Original Article

# Role of Tranexamic Acid in Control of Intraoperative Blood Loss in Women Undergoing Elective Cesarean Section

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## Abstract

Objectives: To compare the mean intraoperative blood loss in pregnant mothers undergoing elective cesarean section after prophylactic tranexamic acid versus 5% glucose (placebo).

Methodology: This double blind, randomized controlled trial study was conducted in department of Obstetrics and gynaecology, Combined Military Hospital Multan from November 2023 to April 2024. Sixty-eight pregnant women aged 20-45 years, at 37-40 weeks of gestation and scheduled for cesarean delivery under spinal anesthesia were consecutively enrolled in the study. Participants were equally randomized to receive either 1g intravenous tranexamic acid or 5% dextrose placebo fifteen minutes before surgery. Intraoperative bleeding was measured using the weight difference of surgical gauze / towels and suction volume. Data were analyzed using SPSS version 23. Mean ± SD for quantitative data and frequency and percentages for categorical data are reported. The independent sample t-test is applied for blood loss comparison between the groups. P-value <0.05 is taken significant.

Results: The maternal age was 32.4±5.1 years and mean gestational age was 37.8±1.3 weeks. The groups were comparable in baseline characteristics except for a higher median number of previous cesareans in placebo group (2 versus 1, p = 0.014). Mean loss of blood was substantially less in tranexamic acid group (501.5±143.8 ml) compared to placebo (813.2± 264.9 ml; p < 0.001). This difference remained after stratification, though not statistically significant among women with last vaginal delivery (p=0.068) or no cesarean section ever (p=0.078).

Conclusion: Prophylactic administration of tranexamic acid reduced intraoperative blood loss significantly during cesarean deliveries.

Key Words: Cesarean section, Tranexamic acid, Blood loss.

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## Introduction

Nearly half of all pregnancy-related deaths are caused by obstetrical bleeding, a potentially lethal clinical manifestation of either normal vaginal delivery or caesarean section.[1] Although obstetrical haemorrhage detection and treatment have advanced significantly in recent years, postpartum haemorrhage (PPH) mortality rates are still very high in some regions.[2] Reducing excessive bleeding during caesarean sections and vaginal deliveries is crucial in order to lower the incidence of serious consequences and obstetrical hemorrhage-related deaths.[3] Even 200 mL of blood loss can be catastrophic for a woman with severe anaemia or a heart disease, but 1000 mL seems to be common for a healthy woman undergoing a caesarean section.[4]

By preventing plasminogen from activating plasmin, the antifibrinolytic drug tranexamic acid (TXA) may enforce a coagulation cascade.[5] It has a proven evidence of reliability and efficacy in reducing bleeding and attempting to reduce the need for transfusions during a variety of scheduled surgical procedures.[6] Recent research has demonstrated that TXA can lessen bleeding in gynaecological conditions such as

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myomectomy, hysterectomy, and menorrhagia.[7] TXA administration after caesarean sections has been the subject of numerous studies, all of which have found it to be beneficial.[8]

Gulzar J et al examined 60 women who were admitted for elective cesarean sections and ranged in age from 20 to 40. TXA (group A) and a placebo (group B) were the two equal groups into which the patients were split. The authors found that group A (20%) had a lower percentage reduction in Hb levels (>10%) 24 hours after surgery than group B (50%), with a p-value of 0.015.[9] A randomized controlled experiment including 160 women who had elective caesarean sections was carried out by Shalaby MA et al. Comparing the placebo group to the TXA group, the estimated intraoperative blood loss was substantially larger (896.8 ± 519.6 versus 583.2 ± 379.6 ml, P <0.001). In comparison to the TXA group, the placebo group had lower postoperative haemoglobin and haematocrit (9.2 ± 1.6 and 27.4 ± 4.1 vs. 10.1 ± 1.2 and 30.1 ± 3.4, P <0.001 and 0.01, respectively), and larger change percentages (15.4 vs. 7.1%, P < 0.001).[10]

Assessing the usefulness of TXA in reducing bleeding with elective C-section is crucial. Uncertainty persists about the magnitude and clinical relevance of prophylactic benefit across different baseline risk populations and health-systems contexts, and guideline recommendations vary. In particularly, meta-analysis indicate large relative benefits in high-risk patients and in some low-resource settings, where a low cost, easy administered- intervention such as TXA could have outsized public-health impact. For these reasons, locally conducted, adequately powered trials remain important: they test effectiveness in populations with different baseline bleeding risks, operative practices, and reduce constraints, and they provide data that can be pulled into meta-analyses to improve precision and inform guidelines development. Our randomized trial therefore addresses a clinically significant question in our setting – whether a single prophylactic IV dose of TXA reduces mean intraoperative blood loss in elective cesarean deliveries – and contributes context-specific evidence that is directly applicable to local practice and to future evidence syntheses. We hypothesized that mean intraoperative blood loss will be lower between intravenous TXA group and to placebo (5% dextrose) in women undergoing elective cesarean deliveries.

## Methodology

This double blind, randomized, controlled trial was performed at Combined Military Hospital Multan in the obstetrics and gynaecology department over a period of 6-months from 1st November 2023 to 30th April 2024. The study was approved from institutional ethics review committee (ERC # 148/2023, dated: 02-10-2023) and registered at clinicaltrials.gov (NCT07013812). A total of 68 women aged 20–45 years, at 37-40 weeks of gestation (on LMP) and planned to undergo c-section under spinal anesthesia were consecutively enrolled in the study. The excluded participants were women having history of allergy to TXA, any past thromboembolic events, and those with placental abnormalities (on antenatal ultrasound). Women history of gestational diabetes and bleeding disorder on medical record were excluded. As per hospital protocol for preoperative preparation, all patients had complete blood count analysis, fasting blood sugar done and coagulation status assessed through prothrombin time and INR. Women with high fasting blood glucose, low platelet count and coagulation disorder were also excluded.

Detailed history was taken, and examination was conducted. Participants characteristics like age, parity, last mode of delivery, any previous cesarean section and previous number of C-section was recorded. Using sequentially numbered, sealed, opaque envelopes, the patients were randomly divided to intravenous tranexamic acid or 5% dextrose (placebo) groups. Study medications were infused fifteen minutes before the surgery over a period of five minutes. The infusions were prepared by the pharmacy department in identical containers and ready to use form and labelled according to randomization sequence. Women in tranexamic acid group were administered 1 gram (10 cc) of TXA diluted in 20 cc of 5% glucose while patients in the placebo group were given 30 cc of 5% glucose.

All cesarean sections were performed under spinal anesthesia by obstetrician having experience of five 5 or more years as per uniform hospital protocol. Duration of surgery was recorded by the in-charge nurse. Estimated intraoperative blood loss was calculated from change in weight of dressings/towels plus the volume in suction jar. The net weight increase of dressings/towels (Wet – Dry) was assumed to represent blood loss and convert to volume using the widely used convention 1g = 1 milliliter. This approximation is based on the density of whole blood being very close to 1g/ml. For suctioned fluids we measured the total fluid volume and subtracted the known volume of irrigation fluids and amniotic fluid (when applicable), with the remainder recorded as blood loss. All the weights were measured on a calibrated

digital scale accurate to 1g.A minimum sample size of 68 women (34 in each group) was calculated through OpenEpi online calculator through formula for mean difference using mean blood loss in tranexamic group as 583.23 ± 379.62 ml and 896.81 ± 519.6 ml in placebo group,[10] with a power of 80% and confidence level of 95%.

The data was analysed through SPSS version 23. Normally distributed quantitative data is presented as mean ± SD (median and IQR if not normally distributed). Frequency and percentages are presented for categorical data. Independent sample t-test (Mann-Whitney U test for non-normal data) is applied for comparing numerical data between the study groups and chi-square test for categorical comparisons. For all the comparisons p-value of < 0.05 was taken as significant.

## Results

The mean age of the women was 32.4 ± 5.1 years with mean gestational age of 37.8 ± 0.8 weeks. The parity ranged from one to eight with median (IQR) of 2 (1). In 53(77.9%) of the women previous delivery was through cesarean section. History of at least one previous c-section was present in 54(79.4%) of cases. The number of past c-sections ranged from none to five with median (IQR) of 2 (1). Age, gestational age, parity, previous mode of delivery and previous cesarean section ever were comparable between the TXA and placebo groups. However, median number of previous cesarean section were high in placebo group in comparison to tranexamic acid group 2(2) vs. 1(2), p-value 0.014. Table I.

The mean duration of cesarean section was 41.9 ± 7.7 minutes, and this was comparable in both the groups. The mean bleeding during cesarean section was 657.4 ± 263.5 ml. The mean volume of blooding was significantly lower in TXA group compared to placebo group (501.5 ± 143.8 vs. 813.2 ± 264.9 ml). Nine cases (13.2%) of postpartum hemorrhage (≥1000 ml blood loss) were observed all in placebo group (p-value = 0.002) Table II. After stratification on demographic characteristics the mean blood loss remained less in TXA in contrast to placebo group. However, the discrepancy was not statistically significant in women who had previous normal delivery (p-value 0.068) and in women who never had previous cesarean section (p-value 0.078). Table III

**Table I: Characteristics of women undergoing elective cesarean section. (N=68)**

| Characteristics | All (N=68) | Tranexamic Acid (n=34) | Placebo (n=34) | p-value* |
|---|---|---|---|---|
| Age (years) | 32.4 ± 5.1 | 33.1 ± 5.1 | 31.7 ± 5.1 | 0.255 |
| Gestational Age (weeks) | 37.8 ± 0.8 | 37.7 ± 0.8 | 37.8 ± 0.8 | 0.540 |
| Parity | 2 (1) | 2 (2) | 3 (1) | 0.401 |
| Previous Mode of delivery | | | | 0.380 |
| SVD | 15 (22.1) | 9 (60) | 6 (40) | |
| C-section | 53 (77.9) | 25 (47.2) | 28 (52.8) | |
| Previous C-section – Yes | 54 (79.4) | 25 (46.3) | 29 (53.7) | 0.230 |
| - No | 14 (20.6) | 9 (64.3) | 5 (35.7) | |

**Table II: Intraoperative of women undergoing elective cesarean section. (N=68)**

| Characteristics | All (N=68) | Tranexamic Acid (n=34) | Placebo (n=34) | p-value* |
|---|---|---|---|---|
| Duration of Surgery (min) | 41.9 ± 7.7 | 40.7 ± 7.0 | 43.1 ± 8.4 | 0.212 |
| Intraoperative blood loss (ml) | 657.4 ± 263.5 | 501.5 ± 143.8 | 813.2 ± 264.9 | < 0.001 |
| Postpartum hemorrhage (Yes) | 9 (13.2) | 0 (00) | 9 (100) | 0.002 |

* Independent sample t-test for means comparison, Fisher's exact test for categorical comparison

**Table III: Effect of demographic features on intraoperative blood loss. (N=68)**

| Characteristics | | Tranexamic acid (n=34) | Placebo (n=34) | p-value* |
|---|---|---|---|---|
| Age (years) | ≤ 30-year | 459.1 ± 113.6 | 781.3 ± 279.8 | < 0.001 |
| | > 30-year | 521.7 ± 154.4 | 841.7 ± 255.7 | < 0.001 |
| Parity | ≤ 2 | 507.5 ± 122.8 | 831.3 ± 278.6 | < 0.001 |
| | > 2 | 492.8 ± 174.2 | 797.2 ± 259.2 | < 0.001 |
| Previous mode of delivery | SVD | 594.4 ± 142.4 | 800.0 ± 258.8 | 0.068 |
| | C-section | 468.0 ± 131.4 | 816.1 ± 270.8 | < 0.001 |
| Previous C-section | Yes | 472.0 ± 129.2 | 813.8 ± 266.2 | < 0.001 |
| | No | 583.3 ± 158.1 | 810.0 ± 288.1 | 0.078 |
| Number of C-sections | 1 | 528.8 ± 132.8 | 743.7 ± 214.4 | < 0.001 |
| | ≥ 2 | 412.5 ± 150.6 | 875.0 ± 295.2 | < 0.001 |

*Independent sample t-test

## Discussion

Postpartum haemorrhage (defined as >1000 ml of blood loss after caesarean birth with a haematocrit fall more than 10%) is one of the most frequent and early consequences following caesarean delivery. In underdeveloped countries, it is the primary reason of maternal deaths. Additionally, it is the primary cause of almost 25% of all maternal fatalities globally.[11] Our study's findings unequivocally showed that preoperative TXA can reduce the average intraoperative blood loss during caesarean deliveries (CD). Strong uterine muscle contractions, release of clotting factors, enhanced function of platelets and increase in fibrinolysis (which lasts for 6–10 hours following birth) are all linked to placental separation during delivery. These facts indicate that TXA's fibrinolytic action can minimize blood loss following delivery, regardless of the method.[12]

The TXA group in our study demonstrated a much lower mean loss of blood volume than the placebo group. TXA has been shown in earlier research to reduce blood loss related to caesarean procedures. One gram of TXA reduced bleeding in full-term patients who had elective c-sections from 700.3 ± 143.9 cc in controls to 459.4 ± 75.4 mL, in 2015, according to an RCT conducted by Maged and colleagues. Only 6 participants experienced bleeding more than 1000 cc. None of them belonged to the TXA group.[13]

Two more investigations confirmed the decrease in blood loss.[14,15] TXA dramatically reduced intraoperative hemorrhage from 896.8 ± 519.6 in those who did not get the medication to 583.2 ± 379.6 in patients who did, according to Shalaby MA et al.[10] In a large multicentre, double-blind RCT, 4431 pregnant patients who had cesarean sections were randomly assigned to get either a placebo or 1 g of TXA. The authors found that 26.7% and 31.6% of TXA and placebo groups, respectively, experienced postpartum haemorrhage (P = 0.003). The distribution of various risk variables may have contributed to the greater PPH rate than the typically stated rates. They concluded that TXA reduced the rate of packed cells transfusion and the frequency of postpartum haemorrhage by day two, but it had no effect on the secondary outcomes associated with haemorrhage, such as the use of extra uterotonic drugs or blood transfusion after delivery.[16]

According to the authors of an Iranian study, the mean intraoperative bleeding volume was 391.1 ± 67.4 cc in the TXA group and 523.8 ± 153.4 cc in the control group. This difference was 132.7 ml, which was substantially smaller. In the TXA group, the rates of bleeding exceeding 1000 ml and 500 ml, as well as the requirement for blood transfusions, were statistically significantly reduced. Six hours after the caesarean delivery, the mean haemoglobin level was statistically significantly less in the placebo group compared to TXA group (11.7 ± 0.5 against 11.3 ± 0.5).[17]

A total of 212 women were randomly divided to one of two groups (106 each in tranexamic acid or placebo) in the study by Neumann BG et al. The TXA group demonstrated an average bleeding of 400.9 mL, whereas the placebo group experienced a mean blood loss of 597.9 mL (P<0.001).[18] These results are consistent with what we have observed. A total of 244 women were randomized to either the trial group or the control group in another Nigerian investigation. Whereas controls were given 10 millilitres of normal saline intravenously, those in the study group got lg (10 millilitres) of TXA. The study group experienced mean intraoperative bleeding 414.0 ml, while the control group experienced an average of 773.8 ml (p < 0.01).[19]

Conversely, Ogunkua OT et al examined 110 women who were randomly divided to one of two groups: tranexamic acid and a placebo (1:1). The tranexamic acid group experienced an average calculated bleeding of 2274±469 mL, while the placebo group experienced a mean bleeding of 2407±388 mL (P>.05).[20] The two groups did not differ much, according to their findings. The probable reason of these findings can be; first, the amount of blood loss reported in their study (mean >2200 mL) was significantly greater than that seen in our population, which may indicate that their study included complicated or high-risk caesarean sections, such as those with placenta previa, accreta, or intraoperative haemorrhage, where TXA may not be as effective on its own. Second, the pharmacological efficacy of tranexamic acid may be impacted by variations in study design, such as variations in the timing and dosage of its administration. For instance, its ability to inhibit fibrinolysis may have been diminished if it had been administered later than uterotonic delivery or skin incision.

Our findings are comparable to those of many investigations. This decrease is probably due to tranexamic acid's antifibrinolytic effect, which prevents plasminogen activation and stabilises clot formation. Reducing blood loss is clinically significant because it can enhance maternal outcomes overall, lower postoperative morbidity, and lessen the need for blood

transfusions, especially in settings with limited resources.

One of our study's advantages was that we used a double-blind, randomized controlled trial (RCT), which reduced observer and selection bias and improved the study's internal validity. Methodological consistency was ensured by using objective blood loss estimation (gauze weight and suction volume) and administering a fixed dose (1g) of tranexamic acid at a predetermined time prior to surgery.

Limitations: The limitations of our study were that the statistical power and generalizability of the results to larger populations or higher-risk obstetric groups were restricted by the relatively small number of participants (n=68). External validity may be limited by the study's single tertiary care hospital setting, particularly in situations with distinct surgical procedures or patient demographics. The results might have been skewed if the placebo group had more prior caesarean procedures, which could have independently increased blood loss.

## Conclusion

We concluded that prophylactic use of TXA markedly decreased intraoperative bleeding during elective cesarean sections, supporting its effectiveness as a blood-conservation strategy. Given its ease of use, TXA may be considered as a routine adjunct in cesarean delivery protocols. To assess the efficacy of TXA on postoperative outcomes, such as delayed bleeding, transfusion requirement, and maternal morbidity across different obstetric risk profiles, larger, multicentre trials with extended follow-up are advised.

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