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Methodology: The present study was performed at the Department of Obstetrics and Gynecology of the AL Haramine Hospital, Sylhet, from June 1, 2017, to November 30, 2017. Subjects were eligible for the trial if the fetus was more than 38 weeks estimated gestational age and they required elective CS. Elective CS was defined as CS performed before the onset of labor.

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Results: Mean hematocrit after surgery was 34.8 ± 2.9 percent in tranexamic acid group and 32.3 ± 3.3 percent in placebo group ($p > 0.05$). Which were statistically significant between two groups (Table III). Compare the incidence of post-partum hemorrhage (PPH) between both study and control groups, it was found that the incidence of post-partum hemorrhage (≥ 500 mL) was more in the control group than in the study group (p -value = 0.032).

Conclusion: Mean hematocrit after surgery was not statistically significant in tranexamic acid group than placebo group. Compare the incidence of post-partum hemorrhage (PPH) between both study and control groups, it was found that the incidence of post-partum hemorrhage was more in the control group than in the study group.

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I. INTRODUCTION

Tranexamic acid (TXA) is an anti-fibrinolytic agent. Its use in primary TKR is supported by many studies that confirmed its efficacy for decreasing blood loss.¹ Cesarean section rates are increasing all over the world. Per partum hemorrhage is one of the most common, life-threatening complications of this procedure.²

The WHO estimates that PPH accounts for nearly 30% of maternal deaths worldwide with an estimated 20 million cases annually.³ In order to reduce maternal morbidity and mortality caused by bleeding, it is important to reduce the amount of bleeding during and after lower segment cesarean section. A popular approach is to minimize peri operative bleeding through the prophylactic use of antifibrinolytic agents such as aprotinin, tranexamic acid and amino caproic acid.³ Reducing bleeding during and after caesarian directly improve the outcomes of cesarean delivery, especially maternal mortality and morbidity. Tranexamic acid is a fibrinolysis inhibitor that has been used for many years to reduce bleeding in various surgical procedures.

II. METHODOLOGY

The present study was performed at the Department of Obstetrics and Gynecology of the AL Haramine Hospital, Sylhet, from June 1, 2017, to November 30, 2017. Subjects were eligible for the trial if the fetus was more than 38 weeks estimated gestational age and they required elective CS. Elective CS was defined as CS performed before the onset of labor. Women were excluded if they had risk factors associated with an increased risk of postpartum hemorrhage (PPH) such as anemia (hemoglobin <7 g%), multiple gestation, antepartum hemorrhage (placenta previa or placental abruption), abnormal placentation (accreta, increta, or percreta), uterine fibroids, polyhydramnios, emergency CS, a history of uterine atony and postpartum bleeding, and a current or previous history of significant disease, including heart disease, liver, renal disorders, or a known coagulopathy. Following informed consent, simple randomization using a random number table was performed by the investigational pharmacy staff, who took no further part in the study. Infusion bags were prepared and labeled as bag A (TA group) containing 1 g/10 mL TA

(Transamin, Fako İlaçları A.Ş., İstanbul, Turkey) diluted with 20 mL of 5% glucose, and bag B (placebo group) containing 30 mL of 5% glucose. Providers and patients were blinded to the contents of the bags until the conclusion of the study.

TA or placebo was slowly administered intravenously over a 5-minute period at least 10 minute prior to skin incision. After delivery, both groups received a 5 IU intravenous bolus of preprepared oxytocin, and then 30 IU oxytocin in 500 mL lactated Ringer's solution was infused at a rate of 125 mL/h. An antibiotic, 1 g cefazolin diluted in 20 mL normal saline, was administered over a 5-minute period. Vital signs (heart rate, blood pressure, and respiratory rate) were checked and noted before the operation, immediately after placental delivery, and 1 and 2 hours after birth. Prothrombin time (PT), active prothrombin time (aPTT), and complete blood count (CBC) were performed before delivery and on the second day after delivery. Estimated blood loss was calculated using the difference in hematocrit values taken prior to and 48 hour after cesarean delivery, according to the following formula:

Estimated blood loss

$$= \text{EBV} \times \frac{\text{Preop hematocrit} - \text{Postop hematocrit}}{\text{Preop hematocrit}}$$

where EBV (estimated blood volume) in mL¼ the woman's weight in kg_85.14 Blood loss >1000 mL during the procedure was defined as excessive bleeding. After discharge, women who received TA were instructed about the signs and symptoms of a thromboembolic event, given written instruction sheets with a diary for symptom documentation, and instructed

to contact one of the coauthors (O.A. or O.C.) immediately if any listed symptom occurred. Women who complained of symptoms were examined by one of the coauthors. All participants and babies were examined for thromboembolic events 3 and 6 weeks after surgery. The primary outcome was the estimated blood loss during CS. Other outcomes were excessive bleeding (defined as an estimated blood loss >1000 mL), the need for blood transfusion, the use of additional uterotonic agents indicating atony (such as an oxytocin infusion or prostaglandin F2a), TA side effects (such as nausea, vomiting, or diarrhea), duration of the mother's postnatal hospital stay, and neonatal outcome.

III. RESULTS

The subject characteristics in the two groups were similar with no statistically significant difference between age, height, weight, gestational age, gravida and duration of surgery (Table I). The heart rate, respiratory rate, systolic BP and diastolic BP in both the Tranexamic acid and Placebo groups, Immediate after placental delivery, 1 hour after placental delivery and 2 hours after placental delivery, it was found that there was no significant statistical difference (Table-II). Mean hemoglobin after surgery was 8.7 ± 0.7 g/dl and 8.1 ± 0.8 g/dl in tranexamic acid and placebo group respectively ($p > 0.05$). Mean hematocrit after surgery was 34.8 ± 2.9 percent in tranexamic acid group and 32.3 ± 3.3 percent in placebo group ($p > 0.05$). Which were statistically significant between two groups (Table III). Compare the incidence of post-partum hemorrhage (PPH) between both study and control groups, it was found that the incidence of post-partum hemorrhage (≥ 500 mL) was more in the control group than in the study group (p -value = 0.032) (Table -IV).

Table I: Demographic characteristics of participants.

	Tranexamic acid (n=50)	Placebo (n=50)	p value
	Mean±SD	Mean±SD	
Age (years)	24.1±3.8	24.7±4.0	0.444 ^{ns}
Height (cm)	154.2±4.1	155.6±4.3	0.099 ^{ns}
Weight (kg)	66.6±6.9	64.7±8.8	0.233 ^{ns}
Gestational age (weeks)	38.3±1.0	38.4±0.7	0.564 ^{ns}
Gravidity	2.1±0.7	2.0±0.9	0.537 ^{ns}
Duration of surgery (min)	44.8±2.6	44.7±2.7	0.851 ^{ns}

ns= not significant

Table II: Vital signs after placental delivery

	Tranexamic acid (n=50)	Placebo (n=50)	p value
	Mean±SD	Mean±SD	
Immediate after placental delivery			
HR (beat/min)	90.4±9.0	92.9±8.7	0.161 ^{ns}
RR (breaths/min)	19.1±4.9	20.5±3.2	0.093 ^{ns}
SBP (mmHg)	120.6±10.8	124.1±11.8	0.125 ^{ns}
DBP (mmHg)	76.0±10.1	79.3±9.8	0.100 ^{ns}
One hour after placental delivery			
HR (beat/min)	92.0±9.1	88.7±8.9	0.070 ^{ns}
RR (breaths/min)	20.2±6.1	21.9±5.2	0.137 ^{ns}
SBP (mmHg)	127.2±9.2	124.4±11.1	0.173 ^{ns}
DBP (mmHg)	78.5±8.7	80.3±10.6	0.356 ^{ns}
Two hours after placental delivery			
HR (beat/min)	91.4±10.2	89.3±8.4	0.264 ^{ns}
RR (breaths/min)	19.8±5.6	20.1±3.3	0.745 ^{ns}
SBP (mmHg)	124.6±11.5	124.1±12.0	0.832 ^{ns}
DBP (mmHg)	79.2±8.1	79.4±8.1	0.902 ^{ns}

ns= not significant

Table III: Comparison of haemoglobin and hematocrit before and 24 h after the surgery in the tranexamic and placebo groups

	Tranexamic acid (n=50)	Placebo (n=50)	P value
	Mean±SD	Mean±SD	
Hemoglobin (g/dl)			
Before CS	9.8±0.8	9.7±1.0	0.582 ^{ns}
After CS	8.7±0.7	8.1±0.8	0.001 ^s
Hematocrit (%)			
Before CS	35.0±2.6	34.1±1.9	0.051 ^{ns}
After CS	34.8±2.9	32.3±3.3	0.001 ^s

s= significant, ns= not significant

Table IV: Comparison of amount of blood loss (PPH) in the tranexamic and placebo groups.

Blood loss from placental delivery to 2 hours postpartum (ml)	Tranexamic acid (n=50)		Placebo (n=50)		p value
	n	%	n	%	
<500mL	43	86.0	34	68.0	0.032 ^s
≥500mL	7	14.0	16	32.0	

IV. DISCUSSION

In this present study it was observed that two groups were similar with no statistically significant difference between age, height, weight, gestational age, gravida and duration of surgery.

In this current study it was observed that heart rate, respiratory rate, systolic BP and diastolic BP in both the Tranexamic acid and Placebo groups, Immediate after placental delivery, 1 hour after placental delivery and 2 hours after placental delivery, it was found that there was no significant statistical difference. Similar study carried out by Ming-ying Gai et al⁴ in China showed that tranexamic acid significantly reduces bleeding from the time of placental delivery to 2 hours

post partum. The study showed significant decrease in the incidence of > 500 ml blood loss in the study group as compared to control group (P=0.029). Zheng et al⁵, showed similar results after vaginal delivery.

In this study it was observed that mean hemoglobin after surgery was 8.7±0.7 g/dl and 8.1±0.8 g/dl in tranexamic acid and placebo group respectively (p>0.05). Mean hematocrit after surgery was 34.8±2.9 percent in tranexamic acid group and 32.3±3.3 percent in placebo group (p>0.05). Which were statistically significant between two groups. Sekhvat et al.⁶ in their prospective study on 90 primi gravidae undergoing CS, found a decrease of blood loss from the end of lower segment CS to 2 h postpartum of only 9 ml (28 versus 37.12 ml in TA and control groups, respectively).

However, they found that this reduction was statistically significant.⁶ This finding has not been described in other studies.^{7,8}

In this series it was observed that compare the incidence of post-partum hemorrhage (PPH) between both study and control groups, it was found that the incidence of post-partum hemorrhage (≥ 500 mL) was more in the control group than in the study group (p-value = 0.032). An estimated blood loss in excess of 500 ml following a vaginal birth or a loss of greater than 1000 ml following caesarean birth has been used for the diagnosis of postpartum hemorrhage.⁹ Assessment of blood loss during caesarean delivery is typically underestimated.¹⁰ The most commonly used methods for such assessment are the visual estimation method, the mathematical calculation measuring the hematocrit (Hct) prior to and 1 h postoperatively and the swab weighing method. The visual estimation method is notoriously inaccurate¹¹; Villeneuve et al. found that obstetricians assessed blood loss inaccurately during CS; an underestimation up to 579 ml¹². Brecher et al. found that blood loss calculated using Hct as a variable gave an average 2.1 times overestimation of intraoperative blood loss compared to visual estimation.¹⁰ The drawbacks of using Hct for calculation of blood loss include the use of body weight in the mathematical calculation which is misleading during pregnancy and the possible bias resulting from hemodilution from the intraoperative fluids given during the operation.¹³ Similar study carried out in India by Mayur et al.¹⁴ showed comparable results reducing the blood loss in the study group. Another study carried out by Ming-Ying et al., in China showed that TXA significantly reduces bleeding from the time of placental delivery to the end of caesarean section, which was 351 mL in the study group while 440 mL in the control group.¹⁵ Zheng et al. showed similar results after vaginal delivery; there was significantly less blood loss in the TXA group (243 mL) when compared to those who receive no treatment (309 mL).¹⁶

V. CONCLUSION

Mean hematocrit after surgery was not statistically significant in tranexamic acid group than placebo group. Compare the incidence of post-partum hemorrhage (PPH) between both study and control groups, it was found that the incidence of post-partum hemorrhage was more in the control group than in the study group.

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