



EFFICACY OF PREOPERATIVE ONE GRAM INTRAVENOUS TRANEXAMIC ACID IN REDUCING INTRAPARTUM BLOOD LOSS IN CAESAREAN SECTION: A RANDOMIZED CONTROL TRIAL

Obstetrics & Gynaecology

Dr. Pragya Mishra	Professor, Department of Obstetrics and Gynecology, Rohilkhand Medical College and Hospital, Uttar Pradesh, India
Dr. Sarita Khushwaha	Department of Obstetrics and Gynecology, Rohilkhand Medical College and Hospital, Uttar Pradesh, India
Dr. Neha Sehrawat	Department of Obstetrics and Gynecology, Rohilkhand Medical College and Hospital, Uttar Pradesh, India
Dr. Namrata Arya	Department of Obstetrics and Gynecology, Rohilkhand Medical College and Hospital, Uttar Pradesh, India

ABSTRACT

Introduction- C-section is a major surgery with greater blood loss than vaginal delivery leading to increased maternal morbidity associated with increased blood loss. Hence it is crucial to reduce the blood loss more effectively in a low-cost and low risk alternative method. Tranexamic acid might reduce the risk of severe anaemia and avoid the need for blood transfusion. Hence this could significantly contribute in reducing maternal morbidity and mortality. **Aim-** To assess the effectiveness of prophylactic 1 gm IV Tranexamic Acid given before c-section in reducing intrapartum blood loss during c-section. **Objectives** 1. To study the effect of tranexamic acid in reducing total blood loss following delivery of placenta, to end of csection, & till 2hrs after c-section, between study and control group. 2. To evaluate the difference in the fall of preoperative and post-op HB level in study and control group. **Method & Methodology-** A Prospective randomized control study was conducted in the department of Obs & Gynae in at RMCH, Bareilly, for a period of 1 year on 64 women undergoing c-section. Patients were allotted to study group and control group. Women with Singleton pregnancy, Delivery by Emergency or Elective csection, Age between 18 and 40 years & Gestational age of 37 to 42 weeks of pregnancy were included in the study in whom 1 gram Tranexamic Acid was administered IV slowly over 5 minutes, at least 10 minutes prior to skin incision. Blood loss was measured from the time of delivery of placenta till the end of the surgery in both the groups. The data collected was analysed by using SPSS version 23. **Result & Conclusion** – There was a significant reduction of mean blood loss from end of cesarean to 2 hours post partum - 95.13 ± 13.60 TXA group and 109.18 ± 14.75 in the control group. Tranexamic acid significantly reduced the amount of blood loss during the lower segment caesarean section. Its use was not associated with any side effects and or complication like thrombosis. Thus, TXA can be used safely and effectively in subjects undergoing LSCS.

KEYWORDS

INTRODUCTION

Postpartum haemorrhage is defined as cumulative blood loss >1000 ml in cesarean section accompanied by symptoms & signs of hypovolemia. Delivery by caesarean section can cause more complication than normal vaginal delivery and one of the most common complication is primary or secondary postpartum hemorrhage.

One third of women undergoing caesarean delivery have blood loss that exceeds 1000ml. So, it becomes imperative to find ways to reduce the volume of blood lost during caesarean section. In association with the high prevalence of anemia this leads to nearly two folds increase in maternal morbidity and mortality with caesarean section¹.

Postpartum hemorrhage remains a leading cause of early maternal death, accounting for about 300,000 deaths worldwide every year, and of morbidity related to anemia, blood transfusion and hemorrhage-related ischemic complications.

Tranexamic acid (TXA) is an anti-fibrinolytic agent and an artificial analog of Lysine. As the fibrinolytic system is being activated from the time of placental delivery, TRANEXEMIC ACID will be effective in controlling the blood loss during CS. TXA acts by binding to the specific sites and competitively inhibit the activation of plasminogen to plasmin, which is responsible for the degradation of fibrin, a protein that forms the frame work of blood clot. With this there is better stabilization of clot thereby reducing the blood loss.

Tranexamic acid, exerts its antifibrinolytic activity by blocking the lysine binding sites of plasminogen & the plasmin molecules, thereby preventing binding of plasminogen and plasmin to the fibrin substrate. Its anti fibrinolytic activity lasts for 6 – 10 hours, it can also control post partum blood loss too.

TXA reduced the incidence of blood transfusion by 39 percent, according to a systematic evaluation of randomised controlled trials of antifibrinolytic drugs in elective surgery patients². TXA has shown to decrease uterine blood loss in non-surgical aspects. A study done on

women with menorrhagia showed significant reduction in mean menstrual blood lost in those treated with TXA³.

Thus, tranexamic acid might reduce the risk of severe anemia and avoid the need for blood transfusion.

Aim

To assess the efficacy of preoperative one gram intravenous Tranexamic Acid given before caesarean section in reducing intrapartum blood loss during caesarean section.

Objectives

1. To study the effect of tranexamic acid in reducing total blood loss following delivery of placenta to end of caesarean section between study and control group.
2. To study the effect of tranexamic acid in reducing blood loss from end of caesarean till 2 hours after caesarean section between study and control group.
3. To evaluate the difference in the fall of preoperative and postoperative haemoglobin level in study and control group.

Method

- This was a randomized controlled trial conducted at Rohilkhand Medical college and hospital, Bareilly, Uttar Pradesh among 64 patients undergoing caesarean section, fulfilling the inclusion and exclusion criteria. Written and informed consent was taken from patients to be a part of this study. Also, approval by ethics committee of hospital was taken.
- A detailed history taking and clinical examination was done, followed by baseline blood investigations. Routine preoperative care was given to all patients. 1gram Tranexamic Acid was administered intravenously slowly over 5 minutes, at least 10 minutes prior to skin incision.
- Blood loss was measured from the suction container and the mops and operating table sheets. Patients were randomly grouped into two groups.

Inclusion Criteria

- Singleton pregnancy,

- Delivery by Emergency or Elective caesarean section,
- Gestational age of 37 to 42 weeks of pregnancy

Exclusion Criteria

- Allergy to Tranexamic Acid,
- Abnormal placenta (abruptio placenta, placenta previa),
- Severe medical illness complicating pregnancy like cardiac, renal, liver diseases,
- Deranged coagulation profile

RESULTS

- The table given below (Table 1) shows, comparison between tranexamic acid group and control groups regarding blood loss from placental delivery to the end of the surgery (mL).

(Table 1)

Blood loss (ml)	Group		P value
	TXA group (n=32)	Control (n=32)	
<500	23 (71.9%)	5 (15.6%)	<0.001*
500 – 750	9 (28.1%)	17 (53.1%)	
>750	0 (0.0%)	10 (31.3%)	
Mean±SD	452.68±86.53	638.18±138.87	<0.001#

- Blood loss from the time of placental delivery to the end of the surgery was significantly lower in tranexamic group than control group. (p<0.001, suggesting that there was statistically significant difference in the blood loss in both the groups.)
- Also, no patient in TXA group had blood loss more than 750ml, whereas 10 patients (31.3%) patients in control group had blood loss more than 750ml

The table given below (Table 2) shows, comparison between tranexamic acid group and control groups regarding blood loss from end of the surgery to the blood loss in first 2 hours postpartum (mL)

- Mean blood loss from the end of the operation to 2-hour after operation, was 95.13±13.60ml in tranexamic acid group and 109.18±14.75ml in control group, which was significantly lower in tranexamic group than in control groups.

In tranexamic acid group only 31.3% patients (i.e. 10) had blood loss more than 100ml whereas 71.9% patients (23 patients) had blood loss more than 100ml in the first 2 hours following cesarean section.

(Table 2)

Blood loss ml	Group		P value
	TXA group (n=32)	Control (n=32)	
≤100	22 (68.8%)	9 (28.1%)	<0.001*
101 – 150	10 (31.3%)	23 (71.9%)	
Mean±SD	95.13±13.60	109.18±14.75	<0.001#

This table (Table 3) shows comparison between tranexamic acid group and control groups regarding hemoglobin reduction (gm/dL)

(Table 3)

	Group		P value
	TXA group (n=32) (HB in gm/dl)	Control (n=32) (HB in gm/dl)	
Preoperative HB (Mean±SD)	10.62±1.04	10.64±1.25	0.936#
Postoperative HB (Mean±SD)	9.91±0.99	9.30±1.06	0.022
Reduction in HB (Mean±SD)	0.71±0.47	1.33±1.05	0.003#

Independent Sample t test[§]

- The reduction in hemoglobin in TXA group was 0.71g% when compared to control group which was 1.33g%.

So the reduction in hemoglobin was significantly less in tranexamic group than in control group (p<0.05) as shown in the table.

DISCUSSION

- In the study by Milani F et al⁴ & Malathi P et al⁸ the mean blood loss from placental delivery till end of cesarean section was 509.5±208.7 & 375.69 ± 158.09 respectively in TXA group and 649.9±234.1 & 410.79.9 ± 79.9 respectively in the control group and this was statistically significant. In the present study the mean blood loss from placental delivery till end of cesarean section is 452.68±86.53 in TXA group and 638.18±138.87 in the control group and this is statistically significant.

- In the study by Milani F et al⁴ & Malathi P et al⁸ showed that the mean blood loss from end of cesarean to 2 hours post partum is 551.8±207.8 & 52±30 respectively in TXA group and 713.1±233.1 & 131±42 respectively in the control group and this is statistically significant. In the present study the mean blood loss from end of cesarean to 2 hours post partum is in 95.13±13.60 TXA group and 109.18±14.75 in the control group and this is statistically significant.
- In their study by Malathi P et al⁸ & by Bhatia SK & Deshpande H⁷ showed that the mean reduction in hemoglobin was 1.34 ± 0.15 & 0.5±0.15 respectively in the TXA group and 1.44 ± 0.88 & 0.9±0.14 respectively in the control group, and this was statistically significant. In the present study the mean reduction in hemoglobin was 0.71±0.47 in the TXA group and 0.71±0.47 in the control group, and this is statistically significant.
- In a study conducted by Mayur G et al⁵, it was discovered that the quantity of blood lost from the end of LSCS to 2hrs postpartum in the TXA- group was 75.71 mL compared to 133.03 mL in the control group (p=0.001) Also, the quantity of blood lost from placental delivery to 2 hours post-partum in the TXA- group was 372.71 mL, compared to 469.70 mL in the control- group. (P=0.003) was lowered considerably.
- In their study by Gungorduk K et al⁶ found out that the mean total blood loss from placental delivery till 2 hours post partum was 499.9±206.4 in the TXA group and 600.7±215.7 in the control group, and this was statistically significant.

Kamel HEH et al⁹ in their study showed that the mean reduction in hematocrit was 2.50 ± 2.50 in the TXA group and 3.80 ± 2.30 in the control group, and this was statistically significant.

A Study by Hemapriya L et al¹⁰ showed that the mean total blood loss from placental delivery till 2 hours post partum was 590.5±190.39 in the TXA group and 696.2±148.18 in the control group, and this was statistically significant, and is similar to our study.

CONCLUSION

Lower segment Caesarean section is the most common surgery performed in obstetrics. Intraoperative blood loss during LSCS causes significant reduction in haemoglobin postoperatively and the need for blood transfusions or intravenous iron therapy was found to be more during postoperative care. The present randomized study demonstrated that 1 gram of intravenous injection Tranexamic acid given 10 minutes before skin incision can be used for prophylactic administration before caesarean section for decreasing blood loss during surgery and after surgery. This drug as proved by this study appears to decrease the blood loss during cesarean section. It also has the extended efficacy in the post-operative period which helps in decreasing blood loss even in the post-operative period. Thus, our results suggest that tranexamic acid can be used safely and effectively to reduce the bleeding resulting during and after lower segment caesarean section.

Funding: No funding sources

Conflict of Interest: None declared

Ethical Approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Cunningham F, Leveno K, Bloom S, Spong CY, Dashe J. Williams obstetrics, 24e. McGraw-hill; 2014:755-756
2. Henry DA, Carless PA, Moxey AJ, O'Connell D, Stokes BJ, Fergusson DA, Ker K. Anti-fibrinolytic use for minimising perioperative allogeneic blood transfusion. Cochrane database of systematic reviews. 2011(3).
3. Matteson KA, Rahn DD, Wheeler TL (2013): Non-surgical management of heavy menstrual bleeding: A systematic review and practice guidelines. Obstetrics and Gynecology 121 (3): 632.
4. Milani F, Haryalchi K, Sharami SH, Atrkarroshan Z, Farzadi S. Prophylactic effect of tranexamic acid on hemorrhage during and after the cesarean section. International Journal of Womens Health and Reproduction Sciences. 2019 1;7(1):74-8.
5. Mayur G, Purvi P, Ashoo G, Pankaj D. Efficacy of tranexamic acid in decreasing blood loss during and after cesarean section: a randomized case controlled prospective study. J Obstet Gynecol India. 2007 May;57(3):227-30.
6. Gungorduk K, Yildirim G, Ascioglu O, Gungorduk OC, Sudolmus S, Ark C. Efficacy of intravenous tranexamic acid in reducing blood loss after elective cesarean section: a prospective, randomized, double-blind, placebo-controlled study. American journal of perinatology. 2011 Mar;28(03):233-40.
7. Bhatia SK, Deshpande H. Role of tranexamic acid in reducing blood loss during and after caesarean section. Medical Journal of Dr. DY Patil University. 2015 1;8(1):21.
8. Malathi P, Anupama D, Habitha P. Effect of injection Tranexamic acid on peri-operative blood loss during Cesarean section. Int Arch Integr Med. 2016;3:280-9.
9. Kamel HE, Farhan AM, Abou Senna HF, Khedr MA, Albhairi AA. Role of Prophylactic Tranexamic Acid in Reducing Blood loss during Elective Caesarean section in Rural Area. The Egyptian Journal of Hospital Medicine. 2018 1;73(6):6886-96.
10. Hemapriya L, More G, Kumar A. Efficacy of tranexamic acid in reducing blood loss in lower segment Cesarean section: a randomised controlled study. The Journal of Obstetrics and Gynecology of India. 2020 Dec;70(6):479-84