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Original Research Article

Prophylactic tranexamic acid for reducing blood loss during caesarean section: a randomised, double-blind, placebo-controlled trial

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ABSTRACT

Background: Tranexamic acid (TXA) is effective in treating established postpartum haemorrhage, but the clinical value of prophylactic administration at caesarean section remains uncertain. We assessed whether intravenous TXA given before skin incision reduced measured blood loss.

Methods: In this single-centre, randomised, double-blind, placebo-controlled trial, 76 women with singleton term pregnancies undergoing caesarean section were allocated to 1 g intravenous TXA (n=38) or saline placebo (n=38). Study infusions were administered over 10 minutes during preoperative preparation; both groups received routine oxytocin prophylaxis. The primary outcome was blood loss measured from placental delivery through the first 2 postoperative hours.

Results: Mean measured blood loss was 521.79±90.94 ml with TXA and 748.58±123.67 ml with placebo (mean difference -226.79 ml, 95% CI -276.41 to -177.17; p<0.001). The mean haemoglobin decline at 24 hours was 0.91±0.40 and 1.97±0.55 g/dl, respectively (mean difference -1.06 g/dl, 95% CI -1.28 to -0.84; p<0.001). Additional intervention for uterine atony was required in 2/38 versus 10/38 women (p=0.012). Atonic postpartum haemorrhage, defined for this study as atony with measured blood loss ≥1000 ml, occurred in 0 versus 3 women (p=0.240). No participant received a blood transfusion, and no thromboembolic events were recorded.

Conclusions: In this small trial, pre-incision TXA reduced measured blood loss over the prespecified observation period and was associated with smaller postoperative haemoglobin declines. Effects on severe haemorrhage, transfusion, and uncommon adverse events could not be established.

Keywords: Tranexamic acid, Caesarean section, Postpartum haemorrhage, Blood loss, Haemoglobin, Uterotonics

INTRODUCTION

Haemorrhage remains an important concern during caesarean delivery because bleeding may arise from placental separation, the uterine incision and other operative tissues. Oxytocin is routinely used to prevent uterine atony, but it does not address the fibrinolytic component of bleeding. This provides a rationale for evaluating an antifibrinolytic agent alongside standard uterotonic prophylaxis.[1]

Tranexamic acid (TXA) limits fibrin breakdown by inhibiting the binding of plasminogen to fibrin.[2] In women who already have postpartum haemorrhage, the WOMAN trial demonstrated a reduction in death due to bleeding when TXA was administered early, particularly within 3 hours of birth.[3] Those treatment findings should not be interpreted as proof that routinely giving TXA before caesarean delivery improves major maternal outcomes.

Smaller trials of prophylactic TXA at caesarean delivery have generally reported less measured blood loss, with

some also reporting reduced use of additional uterotonics.[4,5] The larger TRAAP2 trial found a reduction in its primary composite blood-loss outcome, but not in several haemorrhage-related secondary clinical outcomes.[6] A subsequent trial involving 11,000 women found no statistically significant reduction in maternal death or transfusion.[7] Similarly, the 2024 Cochrane review reported little or no difference in important clinical outcomes, including transfusion.[8] The 2025 WHO consolidated guidelines do not recommend TXA for prevention of postpartum haemorrhage at caesarean birth.[1]

The available studies differ in when TXA was administered and how blood loss was assessed. In the 11,000-participant trial, TXA was administered after umbilical-cord clamping.[7] In our trial, infusion began before skin incision, and blood was measured using suction and weighed materials from placental delivery until 2 hours after surgery. These differences are relevant when interpreting any observed reduction in blood loss.

We therefore compared pre-incision intravenous TXA with saline placebo in women undergoing caesarean delivery, with measured blood loss during the defined observation period as the primary outcome.

We also examined postoperative haemoglobin and haematocrit changes, additional intervention, transfusion, and recorded maternal complications.

METHODS

Study design and setting

This prospective, parallel-group, randomised, double-blind, placebo-controlled trial recruited women in the Department of Obstetrics and Gynaecology, Dr. Radhakrishnan Government Medical College and Hospital, Hamirpur, Himachal Pradesh, India, between August 2025 and February 2026.

Eligible women undergoing caesarean section were recruited consecutively. The trial was prospectively registered with the Clinical Trials Registry-India on 11 August 2025 (CTRI/2025/08/092779).

Participants

Women aged 18-40 years with a singleton term pregnancy between 37 and 42 completed weeks who provided written informed consent were eligible.

Exclusion criteria were multiple pregnancy, pre-eclampsia, macrosomia, polyhydramnios, fibroid complicating pregnancy, placenta previa, placental abruption, placenta accreta spectrum, a history of bleeding disorders, allergy to TXA, systemic cardiac, hepatic or renal disease, prolonged or obstructed labour, and parity greater than four.

Sample size

The sample size was calculated for a comparison of two independent means. An assumed standard deviation of 146.67 ml was used, corresponding to the control-group intraoperative blood-loss standard deviation reported by Sinha et al.[9] The prespecified difference of interest was 100 ml, informed by the approximately 101 ml difference observed by Gungorduk et al.[4] At a two-sided α of 0.05 and 80% power, the estimated requirement was 33.75 women per group, rounded to 34. Allowing 10% attrition increased the planned recruitment to 38 per group (76 overall).

Randomisation and allocation concealment

Participants were assigned in a 1:1 ratio using a computer-generated randomisation sequence prepared before study commencement and maintained in a Microsoft Excel master list. Sequential study codes (TXA-001 to TXA-076) were assigned in order of enrolment. Each code corresponded to a treatment assignment in the pre-generated list, which determined whether the coded preparation contained TXA or placebo.

Allocation was concealed using a digital randomisation master list accessible only to a postgraduate resident who was not involved in patient care, surgery or data collection. This individual prepared identical 10-ml syringes containing either 1 g TXA at a concentration of 100 mg/ml or 10 ml normal saline. Syringes were labelled only with the study code.

Blinding and intervention

Participants, clinical staff, surgeons and data collectors remained blinded to treatment allocation. Unblinding occurred after completion of data collection.

The intervention group received 1 g (10 ml) of tranexamic acid injection IP (100 mg/ml; Marc Laboratories Ltd., unit III, Baddi, Himachal Pradesh, India), and the placebo group received 10 ml of 0.9% sodium chloride. Each preparation was added to 100 ml of 0.9% sodium chloride, giving a total infusion volume of 110 ml, and infused intravenously over 10 minutes during preoperative preparation. Infusion was initiated approximately 20 minutes before skin incision, with this interval estimated from the routine preparation and transfer workflow. Sodium chloride injection IP (IV Tech Healthcare LLP, Aligarh, Uttar Pradesh, India) was used for dilution and placebo preparation.

All caesarean sections were performed under spinal anaesthesia. Routine uterotonic prophylaxis comprised 10 IU oxytocin administered intramuscularly after delivery of the baby and a further 10 IU added to intravenous fluids. Additional intervention was defined as any uterotonic or haemostatic treatment beyond this regimen.

Outcomes and blood-loss measurement

The primary outcome was total measured blood loss from placental delivery until 2 hours postoperatively. This comprised blood loss from placental delivery to the end of surgery and blood loss during the first 2 postoperative hours.

Intraoperative assessment combined suction volume collected after placental delivery with gravimetric measurement of blood-soaked surgical materials. Two separate suction apparatuses were used: the first collected amniotic fluid before placental delivery, and the second was used after placental delivery to collect blood for measurement. Only the volume collected in the second apparatus contributed to the measured blood-loss outcome. Postoperative blood loss was assessed by weighing perineal pads and other blood-soaked materials.

The pre-use dry weight was subtracted from the post-use weight, with a difference of 1 g considered equivalent to 1 ml of blood. Total measured blood loss was the sum of the suction volume and gravimetrically estimated blood loss. Blood loss before placental delivery was not included.

Secondary outcomes were changes in haemoglobin and haematocrit at 24 hours, transfusion requirement, additional uterotonic or haemostatic intervention, adverse effects (including nausea, vomiting and thromboembolic events) and postoperative complications (including febrile morbidity, wound infection and postpartum haemorrhage).

Haemoglobin and haematocrit declines were calculated as the preoperative value minus the 24-hour postoperative value.

For this study, uterine atony requiring intervention was recorded when inadequate uterine contraction or increased intraoperative bleeding prompted additional uterotonic treatment. Atonic PPH was defined as uterine atony associated with measured blood loss of at least 1000 ml. Women treated for atony whose blood loss remained below this threshold were recorded as requiring additional intervention without fulfilling the study definition of PPH.

Haematological assessment and follow-up

Complete blood counts were obtained before delivery and at 24 hours postoperatively. Pulse rate, respiratory rate and blood pressure were monitored immediately after placental delivery and at 1 and 2 hours postoperatively.

During hospitalisation, participants were monitored for febrile morbidity, wound infection, postpartum haemorrhage and symptoms suggestive of deep-vein thrombosis, pulmonary embolism or visual disturbance. Structured telephone follow-up was conducted on postoperative days 14 and 42. Questions addressed new leg pain, swelling or redness; chest pain or breathlessness; visual symptoms; hospital readmission; and emergency consultation. Positive responses were to prompt diagnostic evaluation.

Birth weight, Apgar scores and neonatal intensive care unit admission were recorded as ancillary descriptive observations.

Statistical analysis

Data were analysed using international business machines (IBM) statistical package for the social sciences (SPSS) Statistics, version 22. Continuous variables were reported as means with standard deviations and categorical variables as counts and percentages. Independent-samples student's t-tests were used for comparisons of continuous outcomes. Categorical comparisons used Pearson's chi-square test or Fisher's exact test when appropriate; the additional-intervention comparison used Pearson's chi-square test without continuity correction, and the atonic-PPH comparison used Fisher's exact test.

Treatment effects are presented as mean differences or risk ratios with 95% confidence intervals. Mean differences were defined as TXA minus placebo; negative differences in blood loss or haematological decline therefore favour TXA. Baseline characteristics are presented descriptively without hypothesis testing.

All 76 randomised participants received their assigned intervention and were analysed in their allocated groups. A two-sided p value below 0.05 was considered statistically significant. Secondary outcome findings were interpreted cautiously because several outcomes were assessed.

Ethical considerations

The study was approved by the institutional ethics committee of Dr Radhakrishnan Government Medical College and Hospital, Hamirpur (IEC/2/2025; approval date: 2 August 2025). Written informed consent was obtained from all participants before enrolment.

RESULTS

Participant flow and baseline characteristics

Among 102 women assessed for eligibility, 18 did not meet the inclusion criteria and eight declined participation. The remaining 76 were randomised equally to TXA and placebo. All 76 received the allocated infusion and were included in the analysis; none were lost to follow-up (Figure 1).

Baseline characteristics are summarised in Table 1. The mean ages were 26.63 years in the TXA group and 26.89 years in the placebo group. Nulliparous women accounted for 25/38 and 28/38 participants, respectively, and previous caesarean delivery was recorded in nine and eight women. Acute foetal distress was the most frequent

recorded indication for caesarean section (11/38 with TXA and 10/38 with placebo). Other indications included malpresentation, failed induction, previous caesarean delivery and meconium-stained liquor with an unfavourable Bishop score.

Primary outcome

Mean blood loss during the prespecified interval-from placental delivery until 2 hours postoperatively-was 521.79±90.94 ml in the TXA group and 748.58±123.67 ml in the placebo group. The mean between-group difference (TXA minus placebo) was -226.79 ml (95% CI-276.41 to -177.17; p<0.001) (Table 2). Blood lost before placental delivery was not part of this measurement.

Haematological outcomes

The mean decline in haemoglobin from the preoperative value to 24 hours postoperatively was 0.91±0.40 g/dl with TXA and 1.97±0.55 g/dl with placebo (mean difference -1.06 g/dl, 95% CI -1.28 to -0.84; p<0.001). Over the same interval, haematocrit declined by 2.94±1.37 and 5.94±2.03 percentage points, respectively (p<0.001). The corresponding preoperative and postoperative laboratory measurements are shown in Table 2.

Additional intervention and atonic postpartum haemorrhage

Additional treatment for uterine atony was administered to 2/38 women (5.3%) in the TXA group and 10/38 (26.3%) in the placebo group (risk ratio 0.20, 95% CI 0.05-0.85; Pearson's chi-square p=0.012). This outcome reflected a clinical decision to treat uterine atony rather than a direct measurement of uterine contractility. Of these women, both in the TXA group and seven in the placebo group had measured blood loss below 1000 ml. The remaining three placebo recipients met the study definition of atonic postpartum haemorrhage; no TXA recipient met that definition (Fisher's exact p=0.240). Additional treatment included oxytocin, carboprost or both. No woman in either group required blood transfusion (Table 3).

Maternal and neonatal observations

No thromboembolic or visual events were documented during admission or symptom-based follow-up through postoperative day 42. No postoperative or follow-up complications were recorded in either group. The absence of observed events in this sample does not establish safety for rare outcomes. Mean birth weight was 2.75±0.37 kg in the TXA group and 2.84±0.37 kg in the placebo group. Mean 1-minute Apgar scores were 7.29±0.46 and 7.26±0.45; the mean 5-minute score was 9.00 in both groups. No NICU admission was recorded.

Table 1: Baseline demographic, obstetric and haematological characteristics.

Characteristics	TXA group (n=38)	Placebo group (n=38)
Age (years)	26.63±4.15	26.89±4.75
Body mass index (kg/m²)	25.04±3.76	24.85±3.41
Antenatal booking status		
Booked	27 (71.1)	29 (76.3)
Unbooked	11 (28.9)	9 (23.7)
Parity		
Nulliparous (P0)	25 (65.8)	28 (73.7)
Parous (P≥1)	13 (34.2)	10 (26.3)
Previous caesarean delivery		
Yes	9 (23.7)	8 (21.1)
No	29 (76.3)	30 (78.9)
Gestational age at delivery		
37+0–37+6 weeks	13 (34.2)	17 (44.7)
38+0–38+6 weeks	8 (21.1)	9 (23.7)
39+0–39+6 weeks	12 (31.6)	9 (23.7)
≥40+0 weeks	5 (13.2)	3 (7.9)
Preoperative haemoglobin (g/dl)	11.74±1.25	11.93±1.34
Preoperative haematocrit (%)	35.86±3.72	36.91±3.53

Values are mean±standard deviation or N (%). Percentages use the total number of participants in each group as the denominator. Parity refers to obstetric history before the index delivery. TXA: tranexamic acid

Table 2: Measured blood loss and postoperative haematological outcomes.

Outcome	TXA group (n=38)	Placebo group (n=38)	Mean difference (95% CI)	P value
Total measured blood loss (ml)[a]	521.79±90.94	748.58±123.67	-226.79 (-276.41 to -177.17)	<0.001
Haemoglobin at 24 hours (g/dl)	10.84±1.31	9.97±1.41	0.87 (0.25 to 1.49)	0.007
Haemoglobin decline (g/dl)	0.91±0.40	1.97±0.55	-1.06 (-1.28 to -0.84)	<0.001
Haematocrit at 24 hours (%)	32.91±3.82	30.97±3.21	1.94 (0.32 to 3.56)	0.019
Haematocrit decline (percentage points)[b]	2.94±1.37	5.94±2.03	-3.00 (-3.79 to -2.21)	<0.001

Values are mean±standard deviation. Mean differences are calculated as TXA minus placebo. Decline denotes the preoperative value minus the 24-hour postoperative value. CI: confidence interval; TXA: tranexamic acid. Comparisons used independent-samples Student's t-tests. [a]Blood loss measured from placental delivery until 2 hours postoperatively. [b]The mean difference and confidence interval for haematocrit decline were calculated from the reported group means, standard deviations and sample sizes using a t distribution with 74 degrees of freedom

Table 3: Additional intervention, atonic postpartum haemorrhage and maternal outcomes.

Outcome	TXA group (n=38)	Placebo group (n=38)	Risk ratio (95% CI)	P value
Uterine atony requiring additional intervention[a]	2 (5.3)	10 (26.3)	0.20 (0.05-0.85)	0.012
Atonic postpartum haemorrhage[b]	0 (0)	3 (7.9)	-	0.240[c]
Blood transfusion	0 (0)	0 (0)	-	-
Recorded postoperative complications	0 (0)	0 (0)	-	-
Reported complications at day 14	0 (0)	0 (0)	-	-
Reported complications at day 42	0 (0)	0 (0)	-	-

Values are N (%). Percentages use 38 participants per group as the denominator. CI: confidence interval; TXA: tranexamic acid. Dashes indicate that an effect estimate or statistical comparison is not presented. [a]Additional intervention beyond routine prophylactic oxytocin. The p value is from Pearson's Chi-square test. [b]Uterine atony associated with measured blood loss ≥1000 ml. These participants are included in the additional-intervention row. [c]Two-sided Fisher's exact test

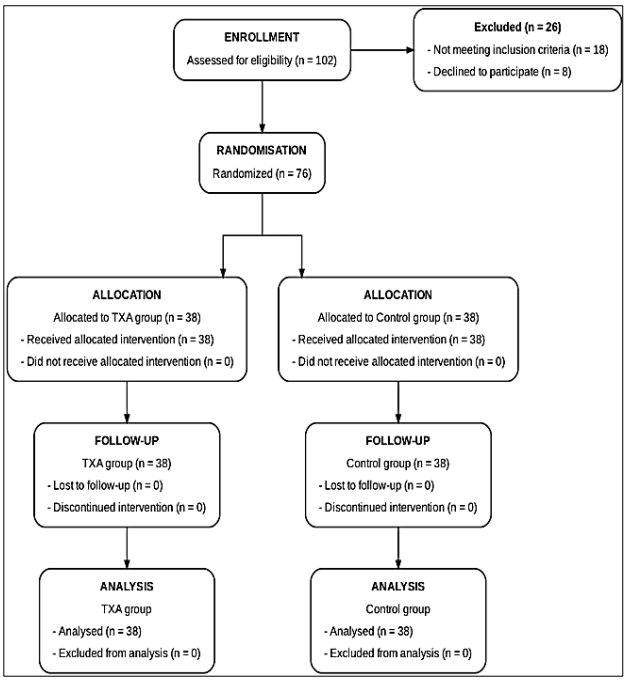


Figure 1: Participant flow through enrolment, allocation, follow-up and analysis.

Of 102 women assessed for eligibility, 18 did not meet inclusion criteria and eight declined participation. Seventy-six women were randomised equally to tranexamic acid or placebo. All received their allocated intervention, completed follow-up and were included in the analysis. TXA: tranexamic acid

DISCUSSION

In this randomised trial, women who received 1 g intravenous TXA before caesarean delivery had a lower mean measured blood loss than women receiving saline placebo. The difference was approximately 227 ml during the interval from placental delivery to 2 hours postoperatively. The TXA group also had smaller 24-hour declines in haemoglobin and haematocrit and fewer additional treatments for uterine atony. These findings concern measured perioperative bleeding; the trial was not large enough to establish a reduction in severe maternal outcomes.

Our primary outcome agrees in direction with several earlier trials reporting lower blood loss after prophylactic TXA. Gungorduk et al described lower blood loss and additional uterotonic use after elective caesarean delivery; similar blood-loss findings were reported by Lakshmi and Abraham and by Sentürk et al.[4,5,10] A meta-analysis by Simonazzi et al also reported reductions across smaller randomised trials.[11] However, variation in study populations, timing of administration and methods of blood-loss assessment makes direct comparison of the magnitude of these differences difficult.

The distinction between blood loss and clinically important haemorrhage is particularly relevant. In TRAAP2, TXA reduced the primary composite of calculated blood loss above 1000 ml or transfusion by day 2 but did not significantly improve several clinical secondary outcomes.[6] In the larger trial reported by Pacheco et al, TXA did not significantly reduce the composite of maternal death or blood transfusion.[7] Our findings should be interpreted in the context of these larger, clinically oriented studies.

The 2024 Cochrane review similarly found little or no effect on estimated blood loss of at least 1000 ml and probably little or no effect on transfusion.[8] Our primary outcome was mean blood loss over a defined period, not the occurrence of life-threatening haemorrhage. It is therefore possible to detect a difference in the mean without demonstrating a difference in the frequency of major bleeding.

Timing is one possible source of between-study variation. We initiated the allocated infusion approximately 20 minutes before skin incision, whereas TRAAP2 administered TXA after birth and the trial by Pacheco et al after-cord clamping.[6,7] A review of preoperative TXA studies reported reductions in early perioperative blood loss and postoperative haemoglobin decline.[12] Nevertheless, our study did not randomise women to different administration times, so it cannot establish that pre-incision dosing is superior.

Our blood-loss assessment combined suction collected after placental delivery with the change in weight of blood-

soaked materials, including postoperative pads. Quantification is preferable to visual estimation for describing measured blood loss, although it is not free of error.[13] In particular, the exclusion of bleeding before placental delivery means that our outcome must not be described as blood loss from skin incision onwards.

The smaller postoperative haemoglobin and haematocrit declines support the direction of the primary result but are not independent measures of the volume lost. Perioperative fluids and physiological redistribution can influence these laboratory changes. We did not measure patient-reported fatigue, functional recovery or quality of life.

The difference in additional treatment for atony should also be interpreted cautiously. Although intervention was less frequent with TXA, there were only 12 events, and the decision to administer additional uterotonics depended on clinical assessment. TXA has an antifibrinolytic mechanism and should not be described as directly improving uterine contraction.

Three placebo recipients and no TXA recipients had atonic postpartum haemorrhage as defined in the protocol, but this comparison was not statistically significant. No transfusions occurred. Similarly, no thromboembolic or visual complications were observed, but rare harms cannot be assessed adequately in a trial of 76 women, particularly with symptom-based follow-up. The individual-patient-data meta-analysis by Ker et al reported a reduction in life-threatening postpartum bleeding without a statistically significant increase in thromboembolic events; its broader populations and treatment contexts should be considered when applying those findings to prophylactic caesarean use.[14]

Strengths of the study include random allocation, concealed assignment, blinding, a saline placebo, consistent uterotonic prophylaxis and a prespecified quantitative blood-loss interval. The principal limitations are the single-centre setting, small sample, selected eligibility criteria and limited capacity to assess severe bleeding or rare adverse events. The trial excluded several factors associated with increased haemorrhage risk; results from a high-risk population, such as that studied by Ortuanya et al, cannot be assumed to apply directly to this sample.[15] The study was powered for a mean blood-loss difference, not for transfusion or maternal morbidity. Several secondary outcomes were examined without adjustment for multiplicity. Blood loss before placental delivery was omitted, and suction/gravimetric measurements may be affected by non-blood fluid contamination. Thurer et al have also demonstrated limitations in gravimetric quantification at caesarean delivery.[16]

The 2025 WHO guidance does not recommend prophylactic TXA for postpartum-haemorrhage prevention at caesarean birth.[1] Our trial does not provide a basis to overturn that recommendation. Its contribution is a quantified estimate of blood loss following pre-incision TXA in a selected population, with uncertainty persisting about whether this translates into clinically important maternal benefit.

CONCLUSION

In conclusion, 1 g of TXA administered intravenously before caesarean delivery reduced measured blood loss from placental delivery through 2 hours postoperatively in this trial. Smaller haemoglobin and haematocrit decline and less additional treatment for atony were also observed. Larger trials are required to determine effects on major haemorrhage outcomes and uncommon adverse events.

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