Section: Anaesthesia

Original Research Article

A HOSPITAL BASED PROSPECTIVE STUDY TO ASSESS THE ROLE OF PROPHYLACTIC TRANEXAMIC ACID IN REDUCTION OF BLOOD LOSS DURING ELECTIVE CAESAREAN SECTION

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Received : 28/05/2025
Received in revised form : 17/06/2025
Accepted : 06/07/2025

Keywords:
Postpartum Haemorrhage (PPH), Tranexamic Acid, Hemoglobin, Blood Loss.

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DOI: 10.47009/jamp.2025.7.5.42

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (5); 203-206

ABSTRACT

Background: Postpartum Haemorrhage (PPH) accounts for the major part of the mortality as well as morbidity like severe anaemia, need for blood transfusion, hospital stay and infection. There is little evidence to support TXA's use in preventing PPH, despite the World Maternal Antifibrinolytic (WOMAN) trial providing evidence for its efficacy in treating PPH that has already been diagnosed.7 The aim of this study to assess the role of prophylactic tranexamic acid in reduction of blood loss during elective caesarean section. **Materials and Methods:** This is a hospital based prospective study done on obstetric and gynecology department at government district hospital Sawaimadhopur, Rajasthan, India during one-year period. 100 prenatal women scheduled for elective CSs had to meet the inclusion criteria in our study. patients were selected randomly and assigned into two groups to receive either 1 g (in 10 ml) of intravenous tranexamic acid dissolved in 100 ml of Normal Saline (study group; n=50) or placebo i.e. 100 ml of Normal Saline (control group; n=50). Blood loss was assessed using the gravimetric method. **Result:** The mean difference in Hb was 0.44±0.13 in the group A while 0.86±0.11 in group B with significantly lower change in Hb level, p-value < 0.001. In current study during surgery the mean blood loos in group-A (with TXA) was 442.68±106.54 ml and in group-B (without TXA) was 860.43±70.64 ml with significantly and postoperative mean bleeding in group A & group B was 97.56±28.52 ml and 146.28±15.76 ml respectively. The mean intraoperative and post-operative blood loss was remarkably low in the group A when matched with the group B. **Conclusion:** Injection tranexamic acid is the, antifibrinolytic agent that can be used for prophylactic administration before caesarean section for decreasing blood loss during surgery. So, in future TA can be utilized in females undergoing caesarean section to reduce burden of blood transfusions.

INTRODUCTION

Postpartum Haemorrhage (PPH) accounts for the major part of the mortality as well as morbidity like severe anaemia, need for blood transfusion, hospital stay and infection. Millennium Development Goal 5 targets for reduction of maternal mortality rate by 75% by 2015, which means 5.5% reduction per year is required. People at high risk of PPH account for only small percent of all maternal deaths. Majority of morbidity and mortality happen in those with no risk factors and cannot be predicted. In an analysis of 1620 women in rural India, it was found that 9.2% experienced PPH. No maternal or socio-demographic factors differed between women with PPH and those without.[1]

Though the incidence of early PPH (occurring within 24 hours of delivery) is lower in caesarean section than vaginal delivery, the former is a major surgery and causes greater blood loss.

The World Health Organization (WHO) defines postpartum hemorrhage (PPH) as a blood loss of 500 mL or more within 24 h of delivery; severe PPH is defined as a blood loss of 1000 mL or more during the same timeframe.[2]

Worldwide rates of caesarean sections (CS) have increased; in India, the rate is 17.2%. This has resulted in high morbidity from significant loss of blood.[3] A solution needs to be devised in order to

ISSN (O): 2687-5365; ISSN (P): 2753-6556

effectively limit blood loss and morbidity in patients undergoing CS.

A lysine analog called tranexamic acid (TXA) inhibits the activation of plasmin and fibrinolysis. Consequently, the mechanism of action of this medication is the stabilization of pre-existing clots rather than the promotion of the development of new ones. This drug is reasonably priced and widely accessible. It also has a 3-year shelf life and can be kept at room temperature. Its half-life is 80 min, and its effects begin to take action 5 to 15 min after administration. Furthermore, breastfeeding is safe because breast milk contains very little (1/100) of this medication.[4]

As a result, it is thought to be extremely valuable in areas like Southern Asia that have few resources. Researchers from a variety of specializations participated in the Clinical Randomization of an Antifibrinolytic in Significant Hemorrhage-2 (CRASH-2) trial, which increased interest in and knowledge about TXA.[5]

The WHO recommends that if PPH is diagnosed within 3 h of birth, administration of TXA is commenced immediately. For PPH treatment, 1 g of TXA is given intravenously over 10 min within 3 h of vaginal or caesarean delivery.[6]

There is little evidence to support TXA's use in preventing PPH, despite the World Maternal Antifibrinolytic (WOMAN) trial providing evidence for its efficacy in treating PPH that has already been diagnosed.[7]

The aim of this study to assess the role of prophylactic tranexamic acid in reduction of blood loss during elective caesarean section.

MATERIALS AND METHODS

This is a hospital based prospective study done on obstetric and gynecology department at government district hospital Sawaimadhopur, Rajasthan, India during one-year period.

All prenatal women scheduled for elective CSs had to meet the following criteria to be included: single pregnancy, age 18–35 years, gestational age 37–42 weeks, live fetus, hemoglobin level more than 9 g/dL within the previous 6 weeks of lower segment caesarean section (LSCS), and LSCS performed under spinal anesthesia.

Pregnancy-related complications, such as severe preeclampsia, multiple pregnancies, polyhydramnios, babies weighing >4 kg, placenta previa, placenta accreta spectrum, as well as two or more prior CSs, intrauterine death, anticoagulation within a week before LSCS, history of seizures, and allergy to TXA, were the exclusion criteria. Potential participants were recruited at the time of admission for their CS.

One hundred term, primiparous / multiparous (parity not more than two) with singleton pregnancy, who were planned to be delivered by elective LSCS were enrolled. patients were selected randomly and assigned into two groups to receive either 1 g (in 10 ml) of intravenous tranexamic acid dissolved in 100 ml of Normal Saline (study group; n=50) or placebo i.e. 100 ml of Normal Saline (control group; n=50).

Methods

Blood loss was assessed using the gravimetric method. Surgical mops, the operation table's perineal sheet, and pads used for vaginal toileting during surgery were weighed before and after the procedure using an electronic scale. The blood collected in the suction machine's bottle (from placental delivery to the end of vaginal toileting) was measured to represent suctioned blood loss, contributing to the total blood loss calculation. Intraoperative blood loss was determined by adding: Blood absorbed by soaked surgical mops (wet weight – dry weight) + Blood absorbed by perineal sheets, surgical drapes, and pads during vaginal toileting (wet weight – dry weight) + Blood collected in the suction container. In addition, uterotonics administered for uterine atony were recorded. In addition, any occurrences of nausea, vomiting, or diarrhoea after drug administration were noted.

Postoperative blood loss was measured from the end of vaginal toileting up to 3 h postpartum using the gravimetric method. A weight of 1 mg was considered equivalent to 1 mL of blood. Hemoglobin levels were estimated to be 48 h after surgery. Participants were monitored for 48 h to detect the development of venous thromboembolism. Unblinding was conducted after assessing all participants for subsequent data analysis.8

Statistical Analysis

The statistical software SPSS version 23.0 has been used for the analysis. Categorical variables are expressed as number of patients and percentage of patients and compared across the groups using Pearson's chi square test for Independence of Attributes/Fisher's Exact Test as appropriate.

RESULTS

The patients' characteristics in the two groups were similar, with no statistical difference between the two groups [Table 1]. There was also no significant difference in regard to obstetric complications (such as pregnancy-induced hypertension; fetal growth restriction; premature rupture of the membranes; poor obstetrical history) and indications for CS including pregnancy with complications; abnormal presentation; abnormal pelvis; fetal distress; previous CS; older primipara; refusal of vaginal delivery between the two groups.

The mean difference in Hb was 0.44±0.13 in the group A while 0.86±0.11 in group B with significantly lower change in Hb level, p-value < 0.001 [Table 2]. In current study during surgery the mean blood loos in group-A (with TXA) was 442.68±106.54 ml and in group-B (without TXA) was 860.43±70.64 ml with significantly and postoperative mean bleeding in group A & group B

ISSN (O): 2687-5365; ISSN (P): 2753-6556

was 97.56±28.52 ml and 146.28±15.76 ml respectively. The mean intraoperative and post-operative blood loss was remarkably low in the group A when matched with the group B.

Table 1: Patient characteristics for study and control groups

Group	Age	Height	Weight	Gestational age	Gravid
Study (N=50)	28.43±4.36	162.23±5.39	70.68±9.25	39.06±1.08	1.03±0.25
Control (N=50)	27.77±4.80	161.45±5.26	70.32±8.77	39.25±1.07	1.04±0.26
P-value	>0.05	>0.05	>0.05	>0.05	>0.05

Table 2: Comparison of difference in hemoglobin (pre-operative and post-operative) and intraoperative & postoperative blood loss in both groups

Parameters	Study group	Control group	P-value
Mean intraoperative blood loss (ml)	442.68±106.54	860.43±70.64	<0.0001**
Mean postoperative blood loss (ml)	97.56±28.52	146.28±15.76	<0.0001**
Mean drop in hemoglobin (g/dl)	0.44±1.13	0.86±0.11	<0.001

DISCUSSION

Tranexamic acid exerts its antifibrinolytic effect by blocking the lysine-binding locus of the plasminogen and plasmin molecules, thereby preventing the binding of plasminogen and plasmin to the fibrin substrate. Tranexamic acid also inhibits the conversion of plasminogen to plasmin by the plasminogen activators.[9] It has been used in the treatment of bleeding for many years. During placental delivery, fibrinogen and fibrin are rapidly degraded, whereas plasminogen activators and fibrin degradation products (FDP) increase due to activation of the fibrinolytic system. This activation can last up to 6–10 h postpartum, causing more bleeding. It was because of this activation of the fibrinolytic system that we decided to use tranexamic acid in this trial.

A study done on the effect of TXA reported that bleeding notably low in TXA group in comparison to control group. The results were same for both intra-operative blood loss was 262.5±39.6 mL and 404.7±94.4 mL, respectively and post-operative blood loss was recorded as 67.1±6.5 mL and 141.0±33.9 mL, respectively.[10] These findings were also in agreement to our findings in terms of reducing blood loos in TA group.

Another study,[11] demonstrated that administration of tranexamic acid at rate of 10 mg per kg body weight reduced the blood loss during period from the end of caesarean section to two hours post-partum. The decline in total blood loss volume from placental delivery to two hours post-partum was also remarkable. This helped in reducing the need for hysterectomy, the chances of severe anaemia were reduced and off course the requirement of blood transfusion.[12] On the other hand, the desired results to decline the blood loss for the period between placental delivery and end of caesarean section, possibly because very late administration of TXA. The need for early administrated of TXA was recommended. So far, a few studies carried out on TXA administration to reduce the blood loss following CS. Gungorduk et al,[13] reported to reduce the post-operative blood loss of about 17% at two hours, in the intervention participants those were given 1 gm of TXA regardless of individual's body weight. A multicenter, randomized control trial published about 18 % blood loss reduction in TXA treated participants.8 These reports are in completely accord with this study. Two meta-analysis described the Tranexamic acid effect to be compared 32.5 mL14 and 75.1 mL15 reduced bleeding, with placebo dose, respectively. Additionally, the findings of study from Iran 10 and France16 also supported this study. Besides, tranexamic acid has the shown to reduce the incidence of PPH in the study group, which is according to results reported by Gai et al and Peitsidis et al,[14] Tranexamic acid statistically reduces the bleeding from placental delivery to two hours post-partum and its use was also safe as far as side effects or indications are concerned. Therefore, TXA can safely be used and because of its effectivity in reducing the bleeding resulting from caesarean section. The mean blood loss reduction when both groups were compared to the control group were 146.34±56.32 ml and 262±31.51 ml for group T1 and T2 respectively.[17] In the duration from placental delivery to the end of caesarean section (T1), The bleeding didn't differ between the tranexamic acid (336.7±151.2) and the control group (368.5±156.4).[11] TXA remarkably reduced the volume of bleeding from placental delivery to the end of caesarean section which was 356.44 ±143.2 ml in the TXA group versus 710.22 ±216.72 ml in the placebo group (p-value less than 0.001).[18] We also found lower blood loos in females having TA.

CONCLUSION

Injection tranexamic acid is the, antifibrinolytic agent that can be used for prophylactic administration before caesarean section for decreasing blood loss during surgery. So, in future TA can be utilized in females undergoing caesarean section to reduce burden of blood transfusions.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556

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ISSN (O): 2687-5365; ISSN (P): 2753-6556