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## Effect of Prophylactic Tranexamic Acid on Peripartum Changes in Hemoglobin Concentration After Vaginal Delivery

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### Abstract

**Objective:** To evaluate the effect of prophylactic intravenous tranexamic acid on postpartum hemoglobin concentration values compared to control. **Methods:** This is a randomized controlled study involving 80 parturients with no apparent risk for PPH in a tertiary hospital who were grouped into two of 40 each. Group A received 10iu of oxytocin intramuscularly with 1000mg of intravenous tranexamic acid within one minute of having vaginal delivery of the baby while group B received intramuscular oxytocin 10iu with 10mls of sterile water and served as the control group. The primary outcome measure was the difference in admission and postpartum hemoglobin concentration (Hemoglobin change). **Result:** During the study period, 80 parturients that were recruited, completed the study. The characteristics of the parturients in the two groups had no significant statistical difference in their demographic characteristics and admission parameters ( $P>0.05$ ). The mean postpartum hemoglobin concentration was significantly higher in the tranexamic acid plus oxytocin group compared to placebo plus oxytocin group ( $10.28 \pm 0.59\text{ml}$ ) versus ( $9.44 \pm 0.62\text{ml}$ )  $p<0.005$ . There was no major maternal side effect in both groups.

**Conclusion:** When compared with placebo plus oxytocin, tranexamic acid plus oxytocin was more effective in reducing postpartum hemoglobin drop after vaginal delivery. Tranexamic acid plus oxytocin is therefore recommended to be part of the active management of the third stage of labor.

**Keywords:** Peripartum Hemoglobin Change; Tranexamic Acid; Vaginal Delivery.

### **Advances to Knowledge:**

- The prophylactic addition of 1000mg of intravenous tranexamic acid in addition to oxytocin is more effective than the use of oxytocin alone in reducing postpartum haemoglobin drop after vaginal delivery.
- Tranexamic acid when used in prophylactic dosage for reduction of postpartum blood loss is safe as 97.5% of the study subjects had no side effects due to the use of the drug.

### **Application to Patient Care:**

- This study shows that tranexamic acid is a safe, effective, and complementary medication that can be used with oxytocin as part of the active management of the third stage of labour.
- Use of 1000 mg of intravenous tranexamic acid in combination with oxytocin helps reduce postpartum haemoglobin drop after vaginal delivery which prevents postpartum anaemia and improves maternal health.

### **Introduction**

Over half a million women died attempting to give birth with 99% of all maternal deaths occurring in underdeveloped countries; yet these tragedies could be prevented.<sup>1</sup> Maternal death throws the immediate family into untold hardship, deprives the children of the much-needed maternal care, and throws the consort into loneliness, agony, and despair as he loses both economic and emotional support. The country loses both material and human resources as these women die in their prime, many of them being the hub of their families.<sup>2</sup>

Postpartum hemorrhage along with hypertension and infection are the triad of causes of maternal deaths in both underdeveloped and developed countries.<sup>1</sup> Postpartum blood loss of 500ml or more following a vaginal delivery or 1000ml or more following cesarean delivery or any amount of blood loss that causes hemodynamic compromise after delivery is called postpartum hemorrhage.<sup>3</sup>

The most common cause of postpartum hemorrhage is uterine atony. (3) Other causes of postpartum hemorrhage include genital tract lacerations, retained products of conception, ruptured uterus, and coagulation defects.<sup>4,5,6</sup>

Apart from maternal mortality, morbidities that may complicate postpartum hemorrhage include anemia, renal failure, puerperal sepsis, and Sheehan's syndrome. Although blood transfusion may

alleviate the anemia and some other complications of PPH, it carries risks of blood transfusion reaction and infection, especially Human Immunodeficiency Virus (HIV) and Hepatitis B.<sup>7,8</sup>

Availability of blood and blood products is still precarious, especially in developing countries with poor blood banking services and epileptic power supply. Even then, blood or blood products are still expensive. Several preventive measures have been used for the reduction of postpartum blood loss.

Prostaglandin E1 analog (misoprostol) or oxytocin in the active management of the third stage of labor (AMTSL) is effective in decreasing maternal blood loss by 30%, risk of postpartum hemorrhage, length of the third stage of labor, and the need for blood transfusion.<sup>9,10</sup>

A meta-analysis on the use of oxytocin in active management of the third stage of labor found that postpartum hemorrhage still occurs despite this "gold standard first-line drug."<sup>10</sup> Also considering that most women in developing countries go into pregnancy and labor with borderline hemoglobin value, minimal blood loss may become critical.<sup>10</sup> Hence there is still a need to determine if there may be more effective means of reducing postpartum blood loss, decrease reduction in postpartum hemoglobin value, reduce postpartum anemia as well as need for blood transfusion.

Tranexamic acid is a potent anti-fibrinolytic derivative of lysine that inhibits both plasminogen activation and plasmin activity by blocking the binding sites thereby preventing the breakdown of already formed blood clots.<sup>11,12</sup> Its safety has been established over several years. It is largely available, affordable, and stable at room temperature hence it will not depend on the erratic power supply and poor infrastructure for preservation. WHO recommends that tranexamic acid should be administered by intravenous route when used in the treatment of primary postpartum hemorrhage.

Tranexamic acid is rapidly absorbed. The onset of action is between 5 to 15 minutes. The duration of action is 3 hours. Approximately 3% is protein bound, primarily to plasminogen. Its half-life is approximately 2 hours and about 95% is excreted unchanged in urine.<sup>12</sup> Tranexamic acid is administered as 1000mg in 10ml given over 10 minutes as a loading dose. It is a heat-stable, safe, and well-tolerated drug. It is useful in the prevention of bleeding after trauma, management of primary menorrhagia, and treatment of IUCD-induced bleeding.<sup>13</sup>

The result of a large randomized controlled trial, the world maternal anti-fibrinogen trial published in 2017 showed that early use of intravenous tranexamic acid (1g) within 3 hours of the onset of postpartum hemorrhage in women in which uterotonic has failed to control their bleeding reduces death due to bleeding regardless of the cause and with no adverse maternal effect.<sup>14</sup> This study examined whether the prophylactic addition of tranexamic acid to routine active management of the third stage of labor following vaginal delivery was a useful tool for the reduction of postpartum blood loss, postpartum anemia, and other complications associated with postpartum anemia including transfusion of blood and its products.

## **Methods**

### **Study Area**

The study was conducted in the labor ward of the University of Calabar Teaching Hospital which also serves as a referral center for primary, secondary, and private health facilities in the state and environs. It is also a training and research center. The study was conducted over three months from 1<sup>st</sup> May to 31<sup>st</sup> July 2023

### **Study Population**

Participants for this study were from the population of pregnant women admitted in the active phase of labor in the labor ward for vaginal delivery who meet the inclusion criteria.

### **Inclusion criteria**

The participants for this study included pregnant women at term in the active phase of labor with a single fetus, longitudinal lie and cephalic presentation, had no contraindication to vaginal delivery and were willing to participate in the study, and had no contraindication to the use of tranexamic acid.

### **Exclusion criteria**

Induction of labor, augmentation of labor, fetal macrosomia, prolonged labor, grand multiparity, cesarean deliveries, polyhydramnios, previous history of primary postpartum hemorrhage, previous uterine surgery, pre-eclampsia/eclampsia, placenta abruption, retained placenta, use of high doses of low molecular weight heparin, bleeding genital tract lacerations/episiotomies, maternal age > 35 years, primigravidae.

## Study design

This was a randomized experimental study on the effects of prophylactic intravenous tranexamic acid plus oxytocin versus oxytocin plus placebo on peripartum change in hemoglobin concentration after vaginal delivery.

## Sample size determination

The minimum sample size for the study was determined using the sample size formula for a randomized control study with numerical outcome as stated below:

$$N = 2 (Z\alpha + Z\beta)^2 \sigma^2 (\mu_t - \mu_s)^2$$

Where N – Minimum sample size  $Z\alpha$ – Standard normal deviate correspondingly to  $\alpha$  level of 5% (i.e. 1.96)  $Z\beta$  – Standard normal deviate corresponding to the power of 80% (i.e. 0.84)  $\sigma$  - Standard deviation of postpartum Hb concentration i.e. 1.4 g/dl  $\mu_t - \mu_s$  - Minimum clinically important difference between pre and postpartum Hb concentration that the study would not want to miss (assumed to be 1.0 g/dl for this study).

Therefore,  $N = 2 (1.96 + 0.84)^2 \times 1.4 \times 1.4 / 1.0^2 = 30.73$

By assuming a non-response rate of 10% and attrition rate of 10% (i.e.  $r = 20\%$  or 0.2), the calculated sample size was adjusted as stated below:

$$N_a = N / 1 - r = 30.73 / 1 - 0.2 = 30.73 / 0.8 = 38.41 \approx 40 \text{ (to the nearest ten).}$$

Hence, 40 parturients were recruited into each of the two arms of the study.

## Randomization/Concealment

Each participant was randomized using a computer-generated random number using the software Research Randomizer. The random numbers generated were then followed sequentially across the rows to determine the group allocation of eligible participants. Each even number was taken for allocation into group A while the odd numbers were taken for allocation into group B. The sequence of allocation subsequently generated was then concealed in opaque envelopes labeled from number 1 to 80 and then used to determine which group each of the eligible participants belonged to as they presented in the labor ward.

Group A received 1000mg (10mls) of tranexamic acid intravenously in addition to 10IU of intramuscular oxytocin within one minute of delivery of the baby.

Group B received 10mls of sterile water intravenously in addition to 10IU of oxytocin within one minute of the delivery of the baby.

### **Concealment**

Tranexamic acid/Sterile water was drawn into each white 10cc syringe, capped, and labeled A or B. The concealment was done by a pharmacist in the hospital who emptied the tranexamic acid ampoules into syringes and then labeled it likewise sterile water without letting the researcher know the constituent.

The labeled syringes containing either tranexamic acid or sterile water were kept in the refrigerator in the labor ward where members of the research team already trained could assess it.

### **Ethical consideration**

Ethical clearance was obtained from the Health Research Ethics Committee of the Teaching Hospital, before commencing the study. The study was registered as a randomized controlled trial with the Pan African Clinical Trial Registry. The following ethical issues were considered in the course of this study. A signed or thumb-printed consent was obtained from each of the participants before recruitment into the study. Participants were educated on the aim, objectives, and procedure for the study and that they could opt out of the study at any point if they so wished without any adverse consequence to them. All information including the patient's identity and, the results obtained was kept confidential by the researcher.

### **Study procedure**

Consecutively, consenting parturients who were admitted to the labor ward in the active phase of labor for vaginal delivery who met the inclusion criteria were involved in the study. History and clinical examination were done to confirm the active phase of labor. A proforma was used to document the social demographic characteristics, vital signs, and other information about the patient. The consenting women had a tourniquet tied on the arm and the site for blood collection was cleaned with a methylated spirit swab, two milliliters of blood were drawn into an EDTA sample container for determination of admission hemoglobin concentration.

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If the hemoglobin concentration was greater than or equal to 10g/decilitre, the women were requested to randomly draw from a pack of envelopes containing a paper that was written 'A' or 'B', group A was the study arm, group B was the control arm of the study. The women in the study arm were given 1000mg (10mls) of intravenous tranexamic acid at the delivery of the baby, while the control group was given 10mls of sterile water.

The third stage of labor was managed actively in both arms using 10iu of intramuscular oxytocin within one minute of delivery of the baby. The deliveries were conducted by experienced Resident Doctors and or experienced midwives to minimize genital tract trauma and associated bleeding. Those patients who voluntarily withdrew, and needed a blood transfusion or cesarean section during labor were dropped out of the study and those with PPH were also removed.

The hemoglobin concentration was analyzed with the 'mission RHb Hemoglobin testing system' a digital hemoglobin meter manufactured by ACON Laboratories Incorporation 10125 Mesa Rim Road, San Diego CA92121, USA Mission RHb Haemoglobin test trip was also used.

The results from the haemoglobinometer were evaluated periodically by repeating tests at the main laboratory and comparing the results with those obtained from the hemoglobin meter.

**Follow up**

The hemoglobin concentration of all participants was repeated 48 hours after delivery. All the participants were monitored until discharge from the Hospital after which they exited the study.

**Quality control**

To ensure quality control, all the tranexamic acids that were used were procured from the same company (Protech Biosystems Pvt. Ltd.) with the same brand name (prexam injection) and batch number, stored under the same temperature, administered to only those that met the inclusion criteria by those trained for the study. The oxytocin that was used was procured from the same company (Shanxi Shuguang Pharm. Co., Ltd.) with the same brand name (pitons oxytocin injection) and batch number, stored under the same temperature, administered to only those that met the inclusion criteria by those trained for the study.

## **Outcome measures**

The outcome measures were as follows: (1) Estimation of Admission hemoglobin concentration; (2) Estimation of Postpartum hemoglobin concentration; (3) Postpartum drop in hemoglobin concentration after 48 hours of delivery. This was calculated from the difference between the admission hemoglobin concentration and hemoglobin concentration at 48 hours after delivery; and (4) Maternal adverse effects of tranexamic acid.

## **Statistical analysis**

Data that was collected was tabulated and analyzed using the IBM statistical package for social sciences, software version 23 (Chicago II, USA). The outcome measures were compared between the two groups. The mean values of continuous variables were tested for statistical significance using a t-test. Discrete values were analyzed for statistical significance using chi-square. The level of statistical significance was kept at  $p\text{-value} < 0.05$ .

## **Results**

Over the study duration, 116 parturients were assessed for eligibility, 36 parturients were excluded while 80 were randomized in the study to receive either tranexamic acid (intervention group) or sterile water (placebo group). A total of 80 parturients who had a normal vaginal delivery and were randomized to receive oxytocin plus tranexamic acid (intervention group of 40) and oxytocin plus placebo (control group of 40) were recruited into this study. The mean ages of the parturients in the intervention and control groups were found to be  $28.88 \pm 3.67$  and  $29.07 \pm 3.29$  respectively. Pregnant women in the intervention and the control groups were found to be similar in terms of the distribution of their age group and parity (Table 1a). Also, the expected gestational ages and babies' birth weights were not significantly different in the two groups (Table 1b).

The proportion of parturients that reported side effects to the drugs is 2.5% and 2.5% in the intervention and control groups respectively. (Figure 2)

## **Comparison of admission hemoglobin concentration**

To assess and compare the mean admission hemoglobin concentration in the intervention and control groups, an independent t-test was carried out. As shown in Table 2 below, there was no significant difference ( $p = 0.809$ ) in the admission Hb concentration between the two groups.



### **Comparison of post-delivery hemoglobin concentration**

To assess and compare the mean post-delivery hemoglobin concentrations in the intervention and control groups, an independent t-test was carried out. There was a significant difference ( $p < 0.001$ ) in the post-delivery Hb concentration between the two groups. The mean post-delivery Hb concentration was found to be significantly higher in the intervention group compared to the control group. (Table 3)

### **Comparison of admission and post-delivery hemoglobin concentration**

A paired t-test was conducted to compare the mean admission and post-delivery hemoglobin concentrations in both the intervention and control arms of the study.

As shown in Tables 4a and 4b, there were significant differences when comparing admission Hb concentrations to post-delivery Hb concentrations in both the intervention group and control arm of the study (i.e.,  $p < 0.001$  in both instances) such that there was a reduction in the mean Hb concentrations post-delivery compared to the time of admission. However, the mean reduction in Hb concentration was higher in the control arm of the study (1.53 mg/dl) compared to the mean Hb reduction in the intervention arm of the study (0.67mg/dl).

### **Discussion**

Postpartum hemorrhage is a life-threatening event. Interventions to prevent postpartum hemorrhage have always been the basic standard of care we provide to our women during delivery. The purpose of this study was to evaluate the effect of prophylactic tranexamic acid administration on peripartum hemoglobin concentration after vaginal delivery.

The result of the present study has demonstrated that the prophylactic addition of 1000mg of intravenous tranexamic acid to routine active management of the third stage of labor after vaginal delivery was associated with a statistically significant reduction in postpartum hemoglobin drop in the intervention (tranexamic acid) group compared to the control (placebo) group.

This finding is consistent with other studies.<sup>17,18,19</sup> The significant reduction in postpartum hemoglobin drop in the intervention group demonstrated in this study may be explained by the effect of tranexamic acid on the reduction in postpartum blood loss due to its action in inhibition of lysis

of fibrinogen formed on the placenta bed and on the minor lacerations that might have occurred in the genital tract during vaginal delivery.

The significant reduction in postpartum hemoglobin drop is particularly important for women in developing countries like ours where anemia caused by either nutritional or environmental factors is prevalent among pregnant women.<sup>20</sup>

A relatively small reduction in postpartum hemoglobin drop may be clinically relevant especially as the mean predelivery hemoglobin of women in this study was 10.96% which further bolsters the need for reduction in postpartum blood loss.

The present study also attests to the safety of tranexamic acid when used prophylactically in the reduction of postpartum blood loss as 97.5% of the study subjects had no side effects of the drug. 2.5% of the study subjects had nausea and vomiting which was not significantly higher in the intervention group compared to the control.

This finding is in keeping with previous studies.<sup>17,18,19,21,22,23</sup> Other side effects recorded in the study done by Duchoy-bettors et al<sup>24</sup> may be due to higher doses (4g) of tranexamic acid used as against 1g of tranexamic acid used in this study.

## **Conclusion**

The mean calculated postpartum hemoglobin concentration in the intervention (tranexamic acid) group was significantly higher than in the control (placebo) group which shows that prophylactic administration of tranexamic acid during vaginal delivery is effective in reducing postpartum hemoglobin drop. It also has a good safety profile when used for this purpose

## **Authors' Contribution**

EEO and MIE conceptualized and designed the study. EEO, MIE and SEA conducted the research, developed the methodology and collected the data. All the authors were involved in drafting the manuscript. EEO and UBA reviewed and edited the manuscript. All authors approved the final version of the manuscript

## Conflict of Interest

The authors declare no conflict of interest.

## Funding

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394 loss in postpartum hemorrhage. Crit Care 2011; 15: R1 17

Accepted Article

395 **Table 1a:** Sociodemographic characteristics of parturients randomized to receive tranexamic acid plus oxytocin and oxytocin plus  
 396 placebo.

Variables	Intervention (n = 40)		Control (n = 40)		X <sup>2</sup>	p-value
	Frequency	%	Frequency	%		
<b>Age group</b>						
21 – 25	8	20.0	6	15.0	0.44	
26 – 30	12	30.0	14	35.0		
31 – 35	20	50.0	20	50.0		
<b>Parity</b>						
1	2	5.0	2	5.0	1	
2	25	62.5	24	60.0	2	
3	7	17.5	9	22.5	3	
4	6	15.0	5	12.5	4	

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 398 **Table 1b:** Clinical characteristics of parturients randomized to receive tranexamic acid plus oxytocin and oxytocin plus placebo.

Variables	Group	N	Mean	Std. Deviation	T	p-value
AGE	Intervention	40	28.88	3.67	-0.26	0.798
	Control	40	29.08	3.29		

EGA	Intervention	40	38.85	0.74	-0.38	0.708
	Control	40	38.93	1.02		
Baby's Birth Weight	Intervention	40	3.50	0.60	-0.39	0.699
	Control	40	3.55	0.55		

**Table 2:** Comparison of admission hemoglobin among **parturients** randomized to receive tranexamic acid plus oxytocin and oxytocin plus placebo.

Variables	Group	N	Mean	Std. Deviation	T	p-value
Admission Hb	Intervention	40	10.95	0.44	-0.24	0.809
	Control	40	10.97	0.49		

**Table 3:** Comparison of post-delivery hemoglobin concentration among **parturients** randomized to receive tranexamic acid plus oxytocin and oxytocin plus placebo.

Variables	Group	N	Mean	Std. Deviation	T	p-value
Post-delivery Hb	Intervention	40	10.28	0.59	6.21	<0.001*
	Control	40	9.44	0.62		

403 \*Significant p-value

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**Table 4a:** Comparison of admission and post-delivery hemoglobin concentrations among **parturients** randomized to receive tranexamic acid plus oxytocin.

Hb Concentration	N	Mean	SD	Mean Hb Difference	T	p-value
Admission Hb	40	10.95	0.45	0.67	10.37	< 0.001*
Post-del. Hb	40	10.28	0.59			

405 \*Significant p-value

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**Table 4b:** Comparison of admission and post-delivery hemoglobin concentrations among **parturients** randomized to receive oxytocin plus placebo.

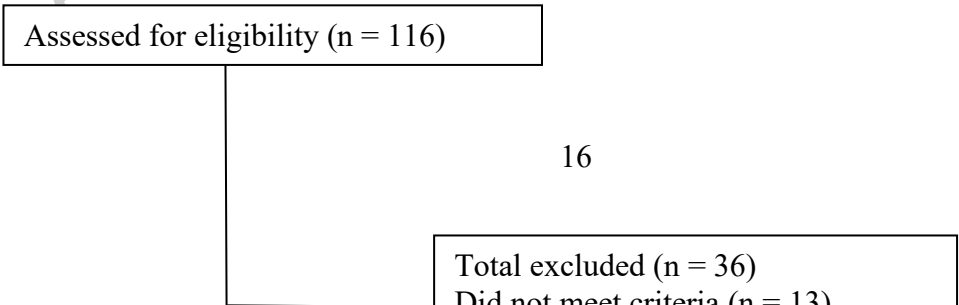
Hb Concentration	N	Mean	SD	MeanHb Difference	T	p-value
Admission Hb	40	10.98	0.49	1.53	18.78	< 0.001*
Post-del. Hb	40	9.44	0.62			

407 \*Significant p-value

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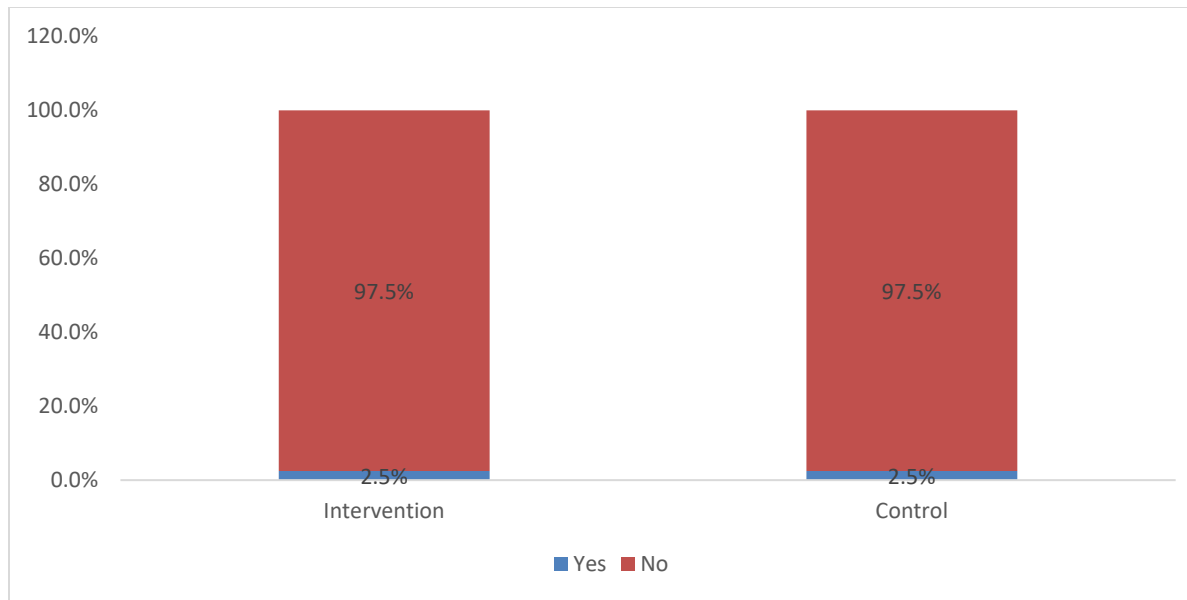
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**Figure 1:** Shows the flow of parturients through the study. Eighty parturients allocated into the groups were analyzed.



**Figure 2:** A bar chart showing the proportion of **parturients** that reported side effects to the drugs among parturients randomized to receive oxytocin plus tranexamic acid and oxytocin plus placebo.