Section: Miscellaneous

Original Research Article

EFFECT OF EPIDURAL ANALGESIA ON FETOMATERNAL OUTCOMES IN NULLIPAROUS SINGLETON PREGNANCIES–A COMPARATIVE CROSS SECTIONAL STUDY

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ABSTRACT

Background: This study was done to mainly assess the mode of delivery, the duration of labour and the effect on the neonate in pregnant women taking Lumbar Epidural Analgesia (LEA) as compared to those without.

Materials and Methods: This comparative cross sectional study enrolled women from the labour room after taking informed consent. Pregnant women were divided into two groups – those opting for LEA formed the first group and those who didn't belong to the second group.

Results: The operative delivery rates were significantly higher in the study group (54% (n=74) in study group vs. 24% (n=36) in control group; P<.001). LSCS rates were significantly lower in the study group (7.3% (n=10) in study group vs. 20.7% (n=31) in control group; P<.001). The duration of first stage of labour was shortened in the study group (212.4±159.9 minutes in study group vs. 271.4 ± 131.5 minutes in control group; P<0.001). The duration of second stage of labour was comparable in the two groups (20 ±9 minutes in study group vs. 23 ±10 minutes in control group; P=0.009). No adverse neonatal outcomes in terms of APGAR score at 5 minutes (8.99 ± 0.12 in study group vs. 8.98 ± 0.183 in control group; P=.938).

Conclusion: Epidural analgesia increased operative vaginal delivery but decreased LSCS rates significantly in nulliparous women. The duration of first stage of labour was shortened in those who had taken epidural analgesia. However Epidural analgesia had no effect on the duration of second stage of labour and neonatal outcomes. Thus Epidural analgesia is a safe and effective method of pain relief with beneficial fetomaternal outcomes.

Keywords: Lumbar Epidural Analgesia (LEA), Caesarean Section (CS), Cephalo-pelvic Disproportion (CPD), Primary postpartum haemorrhage (PPH), Lower Section Caesarean Section (LSCS), Neonatal Intensive Care Unit (NICU).

INTRODUCTION

Labor pain, without dispute, is the most painful experience a woman can undergo during her life.[1] Epidural analgesia is now considered one of the most effectual methods for the relief of pain during labor, and the use of epidural analgesia intrapartum has significantly increased over the past few decades.[2] The American College of Obstetricians and Gynaecologists (ACOG) and American society of Anaesthesiologists (ASA) strongly believe that under no circumstance it is justifiable for a woman to experience pain, and they find maternal request as a reasonable medical indication for relief of pain.[3] Adequate labour analgesia is supposed to decrease pain associated with delivery, be comfortable and acceptable for the parturient woman, enable participation in active labour and guarantee satisfactory progress of labour.[4] Lumbar epidural analgesia (LEA) is now the gold standard for pain

relief in labor.[5] LEA has been proven to effectively relieve pain during labor and delivery.[6,7]

The study was carried out among pregnant women who presented to the labor room of Jubilee Mission Medical College and Research Institute, Thrissur. This study aimed to evaluate the effect of Ropivacaine and Fentanyl epidural analgesia on nulliparous singleton parturients as compared to those not receiving epidural.

Objectives

The primary objective the study was to assess the effect of epidural analgesia on mode of delivery in singleton nulliparous pregnant women. The secondary objective was to assess the effect of epidural analgesia on duration of labour (first and second stage of labour) and neonatal outcome in form of APGAR score at 5 min.

MATERIALS AND METHODS

Study Design: Women who fulfilled the inclusion criteria were selected till the required number of sample size was met using consecutive number method. The trial was undertaken in accordance with current guidelines of the Central Drugs Standard Control Organization, which is the National Regulatory Authority in India, the International Conference on Harmonization Good Clinical Practice, and the Declaration of Helsinki. Written informed consent followed study explanation to patients before screening procedures or assessments.

Study Population

Epidural group

Thorough pre-anaesthetic check-up was carried out in the epidural group. Once the patient demanded epidural, 500 ml of Ringer lactate solution was administered intravenously. Under strict aseptic precautions, the epidural space, at the L2-L3 or L3-L4 intervertebral space, was identified with use of the loss of resistance technique with 18-gauge Tuohy needle.

An epidural catheter was inserted 4-5 cm into the epidural space, and a test dose of 3ml 2% Lidocaine with adrenaline. The patient was under observation for 5 minutes. Whereas maternal tachycardia (>10beats/minute) would indicate intravascular placement of the catheter, and would require the catheter to be repositioned. The test dose, after ruling out intrathecal or intravascular placement, was followed 5 minutes later by a bolus injection of 10 ml of Ropivacaine 0.2% and 12.5µg Fentanyl.

Analgesia was maintained by a 2nd bolus of 10ml Ropivacaine 0.2% and 12.5µg of Fentanyl (i.e. a total of 25µg Fentanyl) and further boluses of 10mL Ropivacaine 0.2% upon the patients' request. Following epidural analgesia, maternal blood pressure, heart rate and sensory blockade levels was assessed throughout labour. Episodes of hypotension (fall of systolic blood pressure >20% from baseline) if present was recorded and managed by rapid intravenous fluid infusion, left uterine displacement or intravenous boluses of 3mg of Mefenteramine and episodes of bradycardia (<60/minute) with 0.6 mg of intravenous atropine, as required. Continuous monitoring of parturient women in the epidural group was managed by the Anaesthesia team, till delivery. Routine labour progress was monitored by the obstetric team

Control group: This group included age matched patients who did not request any analgesia. Labour monitoring was done.

Inclusion Criteria

1. Nulliparous (no previous pregnancies greater than 20 weeks)
2. Singleton pregnancies with vertex presentation
3. ≥36 weeks of gestational age
4. Cervical dilatation > 3cm
5. Adequate contraction with or without oxytocin
6. Voluntarily opting for epidural analgesia

Exclusion Criteria

1. Multiple pregnancies
2. Abnormal placentation
3. Malpresentation
4. Cephalo-pelvic Disproportion (CPD)
5. Cervical incompetence
6. Previous CS
7. Hypertension and associate d disorders
8. IUD
9. Obese patients i.e. BMI ≥ 30 (Prepregnant wt)
10. Major fetal anomalies
11. Coagulopathies
12. Maternal sepsis
13. Local infection at the site of epidural
14. Conversion to spinal analgesia

Statistical Analysis: Based on the comparison of duration of labour observed in an earlier publication "Agrawal D, Makhija B, Arora M, Haritwal A, Gurha P - The effect of epidural analgesia on labour, mode of delivery and neonatal outcome in nullipara of India, 2011-2014; published in the Journal of clinical and diagnostic research in 2014",[8] with 95% confidence level and 80% power, the minimum sample size was 100 in each group.

RESULTS

Total samples collected was 287. The Test group comprised of 137 patients and control group consisteds of 150 patients.

Out of 137 patients in the epidural group, 83.2% belonged to the age group of 20-29 years, 10.2% belonged to 30-40 years of age and 6.6% belonged to <20 years of age. Whereas in the non epidural group, out of the 150 patients, 88.6% belonged to 20-29 years age group, 6.7% belonged to the age group of 30-40 years and rest 4.7% were <20 years of age.

The mean gestational age in the epidural group (test) was 37.68 weeks with a standard deviation of 3.858 weeks years whereas the mean gestational age in the non epidural (control) group was 38.51 weeks with a SD of 4.25 weeks. There was no statistical difference

between the distribution of gestational age in the test and control group.

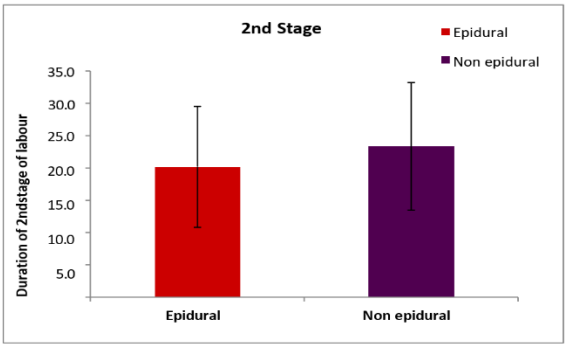
Table 1: Mean duration of 1st stage of labour in the groups studied

Groups	1st Stage		Mann Whitney U score	P Value
	Mean	SD		
Epidural	212.4	159.9	5884.5	<0.001
Non epidural	271.4	131.5		

The mean duration of first stage of labour in the test (epidural) group was approximately 212 minutes with a standard deviation of 159 minutes. Whereas the mean duration of first stage of labour in the control (non epidural) group was approximately 271 minutes with a standard deviation of 131 minutes. This was proven to be statistically significant with the Mann Whitney test with P < 0.001 i.e. the 1st stage of labour was found to be prolonged in the non epidural group [Table 1].

Table 2: Mean duration of 2nd stage of labour in the groups studied

Groups	2nd Stage		Mann Whitney U score	P Value
	Mean	SD		
Epidural	20.1	9.3	6156.5	0.009
Non epidural	23.3	9.9		



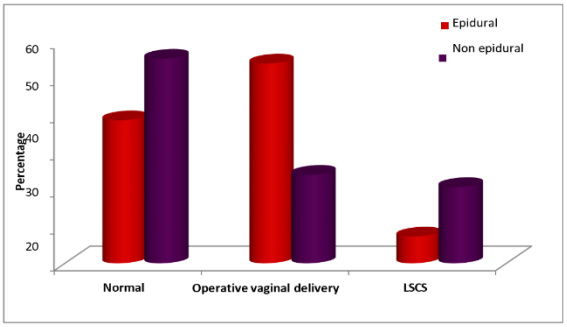


Figure 1: Mode of delivery in the two groups studied

The mean duration of second stage of labour in the test (epidural) group was approximately 20 minutes with a standard deviation of approximately 9 minutes. Whereas the mean duration of second stage of labour in the control (non epidural) group was approximately 23 minutes with a standard deviation of about 10 minutes. This was proven not to be statistically significant with the Mann Whitney test (P = 0.009) i.e. the 2nd stage of labour was found to be prolonged in the non-epidural group but it was found to be not significant [Table 2].

Among the two groups studied, there was higher incidence of operative vaginal delivery in the epidural group (54%) as compared to the non epidural group (24%). However the incidence of LSCS in non epidural group (20.7%) was almost thrice than that of epidural group (7.3%). Consequently the incidence of normal (vaginal) delivery was less in epidural group (38.7%) as compared to non epidural group (55.3%). This was found to be statistically significant by Pearson chi square test (P< 0.001) [Figure 1].

Out of the 10 Caesarean Sections in the epidural group, 70% (n=7) was due to NPOL, 20% (n=2) was because of fetal distress and the rest was indicated due to 2nd stage arrest (10%, n=1). Whereas among the 31 CS in the non epidural group, nearly 80% (n=25) of CS was due to NPOL, about 13% (n=4) was indicated due to fetal distress and the rest was done for cervical dystocia (3.2%; n=1) and 2nd stage arrest (3.2%; n=1). χ 2 (3, N=41)= 1.6397, P = .65043 – statistically not significant [Figure 2].

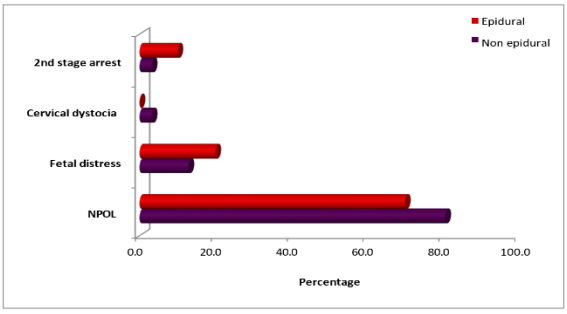


Figure 2: Indication for CS in the groups studied

Table 3: Indication for operative vaginal delivery in the groups studied

Indication for operative vaginal delivery	Epidural		Non epidural	
	N	%	N	%
Cut short 2nd stage	2	2.7	0	0.0
Fetal distress	8	10.8	1	2.8
Inadequate maternal effort	38	51.4	3	8.3

Maternal exhaustion	0	0.0	14	38.9
Poor maternal effort	26	35.1	18	50.0
Total	74	100	36	100

Out of the 74 operative vaginal deliveries in the epidural group, approximately 51% (n=38) was done for inadequate maternal effort, nearly 35% (n=26) was because of poor maternal effort, about 11% (n=8) was done in view of fetal distress and the rest was performed to cut short the 2nd stage (2.7%, n=2). Whereas among the 36 operative vaginal deliveries in the non epidural group, 50% (n=18) of the instrumental deliveries were done due to poor maternal effort, about 39% (n=14) was indicated due to, maternal exhaustion and the rest was done for inadequate maternal effort (8.3%; n=3) and fetal distress (2.8%; n=1) [Table 3].

Table 4: Distribution of vacuum and forceps assisted delivery in the groups studied.

Operative Vaginal Delivery	Epidural		Non epidural	
	n	%	n	%
Forceps	11	14.9	10	27.8
Vacuum	63	85.1	26	72.2
Total	74	100.0	36	100.0

Out of the 74 operative vaginal deliveries in the epidural group, approximately 15% (n=11) was forceps assisted and nearly 85% (n=63) was vacuum assisted deliveries. Whereas among the 36 operative vaginal deliveries in the non epidural group, approximately 28% (n=10) was forceps assisted and nearly 72% (n=26) was vacuum assisted deliveries [Table 4].

Table 5: Distribution of maternal obstetric complications in the groups studied

Maternal obstetric complications	Epidural		Non epidural	
	N	%	N	%
Atonic PPH	6	4.4	3	2.0
MROP	2	1.5	2	1.3
Lateral wall laceration	3	2.2	0	0.0
T2 tear	4	2.9	10	6.7
T3 tear	4	2.9	2	1.3
No complications	118	86.1	133	88.7
Total	137	100	150	100.0

Out of the 137 women studied in the epidural group, 118 (86.1%) did not have any complications whereas 133 (88.7%) women of 150 women studied in the non epidural group did not have any maternal complications. Out of the 13.9% (n=19) who developed complications in the epidural group, 4.4% (n=6) had atonic PPH, 2.9% (n=4) each had T2 tears and T3 tears, whereas the rest was found to have lateral wall laceration of the vagina (2.2%; n=3) and underwent MROP (1.5%; n=2). Out of the 11.3% (n=17) who developed complications in the non epidural group, 6.7% (n=10) had developed T2 tears, 2% (n=3) had atonic PPH, 1.3% (n=2) each had T3 tears and had to undergo MROP, but no one was found to have lateral wall lacerations. The maternal obstetric complications were not found to be statistically significant [Table 5].

The neonatal outcome was measured as APGAR score of the newborn at 5 minutes. APGAR score more than 7 is considered as normal whereas those babies with score less than 7 require medical intervention. In this study no newborns in either group had APGAR scores less than 7. This indicates that there were no adverse outcomes in the babies in terms of APGAR score at 5 minutes in either group [Figure 3].

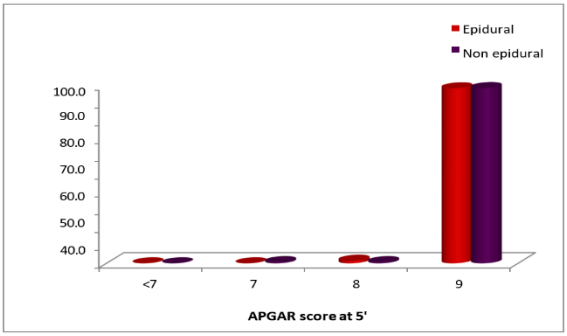


Figure 3: Distribution of APGAR score at 5 minutes in the groups studied

The mean APGAR score at 5' in the epidural group was 8.99 ± 0.12, whereas in the non epidural group was 8.98 ± 0.183. This found to be statistically not significant by Mann Whitney test (P = .938). Hence there was no significant difference in neonatal outcomes in the two groups studied, in terms of APGAR score at 5 minutes.

Table 6: Distribution of birth weight of the newborns in the group studied

Birth weight	Epidural		Non Epidural	
	N	%	N	%
<2.5	15	10.9	10	6.7

2.5-3.5	114	83.2	127	84.7
>3.5	8	5.8	13	8.7
Total	137	100.0	150	100.0

Birth weight of the babies born to either group was documented. There was no statistically significant birth weight difference among the babies born to mothers in the epidural and non epidural group. $\chi 2$ (1, N = 287) = 2.3076, P= .315435 – not statistically significant [Table 6].

Approximately 52% of the babies born to mothers in the epidural group (n=72) and non epidural group (n=78) was admitted in the NICU within 3 days of birth. However this was not found to be statistically significant by Fisher exact test.

DISCUSSION

Since the genesis of inhalational anaesthesia into medical practice in 1847, obstetric analgesia has undergone profound changes. Epidural analgesia for labour has recently become popular and with advancing education, awareness and modernisation of society, pregnant women are now open to the concept of 'painless labor'. This study aimed to find the effect of Ropivacaine - Fentanyl epidural analgesia on labour and neonatal outcomes.

Mode of Delivery

Caesarean delivery is known to be associated with greater anesthetic and surgical risks and so increased Caesarean delivery rates in association would negatively affect the opinion of the practicing obstetrician. The singleton nulliparous women who received epidural analgesia in our study did not have an increased risk of caesarean delivery. In fact the Caesarean delivery rates were significantly lower in the study group. This was in line with the retrospective study by Wu CY and his colleagues in 2005.[9] They studied the effect of Ropivacaine epidural analgesia on the duration of labour and mode of delivery and concluded that caesarean delivery rates were lower in the epidural group. Similar outcome was seen in a more recent study by Zheng S in 2020.[10]

Earlier in the years, several retrospective studies showed an association of epidural analgesia with increased caesarean rates. These included those by Thorp et al. in 1993, Zimmer et al. in 2000, Liang in 2007 and others.[11-13]

Recent studies and reviews however show no difference in Caesarean rates in the epidural group. This finding is reflected in studies by Barbera and Halpern in 2002,[6] Liu and Sia in 2004,[14] Shahram Nafisi in 2006,[15] Anim-Somuah and his colleagues in 2018 (Cochrane Database of Systematic Reviews) and others.[7] In this study, we found that there were significantly increased rates of instrumental deliveries (operative vaginal deliveries). This was similar to most of the studies conducted with respect to epidural analgesia. This included those by Bofill et al. in 1997,[16] Howell et al. in 2001,[17] Wu CY and his colleagues in 2005, Anim- Somuah and his colleagues in 2011,[7] and Newnham and co-workers in 2021.[18]

Increased rates of instrumental deliveries were attributes to motor blockade induced by local anesthetics. However modern techniques use the least concentrations of local anesthetics and the motor blockade caused is very minimal – so and so that the term 'walking epidural' has come into being, since the patient can walk despite the analgesia. This was believed to reduce the incidence of instrumental deliveries consequent to reduced motor blockade, which in turn resulted in better maternal expulsive effort. This reflected in studies by Barbara and Halpern in 2002,[6] Sienko J and associates in 2005,[19] Mousa and co-workers in 2012(20), D. Agrawal and colleagues in 2014,[8] and Zheng S et al. in 2020.[10]

As forementioned above, the rates of instrumental deliveries were higher in the epidural group. However this may also be attributed to lack of defining criteria for instrument application, instrumentation for training purposes even when not indicated and consultant stereotype to assisted vaginal deliveries in epidural analgesia and thereby immoderate increase of assisted vaginal deliveries. This can be considered as the limitation of the study. This is also reflected in the duration of second stage of labour as discussed in the next section.

Duration of Labour

In concordance with studies by Wong et al. in 2005,[21] S Fyneface-Ogan in 2009,[22] and D. Agrawal and colleagues in 2014,[8] our study has demonstrated that first stage of active labour is shortened in those receiving epidural analgesia. This can be attributed to the basic pain relief addressed by epidural analgesia. Epidural analgesia provides very good pain relief thereby reducing maternal release of catecholamines, which consequently decrease the inhibitory effect on the contractility of uterus, resulting in faster cervical dilatation. Decreasing levels of maternal endogenous catecholamines also significantly attenuates maternal acidosis and increase maternal susceptibility to oxytocin administration.

Effect of epidural analgesia on the duration of second stage of labour was studied. There was no significant difference of duration of second stage between epidural and control group i.e. epidural analgesia had no effect on second stage of labour. Although this mirrors the studies by Bofill et al. in 1997,[16] Wong et al in 2005,[21] and S. Nafisi in 2006,[15] unaffected duration of second stage of labour may be attributed to biased and early use of instruments to assist vaginal delivery in those receiving epidural analgesia.

In contrast to this study, Halpern and associates in 1998,[23] Sharma and colleagues in 2004 (24), Wu CY and co-workers in 2005,[9] D. Agrawal and associates

in 2014,[8] and most other studies concluded that epidural analgesia prolonged second stage of labour.

Neonatal Outcomes

The results from our study demonstrated no significant adverse neonatal outcomes, in both the study group and control group, in terms of APGAR score at 5 minutes. Similar results were illustrated in most of the studies. These included those by Barbara and Halpern in 2002,[6] Halpern and associates in 1998,[23] Wu CY and co-workers in 2005,[9] S. Nafisi in 2006,[15] D. Agrawal and colleagues in 2014,[8] Anim-Somuah and his colleagues in 2018 (Cochrane Database of Systematic Reviews),[7] and Zheng S et al. in 2020.[10]

CONCLUSION

This study assessed and analysed the effect of epidural analgesia on singleton nulliparous pregnant women. This study found that lumbar epidural analgesia increased the rates of instrumental deliveries while it significantly decreased the rates of caesarean delivery.

The duration of first stage of labour was found to be significantly shortened with no effect on duration of second stage of labour and no adverse neonatal outcomes. Thus epidural analgesia is a safe and effective method of labour analgesia associated with increased incidence of instrumental delivery without deleterious effect on the mother or the neonate.

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