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Post-Operative Application of Lidocaine with Epinephrine Effectively Mitigates Pain in Women who had Caesarean Section

Post-Operative Application of Lidocaine + Epinephrine

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Abstract:- The number of Caesarean sections performed worldwide is increasing as well as the cost of postoperative treatment. The management of pain post caesarean section is an important aspect of post-operative care which has contributed to high cost of maternal care and may contribute to maternal mortality especially in resource poor settings. This study assessed the safety and effectiveness of surgical site infiltration with lidocaine-epinephrine solution as post caesarean analgesia compared with non-infiltration. It was a prospective randomized controlled clinical trial. One hundred and forty (140) eligible pregnant women scheduled for elective caesarean section at term in University of Medical Sciences Teaching Hospital Complex (UNIMEDTHC) were randomly assigned to the study and control group, each with 70 participants. Surgical sites of the study group patients were infiltrated with 20mls of 2% lidocaine solution (400mg lidocaine+100µg epinephrine) stat while the control group patients were not. Both groups received the same adjuncts analgesic agents whereas rescue analgesics were given only after complaints of moderate to severe pain. The rescue analgesic consumption in the first 24 hours postoperatively was less in the study group compared to the control (120mg; 480mg). The mean time to onset of breastfeeding was significantly early (u =3.567, p < 0.001) in the study group compared to the control group. This study showed that surgical site infiltration with 2% lidocaine+epinephrine solution following caesarean section is safe, reduces pain scores and hence use of rescue analgesics postoperatively, it also increases the time of onset of breastfeeding thereby decreasing patient hospital stay.

Keywords:- *Caesarean Section, Postoperative Pain, Lidocaine, Epinephrine, Anesthesia.*

I. INTRODUCTION

Despite WHO recommendations of 10-15% rate, the rate of Caesarean section (CS) continues to increase globally (WHO, 2015). It is now the most frequent procedure performed during inpatient stays in the United States (HCUP, 2020). Between 1990 and 2014, the global average CS rate increased by 12.4%, with a 4.4 percent yearly rise (Betran *et al*, 2016). In Nigeria, the CS rate varies by care setting and can be as high as 20% in a tertiary hospital (Isah *et al*, 2018; Gunn *et al*, 2017).

With the rising prevalence of CS, it is more important than ever for mothers to recover quickly so they can breastfeed their children. According to Verstrate *et al*, the optimal post-CS analgesic need should be cost effective, simple to administer, and have minimum influence on staff burden, as well as minimal transfer into breast milk with no harmful effect on the baby (Verstrate and Van de velde, 2012). Surgical incision site infiltration with lidocaine for post-CS analgesia is simple to implement, relevant in settings with small workforce and have been demonstrated to be safe in the newborn. Its safety and effectiveness as post-CS analgesia have been demonstrated and reported in literature. However, previous studies were done using heavy Bupivacaine which through long acting is costly and may not be readily available in a resource poor setting hence the need to devise a more affordable and available method.

This study evaluated the safety and effectiveness of surgical incision site infiltration with lidocaine - epinephrine solution as post-caesarean analgesia.

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II. MATERIALS AND METHODS

This study was a prospective, randomised, controlled, single- blinded clinical trial. The study was performed at the Obstetrics and Gynaecology Department of the University of Medical Sciences Teaching Hospital Complexes (UNIMEDTHC), Ondo State. After obtaining ethical approval from the research and ethical committee of the institution, 140 pregnant women were included in the study. The pregnant women were randomly assigned into two (2) different groups with seventy women in each group. Inclusion criteria include; Term pregnancies of 37 to 42 weeks gestation, elective lower segment caesarean sections with or without bilateral tubal ligation, planned spinal anaesthesia and planned Pfannenstiel or low transverse incision. Exclusion criteria include: Known maternal allergy to lidocaine or its derivative, known maternal allergy to pentazocine or derivative, chronic opioids users, maternal age less than 18 years, non-consenting patients, contraindication to breast feeding and history of hypertension.

Term pregnant women scheduled for elective CS were screened within 7 days before and on the day of surgery to validate their eligibility for the study. The screening was done in secluded private setting at the antenatal clinic during their routine antenatal visit and in the antenatal ward when admitted for surgery (routinely 2days prior to the day of surgery). This was to ensure eligible women were given ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. The eligible women were counseled on the study and a written informed consent was obtained from the subject. The information was documented in a study proforma which was later transferred into electronic data base.

One hundred and forty, opaque, sealed envelopes were used and each enclosed a paper with a letter A or B and a code. Each patient picked an envelope from a set and either A or B determined subject's allotted group. The envelopes were not opened and the subjects group not known until immediately prior to the surgical site incision infiltration to maintain the randomisation process. Only participants were blinded to (i.e. were not told) their intervention group. All the caesarean sections were performed by specialist Obstetrics & Gynecologist using similar surgical techniques; the Pfannenstiel technique on the anterior abdominal wall, exteriorisation of the uterus and its repair In one or two layers, non-peritoneal closure as well as subcuticular skin closure were performed in all the cases. The opaque envelope containing the randomisation group of the participant was opened only after the skin closure to maintain the randomisation process.

- *Procedure*

20mls of 2% lidocaine combined with epinephrine was withdrawn into two separate 10mls syringes. A sterile 22-guage 1.5 inch free needle was inserted approximately 0.5 to 1cm into the subdermal layer for the infiltration of the upper and lower edges of the incision site. About 0.5 to 1ml of the Local Anaesthetic (LA) solution (2% Lidocaine+ Epinephrine) was injected to every 1-2cm of the surgical field to ensure total coverage of its entire length. Caution was taken to prevent intravascular injection by first aspirating the blood before injection of the drug while the attending anaesthesists observe the patient for any side effect during and after administration of the drug. Rescuscitation packs (containing anticonvulsant, steroids, and intravenous fluids) were made available in the theatre and sterile techniques were maintained at all stages of the administration of the allotment agent (withdrawal, handling over and injection). Participants' code was recorded in their case notes and side effect was recorded in the anaesthetic record sheet. The participants in group A had their surgical incision site (SIS) infiltrated with 20mls of 2% lidocaine+epinephrine solution. Patients in the group B had non-infiltration of their surgical sites. Both groups received 100mg rectal diclofenac and intravenous paracetamol (600mg, 8 hourly) for the first 48 hours. From the third postoperative day, oral paracetamol (1g, 8 hourly) and diclofenac (50mg 12 hourly) were the adjunct analgesics of choice. Rescue analgesics (30mg of pentazocine intramuscularly) was administered 6 hourly for 48 hours after a patient complained of moderate to severe pain.

For the first 48 hours, the surgical incision site of patients in group A was infiltrated with lidocaine+epinephrine solution together with rectal diclofenac 100mg 24 hourly and then intravenous paracetamol 600mg 8 hourly. Oral paracetamol 1g 8hourly and diclofenac 50mg 12hourly was then administered afterwards. For the first 48 hours, individuals in Group B were given rectal diclofenac 100mg 24 hourly and intravenous paracetamol 600mg 8 hourly, then oral paracetamol 1g 8 hourly and diclofenac 50mg 12 hourly.

Maximum allowable dose (mg/kg) × (weight (kg)/10) × 1/concentration of LA = ml of lidocaine.

Rescue analgesics (30mg of pentazocine) were administered intramuscularly every 6 hours whenever a participant in any of the group complained of moderate or severe discomfort despite prescribed analgesia.

- *Pain Score Measurement*

There are numerous types of scales used in assessing pain intensity in humans but the one-dimensional pain scales have been recommended for assessment of pain intensity in clinical studies involving adult participants. One-dimensional pain scales include the numerical rating scale (NRS), verbal rating scale (VRS) and visual analogue scale (VAS). One-dimensional pain scales generally are measurement instruments for subjective characteristics or attitudes that cannot be directly measured; patient self-reported pain is so critical in the pain assessment method that it has been described as the most valid measure of pain, the 5th vital sign (Sjostrom *et al*, 2000)

Numerical rating pain scale is a pain rating scale first used by Hayes and Patterson in 1921. (Hayes and Patterson, 1921). Scores are based on self-reported measures of symptoms that are recorded with a single handwritten mark

placed at one point along the length of a 10cm line that represents a continuum between the two ends of the scale "no pain'' on the left end (0 cm) of the scale and the worst pain on the right end. Measurements from the starting point (left end) horizontal scale, with its left extremity, 0 pains represent the absence of pain and gradually increase up to the right extremity or 10, which represents worst pain imaginable. The numerical rating scale has been validated for pain assessment, permitting a reliable and consistent measure and study of pain intensity and unpleasantness. There are two forms of NRS; the digital and the paper form. In a study conducted by Domenica *et al* in 2018 on the validation of digital NRS pain scoring with a traditional paper based, it was reported that numerical rating scoring scale in adults found no clinically relevant difference between the traditional paper based NRS assessment and NRS scores obtained from laptop computer and mobile phone based platforms (Domenica *et al*, 2018). Paper form was used in this study.

When responding to NRS paper, the respondents specify their level of agreement to a statement of pain by indicating a position along a continuous line between two endpoints. Although there is conflicting evidences with regard to the advantage of NRS compared with other methods for recording pain. The NRS is still commonly used in clinical setting and was the pain scale used mostly in previous studies on post caesarean analgesia, the choice of NRS is to allow better comparison of results on a wider range with previous studies (Price *et al* ,1983; Rosier *et al*, 2002). The participants of this study were shown and taught how to use NRS paper after filling the consent form. Participants were required to circle the number representing their pain intensity and this was documented on the patient proforma. A written instruction was used to aid the understanding of subjects and other assessors. For the assessment of pain intensity at rest, subject rested quietly in a supine or sitting position for 3-5 minutes before assessing the pain score. Assessment of pain was done at rest, 6, 12, 18 and 24 hours after surgery and prior to rescue analgesic administration.

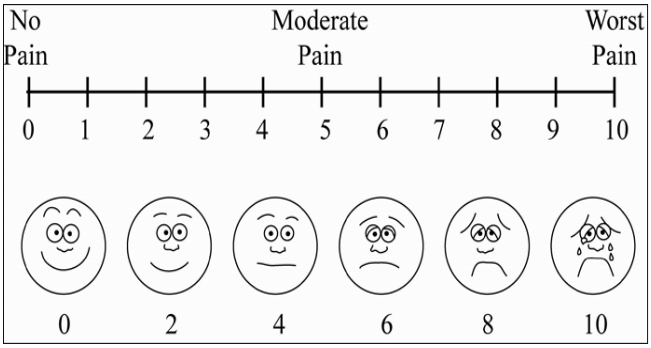

Fig 1 Pain Score Measurement

➢ *Data Analysis*

Data were analysed using SPSS version 25. Continuous data were summarised as means and standard deviation and non-parametric Mann-Whitney (U) tests were used for data that were not nominally distributed. The numerical pain score within the first 24hr post C/S in the two groups were compared using the independent t test. Pearson Chi-square test for categorical variables was done. The level of significance was set at 5% (P = 0.05). The results were represented by appropriate tables.

➢ *Ethical Considerations*

Ethical approval was obtained from the research and ethical committee of the University of Medical Sciences Teaching Hospital, Akure, Ondo State.

III. RESULTS

A total number of 140 parturient participated in this clinical trial. Table 1 showed the socio-demographic patterns of the trial participant. The mean age of participant was 32 years. There were no statistically significant differences in patients' mean ages and body mass indices among the groups (t = 0.01, p = 0.992 and χ^2=5.982, p = 0.200 respectively). There was also no statistically significant difference in the distribution of the patients by their levels of education across the groups (χ^2 = 2.93, p = 0.062).

The obstetric parameters of the trial participants were presented in Table 2. Across the two groups, elective caesarean section without bilateral tubal ligation was the commoner surgery of choice. Participants were mostly multiparous and had 2 previous caesarean sections.

As presented in Table 3, there was no complication recorded among the study group participants during infiltration. The estimated blood loss and duration of surgery showed no statistical significant difference between the two groups (p = 0.084 and 0.065 respectively).

Table 4 showed the measure of effectiveness across the group. The overall mean pain score was less in the study group compared to the control with no statistical significance (t= -1.020, p = 0.310). The mean pain scores at rest, movement, 6hrs, 12hrs, 18 hrs and 24hrs showed no statistical significant difference across the two groups. The mean time to onset of first rescue analgesic request was longer in the study group compared to the control group, however, this difference was not statistically significant (t = 0.385, p = 0.701). The rescue analgesic (pentazocine) consumption in the first 24 hrs postoperatively was less in the study group compared to the control group. 2.9% and 11.42% of the trial participants had moderate to severe pain in the study group and control respectively.

Table 5 shows the length of hospital stay, onset of breast feeding and pattern of wound healing in the groups. The mean time to onset of breastfeeding was significantly early (u =3.567, p < 0.001) in the study group compared to the control group. There was no significant difference in the pattern of wound healing process in the study and control group. Both group had the same length of hospital stay (72 hours).

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Table 1 Sociodemographic Characteristics of Study Participants

Variables	Trial Group		Test	p-value
	Study n (%)	Control n (%)		
Age Mean ± SD (years):	**32.17±3.42**	**32.57±2.45**	**t= -0.01**	**0.992**
Level of Education				
None	0 (0.0)	0 (0.0)	χ^2=2.930	0.062
Primary	3 (4.3)	1 (1.4)		
Secondary Tertiary	21 (30.0)	20 (28.6)		
	46 (65.7)	49 (70.0)		
BMI Level (kg/m2):				
Underweight (<18.5)	0 (0.0)	0 (0.0)		
Normal weight (18.5-24.9)	4 (5.9)	4 (5.9)		
Overweight (25.0-29.9)	14 (20.6)	21 (30.4)	χ^2=5.982	0.200
Class I obesity (30.0-34.9)	36 (52.9)	23 (33.3)		
Class II obesity (35.0-39.9)	10 (14.7)	13 (18.8)		
Morbid obesity (>40)	4 (5.9)	8 (11.6)		
Religion				
Christianity	65 (92.9)	64 (91.4)	χ^2=0.099	0.753
Islam	5 (7.1)	6 (8.6)		
Occupation				
Artisan	4 (5.7)	1 (1.4)	χ^2=3.108	0.088
Civil service	6 (8.6)	2 (2.9)		
Job applicant	3 (4.3)	4 (5.7)		
Teaching	18(25.7)	21 (30.0)		
Trading	39 (55.7)	42 (60.0)		
Marital Status				
Single	0 (0.0)	0 (0.0)	-	
Married	70 (100.0)	70 (100.0)		
Ethnicity				
Yoruba	63 (90.0)	57 (81.4)		
Ibo	7 (10.0)	8 (11.4)	χ^2=3.087	0.200
Others	0 (0.0)	5 (7.1)		

Table 2 Obstetric Parameters of Study Participants

Variables	Trial Group		Test	p-value
	Study n (%)	Control n (%)		
Indication for CS:	3 (4.3)	3 (4.3)	χ^2=3.348	0.020
Bad obstetric history	4 (5.7)	4 (5.7)		
Short inter pregnancy interval	5 (7.1)	5 (7.1)		
2 previous scars	32 (45.7)	33 (47.1)		
3 previous scars	1 (1.4)	0 (0.0)		
Mal presentation	6 (8.6)	7 (10.0)		
Major placenta previa	3 (4.3)	2 (2.9)		
Twin gestation / leading twin breech	8 (11.4)	6 (8.6)		
Elderly primigravida	3 (4.3)	2 (2.9)		
Fetal macrosomia	5 (7.1)	8 (11.4)		
Parity:				
Nulliparous	22 (31.4)	22 (31.4)	χ^2=3.095	0.377
Primiparous	17 (24.3)	10 (14.3)		
Multiparous	31 (44.3)	38 (54.3)		
EGA:				
38 weeks	70 (53.0)	62 (47.0)	χ^2=2.348	0.420
41 weeks	4 (5.7)	4 (5.7)		
No. of Previous C/S:				
0	26 (37.1)	28 (40.0)	χ^2=3.811	0.283
1	10 (14.3)	9 (12.9)		
2	32 (45.7)	33 (47.1)		
3	2 (2.9)	0 (0.0)		
Planned Surgery				
ELLSCS + BTL	10 (14.3)	8 (11.4)	χ^2=0.255	0.614
ELLSCS – BTL	60 (85.7)	62 (88.6)		

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Table 3 Safety Measures, Duration of Surgery and Estimated Blood Loss

Variable	Study n = 70	Control n = 70	Test	p-value
Estimated blood loss (mls)	517.14± 66.42	537.14±69.51	t = -1.740	0.084
Duration of surgery (minutes)	28.30 ± 6.12	34.11 ± 6.95	t = 1.253	0.065
Complications related to surgery Adhesions Nil	 17 53	 18 52	 χ^2=0.038	 0.845
Side effect during wound infiltration Yes No	 0 70 (100.0)	 0(0.0) 70 (100.0)	 -	 -
Complications related to Anaesthesia Yes No	 0(0.0) 70 (100.0)	 0 (0.0) 70 (100.0)	 -	 -

χ^2 = Chi square test value and t = Independent sample t-test value

Table 4 Measure of Effectiveness

Variable	Study n=70	Control n=70	Test	p-value
Time from the end of surgery to first analgesic request Mean ± SD (hours)	13.32 ± 2.32	12.69±2.81	t = 0.385	0.701
Rescue analgesic consumption (mg)	120	480	-	-
Pain score at movement Pain score at rest Pain score 6 hours Pain score 12 hours Pain score 18 hours Pain score 24 hours Mean pain score	2.07±0.46 0.00±0.00 1.30±0.55 1.54±1.67 1.09±0.47 1.54±0.58 1.29±0.32	1.98±0.52 0.00±0.00 1.40±0.57 1.74±1.29 1.33±0.67 1.67±0.50 1.33±0.31	t= 1.027 - t = -1.054 U = 1.249 t =1.464 t = 1.399 t = -1.020	0.306 - 0.294 0.125 0.151 0.164 0.310

t = Independent sample t-test value; U = Mann-Whitney test value

Table 5 Length of Hospital stay, on set of Breast Feeding and Pattern of Wound Healing

Variable	Study n = 70	Control n = 70	Test	p-value
Breastfeeding onset Mean + SD (hours)	13.87±5.02	14.94±9.38	U = 3.567	0.000*
Hospital stay Mean + SD (hours)	72.00±0.00	72.00±0.00	-	-
Wound check at 72hours post Op / discharge Wound edges well apposed	70 (100.0)	70 (100.0)		
Wound check at 2 weeks post natal Satisfactory healing	70 (100.0)	70 (100.0)	-	-
Breastfeeding still sustained at 2 week postnatal Yes	70 (100.0)	70 (100.0)		

U = Mann-Whitney test value

* Statistically significant difference at 0.05

IV. DISCUSSION

In this study, the overall mean pain score among the participants in the intervention group was 1.29. This is lesser than that observed by Ghaenaee *et al* whereby a mean score of 4.13 on the efficacy of lidocaine 2% in post- caesarean deliveries was reported (Ghenaee *et al*, 2015).The differences in these two scores could be due to the variations in the methodology such that the scheduled adjunct analgesics were part of the index study protocol while in the latter, an adjunct was administered only following complaints of pain.

In the present study, there were no statistically significant reductions in post–op pain scores at 6hrs, 12hrs, 18hrs and 24hrs in the study group. This is contrary to several studies that have been recently investigated on bolus intravenous low dose lidocaine administration at the time of anaesthesia induction and maintenance of dosage infusion from delivery to the completion of surgery for postoperative pain management. However, it was found that even up to 24 hours after surgery, pain levels were significantly reduced (Gholipour *et al*, 2017; Hirmanpour *et al*, 2018). However, the discrepancy in this present study and the above findings may be due to the different mode of administration of

lidocaine. This study adopts the infiltration method of lidocaine and epinephrine unlike the bolus intravenous administration used in the previous study.

In this study, mean time to onset of breastfeeding was observed to be shorter in the study group compared to the control group. The 13-hour period observed in the study group was significantly longer than the 2-hour period observed in Ahmed *et al's* study comparing the effectiveness of lidocaine epinephrine with plain lidocaine for post-c-section pain management (Ahmed *et al*, 2016). The variation in this present study and above findings could be due to different hospital protocols for breastfeeding following caesarean delivery. In a similar vein, the intervention group in the present study had a longer time to request more analgesics. This finding is more than that observed by Ahmed *et al* (Ahmed *et al*, 2016). The difference in this present study and above findings could be due to the variations in methodology.

There were no side effects recorded in the intervention group in the present study. This is similar previous studies conducted by Bamigboye and Hofmeyr (2010) and Ahmed *et al* (Bamigboye and Hofmeyr, 2010; Ahmed *et al*, 2016). The reason for this finding may be because lidocaine is an anaesthetic agent and has been used widely for infiltration in minor surgical procedures with negligible complication.

In this study, there was a comparable satisfactory wound healing in both groups based on subjective assessment of the surgical sites at the 2-week postnatal clinic. This is similar to the findings of Xu *et al* whereby he reported that local application of lidocaine can promote wound healing to a certain extent, reduce pain, and promote postoperative skin reconstruction (Xu *et al*, 2019). The reason for this finding may be because lidocaine has an anti-inflammatory property.

This study showed that none of the patients in both groups developed postoperative infection and all were discharged within 72hrs postoperatively. This finding was similar to that of Ahmed *et al* in the aspect of postoperative infection but not in the duration of hospital stay as the latter reported 31.8 hours and 22.4 hours for control and study groups respectively (Ahmed *et al*, 2016). The difference in the duration of hospital stay in this study and the above study may be as a result of different hospital protocols regarding discharge following caesarean section. Patients are routinely discharged 72 hours following caesarean section in UNIMEDTHC.

In the present study, duration of surgery was shorter in the study group compared to the control group. This is contrary to the findings of previous studies whereby a longer duration of surgery in the study group was reported (Nasir *et al*, 2019; Ahmed *et al*, 2016). The reason for this difference may be due to variations in the infiltration of local anaesthetics. In this study, infiltration of local anaesthetics was performed after skin closure unlike in previous studies whereby the infiltration of local anaesthetics was done prior to skin closure.

V. CONCLUSION

The findings of this study indicated that infiltration of the surgical incision site with 2% lidocaine+epinephrine solution post-caesarean section is safe and reduces postoperative pain as well as need for additional analgesic administration.

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- *Not Applicable*

- *Disclosure of Interest*
  There were no competing interests.

- *Authors' Contributions*
  Olubunmi D. Babatola conceived, designed and supervised the work; Odunayo D. Babatola contributed to the conception of the work, B.K. Akinola contributed to the analysis of the work and writing of the manuscript, A.M. Owojuyigbe and O. Akadiri contributed to the critical revision of the article. All authors contributed to the final manuscript.

- *Ethical Approval*
  Ethical approval for this study was obtained from the research and ethical committee of the University of Medical Sciences Teaching Hospital and the study was performed in accordance with the principle of good clinical practice.

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- *Data Availability Statement*
  The data that support the findings of this study are available from the corresponding author, [B.K.A.], upon reasonable request.

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