Section: OBGY



Original Research Article

STUDY OF INTRAVENOUS TRANEXAMIC ACID (TXA) GIVEN PROPHYLACTICALLY IN REDUCING BLOOD LOSS DURING CASAREAN SECTION

Sawrikar Chetan Chandrakant¹, Shelke Swapnil Bibhishan², Pawar Supriya Vishwambhar³

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Corresponding Author:

Dr. Sawrikar Chetan Chandrakant Assistant Professor, Department of OBGY, SRTR GMC, Ambajogai, Maharashtra, India.

Email:Chetan.sawrikar@gmail.com

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ABSTRACT

Background: Postpartum hemorrhage (PPH) is a leading cause of maternal morbidity and mortality worldwide, with caesarean section posing a higher risk of intraoperative and postoperative blood loss. Tranexamic Acid (TXA), an antifibrinolytic agent, has shown promise in reducing surgical blood loss across multiple disciplines. Aim: To evaluate the effectiveness and safety of prophylactic intravenous TXA in reducing blood loss during caesarean section. Materials and Methods: This prospective observational study was conducted at a tertiary care hospital over one year and included 120 antenatal women undergoing elective or emergency caesarean section. Patients were randomly assigned into two groups: TXA group (n=60), who received 1 g intravenous TXA diluted in 100 ml normal saline 15-20 minutes before skin incision, and a control group (n=60), who did not receive TXA. Both groups received standard uterotonic therapy following placental delivery. Intraoperative and postoperative blood loss were measured using suction volumes and gravimetric methods, while hemoglobin changes were recorded preoperatively and 24 hours postoperatively. Maternal haemodynamics, adverse effects, and neonatal outcomes (APGAR scores) were monitored. Statistical analysis included Welch's t-test, chi-square/Fisher's exact test, and 95% confidence intervals, with p<0.05 considered significant.

Results: Mean total blood loss was significantly lower in the TXA group compared to controls (381.5 ± 81.9 mL vs 475.8 ± 48.7 mL; p<0.0001). The mean fall in hemoglobin at 24 hours was also smaller in the TXA group (1.02 ± 0.33 g/dL vs 1.28 ± 0.33 g/dL; p<0.0001). No significant differences were noted in the incidence of PPH, requirement of additional oxytocics, or maternal haemodynamics. Neonatal outcomes, including APGAR scores at 1 and 5 minutes, were comparable between groups. No serious adverse events were reported.

Conclusion: Prophylactic intravenous TXA given prior to caesarean section effectively reduces blood loss and hemoglobin decline without compromising maternal safety or neonatal outcomes. Incorporating TXA as an adjunct to standard uterotonics may improve perioperative outcomes in caesarean deliveries.

Keywords: Tranexamic Acid. Caesarean Section. Postpartum Hemorrhage.

INTRODUCTION

Maternal mortality remains a pressing global health challenge. An estimated 500,000 women die

annually from pregnancy-related causes, with postpartum hemorrhage (PPH) being responsible for nearly one-quarter of these deaths. In India, maternal mortality rates are particularly concerning,

¹Assistant Professor, Department of OBGY, SRTR GMC, Ambajogai, Maharashtra, India. ²Assistant professor, Department of OBGY, SRTR GMC, Ambajogai, Maharashtra, India.

³Assistant Professor, Department of OBGY, SRTR GMC, Ambajogai, Maharashtra, India.

estimated at around 560 per 100,000 live births, with hemorrhage accounting for 35–56% of maternal deaths. The high prevalence of anemia among Indian women further exacerbates this risk.^[1]

One of the most common obstetric procedures is the caesarean section (C-section), accounting for nearly 25–30% of deliveries in many parts of the world. Although it is often a life-saving operation, it carries including substantial risks. infection. thromboembolic events, complications in future pregnancies, and most importantly, hemorrhage. Blood loss during C-section is usually greater than delivery, frequently necessitating transfusion of allogeneic blood products, which introduces the risk of transfusion-related reactions, transmission of blood-borne infections, and increased healthcare costs.[2]

Postpartum hemorrhage, defined as blood loss of more than 500 ml within 24 hours after delivery, is a leading cause of maternal morbidity and mortality. Approximately 1–2% of mothers with PPH die, often within 2–4 hours of onset. Therefore, strategies to reduce blood loss during and after caesarean section are critically important.^[3]

Tranexamic acid is a synthetic lysine analogue that inhibits fibrinolysis by competitively binding to plasminogen, thereby preventing its conversion to plasmin. This stabilizes the fibrin clot and reduces bleeding. TXA has been widely used in various surgical specialties such as cardiac surgery, orthopedic procedures, liver transplantation, and dental extractions, showing consistent efficacy in reducing perioperative blood loss and transfusion requirements. It is approximately ten times more potent than epsilon-aminocaproic acid. [4]

-Aim

To analyze the effectiveness and safety of intravenous Tranexamic Acid (TXA) given prophylactically prior to skin incision in reducing blood loss during caesarean section.

Objectives

- 1. To assess the reduction of intraoperative and postoperative blood loss in patients undergoing elective and emergency caesarean sections.
- 2. To evaluate the efficacy of Tranexamic Acid as an additional agent alongside uterotonics in minimizing hemorrhage.
- 3. To assess the safety profile of intravenous TXA with respect to maternal and neonatal outcomes.

MATERIALS AND METHODS

Source of Data

The study was conducted on antenatal patients admitted for elective or emergency caesarean section at the Department of Obstetrics and Gynecology, tertiary care hospital, India.

Study Design

A prospective observational study was undertaken to evaluate the role of TXA in reducing blood loss during C-sections.

Study Location

Department of Obstetrics and Gynecology, Conducted at tertiary medical college.

Study Duration

From January 2024 to December 2024.

Sample Size

A total of 120 patients undergoing caesarean section were included.

- Study Group (TXA group): 60 patients
- Control Group: 60 patients

Sample size was calculated using the formula:

With expected prevalence = 10%, precision = 0.0537, and confidence level = 95%, the required sample size was approximately 120.

Inclusion Criteria

- Antenatal women aged 19–34 years.
- Singleton pregnancies with gestational age 37– 42 weeks
- Undergoing elective or emergency caesarean section under spinal anesthesia.

Exclusion Criteria

- Placenta previa or placental abruption.
- Severe preeclampsia, gestational or chronic hypertension.
- Multiple pregnancy.
- Heart disease complicating pregnancy.
- Polyhydramnios or macrosomia.
- Known coagulation disorders.
- Severe medical or surgical comorbidities (renal, hepatic, or CNS disease).
- Allergy to tranexamic acid.

Procedure and Methodology

After obtaining written informed consent, patients were randomized into two groups using computer-generated tables.

Study Group: Received intravenous TXA (1 g diluted in 100 ml normal saline), administered 15–20 minutes before skin incision.

Control Group: Did not receive TXA.

All patients received routine uterotonic (Inj. Oxytocin 10 IU in 500 ml Ringer Lactate) after placental delivery.

Observations Recorded:

Clinical observations: Heart rate, respiratory rate, blood pressure monitored intraoperatively and 2 hours postoperatively.

Blood loss: Measured from placental delivery to end of surgery and up to 2 hours postpartum using gravimetric method (weighing sponges and pads) and suction bottle measurement.

Neonatal outcome: Apgar score at 1 and 5 minutes. **Laboratory investigations:** Complete blood count with platelets preoperatively and 24 hours postoperatively; renal and liver function tests; coagulation profile.

Side effects: Nausea, vomiting, headache, thromboembolic events.

Sample Processing

Used mops, pads, and suction collection measured before and after use on an electronic scale.

Blood loss calculated as: Amniotic fluid and preplacental delivery blood were excluded from calculations.

Statistical Methods

Data was recorded in Microsoft Excel and analyzed using SPSS version 24 and GraphPad Prism 5. Continuous variables: Expressed as mean ± SD; analyzed using independent/unpaired t-test. Paired t-test: Used for comparing pre- and postoperative hemoglobin levels. Categorical variables: Compared using Chi-square or Fisher's exact test. A

p-value ≤ 0.05 was considered statistically significant.

Data Collection

All data regarding patient demographics, intraoperative and postoperative observations, laboratory findings, blood loss measurements, and neonatal outcomes were collected prospectively during the study period. Confidentiality was maintained, and ethical approval was obtained prior to initiation.

RESULTS

Table 1: Effectiveness & safety of prophylactic IV TXA (overall)

Table 1. Effectiveness & safety of prophylactic IV TAA (overall)						
Outcome	TXA (n=60)	Control (n=60)	Effect size (95% CI)	Test (df)	p- value	
Total blood loss, mL (placenta→end + 0-2 h)	381.5 ± 81.9	475.8 ± 48.7	MD -94.3 mL (-118.8, -69.9)	Welch t=-7.67 (≈96.1)	< 0.0001	
Fall in Hb, g/dL (pre → 24 h)	1.023 ± 0.336	1.277 ± 0.331	MD -0.253 g/dL (-0.374, -0.133)	Welch t=-4.16 (≈118.0)	< 0.0001	
PPH within 2 h, n (%)	2 (3.3)	2 (3.3)	RR 1.00 (0.15, 6.87)	Fisher's exact	1.000	
Additional oxytocics used, n (%)	3 (5.0)	4 (6.7)	RR 0.75 (0.18, 3.21)	Fisher's exact	1.000	
APGAR 1-min (mean ± SD)	8.85 ± 0.36	8.80 ± 0.40	MD 0.05 (-0.09, 0.19)	Welch t=0.72 (≈116.5)	0.475	
APGAR 5-min = 10, n/N (%)	60/60 (100)	60/60 (100)	=	-	-	

Table 1 compares overall effectiveness and safety outcomes between women receiving prophylactic tranexamic acid (TXA) and controls. The mean total blood loss was significantly lower in the TXA group (381.5 \pm 81.9 mL) compared with controls (475.8 \pm 48.7 mL), with a mean difference (MD) of -94.3 mL (95% CI: -118.8 to -69.9; p<0.0001). Hemoglobin fall within 24 hours post-surgery was also significantly smaller in the TXA group (1.023 \pm 0.336 g/dL) than in controls (1.277 \pm 0.331 g/dL), with an MD of -0.253 g/dL (95% CI: -0.374 to

-0.133; p<0.0001). The incidence of postpartum hemorrhage (PPH) within 2 hours was identical in both groups (3.3%), yielding a relative risk (RR) of 1.00. Similarly, the need for additional oxytocics was comparable (5.0% vs 6.7%, RR 0.75; p=1.000). Neonatal outcomes were unaffected, with no difference in 1-minute APGAR scores (8.85 vs 8.80; p=0.475) and all infants achieving a score of 10 at 5 minutes. Overall, prophylactic TXA significantly reduced blood loss and hemoglobin drop without adverse effects on maternal or neonatal safety.

Table 2: Intra-operative and early post-operative blood loss

Outcome	TXA (n=60)	Control (n=60)	Effect size (95% CI)	Test (df)	p-value
Intra-op blood loss, mL (placenta → end of CS)	333.7 ± 81.6	393.7 ± 48.9	MD -60.0 mL (-84.4, -35.6)	Welch t=-4.89 (≈96.5)	<0.0001
0-2 h post-op blood loss, mL	47.8 ± 9.76	82.2 ± 14.0	MD -34.33 mL (-38.71, -29.96)	Welch t=-15.56 (≈105.2)	<0.0001
Total blood loss, mL	381.5 ± 81.9	475.8 ± 48.7	MD -94.3 mL (-118.8, -69.9)	Welch t=-7.67 (≈96.1)	<0.0001

Table 2 details intra- and early post-operative blood loss. Intraoperative loss from placental delivery to closure was significantly reduced in the TXA group (333.7 \pm 81.6 mL) versus controls (393.7 \pm 48.9 mL), with an MD of -60.0 mL (95% CI: -84.4 to -35.6; p<0.0001). Postoperative blood loss within 2 hours was also markedly lower among TXA recipients (47.8 \pm 9.76 mL) compared to controls (82.2 \pm 14.0 mL), MD -34.3 mL (95% CI: -38.7 to

-30.0; p<0.0001). Consequently, total measured blood loss was reduced by nearly 100 mL in the TXA group (381.5 \pm 81.9 mL) relative to controls (475.8 \pm 48.7 mL), MD -94.3 mL (95% CI: -118.8 to -69.9; p<0.0001). These findings confirm that TXA significantly reduces both intra- and postoperative hemorrhage in caesarean section patients.

Table 3: TXA as an adjunct to uterotonics (clinical efficacy signals)

O	utcome (all received oxytocin)	TXA (n=60)	Control (n=60)	Effect size (95% CI)	Test	p- value
Ne	eed for additional oxytocics, n (%)	3 (5.0)	4 (6.7)	RR 0.75 (0.18, 3.21) • RD -1.67% (-10.05, 6.71)	Fisher's exact	1.000

PPH within 2 h, n (%)	2 (3.3)	2 (3.3)	RR 1.00 (0.15, 6.87) • RD 0.00% (-6.42, 6.42)	Fisher's exact	1.000
Total blood loss, mL (proxy of uterotonic adequacy)	381.5 ± 81.9	475.8 ± 48.7	MD -94.3 mL (-118.8, -69.9)	Welch t	< 0.0001

Table 3 evaluates TXA as an adjunct to routine oxytocin. Despite universal oxytocin use, TXA recipients demonstrated markedly lower total blood loss (381.5 \pm 81.9 mL vs 475.8 \pm 48.7 mL; p<0.0001). However, no differences emerged in clinical endpoints of uterotonic adequacy: the need for additional oxytocics was rare and similar

between groups (5.0% vs 6.7%, RR 0.75; p=1.000), and the incidence of PPH within 2 hours was identical (3.3% in both groups). This indicates that while TXA did not reduce the proportion requiring rescue uterotonics or PPH events, it significantly reduced measured blood loss, highlighting its complementary efficacy alongside oxytocin.

Table 4: Safety profile (maternal haemodynamics & neonatal outcomes)

Safety outcome	TXA (n=60)	Control (n=60)	Effect size (95% CI)	Test (df)	p- value
SBP pre-delivery, mmHg (mean ± SD)	120.10 ± 6.86	120.53 ± 5.58	MD - 0.43 (-2.70, 1.83)	Welch t=-0.38 (≈113.3)	0.705
SBP post-delivery, mmHg	118.60 ± 5.93	118.77 ± 5.46	MD - 0.17 (-2.23, 1.89)	Welch t=-0.16 (≈117.2)	0.873
DBP pre-delivery, mmHg	77.33 ± 5.10	77.27 ± 5.08	MD 0.07 (-1.77, 1.91)	Welch t=0.07 (≈118.0)	0.943
DBP post-delivery, mmHg	79.53 ± 4.55	79.47 ± 4.42	MD 0.07 (-1.55, 1.69)	Welch t=0.08 (≈117.9)	0.935
APGAR 1-min (mean ± SD)	8.85 ± 0.36	8.80 ± 0.40	MD 0.05 (-0.09, 0.19)	Welch t=0.72 (≈116.5)	0.475
APGAR 5-min = 10, n/N (%)	60/60 (100)	60/60 (100)	-	-	-

Table 4 summarizes safety outcomes. Maternal haemodynamics showed no significant differences between groups. Pre-delivery systolic blood pressure (SBP) was 120.1 ± 6.9 mmHg in the TXA group vs 120.5 ± 5.6 mmHg in controls (p=0.705), and post-delivery SBP was similarly comparable (118.6 vs 118.8 mmHg; p=0.873). Diastolic blood pressures were also nearly identical before and after delivery. Neonatal outcomes revealed no adverse effects of TXA: mean APGAR at 1 minute was 8.85 in the TXA group and 8.80 in controls (p=0.475), and all neonates in both groups had APGAR 10 at 5 minutes.

DISCUSSION

Cohort shows a clear reduction in measured blood loss with prophylactic TXA (mean difference \approx -94 mL) and a smaller postoperative hemoglobin fall (MD \approx -0.25 g/dL), with no signal of haemodynamic or neonatal harm. This magnitude and direction are consistent with large earlier RCTs in elective caesarean section (CS). Sentilhes L et al.(2021),^[5] (n=660) reported lower estimated blood loss with 1 g IV TXA before CS (≈ 601 mL vs 500 mL) and fewer women with >1000 mL blood loss or needing extra uterotonics, without maternal-neonatal safety concerns. observed Hb preservation mirrors their finding that TXA reduces post-CS anaemia severity. The intra-operative versus early postoperative pattern in Table 2-moderate intra-op reduction (≈ -60 mL) and marked 0–2 h reduction (\approx -34 mL)-also aligns with prior small RCTs that found TXA most strongly affects early postpartum losses. Chaiyakarn S et al.(2023),^[6] (n=90) showed significantly lower 0-2 h blood loss and higher 24-h Hb with TXA, and Jafarbegloo E et al.(2021),^[7] (n=174) found significant reductions in early postoperative and total blood loss, with minimal intra-op difference. Together, these studies support finding that TXA's antifibrinolytic effect is particularly relevant once the placenta is delivered and uterine wound surfaces are fibrinolytically active.

Meta-analyses have repeatedly confirmed reductions of roughly this order. Stortroen NE et al.(2020), pooled 11 RCTs (\approx 2,500 women) and reported mean total blood-loss decreases around 140 mL, plus smaller Hb/Hct declines and fewer transfusions-closely echoing -94 mL mean difference and smaller Hb fall.

Against these largely positive trials, the more recent, methodologically robust TRAAP-2 trial (NEJM 2021; n \approx 4,100) found that prophylactic TXA at CS reduced its primary outcome-calculated EBL > 1000 mL or red-cell transfusion by day 2-(adjusted RR \approx 0.84), yet most clinically oriented secondaries (transfusions, invasive procedures) were unchanged; the absolute mean EBL difference was \approx 100 mL-almost identical to -94 mL. Table 3 shows no group differences in "additional oxytocics" or early PPH events (both rare), which likely reflects limited power at n=60/arm rather than a true absence of effect on infrequent endpoints.

The very large U.S. multicentre MFMU trial (Assis ID et al.(2023), ^[9] NEJM 2023; n≈11,000) further nuanced expectations: TXA (given after cord clamping) did not reduce the composite of maternal death or transfusion, though there were small improvements in some bleeding-related interventions and Hb change (-0.1 g/dL difference). These data suggest that while TXA reliably trims measured blood loss (as in Tables 1–2), translating

that into fewer transfusions or PPH diagnoses is harder-especially in mixed-risk populations and when dosing is after cord clamp.

Two points from contemporary syntheses help reconcile results with these big trials. First, timing matters: a 2023 systematic review (50 RCTs) found stronger benefits when TXA is given before skin incision versus after cord clamping-exactly how TXA was administered in study (15–20 min preincision). Second, baseline risk modifies effect size: the same review and a 2024 high-risk RCT reported larger absolute reductions among women at elevated PPH risk. Both observations align with sizable reductions in total and early postoperative loss despite unchanged "rescue" outcomes.

Safety in Table 4 (stable SBP/DBP, identical APGARs) is concordant with major trials: TRAAP-2 and the MFMU study saw no increase in thromboembolic events, though nausea/vomiting can be more frequent and Omawumi D et al.(2023),^[10] noted a small uptick in infections without differences in serious adverse events overall. haemodynamic and neonatal neutrality therefore fits the prevailing safety profile.

CONCLUSION

The present study demonstrated that prophylactic administration of intravenous Tranexamic Acid (TXA) prior to skin incision in caesarean section significantly reduced intraoperative and early postoperative blood loss, as well as the postoperative decline in hemoglobin levels, compared to controls. Importantly, no adverse maternal haemodynamic changes or negative neonatal outcomes were observed, and the need for additional uterotonics or incidence of postpartum hemorrhage remained comparable between groups. These findings indicate that TXA is a safe, effective, and well-tolerated adjunct to standard uterotonics for minimizing blood loss during caesarean delivery. Its routine use may contribute to reducing maternal morbidity, especially in resource-limited settings where blood transfusion services are constrained.

Limitations of the Study

- 1. The study was conducted at a single tertiary care center, which may limit the generalizability of the findings to other populations and healthcare settings.
- 2. The sample size of 120, although adequate for primary outcomes, may not have been sufficient to detect differences in rare adverse events such as thromboembolic complications.
- 3. The study included a mixed cohort of elective and emergency caesarean sections, but

- subgroup analyses could not be performed due to lack of stratified data.
- 4. Blood loss estimation was based on gravimetric and suction measurements, which, while practical, may not be as precise as advanced techniques such as hemoglobinometry or photometric assessment.
- 5. The follow-up period was limited to 24 hours postoperatively; therefore, delayed complications, including late postpartum hemorrhage or thromboembolic events, were not assessed.

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