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Preoperative Sodium Bicarbonate Infusion and Maternal and Neonatal Outcomes in Prolonged Obstructed Labour at the Alex Ekwueme Federal University Teaching Hospital, Abakaliki: A Randomized Control Trial

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Abstract

Background: Prolonged obstructed labour is still among the common complications of labour in low resource countries. It becomes complicated by fluid and electrolyte imbalance that should be adequately corrected for better outcomes. Resuscitation with intravenous fluid and electrolyte replacement prior to Caesarean section do not wholly reverse the metabolic acidosis associated with prolonged obstructed labour. Metabolic acidosis is complicated by primary postpartum haemorrhage and birth asphyxia. Sodium bicarbonate as a buffer could effectively correct the metabolic acidosis. **Objective:** This study evaluated the effect of preoperative sodium bicarbonate infusion on maternal and fetal lactate levels as well as clinical outcomes in prolonged obstructed labour. **Methods:** An equivalence randomized control trial that was placebo-controlled in prolonged obstructed labour at Alex Ekwueme Federal University Teaching Hospital, Abakaliki determined the effectiveness of single dose preoperative sodium bicarbonate infusion in correcting metabolic acidosis. Fifty millilitre of 8.4% of 50 mmol/l sodium bicarbonate infusion was given to the intervention group and the other arm, placebo (50 ml of water for injection). Intravenous fluid, 1.5 litres of normal saline was given to both arms during resuscitation. Data were collated and analyzed using IBM SPSS software (version 20, Chicago IL, USA). Mean and standard deviation (mean ± 2 SD) showed the continuous variables. Numbers and percentages showed the categorical variables. Student's t-test was used to compare the means between two groups of continuous variables. While Z-test was used to determine signifi-

cance of statistical measures Chi squared test/Fisher exact test was used to determine relationship between categorical variables. The level of statistical significance was expressed as p-value and was taken to be significant if ≤0.05. **Results:** The median maternal capillary lactate level at one hour was 7.15 ± 1.97 mmol/l in the bicarbonate group and 7.61 ± 1.73 mmol/l in the control group with p value of 0.133 which was not statistically significant. The mean fetal arterial cord blood lactate level in the Bicarbonate arm, was significantly lower, 3.39 ± 0.95 mmol/l than the placebo group, 4.11 ± 1.05 mmol/l with p value < 0.001. The fifth minute Apgar score was less than 7, in 19 (25.7%) in the Bicarbonate arm which was lower than 43 (58.1%) in the control group, 43 (58.1%) which was statistically significant, with p < 0. 001.The newborn admission in Bicarbonate group was 21 (28.4%) while that of the placebo arm was 49 (66.2%), which showed statistical significance with p < 0.001. Only mild side effects were noted in the Bicarbonate group with no statistical significance. **Conclusion:** 50 ml of 50 mmol/l of intravenous sodium bicarbonate infusion preoperatively, had no significant effect on maternal capillary blood lactate level at one hour following administration and this upholds the null hypothesis. It, however, significantly reduced fetal arterial cord blood lactate level at birth. It also significantly reduced birth asphyxia and newborn admission in Newborn intensive care unit. Post-partum haemorrhage was also significantly reduced. It is effective and safe.

Keywords

Obstructed Labour, Prolonged Obstructed Labour, Metabolic Acidosis, Sodium Bicarbonate, Lactate

1. Introduction

Obstructed labour and uterine rupture have contributed immensely to maternal disability for almost three decades [1]. The trend is however changing in the right direction as the number that lived with disability, decreased from 449,260 in 1990 to 397,611 in 2017, representing a decrease of 11.5% over this period [1]. The yearly maternal deaths have decreased from 532000 in 1990 to 303000 in 2015 [2] [3]. The deaths occur mostly in the regions of the world that are less developed [2]. The life time risk of maternal death is estimated to be as high as 1 in 16 to 49 in the regions of the world with poor resource compared with 1 in 2800 in developing regions [2] [3]. Over 70% of these deaths were attributed to obstructed labour and its sequale [3]. Postpartum haemorrhage and sepsis are also leading causes [3]. About 8% of maternal mortality could be accounted for by obstructed labour alone [4] [5]. while birth asphyxia resulting from prolonged obstructed labour account for about 90% of the perinatal deaths [5], Metabolic acidosis, electrolyte derangement, haemorrhage, and infection account for majority of deaths resulting from obstructed labour [6]-[8]. Fluid and electrolyte changes may result from abnormal metabolic activities, starvation, excessive uterine contractions and muscular activities, pyrexia and maternal exhaustion [9]-[11].

Prevalence of obstructed labour ranges from 2% to 8% worldwide [4]. It occurs more in low resource countries than in more economically advantaged countries [4] [5]. Prevalence of 2.6% has been reported in Abakaliki [12]. The prevalence of obstructed labour in an environment is a marker of quality of obstetric care available in that community [12]-[15]. These deaths are partly attributed to haemorrhage, ruptured uterus, infection, metabolic and electrolyte derangement [4] [16]-[18]. Higher lactate levels in blood and amniotic fluid are present in prolonged obstructed labour which adversely affect outcomes [6] [8] [9]. Lactate is produced as a byproduct in prolonged obstructed labour due to the resultant hypoxia that ensues [7]. Myometrial acidosis resulting from metabolic acidosis impairs contraction and increases the risk of primary postpartum haemorrhage, but promotes oxygen transfer to the fetus which reduces the risk of birth asphyxia [6]-[8]. Low Apgar scores may result from exchange of hydrogen ions via the placenta resulting in birth asphyxia [9].

The buffer property of bicarbonate makes it a preferred drug to reverse lactic acidosis during vigorous exercises [10]. A randomized study showed good clinical outcomes with bicarbonate use in difficult labour [10]. During resuscitation, fluids are given as recommended but may not entirely correct acidosis [19], which is associated with prolonged obstructed labour.

Prolonged obstructed labour requires an expedited action to be taken, once the diagnosis is made thus 50 ml of 50 mmol/l of Sodium bicarbonate would be administered preoperatively by intravenous bolus infusion as has been done in other studies involving difficult labour [10] [20]. This study would evaluate whether maternal and fetal lactate levels are affected by preoperative infusion of bicarbonate as the primary outcome measure. Hand held lactate measuring instrument would be used to assay maternal and fetal blood lactate levels in this study as it has been associated with reliable results in related studies [20]. It does not require electricity to function and the operational details are easily understood which makes it a good option in a low resource setting, where cases of prolonged obstructed labour are still prevalent.

Bicarbonate as a buffer could help in reversing metabolic acidosis and its sequalae in patients with prolonged obstructed labour and therefore may offer a good option with respect to clinical outcomes in our environment where this obstetrics complication is still common. Bicarbonate has also been shown to be safe when used in previous studies [21].

Preoperative bicarbonate infusion in prolonged obstructed labour is a novel study. Studies evaluating sodium bicarbonate use in difficult labour has only been done in Europe where oral bicarbonate of soda was used for labour dystocia. Such studies have been suggested for East Africa, but only a study protocol for randomized controlled trial, has been formulated for obstructed labour in Uganda. Studies that were done in Europe did not include obstructed labour as well as neonatal outcomes, following bicarbonate use in labour. There is no study that has evaluated the maternal and fetal outcomes following sodium bicarbonate infusion in

prolonged obstructed labour among the studies reviewed within the limits of our search. None of the studies reviewed, involved a Nigerian or West African study, on use of sodium bicarbonate in difficult labour.

2. Search Methods

Search methods employed to find the review articles were electronic databases and manual search, Medscape, Medline, PubMed, Hinari, Google scholar were the electronic databases used for the search. Journals, textbooks were manually searched Peer reviewed articles were selected for review.

2.1. Justification

Metabolic acidosis is one of the complications of prolonged obstructed labour and may complicate primary postpartum haemorrhage and birth asphyxia with the attendant deleterious maternal and neonatal outcomes. Maternal acidosis may result in lower fetal pH and poor Apgar score in. women with prolonged obstructed labour. Correction of these metabolic derangements is worthwhile in women presenting with prolonged obstructed labour, since this condition is more prevalent in poor countries and almost non-existent in the developed countries. As such the use of sodium bicarbonate to be evidenced based in a standard preoperative protocol may further decrease metabolic acidosis and the associated sequelae among prolonged obstructed labour cases. Sodium bicarbonate use in difficult labour has been studied in Europe with no available study on its use in prolonged obstructed labour. Its effect on Nigerian women in the West African subregion with prolonged obstructed labour, therefore merits evaluation. This study would help to bridge the deficit in knowledge.

2.2. Research Question

Does Sodium Bicarbonate infusion preoperatively have effect on maternal and neonatal lactate levels among patients with prolonged obstructed labour in Alex Ekwueme Federal University Teaching Hospital, Abakaliki?

2.3. Aim and Objectives

The aim of this study is to evaluate effect of sodium bicarbonate infusion on maternal and neonatal lactate levels among patients with prolonged obstructed labour.

The specific objectives are:

1) To evaluate maternal and neonatal outcomes following administration of single dose preoperative sodium bicarbonate

2) To evaluate side effects associated with sodium bicarbonate administration.

3) To evaluate sodium bicarbonate as a buffer.

2.4. Null Hypothesis

Sodium bicarbonate administration does not influence maternal capillary blood lactate level at one hour following administration and neonatal arterial cord blood

at birth, in women with prolonged obstructed labour.

2.5. Alternate Hypothesis

Sodium bicarbonate administration influences maternal capillary blood lactate level at one hour following administration and neonatal arterial cord blood at birth, in women with prolonged obstructed labour.

3. Materials and Methods

3.1. Study Design

An equivalence randomized control trial (RCT). The RCT was double blinded and placebo-controlled evaluating preoperative Sodium bicarbonate infusion and maternal and neonatal outcomes with intention to treat, in prolonged obstructed labour at the Alex Ekwueme Federal University Teaching Hospital, Abakaliki (AEFUTHA). The maternal capillary lactate level was assessed at recruitment and following infusion of the intervention drugs, at one hour. Fetal arterial cord blood lactate level was measured at birth. Maternal capillary blood was collected following a lancet prick on the tip of the left middle finger and the lactate level measured with the portable lactate device. 0.3 ml of the cord blood was syringed and blood lactate level also measured with the portable lactate device. It is battery operated which favours its use in a low resource setting with absent or epileptic electricity supply, its operations are easily understood, as well as being maintenance free requiring no calibration before and during use. Although portable hand-held lactate device is faster and easier to use in clinical setting, the operating costs associated with hand-held device may be high. The cheaper, yet more time-consuming Spectrophotometric analyses have not been jettisoned in the measurement of blood lactate level.

3.2. Study Population

All cases of prolonged obstructed labour who qualified for inclusion and gave consent in AEFUTHA and Mile 4 Hospital (a Comprehensive Centre under AEFUTHA), were included in the study.

3.3. Duration of Study

The study lasted for six months (26th April 2024 to 22nd October 2024).

3.4. Research Assistants

Twelve residents from the various teams made up the research assistants. They were trained on the research methodology as well as understanding of the other aspects of the study. Following ethical approval, meetings were held at regular intervals on the real time assessment of the processes as well as challenges were discussed and solutions proffered. Conscious of the envisaged difficulties in obtaining valid consent in women with prolonged obstructed labour, consent was sought after administration of analgesia and at the same time of taking consent

for caesarean section. Recruitment of patients commenced at Obstetrics and Gynaecology emergency and patients who gave consent. Participants followed up by the team to the theatre and postnatal ward for 24 hours.

3.5. Inclusion Criteria

1) Women who gave consent.
2) Singleton term pregnancies.
3) Confirmed prolonged obstructed labour**.** This occurs when the first and/or second stages of labour last longer than normal with classical signs of obstruction. For first-time mothers, prolonged labour is defined as lasting more than 20 hours, while for those who have given birth before, it is more than 14 hours.

3.6. Exclusion Criteria

1) Obstetrics emergencies such as antepartum haemorrhage.
2) Women with hypertensive disorders.
3) Women with Diabetes Mellitus and other concurrent medical conditions.
4) Renal disease and heart disease.
5) Intrauterine fetal death.
6) Allergy to Sodium bicarbonate.
7) Multiple gestation.
8) Previous scar.
9) Ruptured uterus.
10) Fetal anomaly.

3.7. Departmental Protocol for Management of Obstructed Labour

Classical obstructed labour that presents in Accident and Emergency unit usually involves referred unbooked patients [22]. These women are admitted and detailed history is obtained to identity the risk factors present in the index case. General physical examination carried out and diagnosis of obstructed labour is made. Samples are then taken for investigations. Intravenous access is secured with a wide bore cannula. An indwelling urinary catheter and urine output is monitored. Specimen is collected for bedside urinalysis. Rehydration is commenced with Ringer's lactate or normal saline. Electrolyte imbalance is corrected if indicated in the test result. Parenteral antibiotics is commenced as well as parenteral analgesics. Nasogastric tube is passed to empty the stomach, if this is full. Intravenous Ranitidine 150 mg statim is given. The theatre is booked and anaesthetist informed Neonatologist is also informed. An emergency caesarean section is performed following resuscitation. After delivery, the urinary catheter is left in situ for 10 to 14 days. The patient is counseled and properly assessed for complications before discharge.

3.8. Sample Size Determination

The formula for an equivalence randomized control trial (continuous variables)

as stated by Zhong [23] was used to calculate the sample size.

$$N = 2 \times \left(\frac{Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}}{\delta^2} \right) \times S^2$$

N = Sample size for each group

Z = Standard normal deviate for a one- or two-sided x

δ_0 = clinically accepted margin

S^2 = polled standard deviation of both comparison groups

Substituting

$Z_{1-a/2}$ = 1.96 (According to Zhong *et al.*)

$Z_{1-\beta}$ = 0.845 (According to Zhong *et al.*)

δ_0 = 4.6 (According to study by Wiberg-Itzel *et al.*, 2018)

S = 9.5 (According to study by Wiberg-Itzel *et al.*, 2018)

$$N = 2 \times \left(\frac{1.96 + 0.845}{4.6} \right)^2 \times 9.5^2$$

$N = 2 \times (0.61)^2 \times 90.25$

$N = 2 \times 0.3721 \times 90.25$

$N = 67$

Adding 10% Attrition = 67 = 67/10 = 6.7

$N = 74$

74 women with prolonged obstructed labour were needed in each arm.

4. Informed Consent

The participants were recruited after signing the consent form and the objective of the study was clearly explained to them. Assurances were given to them that a standard management protocol would be observed irrespective of the study. Details of the study drugs as well as processes of specimen collection were explained to them. They were also informed that the outcome of the research could lead to an advancement in Obstetrics practice which could positively influence management outcomes in the future. The participants were told that blood specimen collection would require lancet prick on the finger tip of the mothers and syringing about 0.3 ml of cord blood from their babies. That they might witness slight needle prick pain and amount of blood specimen collected would not be harmful to the mothers and their babies. The participants were told that the study team would make every effort to ensure privacy and confidentiality. Participants were also informed that they were not going to pay for the research as it has been already undertaken by the principal researcher. Voluntary participation and withdrawal of consent at any stage if need be, was also emphasized. For participants younger than 16 years of age and are happy to be part of the study, consent was obtained from their parents/guardians before being re-

cruited to the study.

4.1. Recruitment

The research and ethics committee of Alex Ekwueme Federal University Teaching Hospital, and Mile 4 Hospital gave approval for the study. Women with prolonged obstructed labour who qualified for inclusion were enrolled at the Accident & Emergency after giving their consent.

4.2. Randomization and Concealment

Simple randomization was done using computer-generated numbers (1 - 148) utilizing the software research randomizer®. A set of seventy-four, 4-digit numbers were randomly selected and assigned to one arm and tagged Group "A" (Bicarbonate) while another set of seventy-four 4-digit numbers were also generated for the other arm tagged Group "B" (control).

The bicarbonate group was given 50 ml of 50 mmol/L of sodium bicarbonate by bolus intravenous injection at presentation while Group "B" representing the control group were given 50 ml of injection water by bolus intravenous injection at presentation.

The sealed brown envelopes were numbered in sequence and concealment done. Inscription of numbers 1 - 148 was made on brown envelopes. The hospital Pharmacists in Alex Ekwueme Federal University Teaching Hospital, Abakaliki in collaboration with the colleague at Mile 4 Hospital, Abakaliki did the concealment. The envelopes containing the study drugs were reserved in a cupboard drawer which could be easily accessed by the research team. Those who qualified for the study were assigned numbers in sequence and the appropriate study drug was administered.

4.3. Study Procedure

Brown envelopes, with sequence numbers, 1 - 148, were kept at the Accident and Emergency units of both hospitals. Each of the envelopes contained either 50 ml of 50 mmo/L of sodium Bicarbonate in 10 ml per glass vial or 50 ml of water for injection (placebo) in 10 ml per glass vials. Participants were given a single dose intravenous bolus injection of the study drug as soon as diagnosis of prolonged obstructed labour was made and recruitment done. Other resuscitative measures like rehydration and correction of electrolyte imbalance as well as administration of oxygen were also commenced.

4.4. Outcome Measures

The primary outcome measures included maternal capillary blood lactate level at one hour after sodium bicarbonate infusion and neonatal arterial cord blood lactate level at birth. The maternal capillary blood lactate level was measured at the bedside using a portable lactate measuring device (TD-4261 and strips) at one

hour following infusion of the study drugs using capillary blood specimen obtained following a lancet prick at the fingertip. The arterial cord blood was collected with a 2 ml syringe and measured within 1 minute of birth using the handheld lactate device. The secondary outcome measures included primary postpartum haemorrhage, Apgar scores of less than 7 in the fifth minute and maternal adverse drug effects.

4.5. Quality Control

The lactate monitoring system, which comprises the lactate metre (TD-4261 meter®) and lactate strips (TD-4663®) is validated by XPER technology manufactured by TAIDOC TECHNOLOGY CORPORATION, Wugong 2nd Road, Wugu District, New Taipei city, Taiwan. The measurement range is 0.3 - 22 milli moles, required sample size is 0.8 μL and reaction time of 5 seconds. The strip/meter is stored between 10˚C - 40˚C. Only this product would be used for this study. The tests would be done by the senior registrars and if there are ties, a consultant Chemical Pathologist would act as a tie breaker while a fifth sample will be sent to another Chemical Pathologist for quality assurance.

4.6. Rescue Drugs

Participants that developed adverse drug reactions were administered with 10 ml of 10% calcium gluconate by slow intravenous infusion.

4.7. Procurement, Packaging and Disposal

Drugs used for the study were purchased from the locality (Pauco®, a product of Kwality Pharmaceuticals Ltd, Nag Kalan, Majitha Road, Amritsar - India, distributed by Pauco Pharmaceuticals Industries, Ltd., Anambra state - Nigeria and water for injection from Juhel pharmaceutical, Enugu). Drugs were kept in the Pharmacy of the Accident & emergency units of both hospitals, where other drugs were kept under optimal conditions. The drugs were carefully cross checked for batch number, manufacture and expiry dates. Sharps were disposed of in a safety container. Sharps were subsequently destroyed at the end of the study using the hospital incinerator.

4.8. Data Collection

The sheets were collected and separated by principal investigator at the end of the study, using the randomization sequence. Data was sorted out into the appropriate groups according to the randomization number.

4.9. Statistical Analysis

Data were collated and analyzed using IBM SPSS Software (version 20, Chicago IL, USA). Mean and Standard Deviation (Mean ± 2 SD), showed the continuous variables, numbers and percentages showed the categorical variables. Student's t test was used to compare the means between two groups of continuous variables

while Z test was used to determine significance of statistical measures. Chi squared test/Fisher exact test was used to determine relationship between categorical variables. The level of statistical significance was expressed as p value and was taken to be significant if ≤0.05.

4.10. Ethical Consideration

Approval was granted by the Health and Research committee of the Alex Ekwueme Federal University Teaching Hospital, Abakaliki and Mile 4 Hospital.

4.11. Confidentiality of Data

The study team made every effort to ensure privacy and confidentiality throughout the duration of the study.

4.12. Autonomy

Participation was voluntary and the patients were solely responsible for their decision to participate in the study.

4.13. Beneficence to Participant

The preoperative infusion of sodium bicarbonate may have benefited them from the positive effects. The outcome of this study would lead to better patient care in general.

4.14. Non-Maleficence to Participant

Exclusion criteria was strictly adhered to and rescue drugs were made available to ensure that the study involved no more than minimal harm to the participants.

4.15. Justice

Recruitment was done in a manner that ensured fairness and equity.

4.16. Cost of the Study

This was borne entirely by the investigators.

4.17. Ethic Approval

The ethic approval for this study was obtained from The Research and Ethic Committee, Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State on the 24th February, 2021 with approval number AE-FUTHA/REC/VOL3/2020/074.

5. Result

The study lasted for six months, one hundred and forty-eight participants were enrolled into the study and received either sodium bicarbonate or placebo. Seventy-four participants in the intervention (bicarbonate) group and seventy-four participants in the control (placebo) group. All the patients recruited for the study were analyzed in **Figure 1**.

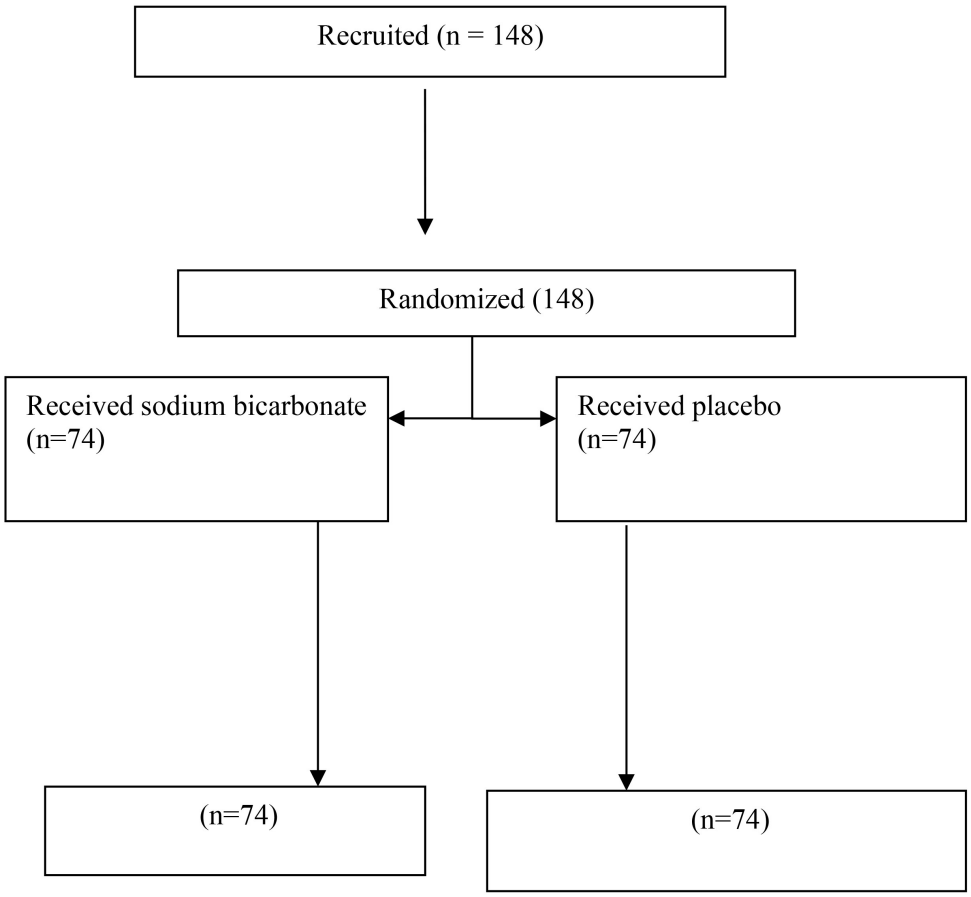

Figure 1. The flow of participants through the study.

Table 1. Comparison of sociodemographic characteristics of participants in Bicarbonate and placebo groups.

Socio-Demographic Data	Bicarbonate Group (n = 74)	Placebo Group (n = 74)	χ^2	P-value
Age (years)				
<20	8 (10.8%)	7 (9.5%)	7.529	0.110
20 - 24	18 (24.3%)	23 (31.1%)		
25 - 29	10 (13.5%)	14 (18.9%)		
30 - 34	27 (36.5%)	13 (17.6%)		
35 - 39	11 (14.9%)	17 (23.0%)		
Occupation				
Artisan	22 (29.7%)	15 (20.3%)	7.275	0.201
Student	20 (27.0%)	14 (18.9%)		
Trading	10 (13.5%)	21 (28.4%)		
Farming	14 (18.9%)	12 (16.2%)		
Teaching	5 (6.8%)	8 (10.8%)		
Civil Servant	3 (4.1%)	4 (5.4%)		

Continued

Religion				
Christianity	69 (93.2%)	68 (91.9%)	0.481*	1.000
African Traditional Religion	4 (5.4%)	4 (5.4%)		
Muslim	1 (1.4%)	2 (2.7%)		
Marital status				
Married	57 (77.0%)	60 (81.1%)	0.367	0.545
Unmarried	17 (23.0%)	14 (18.9%)		
Residence				
Urban	27 (36.5%)	23 (31.1%)	0.483	0.487
Rural	47 (63.5%)	51 (68.9%)		

*Fisher's exact test used.

Table 1 shows the sociodemographic characteristics of participants that received sodium bicarbonate and placebo. There was no statistical difference in both arms.

Table 2. Characteristics of the parturient in both groups.

Maternal	Bicarbonate Group (n = 74)	Placebo Group (n = 74)	Test Statistic	P-value
Age (years)				
mean ± SD	28.16 ± 6.18	27.81 ± 6.02	0.350[a]	0.727
Smokers				
Yes	3 (4.1%)	1 (1.4%)	1.028[b]	0.620
No	71(95.9%)	73(98.6%)		
Weight ≥ 90 kg				
Yes	23(31.1%)	30(40.5%)	1.440[c]	0.230
No	51(68.9%)	44(59.5%)		
Gestational Age (weeks)				
mean ± SD	39.11 ± 1.21	39.22 ± 1.17	0.551[a]	0.582
Base line maternal capillary blood lactate level at presentation (mmol/L)				
mean ± SD	8.12 ± 1.52	7.95 ± 1.92	0.602[a]	0.551

[a]independent sample t-test used; [b]Fisher's exact test used; [c]Chi-square test used.

Table 2 shows baseline characteristics of parturient; age, smokers, weight, gestational age and baseline maternal capillary blood lactate level in both groups. This shows no statistically significant difference between the two.

Table 3. Comparison of outcome measures.

Parameter	Bicarbonate Group (n = 74)	Placebo Group (n = 74)	Z-test	P-value
Maternal capillary blood lactate level at 1 hr (mmol/L)				
mean ± SD	7.15 ± 1.97	7.61 ± 1.73	1.512	0.133
Fetal arterial cord blood lactate level (mmol/l)				
mean ± SD	3.39 ± 0.95	4.11 ± 1.05	4.392	<0.001

Table 3 shows the primary outcome measures; maternal capillary blood lactate level following infusion of sodium bicarbonate, at one hour, to the intervention arm and placebo to the control arm. It also shows the fetal arterial cord blood lactate level at birth for both arms. This showed no statistically significant difference in the maternal capillary blood lactate level. However, there was statistically significant difference in the neonatal arterial cord blood lactate level between the two arms.

Table 4. Comparison of secondary maternal outcomes: maternal complications between the two groups.

Parameter	Bicarbonate Group (n = 74)	Placebo Group (n = 74)	Test Statistic	P-value
Postpartum Haemorrhage				
No	63 (85.1%)	41 (55.4%)	15.654[a]	<0.001
Yes	11 (14.9%)	33 (44.6%)		
Maternal Side Effects				
Muscle twitching/cramps	7 (9.5%)	0 (0.0%)	2.32[b]	0.020
Sleepiness	4 (5.4%)	0 (0.0%)	1.52[b]	0.128
Peeling of skin at injection site	3 (4.1%)	0 (0.0%)	1.17[b]	0.243
Restlessness	2 (2.7%)	0 (0.0%)	0.71[b]	0.477

[a]Chi-square test used; [b]Z-test used.

Table 4 shows comparison of maternal complications of post-partum haemorrhage and side effects resulting from administration of the study drug and the placebo between the groups. Postpartum haemorrhage between the two arms was statistically significant. Side effects resulting from the agents used for the arms was not statistically significant.

Table 5. Comparison of secondary fetal/neonatal outcomes: fetal/neonatal complications.

Parameters	Bicarbonate Group (n = 74)	Placebo Group (n = 74)	χ^2	P-value
APGAR at 5 minutes				
<7	19 (25.7%)	43 (58.1%)	15.988	<0.001
≥7	55 (74.3%)	31 (41.9%)		
NICU[d] Admission				
Yes	21 (28.4%)	49 (66.2%)	21.251	<0.001
No	53 (71.6%)	25 (33.8%)		

[d]neonatal intensive care unit.

Table 5 shows the Apgar score at the fifth minute and new-born admission for both arms in the study. APGAR score at five minutes was statistically significant as well as neonatal intensive care unit admission between both arms.

6. Discussion

Single intravenous bolus infusion of 50 mmol/l of sodium bicarbonate administered preoperatively to participants with prolonged obstructed labour showed no statistically significant difference in reduction of the maternal lactate level at one hour, following its administration, 7.15 ± 1.97 mmol/l for the bicarbonate group and 7.61 ± 1.73 mmol/l for the placebo group, p-value = 0.133. This may be due to ongoing increased production of lactate which often results in high level of acidosis that is associated with prolonged obstructed labours. Comparable findings were reported by Musaba *et al.* [24] 6.4 mmol/l (IQR 3.3, 12.3) for the bicarbonate group and 7.5 mmol/l (4, 15.8) for the placebo group, p-value = 0.087. The findings contrasted with the results of Wiberg-Itzel *et al.* and Wray in Liverpool [10]. This contrast could be due to differences in the routes of drug administration as well as the strategies used in drug administration.

In this study, there was a reduction in the mean fetal lactate levels at birth, 3.39 ± 0.95 mmol/l for the bicarbonate group and 4.11 ± 1.05 mmol/l for the placebo group p-value < 0.001. This impressive outcome could be due to increased blood flow to the uterus during pregnancy. The fetuses could have received adequate amount of sodium bicarbonate through uteroplacental circulation that helps to reduce the degree of acidosis before they were delivered. The findings agreed to those reported by Weiberg-Itzel *et al.* [8] [10] as well as article review by Omo-Aghoja [9]. The reduction could be due to buffer effect of sodium biocarbonate. The findings, however contrasted with those reported by Musaba *et al.* [24], in which the findings were not statistically significant. This contrast may be have resulted from higher fetal lactate levels noted in that study. Lower fetal lactate level noted at birth relative to the supposedly higher levels reported by Musaba *et al.* [24] was unexpected. This could insinuate regional variations in fetal lactate levels.

Only 14.9% of the participants in the bicarbonate group had primary postpartum haemorrhage compared with 44.6% in the placebo group. This showed a statistically significant difference between both groups with p-value < 0.001. This reduction could be due to the buffer effect of bicarbonate on the myometrial capillary lactate levels which increases in dysfunctional labour as had been reported by Quenby and co-workers [7] where women with dysfunctional labour had higher lactate levels, 3.54 mmol/l, p-value < 0.001. The results contradicted the findings by Musaba *et al.* who reported 10% of the study group had primary postpartum haemorrhage compared with 12.2% in the control group, p-value = 0.275 which was not statistically significant but clinically significant considering the relevance of primary postpartum haemorrhage in obstetrics practice in a poor resource setting.

The occurrence of side effects of drugs used for the study showed no statistically

significance difference between the two groups. This agreed to those reported by Weiberg *et al.* in Sweden and Wray [10] in Liverpool regarding the safety profile of the drug. Similar findings were also reported by Musaba *et al.* [24]. The reduction in side effects was possibly due the choice of low dosage of the study drugs as well as availability of rescue drug.

Only 25.7% of the intervention arm had Apgar scores of <7 when compared with the control arm, that had 58.1%, p-value < 0.001. This result was statistically significant. This may be due to the buffer property of bicarbonate with resultant decrease in lactate level. Thus, the risk of birth asphyxia was reduced. The findings agreed with earlier review reported by Omo-Aghoja [9]. A similar study by Musaba *et al.* [24], did not show a significant difference with p-value = 0.75. The contrast with this study may be due to higher fetal lactate reported by Musaba and coworkers.

Newborn intensive care unit admission was 28.4% in the bicarbonate group compared to 66.2% in the placebo group. This showed a statistically significant difference, p < 0. 001. This could be explained by higher Apgar scores at 5 minutes noted in the intervention arm compared to the control arm. The study agreed with review, reported by Omo-Aghoja [9]. Musaba *et al.* [24] however, reported no significant difference in their study possibly due to higher fetal lactate levels recorded in their study.

Potential confounders such as duration of obstructed labour, degree of dehydration and level of resuscitation before surgery, oxytocin use and referral status were not covered in this study. We suggest that further studies in the subject area would help to evaluate the effects of these confounders on maternal and fetal outcomes during prolonged obstructed labour. Also, s all of our participants were admitted for more than 5 days after delivery, no delayed complication from sodium bicarbonate was recorded during this period.

7. Conclusion

This study showed that preoperative bolus infusion of 50 mmol/l of sodium bicarbonate at one-hour following intervention with the drug, did not have significant reduction in the maternal blood lactate levels in patients with prolonged obstructed labour. However, the drug significantly reduced the neonatal lactate levels at birth. It also significantly reduced primary postpartum haemorrhage. The study also showed a reduction in admission into the newborn unit and higher Apgar scores at 5 minutes. Thus, the use of sodium bicarbonate, especially in low resource settings could be considered as an interventional drug to improve both maternal and neonatal outcomes. Sodium bicarbonate also appears to be safe in the short term and effective as those results were achieved with no significant side effects. The null hypothesis that sodium bicarbonate administration does not influence maternal capillary blood lactate at one hour following administration and neonatal arterial cord blood at birth in women with prolonged obstructed labour compared with placebo is accepted for the mother but rejected for the neonate.

8. Recommendation

The result showed that intravenous sodium bicarbonate as a buffer was safe and effective in the reduction of neonatal lactate level with attendant maternal and neonatal benefits especially in low resource setting. The failure of this drug to significantly reduce maternal lactate levels and the unexpected lower neonatal lactate levels noted in the study population require more studies to evaluate that.

Strength of the Study

It was a double blind randomized controlled trial with neither clinician nor the patient being aware of the group assigned. Point of care, battery operated lactate device was used on the bedside to measure lactate levels instead of the time-consuming electricity dependent spectrophotometric method.

Limitations of the Study

This was an institution-based study which may not be an absolute representation of the general population. The follow up period was only for 24 hours which was too short a time for some of the adverse clinical outcomes to manifest.

Authorship Contributions

Principal Investigator and writing the introduction—Dr. C Nwaogwugwu.

Development of methodology—Dr Nwanbunike Ekene Okeke.

Data Collection—Dr. Bartholomew I Olinya and Dr. Chidi Ikenna Ebere.

Analysis of result and development of discussion—Dr Ayodele A. Olaleye and Dr Eziaha Ede.

Conflicts of Interest

There was no conflict of interest declared. The drugs used in the study were obtained from a pharmaceutical shop.

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Appendix

Appendix 1

Research Pro Forma/Data Collection Sheets

1. Name (Initials) _____
2. Age _____
3. Weight ≥ 90 kg Yes _____ NO _____
4. Marital Status _____
5. Occupation _____
6. Religion _____
7. Booking Status _____
8. Residence: Urban _____ Rural _____
9. Parity _____
10. Smoker: Yes _____ No _____
11. Gestational Age _____
12. Time of established active labour _____
13. Cervical dilatation on admission _____
14. Station of presenting part on admission _____
15. Features of obstructed labour: Oedematous vulva _____
    Caput succedaneum _____ Bandl ring _____
16. Identification number of agent administered _____
17. Side effects observed Yes/No _____
18. If yes (16 above) tick as appropriate: Muscle twitching/cramps,
    Restlessness/Peeling of skin at injection site/Sleepiness/Others-specify
19. Maternal capillary blood lactate level at: presentation _____
    _____: 1 hour _____
20. Estimated Blood loss at surgery: <1000 ml _____≥ _____ 1000 ml
21. Apgar score at 5th minute: <7_____ ≥7_____
22. Neonatal arterial cord blood lactate level at birth _____
23. Transfer to Neonatal Intensive Care Unit: Yes/No _____

Name of research Assistant ……

Signature of Research Assistant ……

Date ……

Appendix 2

Drug Information Leaflet

Pauco Sodium Bicarbonate contains Sodium Bicarbonate injection composes of 8.4% w/v. Each ml contains USP 84 mg equivalent to 2 mOsmol. Water for injection USP q.s.

It is an antacid used in treatment of electrolyte deficiency.

It increases plasma bicarbonate; raises blood pH and reverses the clinical manifestation of acidosis. 1 g of Sodium bicarbonate provides 11.9 mEq each of Sodium and bicarbonate. Bicarbonate is a normal constituent of body fluid and normal plasma level ranges from 24 - 31 mEq/L. It is a systemic antacid.

It is indicated in metabolic acidosis, urinary alkalinisation, severe diarrhoea and causal heart burn.

Cardiac arrest: Adults: A rapid intravenous dose of 200 - 300 mEq of bicarbonate given as 7.5% - 8.4% solution. In emergency, administered 300 - 500 ml of 5% sodium bicarbonate injection. Infants: Less than 2 years of age: at a rate of 8 mEq/kg/day of 4.2% solution.

Severe metabolic acidosis: Administer 90 - 180 mEq/L at a rate of 1 - 1.5 L during the first hour. Adjust according to patient's need for further management. Contraindications include cardiac failure and hypertension.

Adverse effects include extravasation of intravenous hypertonic solution may cause severe chemical cellulitis. Too rapid infusion of hypotonic solution may cause local pain and venous irritation; it may result in hypernatremia and alkalosis.

Systemic alkalosis: excess sodium may cause oedema and cardiac failure in patients with renal and cardiac dysfunction.

Frequent monitoring is essential. Avoid overdose and alkalosis. Potassium depletion may predispose to metabolic alkalosis.

The renal clearance of the following agents may be:

decreased: Anorexiants, quinidine, sympathomimetics.

Incompatibility: Avoid adding sodium bicarbonate to parenteral solution containing calcium, precipitation may result. Norepinephrine and dobutamine are incompatible.

Store between temperature 8˚C to 25˚C. Protect from light. Keep out of the reach of children.

5 ampoules of 10 ml in a plastic tray and each tray packed in a carton. 10 of such cartons are packed in a big outer box.