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The Effect of Epidural Labour Analgesia on Neonatal Outcomes: A Prospective Randomised Study

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Authors' contributions

Authors SK and BEA conceived the study with inputs from author TWA for the design of the experiments. Recruitment of patients and counseling were carried out by authors SK and BEA. Data collection was carried out by authors SK, TWA and BEA, supervised by authors DZK, TBA and JBZ. Authors SK and TWA led the data analysis with inputs from authors PPB and JBZ. The first draft of the paper was written by authors SK and BEA and then authors TWA, PPB, JBZ, TBA and DZK contributed to revising and reviewing the paper. All authors read and approved of the final draft before submission.

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ABSTRACT

Introduction: Epidural analgesia is said to have depressive effects on neonates. There seems to be sufficient instances in the literature that have compared maternal outcomes in relation to epidural analgesia. However, there is lack of instances in the literature on neonatal outcomes occurring with respect to epidural labour analgesia. This study therefore aims at unravelling neonatal outcomes following epidural labour analgesia.
Methods: This randomised controlled trial study compared the outcomes of babies of mothers who received epidural labour analgesia with those who did not receive any form of labour analgesia. One hundred and two (102) parturient women were recruited into the study and 51 of them assigned to the epidural group and the other 51 were assigned to the control group. Measures were taken with respect to: APGAR scores at first, fifth and tenth minutes; level of neonatal resuscitation; temperature; and neonatal complications.
Results: It was reveal that there was no statistical difference in the APGAR scores at first, fifth and tenth minutes (P = 0.55, P = 0.33, P = 0.58, respectively). The mean temperatures were 36.13℃ for the control group and 35.61℃ for epidural group (P = 0.40), indicating no statistical significance between the two groups.
Conclusion: Complications noted in epidural group were not statistically different from those in the control group and therefore with proper monitoring, epidural labour analgesia is safe for the foetus and the neonate.

Keywords: Epidural; labour; analgesia; pain; parturient women.

ABBREVIATIONS

TTH : Tamale Teaching Hospital
ASA : American Society of Anesthesiologists
APGAR : Appearance, Pulse, Grimace, Activity, Respiration
Bpm : Beats per minute
EA : Epidural Analgesia
NA : No epidural
N : Numbers
SD : Standard deviation.

1. INTRODUCTION

Childbirth is widely known and accepted as a painful experience for women [1]. Pain experienced during labour has multiple physiological and psychosocial dimensions and its intensity can vary greatly from one woman to another [2]. These factors suggest that pain relief is imperative for women in labour, and epidural analgesia is one of the widely used modes of pain relief. It involves an injection of a local anaesthetic into the lower region of the spine, close to the nerves that transmit labour pain. Epidural and spinal analgesic techniques are the gold standards for pain relief during labour and delivery [3].

The number of parturient women given intra-partum epidural analgesia is reported to be over 50% in many institutions in the United States. A survey of obstetric anaesthesia in the United States indicated that the percentage of women given intrapartum epidural analgesia increased from 22% in 1981 to 77% in 2001 [4]. In the United Kingdom, a little over 33% of parturient women chose epidural labour analgesia in the period of 2008 to 2009 [5].

Studies undertaken on the effects of epidural labour analgesia on the mother and neonate has revealed that neonates born to mothers who received epidural analgesia showed the best neurological and adaptive capacity scores [6,7].

Late preterm and term infants exposed to maternal epidural analgesia in labour are more likely to develop respiratory distress in the immediate neonatal period. Pharmacokinetic studies have shown that fentanyl diffuses freely from the epidural space into the maternal blood and across the placenta due to its high lipid solubility [8]. Neonates are also known to be more prone to respiratory effects of opioids due to the immaturity of their respiratory centres [9].

When investigating different methods of pain relief in parturient women, neonatal outcome has not always been at the forefront; rather, maternal changes such as haemodynamic, fever, length of labour and need for oxytocin or type of delivery have been prominent and often taken as surrogates for neonatal outcome. It is essential to examine the actual baby and to appreciate that labour pain itself has consequences for the baby [10].

A research was conducted by Shrestha et al. [11] to study the immediate effects of maternal epidural analgesia on neonates during early neonatal phase. Those researchers revealed that epidural analgesia does not have any effect on the new-borns with regards to breast feeding and birth asphyxia, but did have effects such as delayed passage of urine and increased incidence of instrumentation.

In another study, vacuum extraction and caesarean section were more frequently performed in the epidural group than the control group. In that study, it was also ascertained that epidural analgesia is associated with slowly progressing labour resulting in an increased rate of instrumental delivery. Thus, instrumental delivery appears to adversely affect the neonatal outcomes more strongly than the analgesia itself [12,13].

The increased availability of epidural analgesia and the favourable experiences of women who have had painless labour with epidural block have reshaped the expectations of pregnant women with respect to labour [7]. As more parturient women demand pain-free labour, it is important that physicians managing labour have a clear understanding of the effects of the procedure on the expected neonates.

A survey of the literature suggests that little is known about neonatal outcome related to epidural labour analgesia among Ghanaian women. Epidural labour analgesia has been introduced as one of the methods of labour analgesia at the Labour Ward of the Tamale Teaching Hospital in Ghana. Only a small number of parturient women patronised this procedure, due to fear and misconceptions such as fetal distress. The aim of this study was to ascertain neonatal outcome following epidural labour analgesia at the Tamale Teaching Hospital.

2. METHODS

This prospective simple randomised control trial study was carried out for six (6) months at the Tamale Teaching Hospital. The Institutional Ethical Committee of the hospital approved the study protocol. Informed consents were obtained from each recruited parturient women. The parturient women with cervical dilatation of 2-7 cm at the first stage of labour were randomly assigned to one of two groups; group one (n=51) for parturient women who received epidural labour analgesia (experimental group) and group two (n=51) for parturient women who did not receive any form of labour analgesia (control group).

Data were prospectively collected for six months. Individual parturient women were assessed and classified according to the America Society of Anesthesiologists (ASA) Physical Status classification.

Prior to insertion of epidural catheter, basic monitors (pulse oximeter, and non-invasive blood pressure) were applied and the baseline vital signs checked and recorded. Data were collected using a questionnaire. Women who had epidural labour analgesia were monitored until delivery and the outcome of delivery pertaining to the neonates was recorded. The same procedure was undertaken for the control group.

All babies that were born to mothers with ASA 1 or 2 and that received epidural labour analgesia during their time of labour were included for the study. Babies born to mothers with ASA 3 or above were excluded from this study. Babies born to mothers with cephalopelvic disproportions, fetal distress, severe haemorrhage, preeclampsia, eclampsia, suspicion of fetal malformation or intrauterine fetal growth retardation, fever of more than 38℃ or history of allergy to local anaesthetics and fentanyl were also excluded from this study.

After an informed consent was duly signed by the subject, epidural puncture was performed at midline approach between 2^{nd} - 3^{nd} or 3^{nd} - 4^{th} lumber vertebrate space, with an 18-gauge Touchy needle. The loss of resistance technique using saline was used to identify the epidural space. Once the needle was appropriately placed in the epidural space, a 20-gauge multi-orifice epidural catheter 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, 1 ml of 0.25% of plain bupivacaine was injected through the needle as a test dose. The parturient women were observed for hypotension, bradycardia (which may indicate accidental injection into subarachnoid space) and they were also questioned as to whether or not they were experiencing dizziness, tinnitus, metallic taste in the mouth or sudden warmth or numbness in the legs. After confirming the epidural space, 5 ml of 0.25% bupivacaine was injected as an initial dose. The catheter was well-fixed to the skin, and the patients were returned to the left lateral position. Five (5) ml of 0.25% bupivacaine + 0.5-

1 mg of fentanyl (in 10 ml of saline) was repeated when necessary as a bolus single dose via the epidural catheter for the maintenance doses. Mother and foetus were closely monitored until delivery. Once the baby was delivered, data were recorded concerning baby and mother by an obstetrician who was blinded to the epidural labour analgesia.

The data obtained were double-entered into Microsoft Excel version 2010 for Windows and validated for data entry errors. Data analysis was carried out using SPSS version 20.0 for Windows, using 95% confidence interval with a P value of <0.05 as was considered statistically significant. Means, median range and standard deviation were calculated for continuous variables; while frequencies and percentages were calculated for categorical variables.

3. RESULTS

Of the 103 parturient women that were recruited for the study, data for 102 comprising 51 each for both epidural and the control groups were included in the analysis. Data for one parturient were excluded in the analysis, because she developed placental abruption and received an emergency caesarean operation.

Results from the study show that 61(59.8%) respondents were within the modal ages group of 20-30 years, 37(36.3%) were within 30-40 years and 4(3.9%) were 40 years and above. The mean gestational ages of the mothers were 39.18 and 39.12 weeks for the epidural and the control group, respectively, and a *P-value* of 0.80 was recorded (Table 2).

It was noted that 32(62.7%) neonates born to mothers of the epidural group were males and 19(37.3%) were females and 31(60.8%) neonates born to mothers in the control group were males and 20(39.2%) were female (See Table 3).

The least weight recorded for the neonates was 2.3 kg and the highest was 3.9 kg. Fourteen (13.7%) neonates had the modal weight of 2.9 kg. A *P-value* of 0.12 was recorded (see Table 3).

3.1 Labour Augmentation and Mode of Delivery

It was realised that 11(21.6%) mothers in the epidural group and 9(17.3%) mothers in the control group had their labour augmented with 5 units of oxytocin in infusion of normal saline. Most mothers in both groups went through labour without augmentation. Forty (78.4%) mothers and 42(82.4%) mothers in epidural group and the control group, respectively, did not have their labour augmented. There was no significant difference in labour augmentation, a *P-value* of 0.62 was recorded (see Table 1).

A review of the mode of delivery showed that 39(76.5%) neonates born to mothers in the epidural group and 46(90.4%) neonates born to mothers in the control group were delivered through spontaneous vaginal delivery. There were 5(9.8%) neonates born to mothers in the control group and 2(3.9%) neonates born to mothers in the epidural group who were delivered through the use of instruments or forceps. Ten (19.6%) neonates were delivered through caesarean operation in the epidural group and none (0%) in the control group. There was a significant difference in the mode of delivery, a *P-value* of 0.00 was recorded (Table 1).

3.2 Independent Samples T-Tests

There was no statistical difference in the APGAR scores at first, fifth and tenth minutes with *P-values* of 0.55, 0.34 and 0.58 respectively. The mean APGAR scores for the first minute were 7.45 and 7.33 for the epidural and control group, respectively. At the fifth and tenth minutes, the mean APGAR scores were 8.84, 9.75 and 8.69, 9.69 for the epidural and the control groups, respectively. The mean temperatures were 36.13 and 35.61℃ for the epidural group and the control group, respectively, and a *P-value* of 0.41 denoting no statistical significance in the two groups (Table 2).

3.3 Level of Neonatal Resuscitation Required and Condition of Neonates

The results of this study show that 46(90%) neonates born to mothers in the epidural group and 42(82.7%) in the control group were given the first level of resuscitation (routine oxygenation). The majority of the neonates fell below category one of resuscitation. Five (9.8%) neonates born to mothers in the epidural group and 8(15.7%) neonates born to mothers in the control group received level 2 resuscitation (positive pressure ventilation). One (2%) neonate born to a mother in the control group and none (0%) in the epidural group received, level 3 resuscitation (chest compressions and drug). A P-value of 0.26 was recorded (Table 3).

The results further indicated that 47(92.2%) neonates born to mothers in the epidural group and 44(86.5%) neonates in the control group were in good condition. Two (3.9%) neonates and 7 (13.7%) neonates born to mothers in the epidural and control group, respectively, were in satisfactory condition. Two (3.9%) neonates born to mothers in the epidural group and none (0%) in the control group were in fair condition. A *P-value* of 0.09 was recorded (Table 3).

3.4 Maternal and Neonatal Complications

There was a record of neonatal complication in 3(5.9%) neonates born to mothers in the epidural group and 4(7.8%) neonate born to mothers in the control group. Forty eight (94.1%) neonates and 47(92.2%) neonates born to mothers in the control and epidural group, respectively, showed no signs of complications. A *P-value* of 0.69 recorded (Table 4).

Table 1. Labour augmentation and mode of delivery

		Epidural analgesia		No analgesia		p-value
		Count	N %	Count	N %	
Labour augmented	Yes	11	21.6%	9	17.6%	0.62
	No	40	78.4%	42	82.4%	
Mode of delivery	spontaneous vaginal delivery	39	76.5%	46	90.2%	0.00
	instrument/forceps vaginal delivery	2	3.9%	5	9.8%	
	caesarean section	10	19.6%	0	0.0%	

Table 2. Comparing the gestational age of mothers, APGAR score and Temp of the neonates

Variable	EA group (n= 51)	NA group (n = 51)	P-value
Gestational age of mothers (mean=SD)	39.18(1.259)	39.12 (1.259)	0.80
APGAR score in first minute (mean=SD)	7.45 (1.101)	7.33 (.887)	0.55
APGAR score at 5th minute (mean=SD)	8.84 (.967)	8.69 (.648)	0.34
APGAR score at 10th minute (mean=SD)	9.75 (.595)	9.69 (.469)	0.58
Temperature of neonate (mean=SD)	36.13 (.567)	35.61 (.641)	0.41

***EA**=Epidural Analgesia, **NA**= No epidural, **N**= numbers, **SD**= Standard deviation, **GA**= Gestational Age of mothers, **Temp.**=Temperature. Data are expressed as number, mean and standard deviation with a P-value of statistical significance ⩽0.05*

Table 3. Level of neonatal resuscitation and condition of neonates

		Epidural analgesia		No analgesia		p-value
		Count	N %	Count	N %	
Level of resuscitation	level 1 (routine oxygen)	46	90.2%	42	82.4%	0.26
	level 2 (positive pressure ventilation)	5	9.8%	8	15.7%	
	level 3 (chest compressions)	0	0.0%	1	2.0%	
	level 4 (chest compressions and drug)	0	0.0%	0	0.0%	
	Total	51	100.0%	51	100.0%	
General condition of the baby	fair	2	3.9%	0	0.0%	0.09
	satisfactory	2	3.9%	7	13.7%	
	good	47	92.2%	44	86.3%	
	Total	51	100.0%	51	100.0%	
Gender	male	32	62.7%	31	60.8%	0.84
	female	19	37.3%	20	39.2%	
	Total	51	100.0%	51	100.0%	
Weight of neonate (kg)	<= 2.5	5	9.8%	0	0.0%	0.12
	2.6 - 3.0	18	35.3%	21	41.2%	
	3.1 - 3.5	21	41.2%	25	49.0%	
	3.6+	7	13.7%	5	9.8%	
	Total	51	100.0%	51	100.0%	

Table 4. Maternal and neonatal complications during and immediate post labour

		Epidural analgesia		No analgesia		P-value
		Count	N %	Count	N %	
Presence of neonatal complication	Yes	3	5.9%	4	7.8%	0.69
	No	48	94.1%	47	92.2%	
	Total	51	100.0%	51	100.0%	
Types of neonatal complications	Asphyxia	1	2.0%	2	3.9%	0.36
	Aspirated muconium	1	2.0%	0	0.0%	
	Bradycardia	0	0.0%	2	3.9%	
	Fetal distress	1	2.0%	0	0.0%	
	Nil	48	94.1%	47	92.2%	
	Total	51	100.0%	51	100.0%	
Types of maternal complications	Cervical edema	2	3.9%	0	0.0%	0.31
	Episiotomy	1	2.0%	0	0.0%	
	Nil	41	80.4%	46	90.2%	
	Perineal tear	7	13.7%	5	9.8%	
	Total	51	100.0%	51	100.0%	

The results also indicated that 1(2%) neonate born to a mother in the epidural group and 2(3.9%) neonates born to mothers in the control group had asphyxia. Muconeum aspiration and fetal distress were also noted. One (2 %) neonate born to a mother in the epidural group and none (0%) in the control group recorded Muconeum aspiration and fetal distress for each complication. However, 2(3.9%) neonates born to mothers in the control group and none (0%) in the epidural group developed bradycardia. A *P-value* of 0.36 was recorded (Table 4).

Maternal complications noted were cervical oedema, episiotomy and perinea tear. Two (3.9%) mothers in the epidural group developed cervical oedema and 1(2%) mother received episiotomy for delivery. Seven (13.7%) mothers in the epidural group and 5(9.8%) mothers in the control group developed perinea tear. A *P-value* of 0.31was recorded for maternal complications (Table 4).

4. DISCUSSION

Pain management during labour has become increasingly requested by pregnant women. The increasing satisfaction of mothers with epidural labour analgesia has made it the “gold standard technique” for providing effective analgesia with few side effects. However, there is the risk of prolongation of the delivery due to reduced uterus activity; subsequent need for various interventions to improve the delivery; and the unknown effects on the neonate which are some of the concerns to many mothers and health care providers in developing countries with poor resources.

The mode of delivery may not be affected by epidural labour analgesia as indicated by Soncini et al. in [14]. In contrast to the above, Gizzo et al. [13] concluded that epidural analgesia has some effect on the trend of labour and delivery. Hasegawa et al. [12] ascertained that epidural analgesia was associated with slowly progressing labour resulting in an increased rate of instrumental delivery due to an excess dose of local anaesthetic that affects the woman’s ability to bear down adequately during the second stage of labour. Anim-Somuah et al. [15] in a comparative study concluded that women who use epidural labour analgesia are at increased risk of having an instrumental delivery. According to Bakhamees and Hegazy [16], epidural labour analgesia does not increase the incidence of caesarean section deliveries. Usually, mothers with epidural analgesia undergo caesarean section as a result of other factors which are not directly related to epidural labour analgesia. The effects of epidural labour analgesia on mothers, which often affect modes of delivery, may lead to some neonatal complication during delivery. In our study, we observed a 19.6% increase in caesarean operations among the epidural group and a 0% increase in the control groups. This emulates and corroborates an observation made by Hasegawa et al. in [12]. In contrast to Anim-Somuah et al. [15], our study observed that 5 (9.8%) of the parturient women in the control group and 2 (3.9%) in the epidural group underwent instrumental/forceps vaginal delivery. This ascertains the notion that epidural labour analgesia, indeed, has an effect on the mode of delivery (*P-value* = 0.00).

The fear and misconceptions of receiving epidural labour analgesia among mothers in developing countries with poor resources have been a major concern to many obstetricians. In comparing the APGAR scores of neonates from both study groups, in order to determine their state of conditions after delivery, this study showed the APGAR score at the first minute of life outside the uterus, yielding no significance difference *(P-value* = 0.55). A similar report was made by Soncini et al. [14] and Mousa et al. (2012). However, neonatal compromises did occur when there was a prolonged second stage of labour. Epidural analgesia has been cited to be associated with lower respiratory APGAR scores among neonates [17]. Whenever maternal hypotension occurred and was not resolved quickly enough it led to fetal or neonatal asphyxia. At the fifth minute, there was no significant difference in APGAR scores after neonatal assessment in both groups (*P-value* = 0.34), which was an observation which Nakamura et al. [6] also submitted in. When the neonates were assessed at the tenth minute, the APGAR scores recorded showed no statistical significance (*P-value* = 0.58). At this level, the neonate might have received enough resuscitation to be able to thrive and adjust well to life. This may potentially supports the assertion that with proper maternal and fetal monitoring epidural analgesia has the possibility of being safe with no significant effect on the neonatal outcome, but would require further research with a larger population sample.

The levels of resuscitation that neonates were exposed to during this study yielded 90% neonates born to mothers in the epidural group and 82.7% in the control group receiving routine care at level one, 1.9% of the neonates born to mothers in the control group received level 3 of resuscitation care and were given positive pressure ventilation with chest compressions. None (0%) in the epidural group received level 3 resuscitation and none in both study groups received level 4 of resuscitation which comprises of; chest compressions, endotracheal intubations and the use of drugs or needed neonatal intensive care. This seemingly suggests that adequate interventions were taken to avert such situations. Our study findings indicate that there was no significance difference in the level of resuscitation among the two study groups *P-value* = 0.26.

The last specific objective was to compare complications arising from the epidural group and the control group. In relation to the general condition of babies and complications noted, 2% of neonates born to mothers in the epidural group and 3.9% in the control group developed asphyxia. Muconeum aspiration and neonatal bradycardia were also noted in the neonates. 2% of each were recorded in the epidural group and none in the control group. Meconium aspiration, however, could not be related to the epidural analgesia.

The overall estimate of neonatal condition using the APGAR scores and complications encountered in the neonate reflects 92% and 86.5% of a good condition in epidural and control group, respectively; with 4% and 13.5% satisfactory condition and 4% and 0% fairly good condition in epidural and control groups, respectively. A *P-value* = 0.09 showed no significant difference in the neonatal conditions among the study groups.

5. CONCLUSIONS

From the results of this study it can be concluded that epidural analgesia does not have significant effect on neonatal outcome but on the mode of delivery. It increases the need for instrumental and caesarean section during delivery. This is corroborated by several studies dully cited in this study. Therefore with proper monitoring epidural labour analgesia is safe for the foetus and the neonate. However, further research is required with a larger population sample with the aim of demonstrating statistically that epidural analgesia does not have any significant effect on neonatal outcome, but on the mode of delivery. The further research may imply an increase in the need for instrumental and caesarean section during delivery. While these facts are corroborated by several studies that were duly cited in this study, one cannot escape the need for further research.

PATIENT CONSENT

In a study such as this, it is important to ensure that subjects understand what it means to participate in the study so that they can decide in a conscious deliberate manner whether they want to participate. A written consent was, therefore, obtained from all the participants after carefully explaining the key issues to be considered before giving consent.

ETHICAL CONSIDERATION

The study protocol was approved by the Institutional Ethical Review Committee.

Permission to undertake the study at the facility was sought via and was granted by the Hospital Management Committee and the head of the Obstetric and Gynecological department. Authorisation was obtained from the department of Research and Developments of the Tamale Teaching Hospital to publish the findings of this study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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