RESULTS

One hundred and forty-eight (148) women were recruited into the study from July 2020 to March 2021, seventy-four were allocated to tranexamic acid group and seventy-four were allocated to the Placebo group based on randomization. However, in the tranexamic acid group two participants were excluded because one had macrosomic baby at birth and the other went into labour while in the placebo group three participants were excluded because one had macrosomic baby at birth and two went into labour. Therefore, data for seventy-two participants in the tranexamic acid group and seventy-one participants in the placebo group were analyzed as shown in figure 1.

The mean ages were 33.56±4.25 and 34.35±3.84 for the tranexamic acid and placebo group respectively and the BMI (kg/m^2) were 33.63±4.27 and 31.93±4.85 for the tranexamic acid and placebo group respectively. The difference in the mean BMI was significant (t=2.185; p-value=0.031) as shown in table 1. The mean gestational age (wks.) and gravidity for the tranexamic acid group were 38.15±0.93 and 4.06±1.91 respectively while the mean gestational age (wks.) and gravidity for the placebo group were 38.34±0.91 and 3.76±1.84 respectively as shown in table 1. The median (range) parity in the tranexemic acid and the placebo groups were 2 (1-4) and 1 (1-4) respectively. The mean parity for the tranexamic acid group and placebo group were 2.01±0.94 and 1.74±0.98 respectively. The mean fetal heart rate (FHR, bpm) for the tranexamic acid group and placebo group were 142.39±7.02 and 141.27±6.83 respectively as shown in table 1.

In figure 2, the main indications for surgery in the tranexamic acid group were previous C/S and myomectomies which accounted for 75.0%, malpresentation accounted for 16.7% and maternal

request accounted for 5.5% while 69.0% had previous C/S and myomectomies, 16.9% had malpresentation, and maternal request accounted for 8.4% in the placebo group.

The mean pre-C/S systolic BP (mmHg) and diastolic BP (mmHg) were 124.76±9.64 and 79.44±6.87 respectively in the tranexamic acid group while the mean pre-C/S systolic BP (mmHg) and diastolic BP (mmHg) in the placebo group were 119.83±22.53 and 76.90±7.94 respectively. The difference in the mean pre-C/S diastolic BP was statistically significant (t=2.048; p=value- 0.042) as shown in table 2. The post-C/S mean systolic and diastolic BP were 119.44±8.20 and 72.86±7.72 respectively in the tranexamic acid group while in the placebo group it was 122.17±8.62 and 75.77±7.19 respectively. The difference in mean post C/S diastolic BP (mmHg) values was also significant (t= 2.335; p-value= 0.021) between the two groups as shown in table 2. Post-C/S, the mean pulse rate was significantly higher in the placebo group (88.89±8.03 bpm) in comparison to the tranexemic acid group (85.35±6.59 bpm), t= 2.885; p-value= 0.005.

The mean blood loss during C/S (mls.) in the tranexamic acid group and placebo group were 503.67±170.20 and 704.55±187.39 respectively. This difference in mean value was significant (t=6.712; p-value= 0.0001) as shown in table 3. After C/S to 2 hours post-surgery (mls), the mean blood loss in the tranexamic acid group and placebo group were 121.42±49.39 and 159.69±69.54 respectively. The difference in mean blood loss after C/S to 2 hours post-surgery was also significant (t=3.798; p-value= 0.001) as shown in table 3. The total mean blood loss from C/S to 2 hours post-surgery (mls) in the tranexamic acid group and placebo group were 624.88±200.76 and 864.24±229.09 respectively. The difference in the total mean blood loss from C/S to 2 hours post-surgery was significant (t= 6.648; p-value= 0.001) as shown in table 3. The pre-C/S mean PCV and post–C/S mean PCV were 32.92±2.34 and 30.68±2.80 respectively

among the group that received tranexamic acid and 33.18±2.90 and 28.07±3.27 respectively among the group that had placebo. The difference in pre-C/S PCV was not significant (t=0.605; p-value= 0.546) while the difference in post-C/S PCV was significant (t=5.131; p-value=0.0001) between the two groups as shown in figure 3.

There was need for additional uterotonic medications in 12 participants, (16.7%), need for blood transfusion in 2 (2.8%) participants among the tranexamic acid group while in the placebo group, 36 (50.7%) participants received additional uterotonic medications and 13 (18.3%) had blood transfusion. The differences in proportions regarding the need for additional uterotonic medications (Chi Square=18.573; p-value= 0.0001) and blood transfusion (Chi Square=9.185; p-value= 0.002) were significant. There was no surgical intervention needed in both groups. These are shown in table 4.

The maternal side effects in the study participants were only nausea and vomiting which occurred in 9 (12.5%) and 1 (1.4%) participants respectively in the tranexamic acid group. There were no side effects among participants in the placebo group. The differences in proportions for the occurrence of nausea in the two groups were statistically significant (p-value=0.006). These are shown in table 5.

The neonatal outcome in the study showed a mean birth weight of 3.27±0.40, APGAR score at 1min was 7.90±0.30 and APGAR score at 5min was 8.99±0.39 in the tranexamic acid group while in the placebo group, the mean birth weight was 3.36±0.38, APGAR scores at 1min was 8.11±0.31, APGAR scores at 5min was 9.01±0.32 as shown in table 6. There was no significant difference between the two groups. In the tranexamic acid group, 1 (1.4%) baby had low birth weight and there was no SCBU admission while in the placebo group, 3 (4.2%) babies had low

birth weight and there was 1 (1.4%) SCBU admission. The differences in proportions were not significant (p-value>0.05) as shown in table 7.

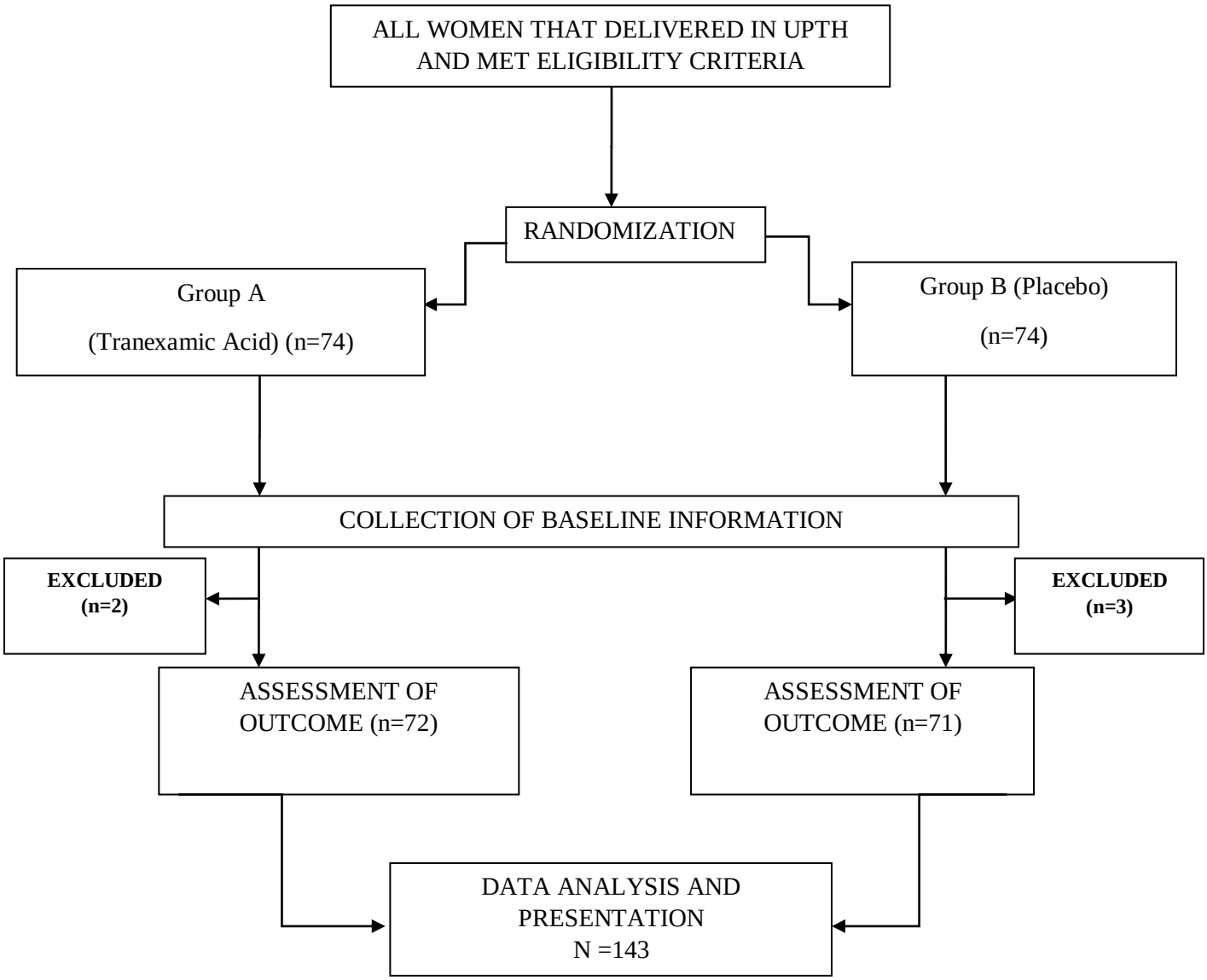

Figure 1: Flow chart of the study protocol showing the number of participants

Table 1: Demographic characteristics of participants

Comparison of mean demographic and obstetric characteristics between the two groups in the study.

	Study group					
	Tranexamic Acid	Placebo			CI	
Variable	**Mean ± SD**	**Mean ± SD**	**t**	**p-value**	**Lower**	**Upper**
Age (years)	33.56±4.25	34.35±3.84	1.146	0.254	-2.161	0.575
BMI (kg/m^2)	33.63±4.27	31.93±4.85	2.185	0.031*	0.161	3.234
Gestational age (wks)	38.15±0.93	38.34±0.91	1.205	0.230	-0.489	0.119
Gravidity	4.06±1.91	3.76±1.84	0.931	0.354	-0.335	0.931
Parity	2.01±0.94	1.74±0.98	1.658	0.100	-0.052	0.595
FHR (bpm)	142.39±7.02	141.27±6.83	0.968	0.335	-1.169	3.412

SD – Standard deviation *Statistically significant FHR-Fetal Heart rate

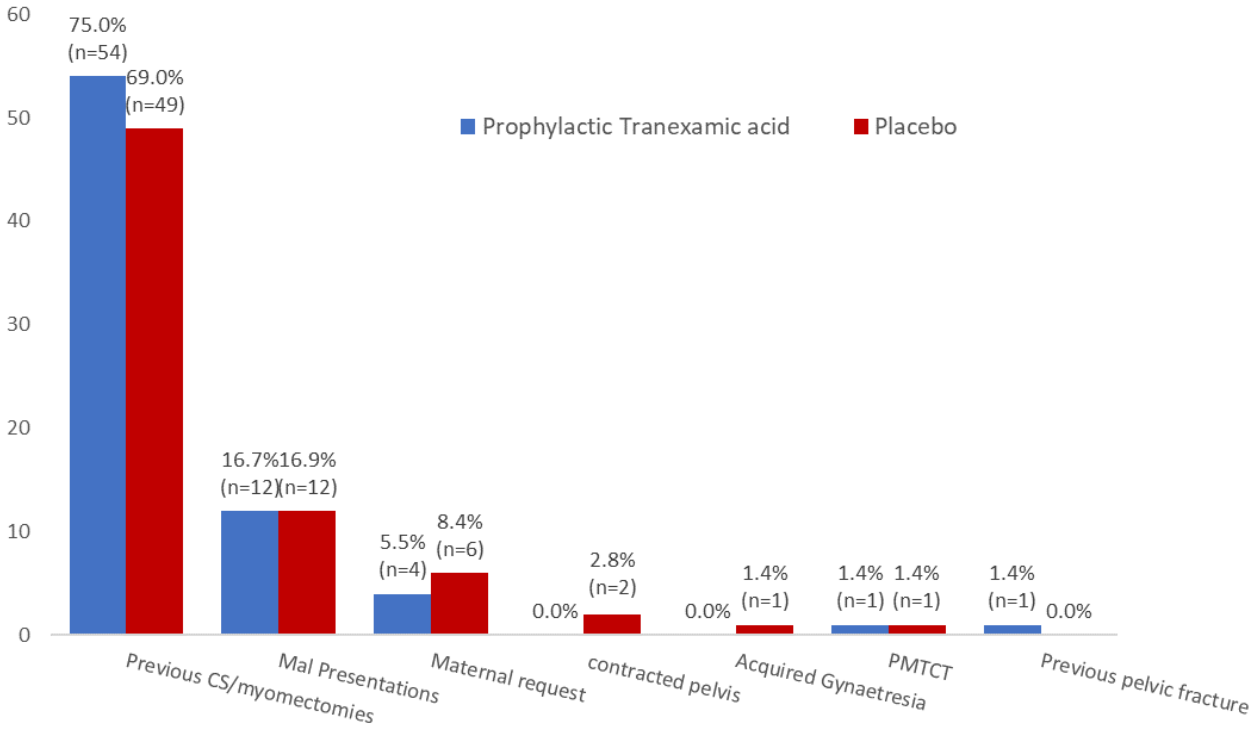

Figure 2: Indications for C/S

Table 2: Baseline and post-C/S clinical characteristics

Comparison of mean clinical characteristics between the two groups in the study.

	Study group					
	Tranexamic Acid	Placebo			CI	
Variables	**Mean ± SD**	**Mean ± SD**	**t**	**p-value**	**Lower**	**Upper**
Baseline clinical characteristics						
Systolic BP (mmHg)	124.76±9.64	119.83±22.53	1.695	0.092	-0.821	10.680
Diastolic BP (mmHg)	79.44±6.87	76.90±7.94	2.048	0.042*	0.089	4.997
Pulse rate (bpm)	83.65±5.06	83.35±5.61	0.337	0.737	-1.465	2.066
Respiratory rate (cpm)	19.82±1.36	19.72±1.39	0.441	0.660	-0.352	0.554
Post C/S clinical characteristics						
Systolic BP (mmHg)	119.44±8.20	122.17±8.62	1.937	0.055	-5.505	0.055
Diastolic BP (mmHg)	72.86±7.72	75.77±7.19	2.335	0.021*	-5.381	-0.446
Pulse rate (bpm)	85.35±6.59	88.89±8.03	2.885	0.005*	-5.966	-1.114
Respiratory rate (cpm)	20.36±1.57	20.38±1.59	0.073	0.942	-0.541	0.503

SD – Standard deviation *Statistically significant

Table 3: Comparison of the primary outcome

Comparison of mean blood loss between the two groups in the study

	Study group					
	Tranexamic Acid	Placebo			CI	
Period in study	Mean blood loss ± SD	Mean blood loss ± SD	t	p-value	Lower	Upper
During CS (mls)	503.67±170.20	704.55±187.39	6.712	0.0001*	-260.05	-141.72
After CS to 2hours post-surgery (mls)	121.42±49.39	159.69±69.54	3.798	0.001*	-260.09	-141.67
Total blood loss from CS to 2hours post-surgery (mls)	624.88±200.76	864.24±229.09	6.648	0.001*	-310.55	-168.18

SD – Standard deviation *Statistically significant

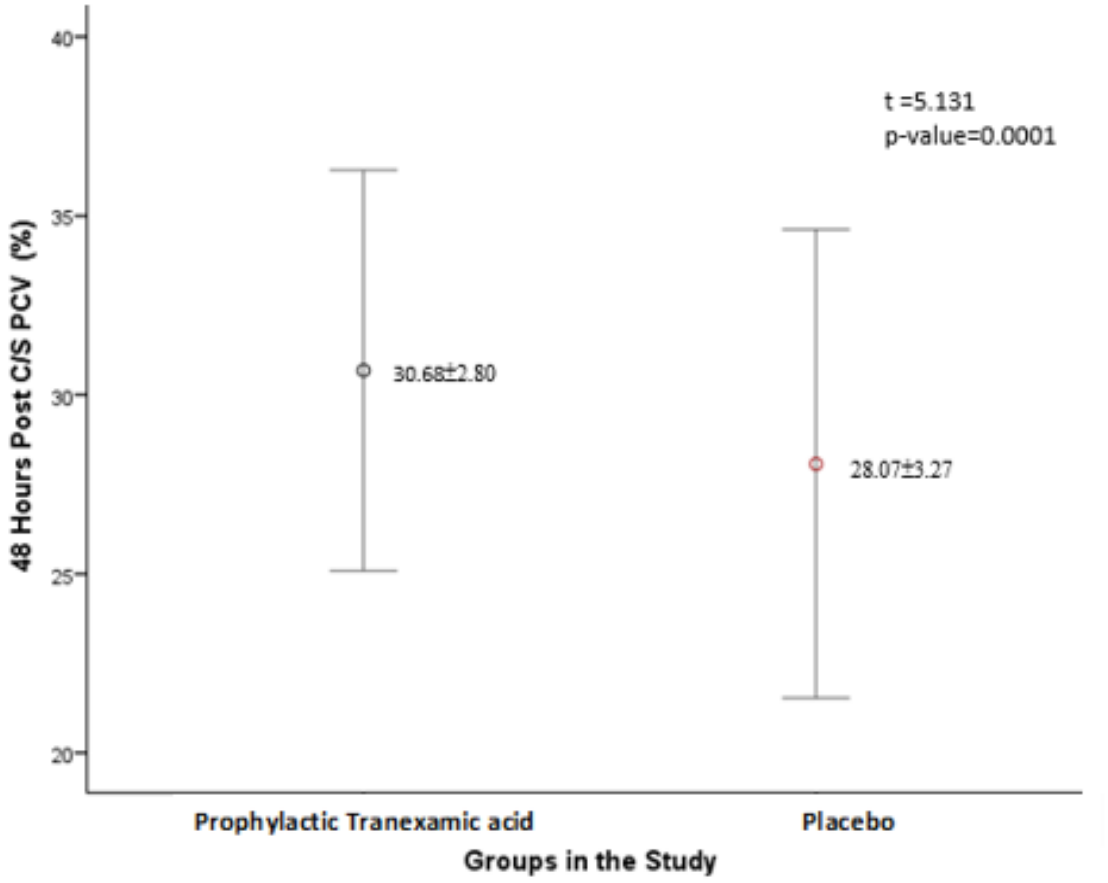

Figure 3: Error bar chart showing the mean and SD 48hours post-C/S packed cell volume in the two groups.

Table 4: Comparison of secondary outcomes

Comparison of secondary outcome variables between the two groups in the study

Variables	Tranexamic Acid N = 72 n (%)	Placebo N = 71 n (%)	Total N = 143 n (%)	Chi Square	p-value
Additional uterotonic medications					
Yes	12 (16.7)	36 (50.7)	48 (33.6)	18.573	0.0001*
No	60 (83.3)	35 (49.3)	95 (66.4)		
Blood transfusion					
Yes	2 (2.8)	13 (18.3)	15 (10.5)	9.185	0.002*
No	70 (97.2)	58 (81.7)	128 (89.5)		
Surgical intervention					
Yes	0 (0.0)	0 (0.0)	0 (0.0)	0.000	1.000
No	72 (100.0)	71 (100)	143 (100.0)		

**Statistically significant*

Table 5: Maternal side-effects

Comparison of maternal side-effects between the two groups in the study

Variables***	Tranexamic Acid N = 72 n (%)	Placebo N = 71 n (%)	Total N = 143 n (%)	Chi Square	p-value
Nausea					
Yes	9 (12.5)	0 (0.0)	9 (6.3)	7.470**	0.006*
No	63 (87.5)	71 (100.0)	134 (93.7)		
Vomiting					
Yes	1 (1.4)	0 (0.0)	1 (0.7)	0.000**	1.000
No	71 (98.6)	71 (100.0)	142 (99.3)		

**Statistically significant **Yates' correction*

****None had dizziness, diarrhea, hypotension, allergic skin reaction or thromboembolism*

Table 6: Neonatal outcomes

Comparison of mean neonatal outcomes in the two groups in the study.

	Study group					
	Tranexamic Acid	Placebo			CI	
Neonatal outcome	Mean ± SD	Mean ± SD	t	p-value	Lower	Upper
Birth weight (kg)	3.27±0.40	3.36±0.38	1.399	0.164	-0.221	0.037
APGAR score at 1min	7.90±0.30	8.11±0.31	0.460	0.640	-0.187	0.209
APGAR score at 5min	8.99±0.39	9.01±0.32	0.468	0.640	-0.146	0.090

SD – Standard deviation

Table 7: Comparison of neonatal outcomes

Comparison of neonatal outcomes of low birth weight and SCBU admission between the two groups in the study

Variables	Tranexamic Acid N = 72 n (%)	Placebo N = 71 n (%)	Total N = 143 n (%)	Chi Square	p-value
Low birth weight					
Yes	1 (1.4)	3 (4.2)	4 (2.8)	**	0.366
No	71 (98.6)	68 (95.8)	139 (97.2)		
SCBU admission					
Yes	0 (0.0)	1 (1.4)	1 (0.7)	0.000***	0.994
No	72 (100.0)	70 (98.6)	142 (99.3)		

SCBU – Special Care Baby Unit *******Fisher's Exact* ********Yates' Correction*