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# SAFETY AND EFFICACY OF PROPHYLACTIC TRANEXANIC ACID IN REDUCING BLOOD LOSS DURING AND AFTER CAESAREAN DELIVERY: A COMPARATIVE STUDY

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#### Abstract

Background: Caesarean delivery is one of the commonest performed obstetrical surgeries. With modern techniques of caesarean section along with intra operative uterotonics the intra operative blood loss is reduced significantly, still it can be reduced further. Tranexamic acid is one of the drugs which is effective in reducing the intra operative blood loss during gastro-intestinal, spinal, cardiac, dental and genitor-urinary procedures. The aim of the study is to find out the safety and efficacy of prophylactic Tranexamic acid in reducing the blood loss during and after caesarean delivery. Materials and Methods: This study is a prospective, randomized, double blinded, placebo controlled interventional study. It was conducted on 910 patients who were divided in study and control group based on computer generated random numbers. The patients in the study group were given 1 gm of Inj Tranexamic acid at the time of surgery and both mother and baby were intensely monitored for any adverse reaction during hospital stay. The intra operative blood loss was measured by quantitative method. Other parameters as intra and post operative blood loss, requirement of additional uterotonics, post op hemoglobin and hematocrit, intra & post operative blood transfusion, Iron infusion, incidence of endometritis and hospital stay were analyzed using SPPS Version 28. Result: There was no major adverse reaction in the mother and neonate in the study group. The intra operative blood loss was significantly lower in the study group (425±127, 572±175 ml, P<0.001). The Post op Hb (10.2±0.64, 9.1±1.2, P<0.001) and Hct (30.2±3.6, 29.1±3.7, P<0.001) was higher in the study group. The incidence of blood transfusion in intra operative obstetrical hemorrhage (04 Vs 10, P-0.016) and post-partum hemorrhage (04 Vs 14, P-0.011) was lower in the study group. Requirement of additional uterotonics was lesser in the study group (45 Vs 65, P-0.016). The study group also has lower incidence of endometritis (05 Vs 14, P-0.037) and duration of hospital stay  $(5.2\pm0.6, 5.8\pm1.4, P<0.001)$ . Conclusion: Intra operative Inj Tranexamic acid is safe to both mother and neonate. It is effective in reducing blood loss during and after caesarean delivery.

## **INTRODUCTION**

Caesarean delivery is defined as the birth of a fetus by laparotomy followed by hysterotomy.<sup>[1]</sup> It was first introduced to the world by a German gynecologist Max Sanger in 1882 and popularized by Munro Kerr in 1926 by lower segment uterine incision.<sup>[2]</sup> The average blood loss considered in caesarean delivery is approximately 800-1000 ml. Modern day caesarean delivery is performed by Pfannensteil-Kerr, Joel-Cohen and Misgav-Ladach techniques and their modifications. These newer techniques of caesarean delivery had lesser intraoperative blood loss apart from other benefits.<sup>[1]</sup> Multiple uterotonic drugs such as Oxytocin, methyl ergometrine and prostaglandins are routinely used to reduce uterine blood loss and to prevent post-partum hemorrhage during and after caesarean delivery.<sup>[3]</sup> The modern techniques of caesarean section have lesser intra operative blood loss and uterotonics had reduced the uterine blood loss during caesarean delivery; still there had been constant search for drugs which can cause further reduction in the blood loss. One such drug is Inj Tranexanic acid which is being used for many years during gastro-intestinal, spinal, cardiac, dental and genitor-urinary procedures to reduce intraoperative blood loss.<sup>[4]</sup>

Tranexanic acid was first introduced by a Japanese researcher Utako Okamato.<sup>[5]</sup> It is a rapidly acting synthetic lysine analogue which prevents the conversion of plasminogen to plasmin thus preventing the clot lysis and maintaining its stability. This causes reduction in bleeding from small blood vessels and capillaries. The CRASH 2 trial,<sup>[6]</sup> conducted in 2010 reported that early administration of Tranexanic acid reduces the severity of bleeding and additional requirement of uterotonics in caesarean delivery. The WOMEN trial,<sup>[7]</sup> conducted in 2017 states that administration of Inj Tranexanic acid is safe and drastically reduces the post partum hemorrhage and maternal death.

Multiple studies done across the world including India suggest that Tranexanic acid is effective in reducing blood loss in caesarean delivery.<sup>[8-14]</sup> However, these studies were conducted on relatively smaller sample size and the safety of the drug was accessed in only few.<sup>[12]</sup>

Our study had included relatively larger sample size. The primary outcome of the study is to investigate the safety and efficacy of prophylactic Tranexanic acid in reducing blood loss during and after caesarean delivery. The secondary outcome was to find out the requirement of additional oxytocics intra operatively and need for blood transfusion during and after surgery in case of post-partum hemorrhage, post op Iron therapy in case of anemia, incidence of endometritis and hospital stay.

## **MATERIALS AND METHODS**

**Study Design, Place and Duration:** The study is a prospective, randomized, double blinded, placebo controlled interventional study. It was conducted at a tertiary care hospital in Pune. The duration of the study was from Dec 18 to June 21.

#### Population

**Source Population:** All antenatal patients who were booked at this centre and underwent elective/emergency Caesarean delivery.

**Study Population:** The study population included the antenatal patients who underwent caesarean section at this centre and willing to participate in the study.

#### **Eligibility:**

#### Inclusion Criteria

**Elective Caesarean:** Antenatal patients who underwent primary or repeat elective caesarean delivery under spinal anaesthesia and willing to participate were included in the study.

**Emergency Caesarean:** Patients who were willing to participate and underwent emergency caesarean section under spinal anaesthesia were included in the study. As per the Institutional policy of this centre, consent was taken after counseling, from all labour cases for emergency caesarean section who were admitted for delivery. This practice was to reduce the valuable time in case a need arises for emergency caesarean section. At the time of obtaining consent for probable caesarean section, they were informed regarding the study by the researcher/duty nurse.

#### **Exclusion Criteria**

Patients who were unwilling to participate, taking prophylactic/ therapeutic LMWH, allergic to Tranexamic acid having cardio-vascular and liver disease were excluded from the study. Patients who had post op hemoperitoneum and reexplored were also excluded from the study

## Sampling Method

Sampling was done by computer generated random numbers and those numbers were allocated to the patients. We allocated even number for the study group and odd number for the control group. The allocated numbers were shared with the anesthetist, prior to the surgery as the injection was to be given under his supervision and obstetrician and patients were kept blinded regarding the number allocation.

**Study Group:** It comprises of the subjects who were to receive Inj Tranexamic acid

**Control Group:** It comprises of the subjects to receive normal saline.

**Dose & Timing of Drug:** A total of 1gm of Inj Tranexamic acid was diluted in 100 ml of normal saline and administered to the patients intravenously without prior test dose at the time of skin incision and 100 ml of normal saline administered to the controls. Both the drug and saline administration were completed in 15 minutes.

#### **Surgical Procedure**

All caesarean sections were done by the faculty and third year junior resident under supervision of the faculty. We followed the steps as Pfannensteil incision, sharp and blunt dissection to reach the peritoneal cavity. UV fold dissection and pushing of the urinary bladder, Kerr's incision over uterus, fetal extraction, cord clamping, spontaneous separation of placenta, uterine exteriorization, closure of uterine incision in two layers and layered closure of the abdominal wall. Immediately after fetal extraction all patients received a combination of 10 IU of Inj Oxytocin as bolus dose and 10 IU intravenously diluted in Ringer Lactate @ 40 drops/minute. The Oxytocin drip was continued in the post operative period for 12 hrs. All patients were administered 03 doses of antibiotics as per institutional policy

**Measurement of Intra operative blood loss:** Measurement of Intra operative blood loss: The intra operative blood loss was measured by Quantitative method.<sup>[15]</sup> A total of 12 surgical sponges of diameter  $30 \times 20$  cm and weight 30 gm (SD 2 g) were taken in each surgery. We had used two suction machines during the surgery to minimize the mixing of blood with the amniotic fluid. One suction machine was used to aspirate the amniotic fluid completely after uterine incision and other was used to aspirate the blood and clots and surgical sponges were used for mopping of blood from the surgical field. The weight of the sponges were converted to blood volume by using the conversion formula of 1 gm/ml (1 gm of wet sponge= 1 ml of blood). Total blood loss was calculated by the calculation as follows;

Total QBL= $\Sigma V$  wet sponge QBL + V suction canister QBL -  $\Sigma V$  dry Sponge

Post operative monitoring: In the recovery room, all patients received post op care as per institutional policy and they were closely observed for any adverse reaction for 48 hrs. The vaginal pads were checked 02 hourly for any excessive bleeding and clots for 06 hrs and loss of blood was measured by quantitative method. On 1st postoperative day the hemoglobin (Hb) and hematocrit (Hct) were measured. Blood transfusion was given to patients with post op Hb < 7 gm on day1/2 and Inj FCM 1000 mg was infused for 7-9 gm on day2 and patients of Hb >9 gm were given oral hematinics. All asymptomatic patients were discharged on post op day 4. Patients who had endometritis were managed by broad spectrum antibiotics and discharged once they became afebrile for 48 hrs.

Sample size calculation: Sample size in each group was calculated by the statistical formula for comparative study as follows:

$$n = \frac{1}{(1-f)} \times \frac{2 \times (Z_{\alpha} + Z_{\beta})^2 \times P \times (1-P)}{(P_0 - P_1)^2}$$

Multiple studies done in our country reveals a reduction of intra operative blood loss by 15-40 %.<sup>[8,11,13]</sup> We had considered a 15 % reduction in blood loss with power of 80% and level of significance of 95% to reject the Null hypothesis. Based on this the values were P0=0.15, P1=0.075, P=0.112, (1-P)=0.888, Za=1.96, Zb=0.84, f=0.05. The sample size calculated is 291 in each group. We had analyzed 455 cases in each group.

## Data Analysis

Data analysis performed by using SPSS (Statistical package for social sciences) Version 28:0. Qualitative data variables were expressed by frequency and Percentage and Chi-square test was used to compare the variables between 2 independent groups. Quantitative data variables were expressed by using Mean and SD and the variables were compared by unpaired t-test and Mann-Whitney U test.

## RESULTS

[Table 1] represents maternal and neonatal demographic details of both the groups. The parameters are maternal age & weight, parity and gestation age in weeks and birth weight. None of the parameters in study and control groups had statistically significance difference.

The indication of caesarean delivery is shown in [Table 2]. The Indications of elective caesarean were post caesarean pregnancy, previous 2 LSCS status, Malpresentation, bad obstetric history, placenta previa, IUGR and Twin gestation. Indications of emergency caesarean delivery were failed induction, non progress of labour, non reassuring NST, fetal distress and cord presentation/prolapse. None of the parameters had statistically significant difference.

The operative parameters of both groups are shown in [Table 3]. There was no significant difference between the mean duration of surgery in both the groups. The mean blood loss of both groups was  $425 \text{ml} (\pm 127) \text{ml}$  and  $572 \text{ml} (\pm 175)$  and this difference was statistically significant (P<0.001). Blood loss in excess of 500 ml was 84 and 135 in both the groups. In study group 70 patients had blood loss between 500-1000 ml as compare to 112 patients of control group. Blood loss in excess of 1000 ml was in 14 patients in study group and 23 patients in control group. This difference was statistically significant (P<0.001). To control the intra operative bleeding mainly from the uterus, there was additional requirement of uterotonics (Oxytocin, Methyl ergometrine, Prostaglandins). It was in 45 patients of study group as compare to 65 patients of control group. This difference was also significant. Intra blood transfusion for operative obstetrical hemorrhage was in 04 patients in study and 10 patients in control group and this difference was also significant.

[Table 4] shows Intra operative blood loss in various categories of caesarean delivery and blood loss associated with it. It also represents the blood loss in relation to maternal weight at the time of caesarean and birth weight of the child. The intra operative blood loss was reduced in patients who had received Inj Tranexamic acid and it was statistically significant in most of them (P<0.001).

[Table 5] represents the intra operative and post operative blood transfusion in study and control group. It was indicated in cases of placenta previa, twin gestation, and non progress of labour, Malpresentation and previous 2 LSCS status. The incidence of blood transfusion was reduced in study group who had received Inj Tranexamic acid.

[Table 6] shows the comparison of pre and post op hemoglobin (Hb), hematocrit (Hct), more than 10% fall in Hb detected on post op day 1. There was no statistically significant difference between pre op Hb & Hct in both the groups. However there was a significant difference of post op Hb & Hct in both the groups (P <0.001). Because of increased intra operative blood loss and post partum hemorrhage, many patients had more than 10% fall in the post op Hb. It was lesser in study group (18) as compare to control group (42) and this difference was significant. The adverse reaction of Inj Tranexamic acid in study group vs control is shown in [Table 7]. All patients and the neonates who received Inj Tranexamic acid were intensely monitored for 48 hrs after administering the drug and no major adverse reaction was noted.

[Table 8] represents the comparison of post op parameters between study and control group. Inj Tranexamic acid was associated with reduced vaginal bleeding in first 06 hrs after surgery and the difference was significant (P<0.001). The incidence of blood transfusion in cases of Post op PPH was in 04 and 15 cases in study and control groups respectively and this difference was also significant. Incidence of endometritis was also reduced in the study group (5 Vs 14). The duration of hospital stay was lesser in study group and this difference was significant (P<0.001). A total of 03 patients in study group and 14 patients in control group received 1000 mg of Inj FCM for post op anemia.

S No	Parameter	Study (N=455)	Control (N=455)	p-value
1	Maternal age (Years)	24.2±3.9	24.5±3.85	0.243
2	Parity			0.625
	0	160	153	
	1 & beyond	295	302	
3	Maternal weight (Kg)			0.962
	< 60	71	72	
	60-90	361	358	
	>90	33	35	
4	Gestational age (Weeks)	38.2±1.4	38.4±1.3	0.025
5	Birth weight			
	<3.0 Kg	161	166	
	3.0-4.0 kg	228	224	0.942
	>4.0 Kg	66	65	

P- Value < 0.05 (Significant) Chi-square test

## Table 2: Indication of caesarean delivery of both groups

S No	Parameter	Study (N=455)	Control (N=455)	p-value
1	LSCS			
	Elective			
	a) Previous LSCS	167	161	
	b) Previous 2 LSCS	28	30	
	c) Malpresentation	15	17	
	d) Maternal request	18	15	
	e) Bad Obs history	23	22	
	f) Placenta previa	08	09	
	g) IUGR	14	15	0.786
	h) Twin gestation	06	06	
	Total	279	275	
	Emergency			
	a) Failed induction	100	104	
	b) Non progress of labour	45	43	
	c) Non reassuring NST	16	18	
	c) Fetal distress	12	13	
	d) Cord presentation/Prolapse	03	02	
	Total	176	180	

P- Value < 0.05 (Significant) Chi-square test

S No	Parameters	Study (N=455)	Control (N=455)	P-value
1	Mean duration of surgery (Min)	34±7.2	33.4±7.1	0.399
2	Mean Blood loss (ml)	$425 \pm 127$	$572 \pm 175$	< 0.001*
3	> 500 ml Blood loss	84	135	
	a) 500-1000 ml	70 out of 84	112 out of 135	< 0.001*
	b) >1000 ml	14 out of 84	23 out of 135	
4	Intra op req of additional uterotonics	45	65	0.042*
5	Blood transfusion for Intra op	04	10	0.016*
	Obstetrical Haemorrhage			

\*P- Value < 0.05 (Significant) Chi-square test

Table 4:	able 4: Comparison of intra op blood loss in different parameters in both groups					
S No	Parameters	Mean Blood loss Group 1 (N-455)	Mean blood loss Group 2 (N= 455)	P value		
1	Maternal weight (Kg) < 60 60-90 >90	410 ±35 ml 478 ±70 ml 595 ±104 ml	$425 \pm 45 \text{ ml}$ $514 \pm 89 \text{ ml}$ $760 \pm 165 \text{ ml}$	0.027 <0.001* <0.001*		
2	LSCS Elective Previous LSCS Previous 2 LSCS Malpresentation	426 ±55 ml 536 ±75ml 480 ±65 ml	472 ±65 ml 680 ±89 ml 540 ±90 ml	<0.001* <0.001* 0.038*		

	Maternal request	486 ±70 ml	520 ±96 ml	0.264
	Bad Obs history	475 ±74 ml	513±94 ml	0.141
	Placenta previa	750±140ml	895±185ml	< 0.001*
	g) IUGR	415±36 ml	447±70 ml	0.163
2	_			
3	Emergency	1-0 -0 1		0.00. <del>*</del>
	a) Failed induction	478±59 ml	518±80 ml	<0.001*
	b) Non progress of labour	665±64 ml	695±135 ml	0.191
	c) Fetal distress			
	d) Cord presentation/ Prolapse	435±56 ml	478±79 ml	0.074
		476±78 ml	545±105 ml	0.054
4	Birth weight (Kg)			
	<3.0 Kg	$445 \text{ ml} \pm 34 \text{ ml}$	$462 \text{ ml} \pm 38 \text{ ml}$	< 0.001*
	3.0-4.0 kg	$468 \text{ ml} \pm 68 \text{ ml}$	$496 \text{ ml} \pm 82 \text{ ml}$	<0.001*
	>4.0 Kg	$475 \text{ ml} \pm 85 \text{ ml}$	$535 \text{ ml} \pm 134 \text{ml}$	0.003*

\*P- Value < 0.05 (Significant) Chi-square test

S No	Parameters	Intra operative Blood trans (N=14)		P-Value	Post operative Blood trans (N=19)		P-Value
		Study (04)	Control (10)		Study (04)	Control (15)	
1.	Placenta previa	02	03	0.480	01	02	0.870
2.	Twin pregnancy	01	02	0.837	01	03	0.827
3.	Non progress of labour	01	03	0.852	01	04	0.946
4.	Malpresentation	-	01	0.512	-	02	0.440
5.	Previous 2 LSCS status	-	01	0.512	01	03	0.827
	Total	4	10		4	14	

\*P- Value < 0.05 (Significant) Chi-square test

S N	Parameters	Study (N=455)	Control (N=455)	p-value
1	Pre op Hb	$11.2 \pm 0.8$	$11.25 \pm 0.9$	0.379
2	Pre op Htc	$33.68 \pm 3.8$	33.21 ± 3.9	0.366
3	Post op Hb	$10.2 \pm 0.64$	9.1 ± 1.2	< 0.001*
4	Post op Hct	$30.2 \pm 3.6$	29.1 ± 3.7	<0.001*
5	>10 % fall in Hb	18	42	0.013*

\*P- Value < 0.05 (Significant) Chi-square test

S N	Parameters	Study (N=455)	Control (N=455)	<b>P-Value</b>
1	Nausea & Vomiting	05	02	0.255
2	Post op Diarrhoea	02	01	0.563
3.	Allergic reaction	0	0	-
4	Maternal bradycardia	01	0	0.317
5	Maternal thrombotic events	0	0	-
6	Liver & Hepatic Dysfunction	0	0	-
7	Seizure	0	0	-
8	Blood in neonatal stool	0	0	-

<sup>\*</sup>P- Value < 0.05 (Significant) Chi-square test

Fable 8: Comparison of post op parameters between both groups					
S No	Parameters	Study (N=455)	Control (N=455)	p-value	
1	Vaginal bleeding in first 06 hrs	50±17 ml	70±25 ml	<0.001*	
2	Blood transfusion for PPH	04	15	0.011*	
3	Endometritis	05	14	0.037*	
4	Hospital Stay (Days)	5.2±0.6	5.8±1.4	<0.001*	
5	Post-partum Iron infusion	03	14	0.007*	

\*P- Value < 0.05 (Significant) Chi-square test

## DISCUSSION

A total of 455 patients received 1 gm of Inj Tranexamic acid during surgery and they were observed for 48 hrs in the post operative period for any adverse reaction. The drug was well tolerated and only few of them had minor adverse reaction. In the study group, 05 patients had intra operative nausea and vomiting (IONV) as compared to 02 in the control group. Intra operative nausea and vomiting is not a sacrosanct side effect of Inj Tranexamic acid as other factors also play an important role. A study done by Semiz et al,<sup>[16]</sup> suggested that factors such as exteriorization of uterus for its repair, spinal & epidural anaesthesia causing intra operative hypotension, stimulation of viscera during surgery

and prophylactic or therapeutic uterotonics are factors which can cause intra operative nausea and vomiting. In our study, IONV was self-limiting and stopped after closure of the rectus sheath in three patients and in remaining two patients antiemetic was required. Many patients had received Inj carboprost (PGF2 $\alpha$ ) for flabby uterus and two of them in the study group developed post op diarrhea which was treated with probiotics. Watery diarrhea is a common side effect of carboprost and can't be attributable to Inj Tranexamic acid.<sup>[17]</sup> One patient had intra operative bradycardia which was treated by displacing the uterus and rushing IV fluids. No other side effect was noted in any of the patients. Since Tranexamic acid prevents clot degradation, there is a concern regarding increased risk of thrombo-embolic events. The CRASH trial had reported that the risk of thrombo-embolic events is greater when a relatively higher dose of Tranexamic acid is used as in trauma cases. A single dose of 1gm is considered a smaller dose and does not have any major adverse effects including vascular occlusive events.<sup>[6]</sup> A metaanalysis done by Peitsidis et al in 2011,<sup>[18]</sup> had reported 2 cases of pulmonary embolism without confirming its relation with Tranexamic acid. Another meta-analysis done by Massimo Franchini et al had not reported any significant side effect including thrombotic events.<sup>[19]</sup> Our study had also not reported any major side effects.

[Table 1 and 2] which represents the demographic details and indications of caesarean delivery in both groups shows no significant difference between the two groups. The mean duration of surgery, pre operative hemoglobin (Hb) and hematocrit (Hct) were also more or less same in both the groups.

The primary objective of the study is to find out the efficacy of Inj Tranexamic acid. The mean intra operative blood loss in study and control groups are 425±127 ml and 572±175 ml respectively and this difference is significant (P<0.001). Inj Tranexamic acid had reduced the intra operative blood loss by 25.6 % in the study group. This finding was consistent with other Indian studies,<sup>[8,11,13]</sup> in which the blood loss was reduced by 15-40 %. Similar findings were found in studies done in Pakistan, Nigeria and Egypt.<sup>[9,10,12,14]</sup> Multiple meta-analyses also support the same.<sup>[18-20]</sup> It is evident from Table 4 that Inj Tranexamic acid reduces intra operative blood loss in both elective and emergency caesarean delivery including cases of placenta previa. The mean blood loss was 750±140 ml and 895±140 ml in study and control groups respectively and this difference is significant (P<0.001).

As per our institutional policy, we administer 10 IU of Inj Oxytocin as a bolus dose and another 10 IU in IV drip. Additional uterotonics are required when the uterus does not contract immediately after fetal extraction. There were 45 (9.8%) patients in study and 65 (14.28%) in control group who had received additional uterotonics to control the uterine bleeding during surgery. Inj Tranexamic acid significantly reduces the requirement of additional uterotonics and

proved by many studies also report similar findings<sup>[9,11,12,22]</sup>

In our study we encountered two groups of patients of obstetrical hemorrhage who received intra operative blood transfusion. The first group was cases of placenta previa and second group consists of patients in which obstetricians encountered flabby uterus while performing the caesarean section. Flabby uterus was seen in cases of twin gestation, non-progress of labour and Malpresentation. In both the conditions, the blood loss is alarmingly high because of the increased vascularity of the uterus.<sup>[24]</sup> Apart from fast, accurate suturing and good surgical technique in cases of placenta previa and giving external massage to the uterus with additional uterotonics in cases of flabby uterus, administering Inj Tranexamic acid is an adjunct to reduce the bleeding and overall reduces the requirement of blood transfusion. We encountered placenta previa and intra operative flabby uterus in 14 cases in both the groups and blood transfusion was given in 04 cases in study as compared to 10 cases in control group. A meta-analysis of 18 RCT in 2018 conducted by Massimo et al,<sup>[19]</sup> suggested that Inj Tranexamic acid is very effective in preventing obstetrical hemorrhage and also recommended its routine use.

Tranexamic acid significantly reduces excess intra operative blood loss. Blood loss >500 ml and <1000ml is seen in 70 (15.38%) patients in study group and 112 (24.61%) patients in control group. Intra operative Blood loss in excess of 1000 ml was seen in 14 (3.03%) cases in study and 23 (5.05) cases in control group and this difference was significance (P<0.001). Similar findings were observed in multiple studies.<sup>[9,11,23]</sup>

Administration of Inj Tranexamic causes reduction of uterine blood loss in the post operative period also. We did a quantitative measurement of blood loss in first 6 hrs and found that the blood loss was lesser in the study group and this difference was statistically significant (P<0.001). Similar finding was observed by Lakshmi SJ et al.<sup>[11]</sup> On post operative day 1, Hb and Hct were done for all patients. The post op Hb in study and control groups were 10.2±0.64 g/dl and 9.1±1.2 g/dl respectively and this difference was statistically significant (P<0.001). There was a fall of Hb to the extent of 10.78 % in control group. The hematocrit was also lesser in control group as compared to study group and this difference is also significant (P<0.001). Similar findings were observed in multiple studies and meta-analysis.[8-20] The beneficial effects of Inj Tranexamic acid continued in the post op period as it significantly reduces the blood transfusion and Inj FCM infusion. A total of 4 patients in study and 15 in the control group (P=0.011) received blood transfusion for post op Hb <7.0g/dl. Similarly only 03 patients in study and 14 in control group (P=0.007) received Inj FCM for post Hb 7-9 g/dl. Incidence of endometritis was lesser in study group. A total of 05 patients had endometritis in the study group as compared to 15 patients in control group (p=0.037). All patients who

had uneventful post operative period were discharged on post op D4. The hospital stay was prolonged in cases of endometritis and anemia. Because of increased incidence of endometritis and anemia in the post op period in the control group, the hospital stay was prolonged. The mean hospital stay in the study and control group was  $5.2\pm0.6$  days and  $5.8\pm1.4$  days and this difference was statistically significant (P<0.001).<sup>[8-13]</sup>

## **CONCLUSION**

The index study found that administration of Intra operative Inj Tranexamic acid is safe to both mother and baby. The drug is efficacious in reducing the intra operative blood loss in caesarean section irrespective of its indication. It can be safely used as an adjunct to uterotonics to control the uterine blood loss and reducing the incidence of intra operative blood transfusion for obstetrical hemorrhage. The benefits of the drug continued in the post operative period also. There is reduced uterine bleeding in the immediate post op period, decreased risk of blood transfusion and Iron infusion for post op anemia, lesser incidence of endometritis and hospital stay. Because of reduction in the blood loss, Inj Tranexamic acid can be a boon to many parts of the world where prevalence of anemia is high.

## Limitations

The study has the following limitations:

- 1. In our study the surgery was done by the faculty and third year residents under supervision of faculty. Although the surgical team followed the same steps of surgery; but it is very difficult to reduce the intra operative blood loss by relatively inexperienced junior surgeon.
- 2. To measure the intra operative blood loss, we had used quantitative method. To prevent the mixing of blood with amniotic fluid, two separate suction apparatus were used. Despite the best effort, there was some degree of mixing of the amniotic fluid and blood and it was very difficult to measure the exact blood loss.

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