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**EFFECT OF INTRAVENOUS TRANEXAMIC ACID ON BLOOD LOSS REDUCTION
DURING AND AFTER CAESAREAN SECTION: A RANDOMISED CONTROLLED STUDY**

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Background: Primary postpartum hemorrhage is one of the leading causes of maternal mortality and morbidity. This has led to different modalities and actions being instituted to reduce hemorrhage after child birth. The need to explore other interventions for reduction of blood loss, besides the use of oxytocic has arisen. Tranexamic acid is an antifibrinolytic agent which has been approved for treating postpartum hemorrhage. The study determined the effectiveness of tranexamic acid in reducing blood loss during and after Caesarean section.

Method: The study was a double blind randomized controlled study on blood loss reduction following administration of 1g of intravenous tranexamic acid on women who underwent Caesarean section at University of Abuja Teaching Hospital. Statistical Product and service production (SPSS) software version 24 was used to analyze the data. A p value of < 0.05 was considered to be statistically significant.

RESULT: The mean post-operative haemoglobin concentration was $9.70 \pm 0.86\text{g/l}$ and $10.50 \pm 0.90\text{g/l}$ in placebo and tranexamic acid group respectively. This was statistically significant (a p value < 0.0001). The mean change (reduction) in haemoglobin concentration was significantly lower in tranexamic acid group $0.49 \pm 0.48\text{g/l}$ with $1.15 \pm 0.16\text{g/l}$ in the placebo. There was also significant reduction in mean change in haematocrit in tranexamic group, $1.06 \pm 3.4\%$ compared to $4.16 \pm 3.98\%$ in placebo group. The average blood loss in tranexamic group was $725.1 \pm 277.9\text{mls}$ compared to $1183.02 \pm 325.9\text{mls}$ in placebo group. This represented 457.92mls reduction in blood loss in those treated with preoperative intravenous tranexamic acid ($p = 0.045$). This was statistically significant. Similarly, the need for additional uterotonics was significant in the placebo group when compared with the study group. The mean duration of surgery and the need for blood transfusion were not statistically significant. There was no difference in the fetal outcomes for both group.

CONCLUSION: This study demonstrated that the use of pre-operative tranexamic acid reduced blood loss and need for additional uterotonics during Caesarean Section. Post

operatively it significantly reduced decrease in haemoglobin and haematocrit concentration there by preventing post- partum anemia.

Key words: Caesarean Section, Postpartum Haemorrhage, Tranexamic acid, Blood loss

Introduction: Caesarean section a common surgical operation in obstetrics has been rising with its attendant complications,¹⁻⁶ commonest amongst others being primary postpartum hemorrhage. Primary postpartum hemorrhage is one of the leading causes of maternal mortality and morbidity.⁴ This has led to different modalities and actions being instituted to reduce hemorrhage after childbirth. Despite interventions, postpartum hemorrhage still remains the major cause of maternal mortality.^{4,5} The need to explore other interventions for reduction of blood loss, asides the use of oxytocic has arisen.

Tranexamic acid is an antifibrinolytic agent which has been approved for treating postpartum hemorrhage.⁶ The option of Tranexamic acid, an antifibrinolytic agent, which is safe, readily available, and heat stable has shown great promise in blood loss reduction. The uniqueness and beneficial promise of Tranexamic acid,^{6,7} and peculiarities of our practice in the subregion, makes its consideration in the reduction of blood loss during and after Caesarean section is a viable one, hence the study. This study aimed to evaluate the effect of intravenous tranexamic acid on blood loss during and after Caesarean section.

Material and Methods: This was a double blind randomized controlled study on the effect of intravenous tranexamic acid on blood loss in women who underwent Caesarean section at the University of Abuja Teaching Hospital, Abuja. The study duration was six months based on the center's average of 9 elective Caesarean sections weekly and the sample size calculated for the study.

Included were all women with singleton pregnancy at 37 - 42 weeks gestation booked for elective Caesarean section, that were willing to participate in the study and do not have any contraindication

to the use of tranexamic acid. Also, patients with more than one previous caesarean section scar and previous myomectomy surgery were also included in the study. Women with known coagulation disorders, medical conditions such as sickle cell disease, chronic hypertension, renal disease, liver disease and diabetes in pregnancy, on anticoagulant therapy a week before Caesarean section, were allergic to tranexamic acid, prior history of thromboembolism, preeclampsia or eclampsia, and with antepartum hemorrhage, those at increased risk of deep vein thrombosis, and those who refused to give consent were excluded.

The minimum sample size was determined using the formula for calculating sample size for a difference in mean of randomized controlled study.⁸

$$N = \frac{2SD^2 (Z_{\alpha} + Z_{\beta})^2}{\Delta^2}$$

Where:

N = required sample size for each group

SD= the standard deviation from a similar study = 551.5⁹

Z_{α} = standard normal distribution corresponding to 95% confidence level and 5% level of significance at 2-tail = 1.96 read from table of statistical figures

Z_{β} = power of study put at 80% = 0.84 read from table of statistical figures

Δ = difference between the mean blood loss in control group and intervention group from the study referenced above = 773 – 414 = 359⁹

$$\begin{aligned} N &= \frac{2 \times (551.5)^2 (1.96 + 0.84)^2}{359^2} \\ &= \frac{2 \times 304152.25(2.8)^2}{359^2} = \frac{2 \times 304152.25 \times 7.84}{128881} \\ &= \frac{4769107.28}{128881} = 37.0039 \approx 37 \end{aligned}$$

An attrition rate of 10% was considered, 41 booked women for elective Caesarean section were recruited for each arm of the study, making a total of 82 participants.

The participants were randomized by means of a computer-generated random number using the software Research Randomizer® by JAVA (Sun Microsystems) 2022. Using this software, forty-one numbers was randomly generated from a pool of one to eighty-two (1 - 82) and assigned to Group A (tranexamic acid group) while the remaining forty-one numbers were automatically assigned to Group B (the placebo group).

Group A received intravenous tranexamic acid 1g at the rate of 1ml/min over 10 minutes, starting 15 minutes before the skin incision while Group B received intravenous sterile water for injection 10ml at the rate of 1ml/min over 10 minutes starting 15 minutes before the skin incision.

Concealment was done in the same type of brown sealed envelopes. These numbers generated by the randomization were inscribed on the envelopes.

Participants that met the inclusion criteria were counseled on the purpose of the study, the mechanism of action of tranexamic acid and its side effects. Those that gave consent signed an informed consent form. The corresponding numbered sealed envelope was then allocated to them. The Caesarean sections were carried out by consultant, and Senior Registrar.

The drug or the placebo was administered by the Anaesthetist to the patient over 10 minutes, without telling the Researcher/the Research Assistant and the patient the content of the envelope (Double Blinding). The treatment drug or placebo was administered 15 minutes before commencement of the surgery. The envelope with its used content (also sealed) were returned to the Researcher who kept all the used envelope/packs in a separate container until the end of the study when the un-blinding was done. All the surgeries were lower segment Caesarean section, carried out by the units' Consultants or Senior Registrars. The surgeries were carried out according to standard Caesarean section technique. Patients whose surgery lasted for more than 90 minutes were excluded from the study to reduce the risk of drug clearance from maternal circulation.

Following delivery of the placenta, all patients received intravenous bolus 10iu oxytocin. Other oxytocic or surgical interventions required to control excessive bleeding were used as indicated. Patients who need blood transfusion also received same as indicated. These interventions were noted. The maternal vital signs (pulse rate, blood pressure and respiratory rates) were taken at 4 specific times; at the delivery of the placenta, at the end of the surgery (Caesarean section estimated to last between 45 minutes to 1hr.30 minutes), 1 hour after the surgery and at 2 hours after the surgery.

The estimated blood loss was derived using the Haemoglobin balance formular

$$\text{Haemoglobin loss (g)} = EBV \times (Hb_i - Hb_f) \times 0.001 + Hb_t^{39}$$

$$\text{Blood loss (ml)} = 1000 \times \text{Haemoglobin loss (g)} / Hb_i^{39}$$

Where, *EBV* is the estimated blood volume (using Nadler's formula),^{36,37,39} *Hb_i* was the initial haemoglobin concentration (g/l), *Hb_f* was the final haemoglobin concentration (g/l), and *Hb_t* was the transfused haemoglobin (1U banked blood = 52g). *Hb_t* is 0 if patient was not transfused. The initial/preoperative haemoglobin concentration was taken before the surgery and final/postoperative haemoglobin concentration was taken 48 hours postoperative. The participants height and weight were measured.

Estimated Blood Volume (*EBV*) in liters was calculated using Nadler formula:

$$(0.3669 \times H^3) + (0.03219 \times W) + 0.1833$$

where H was the height in meters and W was the weight in kilograms.

Blood loss greater than >1,000ml was regarded as excessive blood loss.

Patient weight was taken with a Stadiometer model ZT-150A by Ocean-med company England and height measured using same stadiometer.

Venous blood was collected by venipuncture into an EDTA bottle. The haemoglobin concentration was done using same Sysmex Haematology Autoanalyzer XN550 by Yuesenmed under two dedicated Medical Laboratory Scientists.

The participants were followed up until discharge. The outcome measure were: Estimated blood loss at Caesarean section, postpartum haemorrhage at Caesarean section defined as blood loss $\geq$ 1,000ml, the need for additional uterotonics and interventions (B-Lynch sutures, uterine artery ligation, hysterectomy) to manage primary postpartum haemorrhage, the need for blood transfusion during or after the surgery, and APGAR Scores of the babies.

Data was collated, tabulated then statistically analyzed using the Statistical Product and Service Solution (IBM SPSS; version 24). Continuous variables were presented as mean and standard deviation (Mean $\pm$ 2SD), while categorical variables were presented as numbers and percentages. Chi-square test (X^2) was used for comparison between groups for qualitative variables while student t-test was used for comparison between groups for quantitative variables. A difference with a P value <0.05 was considered statistically significant.

Ethical clearance was sought and obtained from the Health Research Ethics Committee of the University of Abuja Teaching Hospital. In consonance with international and national codes regulating human subject research and Helsinki declaration. Participation was entirely voluntary. Informed consent was obtained from all the participants, and confidentiality of responses was maintained throughout the study.

Results: A total of eighty- two (82) pregnant women booked for elective caesarean section were recruited.

Table 1: Maternal Characteristics of the study participants

	Placebo n (%)	Tranexamic n (%)	Total (%)	Statistic	df	p-value
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Age (years)						
20 – 24	2 (4.9)	5 (12.2)	7 (8.5)	Fe=0.323	4	0.687
25 – 29	11 (26.8)	11 (26.8)	22 (26.8)			
30 – 34	15 (36.6)	11 (26.8)	26 (31.7)			
35 – 39	6 (14.6)	8 (19.5)	14 (17.1)			
≥40	7 (17.1)	6 (14.6)	13 (15.9)	t=0.433	80	0.666
Mean ±SD	32.50 ±5.40	31.90 ±6.30				
Parity						
Nulliparous	4 (9.8)	3(7.3)	7 (8.5)	Fe=0.04	1	0.50
Multiparous	37 (90.2)	38 (92.7)	41 (91.5)			
Mean ±SD	1.68 ±1.09	1.38 ±0.87		t=1.39	80	0.169
Gestational age						
Mean ±SD	38.6 ±1.69	38.2 ±0.68		t=1.41	80	0.164

Fe represents Fisher's exact test while t represents independent t-test Significant at $p < 0.05$.

Table 1 shows the maternal characteristics of the study participants. There was no significant difference among the two groups. The mean age of the participants was 32.50 ± 5.40 and 31.90 ± 6.30 in the placebo (control) and tranexamic acid (study) groups respectively. The multiparous women made up majority of the participants in both groups; 90.2% and 92.7% in the placebo and tranexamic acid group respectively. The mean gestational age in each group was 38 weeks.

Table 2. Haematological Changes and Interventions among the Participants

	Study group		Mean diff.	t	p-value
	Placebo	Tranexamic			
Haemoglobin concentration (g/l)	Mean ±SD	Mean ±SD			
Preoperative	10.9 ± 0.60	11.03 ± 0.87	0.17	1.03	0.303

Postoperative	9.70 ±0.86	10.50 ±0.90	0.83	4.32	<0.0001
Change in haemoglobin	1.15 ±0.16	0.49 ±0.48			
Haematocrit (%)					
Preoperative	33.29 ±2.60	32.69 ±1.83	0.6	1.19	0.235
Post-operative	29.11±2.57	31.63±2.70	2.52	4.32	<0.0001
Change in Haematocrit	4.16±3.98	1.06±3.4	3.1		
	1183.02				
Blood loss (mls.)	±325.9	725.1 ±277.9	457.92	2.02	0.045
Duration of surgery					
(minutes)	57.73 ±10.7	53.72 ±16.6	4.4	1.02	0.313
Need for blood transfusion	11 (26.8)	6 (14.6)	17 (20.7)	Z=1.36	0.173
Blood loss more than					
1000mls	10 (24.4)	6 (14.6)	16 (19.5)	Z=1.11	0.265
Additional oxytocics					
required	36 (78.3)	13 (28.3)	49 (53.3)	Z=3.2	<0.0013

Fisher's Z proportion test Significant at $p < 0.05$ while t represents independent t -test Significant at $p < 0.05$

Table 2 shows the haematological changes and interventions in the study. The mean pre-operative haemoglobin concentration was $10.9 \pm 0.60 \text{g/l}$ and $11.03 \pm 0.87 \text{g/l}$ in placebo and tranexamic acid groups respectively. The mean post-operative haemoglobin concentration was $9.70 \pm 0.86 \text{g/l}$ and $10.50 \pm 0.90 \text{g/l}$ in the placebo and tranexamic acid group respectively. The mean change (reduction) in haemoglobin concentration was significantly lower in the tranexamic acid group $0.49 \pm 0.48 \text{g/l}$ compared to $1.15 \pm 0.16 \text{g/l}$ in the placebo group. There was also significant reduction in mean change in haematocrit in the tranexamic group, $1.06 \pm 3.4\%$ compared to $4.16 \pm 3.98\%$ in the placebo group.

The Tranexamic group had statistically significant reduction in mean blood loss. The average blood loss in the tranexamic group was $725.9 \pm 227.9 \text{mls}$ compared to $1183.02 \pm 325.9 \text{mls}$ in the placebo group. This represented 457.92mls reduction in blood loss in those treated with preoperative intravenous tranexamic acid ($p = 0.045$). This was statistically significant. The mean duration of surgery was $53.72 \pm 16.6 \text{minutes}$ in the tranexamic acid group and $57.73 \pm 10.7 \text{minutes}$ in the placebo group. This represents a 4.40-minute decrease in average

operating time in the tranexamic acid group with a p-value of 0.31. This was not statistically significant.

Considering need for blood transfusion, 11 (26.8%) of the participant in the placebo group needed blood transfusion, while 6 (14.6%) were transfused in the treatment group. However, this was not statistically significant.

In the placebo group, 36 (78.3%) participants required additional oxytocics compared to only 13 participants (28.3%) in the tranexamic acid group. This was statistically significant with (p-value <0.0013). Despite having more participants in the placebo group (24.4%) that had blood loss >1000mls compared to tranexamic acid group (14.6%), they were not statistically significant (p=0.26).

Table 3: Neonatal outcome

	Placebo n (%)	Tranexamic n (%)	Total	Statistic	df	p-value
Apgar Score						
1 st minute						
<7	7 (17.1)	11 (26.8)	18 (22.0)			
7 & above	34(82.9)	30 (73.2)	64(78.0)	$\chi^2=1.14$	1	0.286
Mean $\pm$ SD	7.0 $\pm$ 0.72	7.0 $\pm$ 1.5		t=0.862		0.391
5 th minute						
<7	0 (0.0)	1(2.4)	1 (1.2)			
7 & above	41 (100.0)	40(97.6)	81(98.8)	Fe=0.481		
Mean $\pm$ SD	8.0 $\pm$ 0.57	8.0 $\pm$ 0.85		t=0.166		0.869

Fe represents Fisher's exact test while χ^2 represents chi-square and t= Independent samples t-test Significant at p<0.05

Table 3 shows the neonatal outcome in both groups. There was no significant difference in Apgar score in the babies of both groups of study participants. The p-value for the mean APGAR score was 0.391 in the 1st minute while in the 5th minute it was 0.869.

Also, no major side effect was encountered during the study. Figure 1 illustrated the side effects in both group with no significant difference.

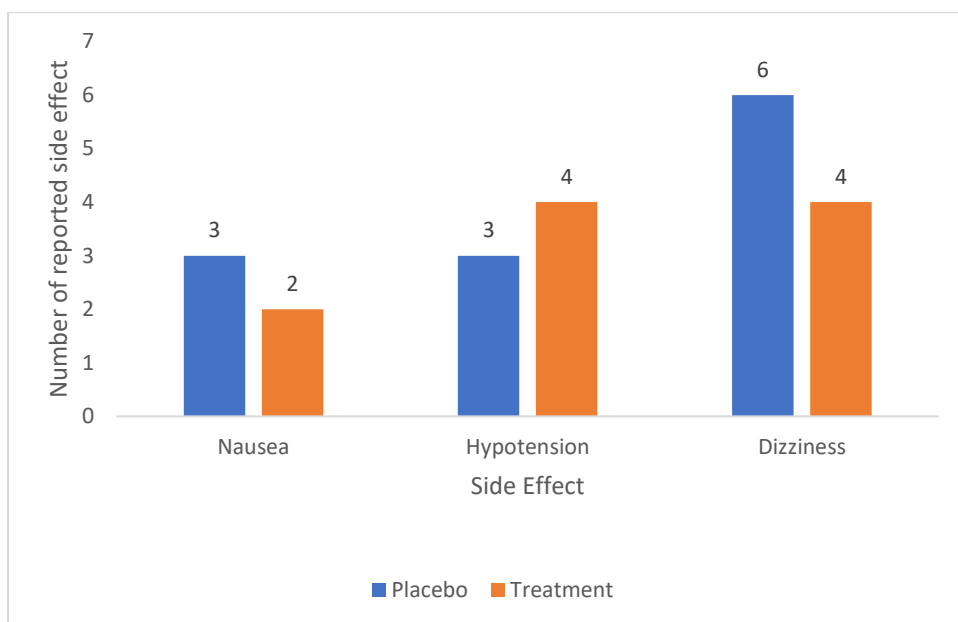


Figure 1: Side Effect

Discussion: Postpartum haemorrhage remains a leading cause of maternal death worldwide. About 14 million women experience postpartum haemorrhage each year.¹¹ Steps towards reducing the incidence and impact of postpartum haemorrhage would significantly contribute to reducing maternal mortality and morbidity. Postpartum haemorrhage is also one of the complications of Caesarean section.¹²⁻¹⁴. Caesarean section is a lifesaving procedure. Some studies have explored the use of tranexamic acid in the prevention of postpartum

haemorrhage.¹⁵⁻¹⁸ Tranexamic acid, an antifibrinolytic agent was used to compare with placebo in reducing blood loss during and after Caesarean section. Tranexamic acid works by binding on the 5 lysin binding site there by inhibiting plasminogen. This inhibits plasmin formation and hence fibrinolysis.⁶

Analysis of the social demographics showed no statistical difference in the study group and the control group in relation to age educational status and occupation. Hence the study social demographics was homogenous.

There was a significant difference in the mean post operative haemoglobin in the study group and the control group, in this study. The mean post-operative haemoglobin concentration was significantly higher in the tranexamic group compared to the placebo group. The mean change (reduction) in haemoglobin concentration was significantly lower in the tranexamic acid group. Similarly, there was also a significant difference in the haematocrit values between the study and the control group. This was also the findings in the study done by Oseni and coworkers which showed the average post-operative haemoglobin level to be 10.1g/dl in the study group and 9.5g/dl in the control group, with a p value of <0.01.⁹ The average post-operative haematocrit was 31.5% in the study group while in the control group it was 29.9%. The effectiveness of tranexamic acid in reducing decrease in post-operative haemoglobin and haematocrit leads to less incidence of postpartum anemia, postpartum blood transfusion and other complications.

This study showed a significant reduction in blood loss in the tranexamic acid group when compared with the placebo group. The finding was similar to that in the study by Obi et al which showed a significant blood loss reduction in tranexamic group with average blood loss being 566.8 ± 267.4 and that of the placebo was 819.1 ± 348.4 .¹⁹ Comparably the study done by Shalaby et al which showed that the average blood loss in the placebo group was 896.81 ± 519.6 while that of the tranexamic group was 583.23 ± 379.62 mls. This study mainly considered high

risk patient who had risk factors for postpartum haemorrhage and still found a significant reduction in blood loss for the Tranexamic acid group. The study done in West Bengal found there was a difference of 191.74mls of blood loss ($499.11 \pm 111.2\text{ml}$ and $690.85 \pm 198.41\text{ml}$ in tranexamic acid and placebo respectively).²⁰ Also another study done in Port-Harcourt, reported a significant difference in blood loss in the study group and control group ($624.8 \pm 200.76\text{mls}$ and $864.24 \pm 229.09\text{mls}$ in study and control groups respectively) ¹⁸ while 160.5ml difference in blood loss ($436.5 \pm 118.07\text{mls}$ and $616.5 \pm 153.34\text{mls}$ in study and control groups respectively) was found in India.¹⁷ Preoperative administration of tranexamic acid group may have inhibited fibrinolysis during Caesarean section resulting in reduced blood loss in the study group compared to the control. However, the variation in the difference in the blood loss may be attributed to the different methods used in estimation of blood loss. Some of the above studies combined both gravimetric method of estimation and the haemoglobin balance formula with haematocrit estimation alone, while other studies used gravimetric method of estimation of blood loss and visual estimation of blood loss.

Administration of intravenous tranexamic acid prior to incision significantly reduced the need for additional uterotonics as compared to placebo. This is due to its potent antifibrinolytic effect which is able to control bleeding there by limiting the need for additional uterotonics. A double blinded randomized controlled trial was conducted among 160 women who underwent Caesarean section at a maternity hospital in Cairo showed similar findings of less need for uterotonics for the tranexamic group when compared to placebo.¹⁵

In contrast, a multicenter double blind randomized controlled trial done in 27 French maternity hospitals, showed no significant differences in mean gravimetrically estimated blood loss or in the use of additional uterotonics or blood transfusion amongst the women, There was a significantly lower incidence of calculated estimated blood loss among the group that received tranexamic acid when compared to placebo.²¹ The study used the gravimetric method of

estimation of blood loss which has a limitation of being contaminated by liquor. Also, blood in the peritoneal cavity may not be considered while estimating the blood loss. This can lead to error in blood loss estimation.

Despite more participants having blood loss greater than 1000mls in the placebo group than in the study group, it was not statistically significant. There was also no significant difference in the APGAR scores of both the study group and the placebo group. This was a similar finding as that of Sahu and Nalini thus validating tranexamic acid safety profile.¹⁷

Conclusion: This study demonstrated that the use of pre-operative Tranexamic acid reduced blood loss and need for additional uterotonics during Caesarean Section. Post operatively it significantly reduced decrease in haemoglobin and haematocrit concentration thereby preventing post-partum anemia. There were no major side effects encountered hence a good safety profile and there was no difference in the APGAR scores of the babies in both study groups. Therefore, it's a good adjunct in reducing post-partum haemorrhage and its complications. A multicenter randomised control trial on effect of tranexamic acid on blood loss during and after caesarean section is suggested for a wider conclusion.

Abbreviation

FCT: Federal Capital Territory

EBV : Estimated blood volume (using Nadler's formula)

Hb_i: initial haemoglobin concentration (g/l)

Hb_f: final haemoglobin concentration (g/l)

Hbt: transfused haemoglobin

EDTA: Ethylenediaminetetraacetic acid

SPSS: Statistical Product and Service Solutions

%- Percentage

p-value- Probability value

SD: Standard deviation

Mean diff: Mean difference

df: degree of freedom

g/l: gramme per litre

Declarations

- **Ethics approval and consent to participate:** The ethical clearance for the study was in accordance to Helsinki. This was sought and obtained from the University of Abuja Teaching Hospital Health Research and Ethical Committee.
- **Consent for publication:** Not applicable
- **Availability of data and materials:** Yes
- **Competing Interest:** None
- **Funding:** No funding to be declared
- **Author contributions:** The contents of this article were conceptualized and developed by Okere after a problem identification and discussion with Francis O. Adebayo and Teddy Agida. Francis O. Adebayo, Teddy Agida supervised the conduct of the study. Francis O. Adebayo, Teddy Agida, Ayogu Malachy, Gift Tom-George and Uchechukwu George Ogbu supervised the analysis of the data and write up of the final report. Hajarrah Aliyu-Bima was part of data collection. All the authors discussed the results and contributed to the final manuscripts.
- **Acknowledgement:** Not applicable
- **City in the (Aff2):** Abuja
- **Clinical Trial:** Yes
- **Clinical Trial Registry:** pactr.samrc.ac.za
- **Clinical Trial Number:** PACTR202406748563034
- **Registration date:** 26th June 2024
- All data generated or analysed during this study are included in this manuscript and its supplementary information files.
- Our study adheres to CONSORT guidelines and a completed CONSORT checklist was included as an additional file

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