



Research Article

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The Efficacy of Prophylactic Tranexamic Acid in Reducing Perioperative Blood Loss During Caesarean Section: A Randomized, Double Blind Control Trial



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Abstract

Background: The caesarean section rate is increasing worldwide. There is an increased need of blood transfusion in patients who undergo caesarean section when compared to those who have a vaginal delivery, post-partum haemorrhage being commoner in the former group of women. The search for a peri-operative agent that minimizes blood loss and reduces the need for blood transfusion peri-operatively cannot, therefore, be overemphasized.

Objectives : Although several studies have confirmed the efficacy of tranexamic acid in reducing perioperative blood loss, there have been very few of these studies from Nigeria. This study sought to estimate and compare blood loss; determine and compare the incidence of postpartum haemorrhage (PPH) and the need for postoperative blood transfusion among women who had preoperative tranexamic acid and those who did not, following delivery by caesarean section at the Federal Medical Centre, Yenagoa, Bayelsa State Nigeria.

Methodology: This study is a double blind, clinical control trial (superiority design), consisting of 110 parturients at term requiring lower segment Caesarean section randomized into 2(two) equal groups (Experimental and Control). The experimental group received 1g of tranexamic acid 20 minutes before commencement of the surgery while the control group received a placebo. Using a self-designed study proforma, parturients' information including age, weight, and clinical data like preoperative haemoglobin concentration, postoperative haemoglobin concentration 48 hours postoperatively, estimated blood loss (EBL), occurrence of PPH (blood loss >1000 ml) and need for blood transfusion was collected. Blood loss was calculated using the Bourke and Smith equation. An intention-to-treat analysis was done, estimated blood loss in the two groups was compared using z-test, pre- and post-operative haemoglobin concentration were compared using paired 't' test, while the occurrence of PPH and need for blood transfusion between the two groups were explored using Chi-square test of proportion. The Level of significance was set at p value <0.05.

Results: The incidence of primary PPH was lower in the tranexamic acid group compared to the placebo group (20.0% versus 47.3%, respectively, p = 0.004). Perioperative EBL was reduced in the experimental group with mean EBL 682.38±479.69ml vs 1084.57±622.90ml in the placebo group (p-value 0.001). The need for blood transfusion was lower among women in the tranexamic acid group compared to the placebo group: 3.64% vs 27.27% (p = 0.001).

Conclusion: Intravenous tranexamic acid given prior to skin incision at caesarean section significantly reduced perioperative blood loss, the need for blood transfusion and the incidence of primary postpartum haemorrhage among women undergoing CS.

Introduction

The incidence of caesarean delivery is increasing [1], and the average blood loss during Caesarean delivery (1000ml) is double the amount lost during vaginal delivery (500 ml) [2]. Averagely, haematocrit falls by 10% following CS and blood transfusion is required in about 6% of women undergoing Caesarean delivery compared with 4% of women who have a vaginal birth [3].

Numerous methods for performing CS exist; the aim of every CS is a safe delivery of the infant with minimal maternal morbidity. Operative morbidities include haemorrhage and anaemia.

Postpartum haemorrhage (PPH) is a potential life-threatening complication of both vaginal and Caesarean deliveries [4]. It is reported that PPH accounts for nearly 25% of maternal deaths

and approximately 12% survivors after PPH suffer from severe postpartum anemia [5]. Recently, the rate of Caesarean section has increased in both developed and developing countries, which would result in an increased risk of PPH. Following a study carried out in Federal Medical Centre, Owerri [6], Nigeria, the rate of PPH is 3.4%. PPH following caesarean section contributed 56.4% of the total cases of complications associated with caesarean section.

According to Nnadi et al. [7] in a cross-sectional study done in Sokoto to determine the maternal and foetal outcomes following Caesarean deliveries over a period of 2 years, it was noted that of 504 women that had caesarean deliveries, 13.3% had complications. The commonest complication was primary PPH which was seen in 59.7% of these complications. In a six-year audit at Ladoko Akintola University of Technology, Ogbomoso, Nigeria, by Adekanle et al. [8] the average incidence of postpartum haemorrhage during caesarean section was 4.4%.

Although there has been a remarkable improvement in the prevention and treatment of PPH in recent years, deaths due to PPH remain relatively common in some parts of the world. To reduce the occurrence of major morbidity and mortality due to PPH, it is very vital to reduce blood loss at caesarean section and vaginal delivery. The sixth Saving Mothers report on maternal deaths in South Africa for 2011-2013 identified 221 deaths due to bleeding associated with caesarean delivery [9]. This represents an increase from 180 during 2008-2010, 141 in 2005-2007 and 78 in 2002-2004. This shows that there has been an increasing trend in maternal deaths due to bleeding associated with caesarean delivery. In the University of Benin Teaching Hospital, maternal mortality following Caesarean Section is 7.8 per 1000 [10]. Most of these deaths were associated with primary PPH. Also, at the University of Maiduguri Teaching Hospital, Maiduguri Nigeria, 43.2% of women who underwent caesarean section had primary postpartum haemorrhage [11].

The problems associated with blood transfusion cannot be overemphasized. Blood and blood products may not be readily available when they are needed for transfusion, particularly Rhesus negative blood and other blood products, especially in our environment. Even when they are available, the cost of transfusion is prohibitive in some instances and some patients may not readily afford them. Transfusion-related complications can be categorized as acute or delayed, which can be divided further into the categories of non-infectious [12] and infectious [13]. Acute complications occur within minutes to 24 hours of the transfusion, whereas delayed complications may develop days, months, or even years later. The AABB (formerly known as the American Association of Blood Banks) uses the term "non-infectious serious hazards of transfusion" to classify non-infectious complications [13]. Transfusion-related infections are less common because of advances in the blood screening process; the risk of contracting an infection from transfusion having decreased 10,000-fold since the 1980s. Non-infectious serious hazards of transfusion are up to

1,000 times more likely than an infectious complication. However, there has been no progress in preventing non-infectious serious hazards of transfusion, despite improvements in blood screening tests and other related medical advances. Therefore, patients are far more likely to experience a non-infectious serious hazard of transfusion than an infectious complication.

Medications, such as oxytocin, misoprostol, prostaglandin F2a, and methylergonovine, have been used to control bleeding during and after caesarean section [2]. Tranexamic acid, a synthetic derivate of the amino acid lysine, is an antifibrinolytic that reversibly inhibits the activation of plasminogen, thus inhibiting fibrinolysis and reducing bleeding. Tranexamic acid may enhance the effectiveness of the patient's own haemostatic mechanism [14]. Tranexamic acid has been used to reduce blood loss and the need for allogenic blood transfusion in cardiac surgery, liver transplantation, and orthopaedic surgical procedures [15]. In gynaecology, Tranexamic acid is most commonly used to treat idiopathic menorrhagia and is an effective and well-tolerated treatment when administered orally [16]. Bleeding associated with pregnancy (placental abruption, placenta praevia) has also been treated with tranexamic acid. A number of researchers have worked in this subject area. However, most of the studies have concentrated mostly in the Asian countries especially in India. There is paucity of published data for studies in this subject area in Nigeria and indeed Africa in general.

This randomized, double-blind, placebo-controlled study evaluated the effect of tranexamic acid on perioperative bleeding in women undergoing caesarean section with the aim of providing a safe and effective pharmacological therapy for reducing blood loss. In evaluating the efficacy of tranexamic acid in reducing blood loss during caesarean section, we hypothesized that 'Intravenous tranexamic acid when given preoperatively will not reduce blood loss during caesarean section and need for blood transfusion after caesarean section' (Null Hypothesis), and the Alternative Hypothesis states 'Intravenous tranexamic acid when given preoperatively significantly reduces blood loss during caesarean section and also reduces the need for blood transfusion'.

Methods

Study Area

This study was carried out at the Obstetrics and Gynaecology department of the Federal Medical Centre (FMC), Yenagoa, Bayelsa State, South-South, Nigeria. Bayelsa state has a population of 1.7 million people according to 2006 population census by the National Population Commission with women constituting 48.7% of the population [17]. They are predominantly Christians and Ijaw. They are mainly rural dwellers. Majority of the women are fishermen and farmers with few being civil servants and traders. Marriage is mainly by cohabitation and teenage pregnancy rate is quite high due to high rate of poverty and illiteracy. The FMC, Yenagoa is one of the two tertiary health institutions

located in Bayelsa state and its core mandate revolves around service, training and research. The Obstetrics and Gynaecology department is made up of two obstetric units, one in the main hospital in Yenagoa and the other at Otuoke, a rural outpost of the hospital. These units have a total average of about 2,500 deliveries annually with a caesarean section rate of 30% (unpublished departmental annual report, 2018) and serve as a referral centre for hospitals in Bayelsa State and neighbouring Delta and Rivers State, in Nigeria. It has a well-equipped labour ward theatre and a standard haematology laboratory with haematologists.

Study Design

This is a double-blind, randomized clinical control trial. It is a clinical superiority design.

Study Population

The study population consisted of women of reproductive age, singleton, and term pregnancy. Term pregnancy defined as gestational age of 37 completed weeks to 41week 6 days. Exclusion criteria in the study include parturients with obstructed labour, polyhydramnios, prolonged labour, intrauterine foetal death, previous history of postpartum haemorrhage, anaemia in pregnancy at the time of surgery, history of thromboembolism, bleeding disorders, abnormal placentation, antepartum haemorrhage, co-existing uterine fibroid and allergy to tranexamic acid.

Sample Size

The sample size was determined using the formula for calculating sample size for randomized control trial of clinical superiority design with dichotomous variables [18].

N = Minimum required sample size, $Z_{1-\alpha}$ = percentage point of the normal distribution corresponding to the two-sided significance level at 5% (95% Confidence interval) = 1.96, $Z_{1-\beta}$ = one sided percentage point of the normal distribution corresponding to 100% minus 20% (thus power of 80% for the study) given as 0.84, d = difference in incidence of PPH in control group and the experimental group [19]. P_1 = incidence of PPH in the control group reported as 0.632 in a previous study and P_2 = incidence of PPH in the experimental group, δ = A clinically acceptable incidence of PPH 5-10% [20].

After substitution, the minimum sample size obtained was 50 per group. Giving allowances for 10% attrition rate, the minimum sample size required for this study was 55 participants per group. Therefore, 110 participants were randomized into 2 groups for the study.

Study Instrument

The data for this study was collected using a self-designed, structured proforma with 15 items. The items included the sociodemographic characteristics of participants like age and ethnicity, parity, gestational age, study group, indication for

surgery, duration of surgery, blood loss at surgery, need for blood transfusion, pre- and post-operative haemoglobin estimation. Post-operative packed cell volume was assessed forty-eight hours after surgery.

Study Procedure

Parturients were recruited for the study from the antenatal clinic of FMC Yenagoa where women who met the eligibility criteria for the study were noted and counselled and preliminary consent obtained. They were informed about the objectives and benefit of the study, the safety profile and the possible side effects of tranexamic acid. On presentation in labour, as consent for CS was obtained, a signed informed consent was also obtained for the study from parturient and were enrolled for the study. Following informed consent, the patient received the content of an envelope picked at random, which may either be 1g tranexamic acid (10ml of tranexamic acid diluted with 20ml of 5% dextrose saline) or the placebo (10ml of water for injection mixed with 20ml of 5% dextrose saline). The TXA or placebo was slowly administered intravenously over a 5-minute period at least 20 minutes prior to skin incision. The injection was administered by the Anaesthetist and the randomization code was recorded in the patient's case file. All the surgeries were carried out by at least a Senior Registrar, under regional anaesthesia. After delivery, both groups received a 10 I.U. intravenous bolus of oxytocin.

Blinding

Packing, sealing, and numbering of medication was performed by a Pharmacist who took no further part in the study. The tranexamic acid in 10ml ampoules (1g) was masked with an opaque masking tape. Water for injection in a similar shaped container (10ml) were also masked with same tape. This is done to ensure that the researcher and co-investigators were not aware of what the patient received during the study.

Randomization

The masked tranexamic acid and water for injection were numbered with the randomization codes generated from WINPEPI application software and packed in sealed envelopes. The randomization schedule was kept by the Pharmacist who prepared the medication till the end of the study.

Blood Loss Estimation

Estimated blood loss was calculated using the difference in haematocrit values taken prior to and 48 hours after caesarean delivery, according to the following formula:

Where EBV (estimated blood volume) in ml = the woman's weight in kg x 85. This is based on the Bourke and Smith equation [21]. Blood loss >1000 ml during the procedure is considered as excessive bleeding (primary PPH). The haematocrits were determined by a Senior Registrar in the department of haematology using an auto-analyser to ensure uniformity and reliability of results.

Study Drug

Prexam injection, a brand of Tranexamic acid manufactured by Protech Biosystems (PVT.) Ltd, in India was used for the study. The drugs were stored in the drug showcase in the labour ward theatre where the temperature is less than 25 due to effective air-conditioning.

Data Analysis

Statistical analysis was done using statistical software (SPSS for windows; version 24, SPSS Inc.; Chicago, USA). Mean and standard deviation were calculated for age, weight, duration of surgeries, blood loss etc. Number of patients that had PPH, number that needed blood transfusion, indications for Caesarean section were summarized in frequencies and percentages. Using z-test the difference between the mean values of estimated blood loss, duration of surgeries were investigated. Paired t test was used to uncover the relationship and compare the mean values between pre- and post-operative haematocrit concentrations. Chi-square test was used to explore the relationship between the use

of Tranexamic acid and the incidence of PPH and need for blood transfusion. Level of significance is taken as p value < 0.05.

Ethical Consideration

Ethical approval for this study was obtained from the Ethical Committee of the Federal medical centre, Yenagoa, Bayelsa state. All parturients were recruited into the study after adequate information was provided, and informed consent was obtained. The right to participate or to withdraw from the study was respected for every eligible participant. Administration of intravenous tranexamic acid and the Caesarean section was carried out using standard technique and with due competence to ensure that benefits are maximized, and harm minimized. The cost of the tranexamic acid, pre- and post-operative haemoglobin estimation were borne by the researchers. All parturients in the obstetric units were treated equally. Refusal to participate in the study did not alter the management of patients. Women who developed postpartum haemorrhage were managed using the standard treatment protocol for this Figure 1.

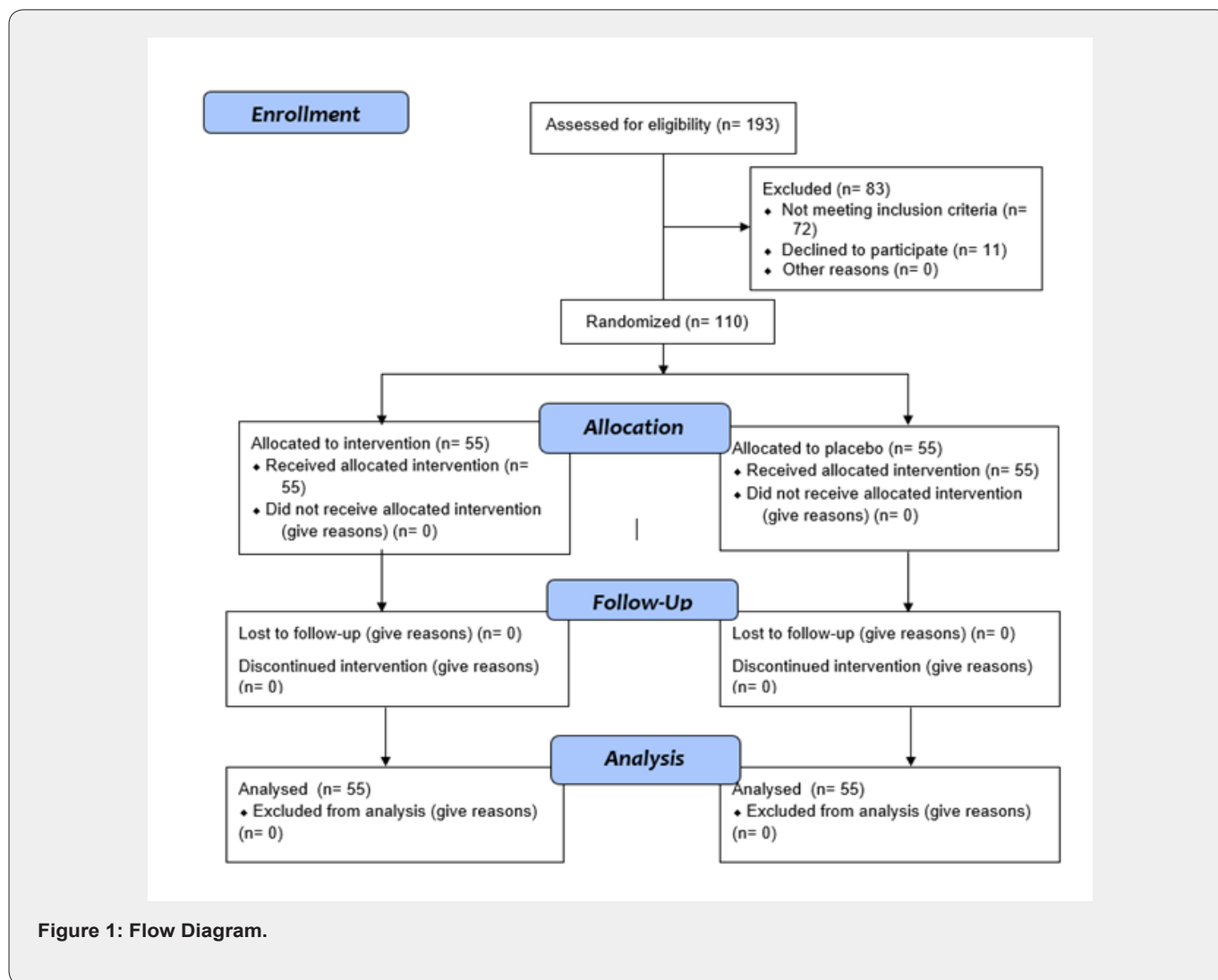


Figure 1: Flow Diagram.

Results

Introduction

One hundred and ninety-three eligible parturients were screened for the trial, out of which 110 (56.9%) who met the eligibility criteria were recruited for the trial. Equal numbers (55) were allocated randomly to both the experimental and control groups. All recruited parturients completed the trial and were included in the analysis (Intention-to treat Analysis)

Sociodemographic characteristics of parturients in the experimental and control groups

Most of the parturients in the experimental (47.3%) and control (41.8%) groups were between ages 30 and 34 years. The

mean ages for the experimental and control groups were 32.3 ± 4.2 years and 32.8 ± 4.3 years, respectively. Most parturients were of the Ijaw ethnic group (45.5%), however 36.4% of the participants in the experimental group were Ijaw, and 54.5% of those in the control group were Ijaw. The parturients were almost evenly distributed in the parity subgroup with most parturients being primiparous women (30.0%) while grand multiparous women were the fewest (18.2%). Furthermore, there is no statistically significant difference (p > 0.05) between the parturients in the experimental and control group in relation to age, ethnicity, and parity. However, it was observed that in relation to weight the participants in the control group (Z = 2.92; p - 0.004) significantly weighed more than those in the experimental group with mean weight of 83.1 ± 13.2kg and 75.8 ± 13.1kg respectively (Table 1).

Table 1: Sociodemographic characteristics of participants in the experimental and Control groups.

Characteristics	Total N = 110 (%)	Experimental Group N = 55 (%)	Control Group N = 55 (%)	Test of Significance	df	P Value
Age Group						
≤ 29 years	25 (22.7)	11 (20.0)	14 (25.5)	X ² = 0.54	2	0.762
30 – 34 years	49 (44.5)	26 (47.3)	23 (41.8)			
≥ 35 years	36 (32.7)	18 (32.7)	18 (32.7)			
Mean Age ± SD in years	32.5 ± 4.2	32.3 ± 4.2	32.8 ± 4.3	Z = 0.43	108	0.514
Mean Weight ± SD in Kg	79.5 ± 13.6	75.8 ± 13.1	83.1 ± 13.2	Z = 2.92	108	0.004
Ethnicity						
Ijaw	50 (45.5)	20 (36.4)	30 (54.5)	X ² = 9.09	4	0.059
Igbo	35 (31.8)	19 (34.5)	16 (29.1)			
Urhobo/Isoko	8 (7.3)	3 (5.5)	5 (9.1)			
Yoruba	5 (4.5)	5 (9.1)	0 (0.0)			
Others	12 (10.9)	8 (14.5)	4 (7.3)			
Parity						
Nullipara	28 (25.5)	16 (29.1)	12 (21.8)	X ² = 0.84	3	0.841
Primipara	33 (30.0)	16 (29.1)	17 (30.9)			
Multipara	29 (26.4)	14 (25.5)	15 (27.3)			
Grandmultipara	20 (18.2)	9 (16.4)	11 (20.0)			

Baseline clinical characteristics of parturients in the experimental and control groups

Table 2 shows a baseline description of the clinical features of women in the 2 groups of the trial. While 94.5% and 83.6% of the women in the control group and experimental group were between 37- and 40-week gestation respectively, about 1 in 10 of the women (10.9%) recruited for the trial were greater than 40 weeks' gestation. Parturients in the high-risk group for post-partum haemorrhage were 52.7% in the control group and 41.8% in the experimental group. Although there was no parturient with uterine fibroids in the control group, there was no significant difference between the experimental group and the control group in relation to the presence of uterine fibroid. There was

no statistically significant difference in the risk for post-partum haemorrhage and also in the estimated gestation age, between parturients in the experimental and control groups. Pre-operative PCV in the control group was significantly higher than the experimental group (Z = 4.68; p - 0.033) with mean PCV of 34.5 ± 2.8% and 33.4 ± 2.8% respectively (Table 2).

Incidence of postpartum haemorrhage among parturients in the experimental and control groups

Table 3 shows that of the 110 participants in this trial, 37 had post-partum haemorrhage perioperatively, giving an incidence rate of 33.6% for post-partum haemorrhage (PPH). However, while about 1 in 5 of women in the experimental group had PPH

(20.0%), almost half of the control group had PPH (47.3%). The proportion of women who had PPH in both groups was found to be different statistically ($X^2 = 9.16$; $p = 0.004$). Furthermore, 15 parturients (27.3%) in the Control group had blood transfusion,

while only 2 parturients (3.6%) in the experimental group needed blood transfusion. There was a significant difference ($X^2 = 11.75$; $p = 0.001$) in the proportion that needed blood transfusion in the two groups (Table 3).

Table 2: Baseline clinical characteristics of parturient in the experimental and control groups.

Characteristics	Total N = 110 (%)	Experimental Group N = 55 (%)	Control Group N = 55 (%)	Test of Significance	Df	P Value
Estimated Gestational Age						
37 – 40 weeks	98 (89.1)	46 (83.6)	52 (94.5)	$X^2 = 3.37^{**}$	1	0.067
>40 weeks	12 (10.9)	9 (16.4)	3 (5.5)			
Risk for Post-partum Haemorrhage						
Low risk	58 (52.7)	32 (58.2)	26 (47.3)	$X^2 = 1.31$	1	0.252
High risk	52 (47.3)	23 (41.8)	29 (52.7)			
Fibroid						
No Fibroid	106 (96.4)	51 (92.7)	55 (100.0)	$X^2 = 4.15^{**}$	1	0.118
Fibroid	4 (3.6)	4 (7.3)	0 (0.0)			
Pre-operative PCV						
mean \pm SD in %	33.9 \pm 2.9	33.4 \pm 2.8	34.5 \pm 2.8	$Z = 4.68$	108	0.033*
Duration of Surgery						
mean \pm SD in minutes	62.1 \pm 20.9	63.0 \pm 23.0	61.3 \pm 18.7	$Z = 0.42$	108	0.677

*Statistical significance; **Chi-square reported is the Fisher's exact Chi-square.

Table 3: Post-operative features in the experimental and control groups.

Characteristics	Total N = 110 (%)	Experimental Group N = 55 (%)	Control Group N = 55 (%)	Test of significance	df	pValue
Need for Blood Transfusion						
No Transfusion	93 (84.5)	53 (96.4)	40 (72.7)	$X^2 = 11.75$	1	0.001*
Transfusion	17 (15.5)	2 (3.6)	15 (27.3)			
Post-Partum Haemorrhage (PPH)						
No PPH	73 (66.4)	44 (80.0)	29 (52.7)	$X^2 = 9.16$	1	0.004*
PPH	37 (33.6)	11 (20.0)	26 (47.3)			
Post-operative PCV						
Mean \pm SD	29.6 \pm 3.3	30.0 \pm 3.0	29.2 \pm 3.6	$Z = 1.17$	108	0.091
Estimated Blood Loss (EBL In ml)						
Mean EBL (Calculated)	883.5 \pm 589.1	682.3 \pm 479.7	1084.6 \pm 622.9	$Z = 3.79$	108	0.017*

*Statistically significant

Estimated Blood Loss (EBL) among parturients in the experimental and control groups

Table 3 reveals that the mean estimated blood loss in the trial was 883.5 \pm 589.1ml by calculation. The mean difference in the estimation was significantly higher in the control group when compared to the experimental group ($Z = 3.79$; 0.017).

Table 4 demonstrates the variability in the packed cell volumes before and after surgery between the two trial groups. While the

mean difference in packed cell volume pre- and post-operative in the control group was 5.3% and showing a variability of 3.0%, the mean difference between the pre- and post-operative packed cell volume in the experimental group was 3.4% with a variability of 2.5%. Though these differences are statistically significant in both groups, the magnitude of the test of significant is greater in the control group. Post-operative PCV also correlated more with pre-operative PCV in the Experimental group ($r = 0.61$; $p < 0.001$) than in the Placebo group ($r = 0.57$; $p < 0.001$).

Table 4: Results of Paired 't' test for Pre- and Post-operative PCV among the Experimental and control groups.

Variables	Experimental Group (N = 55)	Control Group (N =55)
Pre-operative PCV	33.4 ± 2.8	34.5 ± 2.8
Post-operative PCV	30.0 ± 3.0	29.2 ± 3.6%
Mean difference ± SD	3.4 ± 2.5	5.3 ± 3.0
95%CI for mean difference	2.72 – 4.11	4.48 – 6.12
z-test (p Value)	9.84 (< 0.001)	13.01 (< 0.001)
Pearson correlation co-efficient (p Value)	0.61 (<0.001)	0.57 (<0.001)

Discussion

In this study, the mean estimated blood loss in the study group was significantly lower in the experimental group than the placebo group. The study demonstrated that preoperative administration of 1g intravenous tranexamic acid 15 minutes prior to skin incision was associated with a relative difference of 37.1% in blood loss between the experimental and placebo groups at caesarean delivery. This value is similar to the 30.8%, 34.0%, and 30.0% reduction in blood loss reported by Umeora et al. [22] in Abakaliki, Maged et al. [23] in Cairo, Egypt and Ahmed [24] in Ismaila, Egypt respectively. However, Ifunanya et al. [25] from Abakaliki reported a slightly higher reduction in blood loss (45.0%) attributable to preoperative administration of Tranexamic acid. These differences in blood loss may be because of the different time intervals used in assessing the blood loss and the different methods used in the estimation of blood loss in the various studies. While some studies used gravimetric method and assessed blood loss after 2 hours of caesarean section, others used change in haematocrit and assessed blood loss after 48 hours of the surgery. This study also used the haematocrit change after 48 hours using the Bourke and Smith equation.

Furthermore, the incidence of primary postpartum haemorrhage was significantly reduced in the experimental group compared to the placebo group. About 47.0% of the patients in the placebo group had primary postpartum haemorrhage compared to 20.0% in the study group. This was statistically significant (p= 0.004). This reduction in the risk of primary postpartum haemorrhage had been reported in similar randomized control studies in which risk of primary postpartum haemorrhage was an outcome variable [3,22,23]. The significant reduction in blood loss is particularly important in this centre where the cost of blood transfusion is relatively high, with blood being not easily available nor affordable by our obstetric patients.

The difference in the number of patients that received blood transfusion was statistically significant in both groups. About 27.0% of the patients in the control group received blood transfusion while only about 4% of the study group were transfused with blood (p= 0.001). This is consistent with the findings in the systematic reviews done by Shahid et al. [26] and

Novikova et al. [27]. However, it is at variance with the studies done by Gungordurk et al. [3], Umeora et al. [22] and Maged et al. [23] who found no statistical difference in the number of people who received blood transfusion in both groups.

The major strength of this randomized, controlled study is because it was a prospective, double blinded study. The blinding carried out by the pharmacist minimized any bias by ensuring that the researchers did not know what patients were getting until results were analyzed at the end of the study. The study is not without limitations. The tranexamic acid-related risk of thrombosis or changes in foetal APGAR scores were not evaluated in this study, though, no case of an adverse event was noticed in the babies delivered during the study. It is important that further studies investigate the effect of the drug on the babies.

This study demonstrates that preoperative administration of intravenous tranexamic acid significantly reduced blood loss at caesarean section. It also significantly reduced the incidence of primary postpartum haemorrhage as well as the need for blood transfusion. It is, therefore, recommended that 1g of intravenous tranexamic acid should be given slowly over 10 minutes routinely, 20 minutes before skin incision during Caesarean section subject to results of studies that would confirm that there is no associated adverse effect to the unborn baby.

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