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Comparative Effects of Two Epidural Analgesia Maintenance Techniques on Labor Outcomes in Primiparous Women

Ige Olufemi Adebayo[1*], Ige Kolawole Alexander[2], Kolawole Israel Kayode[1]

[1]Department of Anesthesia, College of Health Science, University of Ilorin, [2]Department of Anesthesia, Afe Babalola Multisystem Hospital, Ado-Ekiti.

***Correspondence:** Olufemi Adebayo Ige. Email: femiigedoc@yahoo.com

ABSTRACT

Background: Labor is characterized by regular, painful uterine contraction and epidural analgesia is considered the most effective method for relieving labor pain. Motor block from epidural local anaesthetic administration can affect labour outcomes. The technique of epidural local anaesthetic administration can also affect the outcome of labour. This study aimed to compare the progress of labor and delivery outcomes in women whose labor pain was managed with patient-controlled epidural analgesia (PCEA) and clinician-administered intermittent bolus epidural analgesia.

Methods: This prospective randomized study recruited 80 primiparous parturients in the active phase of labor in two groups. They received either self-administration of 5 ml of 0.125% bupivacaine + 2 µg fentanyl/ml of bupivacaine through the PCEA pump with a lockout interval of 20 minute or hourly clinician-administered 10 ml of the same study solution. The outcome measures were duration of labor, foetal heart rate, APGAR score, mode of delivery, and willingness to request epidural analgesia in subsequent deliveries. Data was analysed after normality test with Shapiro-Wilk test. Continuous variables such as age and duration of stages of labor were analysed using the Student t-test. Nominal data such as mode of delivery was analysed using Chi square test or Fisher's exact test as appropriate. Statistical significance was set at p-value of <0.05.

Results: The mode of delivery was comparable between groups. There was no significant difference in duration of the first ($p = 0.422$) and second ($p = 0.947$) stages of labor between the two groups. Foetal outcomes were not adversely affected and the median APGAR scores at 5 minutes were comparable ($p = 0.083$) between the two groups. The willingness to request epidural analgesia during labor for the next delivery was similar in the two groups ($p = 0.414$).

Conclusion: Hourly intermittent epidural bolus administration of bupivacaine with fentanyl had no adverse effects on labor and foetal outcomes compared to PCEA. Thus, it is recommended for use in low-resource regions without electronic infusion pumps.

Keywords: Labour analgesia, patient controlled epidural analgesia, intermittent bolus administration, bupivacaine, epidural in labour.

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INTRODUCTION

Labour is characterized by regular, painful uterine contractions that bring about a progressive thinning and dilation of the cervix. The management of labour pain remains a critical component of obstetric care as the pain of childbirth has been described as severe and even excruciating (1). When labour pain is untreated or poorly treated, it can result in poor labour outcomes with increased rates of foetal distress, caesarean section, postpartum haemorrhage and prolonged labour (2).

Several methods are available for labour analgesia, ranging from non-pharmacological, through inhalational agents and parenteral opioids to neuraxial labour analgesia (3). Epidural analgesia is regarded as the most effective method for pain relief during labour (4). Several techniques have been recommended for maintenance of epidural analgesia. They include intermittent bolus doses by healthcare providers, continuous infusion, and patient controlled epidural analgesia (PCEA), with or without continuous background infusion (5). These techniques have been found to have different impact on labour outcomes such as the duration of the second stage (4).

PCEA is favoured over clinician administered epidural boluses but the requirement for an electronic pump has prevented its wide application in resource limited regions. This has led to a renewed interest in intermittent epidural boluses with one study reporting effective labour analgesia with no prolongation in duration of first or second stages of labour (6). The objective of this study was to compare labour and foetal outcomes when bupivacaine-fentanyl combination was administered either as PCEA or clinician administered intermittent epidural boluses.

METHODS

Study setting, design and population

The study was a prospective, randomized study carried out at a 600-bedded University Teaching Hospital in Nigeria. Subjects recruited into the study were primiparous women, aged between 18 and 40 years in labour.

Sampling technique

Patients were randomly assigned into two groups (Patient controlled epidural analgesia, (PCEA) and hourly intermittent epidural bolus, (HIEB) by simple, random balloting.

Sample size determination

Sample size was calculated using the formula of St. George's University of London for comparing means $n = [A + B]^2 \times 2 \times SD^2/DIFF^2$ (7). Where n is sample size, A is the significance level set at 1.96, B is the power of the study (80%) corresponding to 0.84, SD is the standard deviation and DIFF is the difference in volume of local anaesthetic required.

In a previous study (8), the durations of second stage of labour were 23.5 and 28.5 mins in the epidural and non-epidural groups respectively and the standard deviation of the duration of second stage for the epidural group was 4.8. After a 10% attrition rate was factored in, the final sample size was 40 per group.

Inclusion and exclusion criteria

All consenting primiparous parturients who were aged between 18 and 40 years in active phase of labour (cervical dilatation = 4 cm), ASA physical status I or II with singleton term pregnancy and cephalic presentation were included in the study. Exclusion criteria were patient refusal, morbidly obese patient, short stature-height < 140 cm, cervical dilatation > 5 cm, parenteral opioid use within 1hr, allergy to amide local anaesthetics, neurological/psychiatric disease, abnormal lie/presentation and any irregularity in foetal heart rate.

Pre-procedure assessment / preparation

Primiparous parturients were educated on the various methods for pain relief in labour, counselled on PCEA and healthcare providers HIEB as satisfactory options for maintenance of pain relief in labour. They were also taught on how to use the PCEA pump by the researcher at the ante natal clinic and subsequently upon arrival at the labour ward. On parturients' arrival at the labour ward, the research assistant randomized the parturients into either group PCEA or HIEB. The patients' age, height, weight and body mass index were recorded. The baseline vital signs such as pulse rate, non-invasive blood pressure, respiratory rate, peripheral arterial oxygen saturation were taken and recorded. Patients' cervical dilatation and foetal heart rate were also recorded.

Epidural procedure

A 16 G/18 G wide-bore IV cannula was used to secure intravenous access and parturients were preloaded with 0.9% saline at 15 ml/kg over 15 minutes. An epidural catheter was then inserted aseptically by the researcher into the L3-4 or L4-5 interspace after local infiltration.

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All the patients received an initial bolus dose of an admixture 10 ml of 0.125% plain bupivacaine with 2 µg/ml fentanyl 3 mins following the test dose. The aim was to achieve a sensory block at the level of T10 sensory dermatome. The level of sensory block was assessed using loss of temperature sensation with methylated spirit-soaked swabs until a minimum sensory level of T10 was achieved. Patients' haemodynamic parameters, pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP), were monitored by the research assistant every 5 min for the first 30 mins and subsequently every 15 mins till delivery.

For parturients in whom there was failure of pain relief (defined as verbal rating score [VRS] of 2 or more) on a VRS of no pain =0, mild pain =1, moderate pain =2 and severe pain =3, 20 minutes after the initiation dose of epidural analgesia has been given, additional 5mls of study solution was given. Pain relief was reassessed again after 20 minutes and if VRS was still 2 or more the patient was withdrawn from the study.

Group PCEA had their analgesia maintained by programmed self-administration of 5mls of 0.125% bupivacaine + 2 µg/ml fentanyl through the PCEA pump at the first experience of pain with a lockout interval of 20 minutes without background infusion. Group HIEB had their analgesia maintained every hour with 10ml of 0.125% bupivacaine + 20µg fentanyl administered by an anaesthesia resident who also doubled as the research assistant. Epidural analgesia was initiated at a cervical dilatation of ≥3 cm.

The start of the study was when bilateral T10 sensory block was achieved, and the end was when the baby was delivered or when the decision to do Caesarean section was taken. The first stage of labour was timed from the initiation of epidural analgesia at 3cm cervical dilatation to 10 cm dilatation, duration of second stage of labour was timed from full cervical dilatation to delivery of the baby; mode of delivery (spontaneous vaginal delivery, instrumental vaginal delivery or caesarean section) and neonatal Apgar score were noted and recorded. The foetal heart rate was continuously monitored with a cardiotocograph (Model 0128, Vapro GE Medical System Ltd, Bangalore, India). One hour after delivery, parturients were asked about willingness to request for epidural in their subsequent deliveries.

Data analysis

Data generated was analysed using the IBM SPSS statistics software version 25 (Armonk, New York, USA). Normality of data distribution was tested with Shapiro-Wilk test. Normally distributed continuous data such as age and duration of stages of labour, were summarized in means and standard deviation and analysed using the student's *t*-test. Nominal data such as mode of delivery were summarized as percentages and proportions and analysed in the two groups using Chi square test or Fischer's exact test as appropriate. Ordinal variables such as ASA grading, APGAR score, were summarized as median and range and analysed using Mann-Whitney U test for non-parametric data. A p-value of <0.05 was considered statistically significant.

Ethical consideration

Ethical approval was obtained from the Ethical Review Committee of the University of Ilorin Teaching Hospital with approval number ERC PAN/2068/07/1912. Written informed consent signed and dated was obtained from all patients following comprehensive explanation of the procedure to them by the investigator. An interpreter was used for parturients who had no formal education or were unable to understand English language. All participants were assured that the principles of beneficence (striving to maximize potential benefits), and non-maleficence (ensuring that no harm is done to participants) will be strictly adhered to.

Hypotension, a known complication of neuraxial blocks, was monitored by checking maternal blood pressure every 5 mins for the first 30 mins and subsequently every 15 mins till delivery. If there was presumed intrathecal or intravascular catheter placement (blood or cerebrospinal fluid aspirated from the catheter or inability to flex the knees after the test dose), the catheter was removed and the patient withdrawn from the study.

RESULTS

Eighty parturients were recruited into the study out of which forty parturients were randomized into the patient-controlled epidural analgesia (PCEA) group and forty parturients into the hourly intermittent epidural bolus (HIEB) group. Following unsatisfactory pain relief after additional epidural initiation dose (10mL plain bupivacaine + 20µg fentanyl) at 20th mi-

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nute, two parturients in the PCEA group and one in the HIEB group were withdrawn from the study. Thirty-eight parturients in the PCEA group and thirty-nine in the HIEB group completed the study.

Demographic data

The two groups were comparable in terms of gestational age, and ASA class. The mean ages were comparable in both groups; 27.3 ± 4.38 years versus 26.5 ± 3.58 years in group PCEA and group HIEB respectively (p = 0.22). The mean weight, height, BMI and gestational age were also comparable between the two study groups, p values were 0.28, 0.12, 0.17 and 0.08 respectively (Table I).

Table I: Comparison of demographic variables in the study groups (independent t-test)

Variables	PCEA	HIEB	t	*p* value
Age (years)	27.3 ± 4.38	26.5 ± 3.58	0.91	0.22
Weight(kg)	81.2 ± 10.05	79.6 ± 7.97	0.79	0.28
Height (cm)	166.4 ± 3.75	164.7 ± 3.04	2.23	0.12
BMI (kg/m2)	29.2 ± 3.16	29.3 ± 2.45	-0.10	0.17
Gestational Age (Weeks)	38.8 ± 1.20	38.7 ± 1.72	0.17	0.08

t = test statistic

Labour outcomes

The mean duration of first stage of labour was comparable in the two groups, with p vales of 0.42 and 0.95 respectively (Table II).

Out of the 77 parturients, 66 (85.5%) had spontaneous vaginal delivery, 3 (3.9%) had vacuum assisted vaginal delivery while 8 (10.4%) parturient were delivered through caesarean sections. The modes of delivery were similar in the two groups, p = 0.64. In the PCEA group 34 (89.5%) parturients delivered spontaneously per vagina, 1 (2.6%) had vacuum assisted vaginal delivery and 3 (7.9%) parturients were delivered of their babies through caesarean sections, while in the HEIB group 32 (82.1%) parturients, 2 (5.1%) parturients and 5 (12.8%) parturients delivered their babies through spontaneous vaginal delivery, vacuum assisted vaginal delivery and Caesarean delivery respectively (Table III).

Table II: Comparison of labour characteristics and outcome in the study groups (independent t-test)

Variables	PCEA	HIEB	t	p value
Duration of first stage of labour (minutes)	395.6 ± 52.50	423.8 ± 45.67	-2.4	0.42
Duration of second stage of labour (minutes)	20.2 ± 6.81	22.6 ± 6.53	-1.5	0.95
Volume of study drug consumed (mL)	77.4 ± 7.33	74.6 ± 8.91	1.48	0.37

Table III: Comparison of modes of delivery in the study groups (Chi-square test)

Variable	PCEA	HIEB	Total	χ^2	*p* value
Spontaneous vaginal delivery	34 (89.5)	32 (82.1)	66 (85.7)	0.88	0.64
Vacuum assisted delivery	1 (2.6)	2 (5.1)	3 (3.9)		
Caesarean delivery	3 (7.9)	5 (12.8)	8 (10.4)		

χ^2 = chi square test statistic

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Foetal outcomes

The foetal heart rate (FHR) before the procedure commenced was also found to be comparable in the two groups (Fig 1). The mean FHR was 135.4 ± 6.95 bpm in group HIEB compared to 136.1 ± 5.97 bpm in group PCEA, with p = 0.63. The Apgar scores in the two groups were comparable (Table IV). The median (range) Apgar scores at 1minute were 7 (5-8) in group PCEA and 7 (4-9) in group HIEB, p = 0.37, as such there was no statistically significant difference between the groups. The median Apgar scores at 5 minutes were 9 (6-9) in group HIEB and 9 (7-9) in group PCEA (p = 0.08) which was also not significantly different.

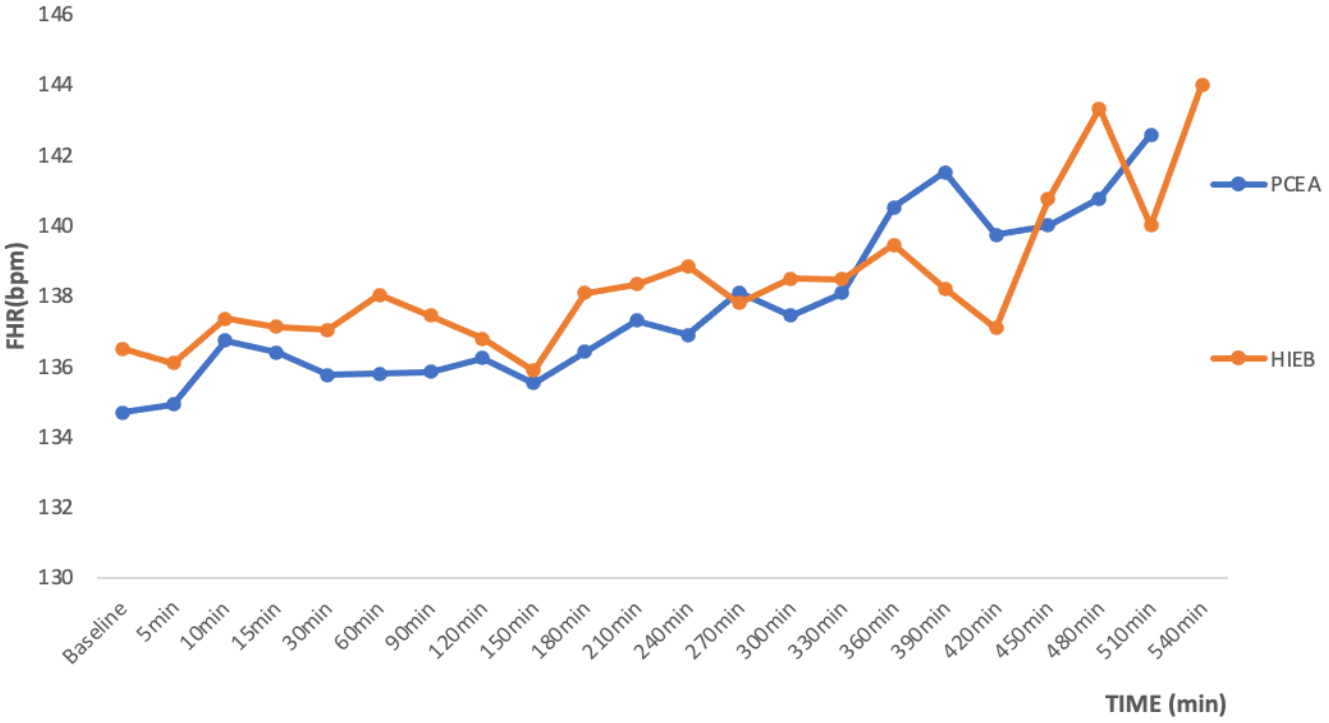

Figure 1: *Comparison of foetal heart rate (FHR) during labour in the two groups.*

Table IV: Comparison of neonatal outcomes in the study groups (Mann-Whitney U test)

Variables	PCEA	HIEB	U	*p* value
Apgar at 1 minute	7 (5 - 8)	7 (4 - 9)	657.00	0.37
Apgar at 5 minutes	9 (7 - 9)	9 (6 - 9)	596.00	0.08

U = test statistic

Willingness to request epidural analgesia in subsequent deliveries

Willingness to request epidural analgesia in labour during next delivery was also similar in the two groups, p = 0.42. Thirty-six (94.7%) women in the PCEA group and 35 (89.7%) women in the HIEB group were willing to request epidural labour analgesia in their next delivery. Overall, 71 (92.2%) women are willing to request epidural analgesia in labour in their next delivery while 6 (7.8%) women were not willing, 2 (5.3%) in the PCEA group and 4 (10.3%) in the HIEB group.

DISCUSSION

This study showed that there was no difference in the duration of labour, mode of delivery, neonatal outcome and willingness to request for epidural analgesia in subsequent deliveries with maintenance of epidural analgesia by either intermittent bolus administration or programmed patient controlled epidural administration.

The mean duration of the first stage of labour in the current study was comparable in the two groups. This is consistent

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with the findings of another study (6). Although, early observational studies on epidural analgesia in labour suggested a direct link between epidural use and prolongation of labour (9), recent studies have demonstrated that the epidural was not the factor of critical importance but the doses administered and the timing of these doses (10). Provision of effective analgesia in the first stage of labour has been found to decrease the inhibitory effect of endogenous maternal catecholamines on uterine contractility (11). Fyneface-Ogan et al (8) in a study that compared the effects of epidural analgesia and non-epidural analgesia on the characteristics of labour found that the duration of first stage of labour was shortened in the epidural group because of provision of effective analgesia.

The current study also found that the duration of second stage of labour and the rate of instrumental vaginal deliveries was comparable in the two groups. This is similar to the findings of another study (12). Paech et al (13) however found a longer duration of second stage of labour in the PCEA group. The disparity could be attributed to the significantly higher mean volume of bupivacaine consumed in the PCEA group, which could have caused a motor block resulting in reduced ability to push in the second stage. In a review article, Callahan et al (14) reported that reducing LA motor blockade by administering lower doses LA have resulted in comparable duration of second stage of labour and rate of instrumental vaginal deliveries between epidural and non-epidural analgesia for labour. Therefore, the dose of LA can be said to be more important than the technique of administration.

The incidence of operative delivery in the current study was low (7.9% and 12.8%) and similar in the two study groups, PCEA and HIEB respectively. This can be attributed to the use of similar volumes of low concentration bupivacaine and absence of motor block in the two study groups. The results are consistent with the findings of other similar studies (13,15) that epidural analgesia with low concentration of LAs is not an important causal factor of operative deliveries. Furthermore, when epidural analgesia is administered at a cervical dilation of ≥3 cm as done in our patients, regardless of technique of maintenance, does not significantly increase the duration of first and second stages of labour and cesarean delivery rates (9-10,16).

In the current study the APGAR scores were similar in both groups at 1 and 5 minutes respectively. A review article by Callahan et al (14) found that epidural analgesia was not associated with negative neonatal outcomes; APGAR scores were preserved while the risk of neonatal acidosis, based on measurements from cord blood pH, was reduced. The findings of favourable neonatal outcomes using 5-Apgar score in the current study was consistent with the findings of Callahan et al (14) and indeed many other studies that have compared different methods of maintenance of epidural labour analgesia (12,17). However, measurement of neonatal oxygenation and pH would have given a more objective measure of immediate neonatal outcomes.

The fact that majority of patients in both groups expressed willingness to request epidural analgesia in their subsequent labour is not surprising because epidural analgesia has consistently demonstrated high maternal satisfaction, improved labor experience, and superior pain control compared to other non-neuraxial options (9).

Conclusion, recommendations and limitations

Epidural labour analgesia maintained through hourly intermittent epidural boluses was comparable to the use of a PCEA pump in the duration of first and second stages of labour, modes of delivery, APGAR scores and willingness to request for epidural analgesia during subsequent deliveries. This has important implications for low-resource settings where patient-controlled epidural analgesia pumps are not widely available. Hourly intermittent epidural bolus is recommended as a safe method of maintenance of epidural labour analgesia in resource challenged regions where PCEA pumps are not available. The inability to blind the researchers and outcome assessors to the intervention groups due to the presence of the PCEA electronic infusion pump was a limitation in this study.

Author contributions

Dr Ige Olufemi, Dr Ige Kolawole and Prof Kolawole Israel contributed to the study concept and design, acquisition, analysis, and interpretation of data and drafting the article for important intellectual content. All authors agree to be accountable for the accuracy and integrity of all aspects of the work.

Declarations

Consent for publication: Not applicable.

Conflict of interests: The authors have no competing interests to declare.

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Availability of data and materials

Data will be available upon reasonable request with the first author.

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