), non-invasive blood pressure (NIBP) and Pulse oximetry. (CSI Criticare, Waukesha, Wisconsin) NIBP was recorded every 10 minutes initially for one hour after test drug administration, thereafter at regular intervals every hourly. Women in group 2 were monitored with hourly pulse, BP and respiratory rate. In both the groups pain was assessed by a 10 cms long marked visual analogue scale and numerical rating scale (NRS). All participating women were explained about the Visual Analogue Score and Numerical rating scores (VAS/NRS) where 0 means no pain and 10 means worst, unimaginable pain. Pain was scored at one hourly interval throughout the study period. Sedation was assessed by attending obstetrician on a S-point sedation score every hourly. No subsequent analgesia was given if sedation score was >2, Progress of labour was assessed by partogram maintained for each women Maternal satisfaction was recorded within 24 hours of delivery by the attending obstetrician on a five

Point descriptive score of excellent, very good, good, fair or poor. Maternal hypotension was defined as systolic BP < 90 mmhg or reduction in arterial blood pressure > 30 mmHg from base line. For treatment of hypotension, boluses of phenylephrine 50ug was used.

Labour Monitoring:

In both the groups labour monitoring was done by using WHO partograph.

Fetal Monitoring:

This was done using cardiotochography (CTG) (Huntleigh Health Care monitor, United Kingdom) or intermittent auscultation. Intermittent auscultation was done every 15 min in first stage and every 10 min in second stage. Fetal heart rate was recorded immediately after contraction. Cardiotocography was performed for at least half hour after each dose of analgesia. In case of any fetal heart rate abnormalities and suspected fetal distress continuous cardiotocographic monitoring was done along with another method for fetal rescue i.e left lateral position, hydration, oxygen supplementation or omitting oxytocin were taken till heart rate normalizes. If CTG showed evidence of continued fetal heart

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Table 1: Maternal complications

Complications	Epidural No. (%)	Tramadol No (%)	Total No (%)
Yes	6 (20%)	3 (10%)	9 (15%)
No	24 (80%)	27 (90%)	51 (85%)
Total	30 (100%)	30 (100%)	60 (100%)

Table 2: Maternal Opinion about Analgesia

Opinion	Epidural No. (%)	Tramadol No (%)	Total No (%)
Excellent	24 (77.4%)	1 (3.4%)	25 (41.7%)
Fair	2 (6.5%)	7 (24.1%)	9 (15.0%)
Good	5 (16.1%)	4 (13.8%)	9 (15.0%)
Poor	0 (0.0%)	17 (58.6%)	17 (28.3%)
Total	31	29	60

Table 3: Future desire for use in next Pregnancy

	Epidural No. (%)	Tramadol No (%)	Total No (%)
Consider	1 (3.4%)	3 (10.0%)	4 (6.8%)
No	1 (3.4%)	21 (70.0%)	22 (37.3%)
Yes	27 (93.1%)	6 (20%)	33 (55.9%)
Total	29	30	59

Table 4: Establishment of breast feeding

Breast Feeding Time	Epidural No. (%)	Tramadol No (%)	Total No (%)
<12 hrs	26 (89.7%)	29 (96.7%)	55 (93.2%)
12-24 hrs	2 (6.9%)	0 (0.0%)	2 (3.4%)
>24 hrs	1 (3.4%)	1 (3.3%)	2 (3.4%)
Total	29	30	59

Table 5: Neonatal Complications

Complications	Epidural No. (%)	Tramadol No (%)
Secondary Apnea	0 (0.0%)	1 (3.33%)
Congenital Malformation	1 (3.34%)	0 (0.0%)
Congenital Pneumonia	0 (0.0%)	1 (3.33%)
Jaundice	13 (44.82%)	13 (43.33%)
TTN	0 (0.0%)	2 (6.66%)
Subconjunctival Hemorrhage	0 (0.0%)	1 (3.33%)
Total	14	18

Table 6: Postnatal follow up

Postnatal discharge	Epidural No. (%)	Tramadol No (%)	Total No (%)
1	15 (51.7%)	15 (50.0%)	30 (50.8%)
2	0 (0.0%)	4 (13.3%)	4 (6.8%)
3	4 (13.8%)	4 (13.3%)	8 (13.6%)
4	3 (10.3%)	1 (3.3%)	4 (6.8%)
>5	7 (24.1%)	6 (20.0%)	13 (22.00%)
Total	29	30	59

RESULTS

Comparison of maternal complication rate in each group has been shown in table 1. In epidural group complication were one case each of motor weakness, ketosis, atonic PPH and 2 cases of fever. In tramadol group one had ketosis and two women had fever. 3rd degree perineal tear occurred in one women in epidural group. One woman in each group had intrapartum urinary retention and needed catheterization.

12-24 hours following delivery maternal satisfaction regarding labour analgesia was enquired in each group and the response is shown in table 1. Significantly higher proportion of women receiving epidural analgesia opined it to be excellent (table 2). 27 women (93%) who received epidural analgesia expressed their desire to use it again in next pregnancy as compared to 20% in tramadol group (table 3). Two women in epidural group opined against its use in future pregnancy. Seventy percent of women in tramadol group opted for alternative analgesics if given choice. This was statically significant.($p<0.001$) One woman who had intrauterine fetal death was not asked for future use and was excluded from results. In epidural group 90% of neonates and 97% of neonates in tramadol group were reported to have established breast feeding within 12 hrs of delivery (table 4).

Table 5 reports neonatal complications. One neonate in epidural group received BMV for 30 second due to respiratory distress. One minute Apgar score in this neonate was 7 and 5 minutes Apgar was 9. Gestation at delivery was 36+4 and weight 1.8kg (SFD-1). This neonate did not require nursery or NICU care.

Three neonates in tramadol group had respiratory distress and only one required nursery care for 2 days and the cause of respiratory distress was congenital pneumonia with HMD and was discharged from hospital at D8 of life. Gestation at delivery was 36 weeks and birth weight were 3.3kg one and 5 mins Apgar score in this neonate was 8 and 9 respectively.

Duration of rupture of membrane in woman of this neonates was 21 days and was treated for the same with antibiotics. In other two neonate cause of respiratory distress was TTN and secondary apnea respectively. None of these neonates required NICU. The one with TTN required phototherapy for 1 day and was discharged on day 2 of life whereas neonate with secondary apnoea required phototherapy for 7 days and was discharged on day 8 of life. One of the neonates in epidural group had multiple malformation like cleft lip, palate, microtia, left side absent ear, congenital heart disease which was compatible with life and did not required nursery or NICU care. Breast feeding was started from second hour of life and was discharged on day 5 of life. There was no significant difference between the neonate's requiring phototherapy between both groups. One neonate in tramadol group received phototherapy for 8 days whereas 3 women in epidural group received phototherapy for 7 days. No women in either group required exchange transfusion.

Following delivery both maternal and neonatal follow up was done till discharge from hospital. There was no caesarean or episiotomy wound infection in both group (table 6).

DISCUSSION

Dystocia of labour was diagnosed in active phase of labour using partograph when there was protracted or arrest of cervical dilatation. Augmentation of labour was done using oxytocin according to the labour room protocol with maximum dose of oxytocin being up to 12mU/min. In induced labours after diagnosis of dystocia in first stage oxytocin was continued in escalated doses till contractions were judged adequate. Progress of labour was monitored by assessing the grade of contractions, progress of cervical dilatation and descent of fetal head. Maternal vitals were also watched for. Fetal heart rate was monitored by intermittent auscultation and cardiotocography.

In our study it was found that there was no significant difference between the groups in establishment of breast feedings. Majority of neonates established breast feeding with in 12 hrs of delivery.

Albani et al in their large retrospective study reported that epidural use did not affect breast feeding initiation and maintenance.[6] In a study by Gizzo et al it was concluded that epidural analgesia had little effect on trend of labour and duration of first breastfeed.[7] Nissen et al in their study on effects of routinely given labour analgesics on breast feeding behaviour reported that epidural analgesia promoted breast feeding, while intrapartum opioids delayed the initiation of neonatal sucking behaviour.[8] In another study by Gaiser et al it was concluded that intrapartum epidural analgesia does not adversely affect a baby's or mother's ability to breast feed.[9]

Halpern SH et al also reported that in a hospital that strongly promotes breastfeeding, epidural labor analgesia with local anesthetics and opioids does not impede breastfeeding success and recommended that hospitals that find decreased lactation success in parturients receiving epidural analgesia reexamine their postdelivery care policies.[10]

The most critical factors for breastfeeding success are analgesia, support, good labour experience and educating the mother.[9]

On follow up in our study it was found that there was no neonatal sepsis, NICU care of neonates in either group. Three neonates in tramadol group had respiratory distress and only one required nursery care for 2 days and the cause of respiratory distress was congenital pneumonia with HMD and was discharged from hospital at day 8 of life. 1 and 5 mins Apgar score in this neonate was 8 and 9 respectively. Duration of rupture of membrane in the mother of this neonate was 21 days and was treated for the same with antibiotics.

There is widespread unwillingness among obstetricians to use epidural analgesia in abnormal labour though these women require better analgesia.

Our study results suggest that epidural analgesia does not increase caesarean section rate rather it might reduce it.

Neonates who are of prime concern in abnormal labour are likely to benefit from use of epidural analgesia. There was a trend towards better base excess in neonates with use of epidural analgesia.

However, there was one serious concern. Epidural analgesia prolongs second stage and prolonged second stage increases the risk of acidosis. There was one intrapartum fetal demise in epidural group in second stage where second stage was prolonged, and patient did not receive optimal care. In this patient duration of second stage was more than two hours and fetal hypoxia occurred during second stage was missed due to work overload in busy labour room. Berglund et al in their study suggested that compared with non-dystocic deliveries, the OR for sub standard care in dystocic deliveries was fivefold higher and was further increased if epidural anesthesia or opioids were used.[11]

We suggest this study should be done in larger number of patients with dystocia.

CONCLUSION

To conclude, our study results suggest epidural analgesia might have edge over narcotic analgesics in dystocia. Neonates are more likely to get benefit. However epidural analgesia might increase second stage complications and vigilant care whenever mother on epidural analgesia is mandatory.

Most common maternal complication in epidural group was numbness and in tramadol group was vomiting. All most all (93%) of women in epidural group were satisfied with type of analgesia and more than 77% of women reported it to be excellent. In tramadol group only 41% reported analgesia as fair and good but rest of them were dissatisfied with type of analgesia (p-0.001).

Ninety three percent of women in epidural group desired to use it again in next pregnancy as compared to 20% in tramadol group. Urinary retention needing catheterization was similar in both groups.

Most of neonates in both the groups had established breast feeding with in 12hrs. There was no difference between the groups in the incidence of neonatal jaundice requiring phototherapy. No neonates in either group required NICU or nursery care. More than 50% of neonates in both groups were discharged within 2 days delivery.

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