International Journal of Community Research http://www.arpjournals.com
ISSN: 2315 – 6562 E-ISSN: 2384 – 6828

EFFECT OF PREOPERATIVE TRANEXAMIC ACID ADMINISTRATION ON INTRAOPERATIVE BLOOD LOSS DURING CAESAREAN SECTION: A RANDOMIZED CONTROLLED TRIAL AT IRRUA, NIGERIA

***[1]Olugbenga, O.E., [1]Eigbefoh, J., [1]Okome, G.B.O., [2]Olugbenga, M.A., [1]Okogbo, F., [1]Eifediyi, R.A., [1]Momoh, M., [3]Omosofe, F., [1]Isabu, P., [4]Alikah, S.O., [1]Ikheloa, J., [1]Omorogbe, F.I., [1]Okogbenin, S.A., [1]Njoku, A.I., [1]Okoeguale, J., [5]Adedayo, M., [6]Aigbiremolen, A.O., [7]Otaigbe, O., [8]Nkweya, V.F.**

[1]Department of Obstetrics and Gynaecology, Irrua Specialist Teaching Hospital Irrua, Edo State, Nigeria; [2]Department of Human Anatomy, Ambrose Alli University, Ekpoma, Edo State, Nigeria; [3]Department of Anaesthesia, Irrua Specialist Teaching Hospital Irrua, Edo State, Nigeria, [4]Department of Paediatrics and Child Health (Neonatology unit), Irrua Specialist Teaching Hospital Irrua, Edo State, Nigeria; [5]Department of Pharmacy and therapeutics, Irrua Specialist Teaching Hospital Irrua, Edo State, Nigeria; [6]WHO Emergency Programme, WHO Edo State Office, WHO Nigeria; [7]Department of Community Medicine, Irrua Specialist Teaching Hospital Irrua, Edo State, Nigeria; [8]Department of Clinical Sciences, Irrua Specialist Teaching Hospital Irrua, Edo State, Nigeria.

Corresponding Author's Email: olorung@gmail.com

ABSTRACT

Tranexamic acid combats primary postpartum haemorrhage, but its preoperative use could significantly reduce morbidities and mortality especially during Caesarean sections. This study at Irrua Specialist Teaching Hospital, Irrua, Edo State, Nigeria, was designed to determine the effect of preoperative tranexamic acid on intraoperative blood loss and the need for additional oxytocic during Caesarean sections. The double-blinded randomized placebo-controlled trial method was used and the study involved 208 randomly assigned women that met the inclusion criteria, and aged 18years and above for primary Caesarean section. Data analysis was done with statistical significance considered at p-value of <0.05. The results showed that the mean blood loss (502.84±234.565 ml) in the tranexamic acid group was significantly less than the mean blood loss (699.46±177.407 ml) in the placebo group (t=6.75; p<0.01), but the tranexamic acid group had an 81% reduced risk of requiring additional oxytocic compared to the placebo group, without any significant difference in 1st minute (p= 0.394) and 5th minute (p=0.737) APGAR scores. These findings suggest a significant reduction in intraoperative blood loss and additional oxytocic requirement, without additional maternal or perinatal risks following preoperative use of tranexamic acid.

Keywords: Preoperative, Tranexamic acid, Caesarean section, hemorrhage, blood loss

INTRODUCTION

In 1834, while referring to massive obstetric haemorrhage, *James Blundell*, an English obstetrician who performed the first successful transfusion of human blood to a patient for haemorrhage, wrote that:

> *"It is clear that when patients are in this condition, trembling upon the very brink of destruction, there is but little time for you to think what ought to be done; these are moments in which it becomes your duty not to reflect, but to act"* (Ellis, 2007).

Peripartum haemorrhage (PPH) is still the leading cause of maternal morbidity and mortality in developing countries. Despite advances in the prevention, diagnosis and treatment, massive blood loss during pregnancy and delivery remains a threat and therefore, the prevention of maternal mortality requires prompt interventions (Ajenifuja *et al.*, 2010). Thus, Caesarean section as a procedure has been identified as a common indication for blood transfusion in obstetric practice, because it involves the risk of major intra-operative blood loss (Matot e*t al*., 2004).

The average blood loss at Caesarean section is about 500-1000ml, and the suboptimal haemoglobin levels of women in developing countries embarking on the voyage of

Endorsed By: *Innovative Science Research Foundation (**ISREF**)* and *International Society of Science Researchers (**ISSCIR**).*
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate)*

pregnancy, predispose them to the risk of having multiple blood transfusions or death from obstetric haemorrhage, which, if not checked, will remain a significant contributor to maternal morbidity and mortality (Sanyu Research Unit, 2012).

Attempts to reduce deaths from PPH worldwide are complicated by the fact that many deaths still occur in our hospital settings despite the above measures, and death can occur within short space of time before transfer to a health facility is possible (Prendiville *et al*, 2000; Cotter and Ness Tolosa, 2001).

Tranexamic acid has shown satisfactory outcomes when administered during Caesarean sections (Gai *et al*., 2004; Gohel *et al*., 2007; Sekhavat *et al*., 2009; Rashmi *et al*., 2010; Gungorduk *et al*., 2011). TXA has also shown capacity to significantly reduce death due to bleeding in women with primary post-partum haemorrhage as concluded from the WOMAN trial; with recommendations that it should be given as soon as possible after bleeding onset (Shakur *et al*., 2017).

Recent evidence from systemic review of metaanalysis indicate that a single preoperative dose of TXA significantly reduced intraoperative blood loss without increasing perinatal or maternal risks (Heyns *et al*., 2021). This buttresses the prophylactic approach to TXA usage prior to the onset of primary post-partum haemorrhage, as described in a previous study in India in which 1g of intravenous TXA was administered. A similar outcome was achieved in some Chinese studies with the administration of 10mg/kg of intravenous TXA (Goyel *et al*., 2011; Jiajung *et al*, 2013). Interestingly, a significant reduction in haemorrhage at CS following preoperative administration of 1g of TXA was achieved by Obi *et al*. (2019) in Abakaliki, Nigeria. These studies over a period of time have demonstrated that preoperative intravenous tranexamic acid can significantly reduce intraoperative blood loss in the test group as compared with blood loss in the control group.

The World health organization as well as other systematic reviews of meta-analysis have recommended that TXA should be used in all cases of PPH, regardless of whether the bleeding is due to genital tract trauma or other causes, and that it should be administered at a fixed dose of 1g in 10mL (100mg/mL) IV at 1mL per minute (i.e., administered over 10 minutes), with a second dose of 1g IV if bleeding continues after 30 minutes (WHO, 2017; Luigi *et al*., 2018). However, a generally acceptable and categorical stance on preoperative administration of TXA is yet to be taken, hence the need to further explore the prophylactic usage of TXA in reducing blood loss at CS in a suburban population, and to significantly reduce the burden primary PPH contributes to maternal morbidity and mortality.

This trial set out to determine the effect of preoperative tranexamic acid (1g) administration on blood loss during lower segment Caesarean section, when compared with placebo, as well as its impact on the need for additional oxytocic requirement.

MATERIALS AND METHODS

Study Design: This was a prospective, randomized, double-blinded controlled study at the Obstetrics and Gynaecology Department of Irrua Specialist Teaching Hospital (ISTH), Irrua, Edo State, Nigeria, from April to September 2019.

Ethical Considerations: This study was conducted following an ethical approval by the Health Research Ethics Committee of Ambrose Alli University, Ekpoma, Edo State, Nigeria.

Sample Size: The formula for calculating sample size when the outcome measure is a continuous variable in randomized controlled trials was used (Zhong *et al*, 2009):

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta}}{\delta_0} \right)^2 \times s^2$$

Where:
N is sample size per group;
$\mathbf{Z}_{1-\alpha}$ being Standard deviation for α level of 5% which was 1.96,
$\mathbf{Z}_{1-\beta}$ is the standard table value for power of 80% put at 0.845,
$\boldsymbol{\delta}_0$ was 2.5 which is the clinically detectable margin from a previous study in LASUTH Lagos (Akinola *et al*., 2010).
S being the standard deviation of packed cell volume levels of CS patients in the same LASUTH study, which was 6.1. An attrition rate of 10% was considered; thus, a minimum sample size of 104 in each group was estimated.

Therefore, a total of 208 subjects were recruited for the study, but 204 were eventually included in the final data analysis.

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

Randomization and Blinding: Two hundred and eight consenting pregnant women that were admitted into the antenatal ward or labour ward and aged 18years and above for emergency or elective Caesarean section, and also met the inclusion criteria for the study, were randomized into two groups to receive 10mls of TXA –an equivalent of 1g, and 10mls of placebo respectively. Blinding was done by given equal volume of both clear solutions in similar vials kept in same sized envelopes prepared and sealed by a pharmacist who is part of the hospital trial steering committee with numbers ranging from 1-208. The blinding key was only made available after data analysis. All the participants underwent a routine bed side basic obstetric ultrasound scan before surgery (if none was previously done after 36weeks gestation to determine any additional risk for haemorrhage at surgery).

Data and Sample collection: Recorded data were age, parity, intraoperative blood loss, additional oxytocic requirements, neonatal APGAR scores. The researcher and trained research assistants obtained informed consents, administered questionnaires, weighed pads/towels and drapes before and after surgery. The women included were categorized as category 1 by the Anaesthetist using the American Society of Anaesthesiologists classification (i.e. ASA1), and scheduled for emergency or elective CS via Pfannenstiel incision under spinal anesthesia. Parturients with known allergy to TXA and those undergoing emergency CS due to fetal distress, cord prolapse, uterine rupture, or any other indication for a category 1 CS were not included. Those who failed to give a written consent and those from whom an informed consent could not be obtained due to maternal collapse, eclampsia, mental impairment or peri-mortem CS, were also excluded. Women with thrombophilias, established renal impairment, bleeding disorders and those with additional risk of excessive blood loss apart from the Caesarean Section such asprevious CS, multiple gestation, antepartum haemorrhage, coexisting uterine fibroid and polyhydramnios, were similarly excluded.

Primary outcome: the total blood loss at surgery

Secondary outcomes: the requirement for additional oxytocic and perinatal effect of TXA.

Procedure for Administration of Anaesthesia and Drugs: All solutions were prepared and given by an anaesthetist who was also blinded to the actual agent being given to the patient. Anaesthetic protocol was the same in all patients and consisted of spinal anaesthesia with 2.5mg of hyperbaric Bupivacaine 0.5% (Marcaine 0.5%®, ASTRAZENECA, UK) and 10 mg of pethidine (Demerol®, PFIZER, USA). All patients received a co-loading with 20 ml/kg of 0.9% saline solution. The content of both ampoules were drawn up into a 10mL syringe using the 21-G needle that was provided. Before administration, the expiry date was checked for both substance and the randomization number confirmed. The contents of the syringe (total volume 10mL) was administered by the anaesthetist after induction of anaesthesia as a slow intravenous injection at a rate of about 1 mL/min using the standard local intravenous administration procedure. 10IU of oxytocin (OXYTOCIN®, MEDIPHARM, CHINA) were given intravenously immediately after delivery; then 20IU was given via 500mls of infusion as well as 1000mcg of misoprostol (CYTOTEC®, PFIZER, USA), which was administered to all the participants. A complementary dose of oxytocin was given intraoperatively upon request of the surgeon, and noted in the report as "additional oxytocic requirement", for the purpose of data analysis. Injection methylergometrine0.5mg IM was used as secondary uterotonic agent in those in whom it is not contraindicated where necessary.

Delivery and Estimation of Blood Loss: All the surgeries were carried out by a senior registrar or a consultant and assessment of blood loss commenced after the skin incision by using digitally pre-weighed surgical towels, while ensuring a separate collection of blood and amniotic fluid in two separate suction sets. Suction of amniotic fluid into the first suction set commenced soon after rupturing the fetal membranes (if unruptured) through a small incision over the uterus, while mopping blood from the uterine incision with the surgical towel. Suction of blood into the second set commenced after delivery of the baby.

Intra-operative blood loss was assessed by volumetric and gravimetric methods i.e. a direct measurement of blood suctioned into the blood suction set in addition to the difference between the total postoperative weight of surgical towels/swabs/drapes and their preoperative weight in grams; where a difference of 1g is taken to correspond with 1ml of blood.

The Neonatologists were present at all 208 deliveries in order to determine the neonatal outcome including APGAR scores and the need for neonatal intensive care admission. Any suspicion of maternal or neonatal

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

tranexamic acid drug side effects was to be stated and managed appropriately.

Data Analysis: Data were recorded, tabulated and analysed using Statistical package for social sciences (SPSS® version 21.0). Normal distribution was checked before analysis. Numerical variables were presented as mean and standard deviation (SD). Student t-test was used for comparison of quantitative variables between groups. A difference with P value <0.05 was considered as statistically significant.

RESULTS

The age distribution, occupation and other socio-demographic features of the participants are shown in Table 1a and 1b. There was no significant difference between the two study groups with regards to mean age, marital status, ethnicity, level of education and occupation with p-values 0.441, 0,386, 0.093, 0.546 and 0.568 respectively. The mean blood loss was significantly lower in the TXA group (502.84 ± 234.565ml) compared to the Placebo (699.46 ± 177.407ml). Patients who received TXA had an 81% reduced risk of need for additional oxytocics compared to the placebo group and this difference was statistically significant. No perioperative complications were noted and attributable to TXA; especially no allergic reactions, postoperative thromboembolism or neonatal complications.

TABLE 1a SOCIODEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS

VARIABLE	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	X^2	P
AGE (Years)				
20 – 24	8 (7.8)	9 (8.8)	t = 0.77	0.441
25 – 29	30 (29.4)	35 (34.3)		
30 – 34	44 (43.1)	37 (36.3)		
≥ 35	20 (19.6)	21 (20.6)		
MARITAL STATUS				
Single	7 (6.9)	4 (3.9)	1.902	0.386
Married	94 (92.2)	98 (96.1)		
Widowed	1 (1.0)	0 (0.0)		
ETHNICITY				
Esan	62 (60.8)	61 (59.8)	18.804	0.093
Bini	1 (1.0)	4 (3.9)		
Igbo	6 (5.9)	9 (8.8)		
Yoruba	2 (2.0)	6 (5.9)		
Urhobo	1 (1.0)	1 (1.0)		
Akoko Edo	2 (2.0)	0 (0.0)		
Etsako	10 (9.8)	15 (14.7)		
Owan	13 (12.7)	2 (2.0)		
Isoko	2 (2.0)	1 (1.0)		
Fulani	1 (1.0)	0 (0.0)		
Gwarri	1 (1.0)	0 (0.0)		
Igarra	1 (1.0)	1 (1.0)		
Ika	0 (0.0)	1 (1.0)		

Mean age ± SD = 31.05 ± 4.662 years (TXA); Mean age ± SD = 30.52 ± 4.579 years (Placebo)

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

TABLE 1b SOCIODEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS

VARIABLE	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	X^2	P
LEVEL OF EDUCATION				
No formal education	3 (2.9)	2 (2.0)	2.128	0.546
Primary	17 (16.7)	11 (10.8)		
Secondary	47 (46.1)	55 (53.9)		
Tertiary	35 (34.3)	34 (33.3)		
OCCUPATION				
Student	9 (8.8)	9 (8.8)	2.020	0.568
Unskilled	56 (54.9)	62 (60.8)		
Semi-skilled	18 (17.6)	11 (10.8)		
Skilled	19 (18.6)	20 (19.6)		

Mean age ± SD = 31.05 ± 4.662 years (TXA); Mean age ± SD = 30.52 ± 4.579 years (Placebo)

The parity, booking status, and gestational age at delivery of the respondents are shown in Table 2. There was no statistically significant difference between the two groups (P is 0.864, 0.068 and 0.524 respectively)**.**

TABLE 2: OBSTETRIC HISTORY OF RESPONDENTS:

VARIABLE	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	X^2	P
PARITY				
Zero	38 (37.3)	45 (44.1)	1.890	0.864
One	13 (12.7)	12 (11.8)		
Two	21 (20.6)	22 (21.6)		
Three	19 (18.6)	13 (12.7)		
Four	6 (5.9)	6 (5.9)		
Five or more	5 (4.9)	4 (3.9)		
BOOKING STATUS				
Booked	77 (75.5)	65 (63.7)	3.337	0.068
Unbooked	25 (24.5)	37 (36.3)		
GESTATIONAL AGE (Weeks)				
< 34	5 (4.9)	4 (3.9)	1.291	0.524
34 – 37	9 (8.8)	14 (13.7)		
37 – 42	88 (86.3)	84 (82.4)		

There was no statistically significant difference between the two groups as regards to baseline preoperative packed cell volume, and as indicated in table 3 below, showing the haematocrit pattern in both groups (p= 0.318).

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

TABLE 3: PREOPERATIVE PACKED CELL VOLUME:

PACKED CELL VOLUME (%)	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	*T*	P
<30.0	4 (3.9)	2 (2.0)	1.00	0.318
30.0 – 33.0	30 (29.4)	31 (30.4)		
33.1 – 36.0	42 (41.2)	33 (32.4)		
> 36.0	26 (25.5)	36 (35.3)		

Mean packed cell volume ± SD = 34.58 ± 2.978% (TXA)
Mean packed cell volume ± SD = 35.00 ± 3.025% (Placebo)

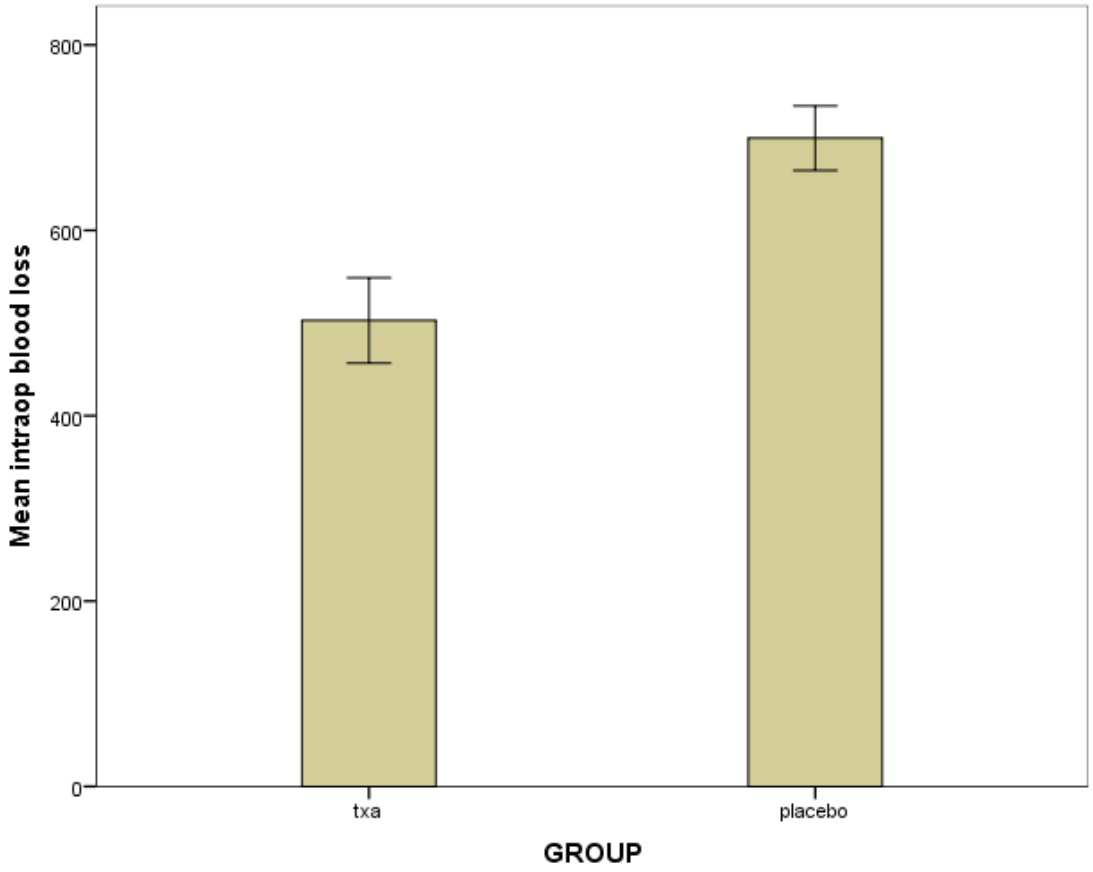

FIGURE 1: MEAN INTRAOPERATIVE BLOOD LOSS IN THE TWO GROUPS

The amounts of blood loss in the test group, compared to the placebo group, are shown in Figure 1 and Table 4 below. The values obtained indicated that the mean intraoperative blood loss was less in the TXA group than in the placebo group (502.84 ± 234.565 ml vs 699.46 ± 177.407 ml), and the recorded difference was statistically significant (P< 0.01).

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

TABLE 4: INTRAOPERATIVE BLOOD LOSS

BLOOD LOSS (ml)	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	*T*	P
< 500	56 (54.9)	11 (10.8)	6.75	< 0.01*
500 – 1000	43 (42.2)	90 (88.2)		
> 1000	3 (2.9)	1 (1.0)		

*Statistically significant
Mean blood loss ± SD = 502.84 ± 234.565 ml (TXA)
Mean blood loss ± SD = 699.46 ± 177.407 ml (Placebo)

Table 5 below demonstrates the need for additional oxytocic and the comparison between both groups. The patients who received TXA had an 81% reduced risk of need for additional oxytocics compared to the placebo group and the difference was statistically significant (RR 0.19; 95%CI= 0.10-0.34).

In Table 6 below, the difference between the mean neonatal birth weights in both groups was not statistically significant (p= 0.082).

TABLE 5: NEED FOR ADDITIONAL OXYTOCICS:

VARIABLE	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	RR	95% CI
Additional Oxytocics				
Required	10 (9.8)	54 (52.9)	0.19	0.10 – 0.34*
Not required	92 (90.2)	48 (47.1)		

*Statistically significant

TABLE 6: NEONATAL BIRTH WEIGHT:

WEIGHT (Kg)	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	*T*	P
< 1.5	2 (2.0)	2 (2.0)	1.75	0.082
1.50 – 2.00	5 (4.9)	5 (4.9)		
2.01 – 2.50	11 (10.8)	10 (9.8)		
2.51 – 3.00	32 (31.4)	19 (18.6)		
3.01 – 3.50	29 (28.4)	32 (31.4)		
3.51 – 4.00	21 (20.6)	25 (24.5)		
> 4.00	2 (2.0)	9 (8.8)		

Mean birth weight ± SD = 3.05 ± 0.609 (TXA);
Mean birth weight ± SD = 3.21 ± 0.673 (Placebo)

The APGAR scores from both groups showed no statistically significant difference between the 1st and 5thminute APGAR scores as shown in Table 7 (P=0.394 and P=0.737 respectively).

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

TABLE 7: APGAR SCORE:

APGAR SCORE	TXA Frequency (%) n = 102	PLACEBO Frequency (%) n = 102	X^2	P
FIRST MINUTE				
<4	1 (1.0)	1 (1.0)	0.726	0.394
4 – 6	14 (13.7)	19 (18.6)		
7 – 10	87 (85.3)	82 (80.4)		
FIFTH MINUTE				
< 4	1 (1.0)	1 (1.0)	0.113	0.737
4 – 6	1 (1.0)	0 (0.0)		
7 – 10	100 (98.0)	101 (99.0)		

DISCUSSION

The study demonstrated a statistically significant difference in intra-operative blood loss between both groups, with a reduction in blood loss by up to 28.1% compared with the control group with tranexamic acid (TXA) use; implying that women who received preoperative tranexamic acid had less intraoperative blood loss than those who received placebo. This is similar to the findings in previous studies by Goyel *et al*. (2011), Jiajung et *al*. (2013) and Obi *et* al. (2019), in which preoperative TXA was also associated with less intraoperative blood loss among the study group. A reduction in blood loss by 30.8% from the study by Obi *et al*. (2019) is similar to the findings in this study, wherein a reduction in blood loss by approximately a third with preoperative TXA was observed.

The overall benefit could also be related to a synergistic effect between tranexamic acid and other oxytocics utilized for all participants in this trial such as misoprostol which also helps in reducing peripartum blood loss (Elsedeek *et al*., 2012). Moreover, three of those who were given TXA had an intraoperative blood loss in excess of 1000mls probably due to the fact that there are other individual factors that determined blood loss independent of TXA administration such as uterine atony; this makes judicious use of oxytocics as a much relevant intervention despite the benefits seen with TXA administration in this study.

The pre-operative packed cell volume was not significantly different in both categories (p=0.318), with a mean of 34.5% and 35% for the test group and placebo group respectively. This is in line with the 32.3% and 32.2% (p=0.5951) reported by Obi *et al*. (2019) in Ebonyi State, Nigeria. Emmanuel *et al*. (2021) had also reported a mean packed cell volume of 34.5±2.34 among pregnant women, compared with 43.30±3.23 in the non-pregnant women in Ido, Ondo State, Nigeria; indicating varied haematocrit levels among pregnant women in various regions.

Furthermore, there was an 81% reduced risk in the need for additional oxytocic in women that received TXA as compared with the placebo group which was statistically significant. This is relevant in the light of known side effects associated with excessive use of various oxytocics in this parturients. Hence, a multidimensional approach in combating blood loss in situations like these appears more beneficial.

On birth weight, no statistically significant difference was observed. The TXA group had a mean neonatal birth weight of 3.05±0.609kg, compared with 3.21±0.673kg in the placebo group. Also, the 1st and 5th minute APGAR scores showed no statistically significant difference in both groups. Similar findings from some other local studies had shown that preoperative TXA reduced blood loss without significantly affecting neonatal birth weight or APGAR scores. (Obi *et al*., 2019). This gives more credence to the fact that TXA when judiciously utilized is of much benefit with no significant adverse effect on the new born.

Globally, the benefit of postpartum TXA administration with respect to significant reduction in maternal morbidity and maternal mortality has been demonstrated by the WOMAN trial (Shakur *et al* 2017). However, a more prophylactic approach in combating primary post-partum

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

haemorrhage by preoperative administration of 1g TXA as shown in this study is significantly beneficial; without necessarily waiting for bleeding to ensue before an intervention like this is instituted.

In conclusion, the results of this study demonstrate a significant reduction in intraoperative blood loss and less need for additional oxytocic in women who had preoperative TXA administration without significant adverse perinatal effect.

Limitations: Some limitations of this study were duly noted and herein documented for attention in subsequent studies.

1. The absence of critical analysis of the duration of surgery; though all the procedures were within the average duration of 45 minutes.

2. The fact that the study was a single hospital-based study; as a multicentre assessment of the observations will make them more generally acceptable.

Recommendation: Preoperative TXA should be considered for prophylactic use during Caesarean section to reduce bleeding and the need for additional oxytocic requirement.

REFERENCES

Ajenifuja, K.O., Adepiti, C.A. and Ogunniyi, S.O. (2010): Postpartum haemorrhage in a teaching hospital in Nigeria: a 5-year experience. *Afr Health Sci.*; 10(1): 71-74.

Akinola, O.I., Fabamwo, A.O., Tayo, A.O., Rabiu, K.A., Oshodi, Y.A. and Onyekwere, C.A (2010).Evaluation of blood reservation and use for Caesarean sections in a tertiary maternity unit in south western Nigeria.*BMC Pregnancy Childbirth*; 10(57): 1-6.

Cotter, A. and NessTolosa, J. (2001).Prophylactic oxytocin for the third stage of labour.*Cochrane Database Syst Rev*; (Issue 4). Art. NoCD001808.

Ellis, H. (2007). Surgical Anniversaries: James Blundell, pioneer of blood transfusion *BJOG*; 68: 8.

Gai, M.Y., Wu, L.F., Su, Q.F. (2004): Clinical observation of blood loss reduced by tranexamic acid during and after caesarian section: a multi-center, randomized trial. *EJOG ReprodBiol*; 112:154–157.

Elsedeek, M.S. (2012). Impact of preoperative rectal misoprostol on blood loss during and after elective cesarean delivery.*Int J GynaecolObstet*; 118(2):149-152.

Emmanuel I.O., Oluwayanmife J.A., Chukwuma J.O., Gertrude U.O., Adaobi M.I., Pat U.O. et al(2021). Assessment of haematological changes in pregnant women of ido,ondo state,nigeria.J Res Med Dent Sci, 9(4): 145-148.

GohelMayur, P.P., Gupta, A. and Desai, P. (2007): Efficacy of tranexamic acid in decreasing blood loss during and after cesarean section: A randomized case controlled prospective study. *J ObstetGynecol India*; 57:227–230.

Gungorduk, K., Yildirim, G. and Asicioglu, O. (2011): Efficacy of intravenous tranexamic acid in reducing blood loss after elective cesarean section: a prospective, randomized, double-blind, placebo-controlled study. *Am J Perinatol*; 28:233–240.

Heyns, M., Knight, P., Steve, A.K. and Yeung, J.K. (2021). A Single Preoperative Dose of Tranexamic Acid Reduces Perioperative Blood Loss: A Meta-analysis. *Ann Surg*; 273(1):75-81.

Jiajung, X, Wei, G. and Yignan, J. (2013).*Archives of Gynaecology and Obstetrics*; 287(3): 463–468.

Lian, L., Richard, F.W.B., Momade, C., Elvira, L., Ines, B., Patricia, S. and Annette,V. Maternal death and postpartum haemorrhage in sub-Saharan Africa – A pilot study in metropolitan Mozambique. *Res PractThrombHaemost*; 4(3): 402-412.

Luigi, D., Gabriele, S., Mariavittoria, L., Luigi, C., Antonio, R., Pierluigi, G.*et al*. (2018).Tranexamic acid for treatment of primary postpartum haemorrhage after vaginal delivery: a systematic review and meta-analysis of randomized controlled trials. *J. Matern-Fetal Neonatal Med*; 1500544.

Matot, I., Einav, S., Goodman, S., Zeldin, A., Weissman, C., Elchalal, U. (2004): A survey of physician's attitude towards blood transfusion in patients undergoing caesarean section. *Am J ObstetGynecol*; 190: 462-467.

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)

Obi, V.O., Umeora, O.U. J., Dimejesi, I. B.O., Asiegbu, O., Mgbafulu, C.C., Ifemelumma, C.C. and Obi, C.N. (2019). Efficacy of intravenous tranexamic acid at reducing blood loss during elective caesarean section in Abakaliki: A double blind randomized placebo controlled trial. *African Journal of Medical and Health Sciences*; 18(2), 10-17.

Prendiville, W.J.,Elbourne,D.andMcDonald, S. (2000).Active versus expectant management in the third stage of labour.*Cochrane Database Syst Rev*; 3.Art. NoCD000007

Rashmi, P.S., Sudha, T.R. and Prema, P. (2010): Roll of Tranexamic acid in reducing blood loss during and after cesarean section a randomized case control prospective study. *J Med Res Pract*; 1:40–3.

Sanyu Research Unit, Department of Women's and Children's Health, Liverpool Women's Hospital, University of Liverpool, Liverpool, UK: "The prevention and treatment of postpartum haemorrhage: what do we know, and where do we go to next?".*BJOG*; 122 (2): 202–210.

Sekhavat, L., Tabatabaii, A. and Dalili, M. (2009): Efficacy of tranexamic acid in reducing blood loss after cesarean section. *Int J GynaecolObstet*; 22:72–75.

Shakur, H. Roberts, I. and Fawole, B. (2017): "Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial". *The Lancet*; 389 (10084): 2105–2116.

World Health Organization (WHO). Updated WHO Recommendation on Tranexamic Acid for the Treatment of Postpartum Haemorrhage. Geneva, Switzerland: WHO; 2017.

Zhong, B. (2009). How to calculate sample size in randomized controlled trial. *J Thorac Dis*; 1(1):51-4.

AUTHORS CONTRIBUTIONS

Conceptualization of this study was by Prof. Eigbefoh J and Dr Olugbenga OE, while Dr Okome GBO and Dr Aigberemonlen A., contributed to the study design. Literature review was contributed by Dr Olugbenga OE and Dr Isabu P, while randomization and blinding were by Pharm Adedayo M. and Prof Okogbo F. Data collection was contributed by Dr Olugbenga OE and Dr Okoeguale J. Anaesthesia and drug administration were supervised by Dr Omosofe F., while estimation of blood loss was carried out by Dr Olugbenga OE and Dr Nkweya VF. Neonatal resuscitation and allocation of APGAR scores was supervised by Dr Alikah SA., while Dr Osahon O carried out the data analysis. Dr Omorogbe FI, Dr Momoh M and Dr Ikheloa J, contributed immensely to the ideas elucidated in the study, while the final editing was done by Olugbenga MA. All other authors reviewed and approved the manuscript for publication.

Endorsed By: *Innovative Science Research Foundation* (***ISREF***) and *International Society of Science Researchers* (***ISSCIR***).
Indexed By: *African Journal Online (AJOL); Texila American University; Genamics; Scholarsteer; EIJASR; CAS-American Chemical Society*; and *IRMS Informatics India* (*J-Gate*)