http://www.cjmb.org
doi 10.34172/cjmb.2025.5038
Open Access Original Article
Crescent Journal of Medical and Biological Sciences
Vol. 12, No. 4, October 2025, 208–215
eISSN 2148-9696

Efficacy of Tranexamic Acid Injection With Oxytocin in Preventing Bleeding During and After Elective Cesarean Section: A Randomized Controlled Trial

Ramesh Baradaran Bagheri[1], Zahra Sadat Khonsarian[2*], Shima Mohammadian[2*]

Abstract

Objectives: Postpartum hemorrhage (PPH) is a leading cause of maternal mortality worldwide. The present study aimed to investigate the effect of tranexamic acid (TXA) injection with oxytocin verses oxytocin alone in preventing bleeding during and after elective cesarean section.

Materials and Methods: This randomized, double-blind, placebo-controlled clinical trial enrolled 200 full-term, singleton pregnant women candidates for elective cesarean section. Patients were randomly assigned to either an intervention group (n=100) or a control group (n=100). The intervention group received 1 gram of TXA administered intravenously 20 minutes before skin incision. The control group received an identical volume of placebo (0.9% saline). Both groups subsequently received 30 units of oxytocin in 500 mL of Ringer's lactate solution after umbilical cord clamping. Primary outcomes were intraoperative and postoperative blood loss. Secondary outcomes included the need for additional uterotonics, changes in hemoglobin levels, and the incidence of adverse effects.

Results: The study found no significant differences between groups in terms of maternal age, gestational age, parity, gravidity, body mass index, and infant weight. The mean intraoperative blood loss was 466.0 ± 110.5 ml in the intervention group and 491.1 ± 102.1 mL in the control group ($P=0.18$). The mean postoperative blood loss was 505.7 ± 113.1 ml and 507.1 ± 77.3 ml, respectively ($P=0.81$). There were no significant differences in pre- and post-operative hemoglobin levels, need for additional uterotonics, or other hematologic indices. While 9 patients (9%) in the intervention group and 4 patients (4%) in the control group reported side effects such as nausea and vomiting, this difference was not statistically significant ($P=0.15$).

Conclusions: The findings suggest that intravenous administration of 1 gram of TXA before cesarean section along with oxytocin does not reduce bleeding during and after elective cesarean section in low-risk women. Therefore, its routine use is not recommended for this population.

Keywords: Cesarean delivery, Bleeding, Oxytocin, Tranexamic acid, Prevention

Introduction

Postpartum hemorrhage (PPH) is a leading cause of maternal mortality worldwide, accounting for 15% of all maternal deaths (1). According to the World Health Organization, PPH is defined as blood loss equal to or greater than 1000 mL with clinical findings of hypovolemia 24 hours after the birth process, regardless of delivery method (2). The cesarean delivery rate has increased to 25%-30% in many regions, resulting in higher blood loss compared to vaginal delivery (3). In fact, a study found that the average blood loss during cesarean delivery is significantly higher than during vaginal delivery (4).

Bleeding complications during cesarean delivery are a major concern, as they can lead to serious morbidity and mortality. Hemostatic abnormalities, which can be caused by uncontrolled bleeding, have been neglected in the initial treatment of PPH. However, recent evidence suggests that extensive tissue damage can lead to increased fibrinolysis and play a role in blood coagulation and bleeding (5).

Tranexamic acid (TXA) is an antifibrinolytic drug that has been shown to reduce bleeding in various settings, including orthopedic, cardiovascular, and traumatic injuries (6-8). TXA blocks the binding site of lysine on plasminogen, reducing its fibrinolytic effect and subsequent bleeding (9). Studies have also demonstrated that TXA is more effective in reducing severe bleeding caused by menstrual disorders compared to non-steroidal anti-inflammatory drugs (NSAIDs) and other drugs; some of the antioxidant components can protect the reproductive system through reduction in inflammatory factors (10, 11).

The third stage of labor, when the placenta is delivered, is characterized by activation of the fibrinolytic system and rapid decrease in fibrinogen levels. This activation can continue for up to 10 hours after delivery, leading to further bleeding. Antifibrinolytic agents like TXA may be used alone or in combination with other drugs to reduce bleeding during this stage and postpartum bleeding.

Received 9 December 2024, **Accepted** 13 September 2025, **Available online** 29 September 2025

[1]Department of Obstetrics and Gynecology, Faculty of Medicine, Alborz University of Medical Sciences, Karaj, Iran.
[2]Department of Obstetrics and Gynecology, Kamali Hospital, Alborz University of Medical Sciences, Karaj, Iran.
*Corresponding Authors: Zahra Sadat Khonsarian, Email: z.Khonsarian@gmail.com; Shima Mohammadian, Email: shima792003@yahoo.com

Key Messages

- Tranexamic acid does not reduce bleeding in low-risk elective cesarean sections when used with oxytocin.
- Routine TXA use is not recommended for low-risk cesarean deliveries due to lack of benefit.

Furthermore, TXA has been shown to be effective in reducing PPH in women with risk factors for postpartum bleeding (12).

A recent systematic review found that TXA reduced total blood loss during and after surgery in patients at high risk of bleeding during cesarean delivery (13). There is a strong scientific justification for the use of antifibrinolytic agents to minimize blood loss during labor, although limited studies have been conducted in this area. A recent 2020 systematic review showed that TXA was effective in reducing total blood loss both intraoperatively and postoperatively in patients at high risk of bleeding during cesarean delivery (2). However, more clinical trials with sufficient sample sizes are needed to confirm these findings. Therefore, this study aims to investigate the effect of TXA injection with oxytocin verses oxytocin alone before elective cesarean section in preventing pre- and post-operative bleeding.

Materials and Methods

Study Design and Setting

This was a randomized, double-blind, placebo-controlled clinical trial conducted at Kamali Hospital, affiliated with Alborz University of Medical Sciences, Iran, between 2022 and 2023. The study protocol was approved by the Ethics Committee of Alborz University of Medical Sciences (Ethics Code: [IR.ABZUMS.REC.1401.146]) and registered prospectively with the Iranian Registry of Clinical Trials (identifier: IRCT20211109053019N1). Written informed consent was obtained from all participants.

Study Population and Inclusion/Exclusion Criteria

The study population consisted of pregnant women who were candidates for elective cesarean delivery and met the eligibility criteria. The inclusion criteria were as follows: the women were 18 years or older, had a singleton pregnancy, and were at least 34 weeks gestation. They also had a preoperative hemoglobin level of 10 g/dL or higher, and a platelet count of 100 000/μL or higher.

The exclusion criteria were designed to ensure the safety and well-being of the participants. These included women with a history of thrombosis, arterial disease, or other cardiovascular, renal, or hepatic disorders. Women with autoimmune diseases, sickle cell disease, or severe hemorrhagic disease were also excluded. Furthermore, women with placenta accreta or invasive abnormal placenta, preeclampsia or eclampsia, hemolysis with low platelets, intrauterine fetal death, or known sensitivity to TXA were not included in the study. Other exclusion criteria included multiple pregnancy, severe polyhydramnios, uterine fibroids, history of recurrent miscarriage, rheumatic disease, varicose veins, prepartum bleeding, and a previous history of PPH.

Demographic Characteristics and Laboratory Results

Demographic characteristics, including age and body mass index (BMI), were recorded for each participant. Additionally, medical history, obstetric history, and current pregnancy details were collected. Laboratory results, including hemoglobin and hematocrit levels, complete blood count (CBC), partial thromboplastin time (PTT), prothrombin time (PT), and international normalized ratio (INR), were also recorded.

Sample Size Calculation

The sample size was calculated based on a previous study by Gungorduk et al (3), assuming a mean difference in blood loss of 150 mL between groups, a standard deviation of 200 mL, a power of 80%, and an alpha error of 0.05. Using G*Power software (version 3.1), the calculated sample size was 90 patients per group. Accounting for a potential 10% dropout rate, a total of 200 women (100 per group) were enrolled.

Randomization and Blinding

Eligible participants were randomly assigned to either the intervention (TXA) or control (placebo) group in a 1:1 ratio. The randomization sequence was computer-generated by a statistician not involved in the study using block randomization with varying block sizes. The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE), which were prepared and kept by the hospital pharmacy. The study drug (TXA) and the placebo (0.9% saline) were prepared by the pharmacy in identical 20 mL syringes, ensuring that the patients, surgeons, anesthesiologists, and outcome assessors were all blinded to the group assignment.

Intervention

All patients received antibiotic prophylaxis (cefazolin 1 g intravenously) before skin incision. Spinal anesthesia was administered to all participants, and the transverse method was used to perform uterine incision on the lower uterine segment.

In the intervention group, TXA (1 g in 20 mL) was administered intravenously in the operating room 20 minutes before skin incision. The control group received an identical volume of placebo (20 mL of 0.9% saline) at the same time point. After umbilical cord clamping, all patients received 30 units of oxytocin in 500 mL of Ringer's lactate solution, infused over 4 hours.

Surgical Procedure

After the cesarean section, the placenta was removed through controlled traction and the uterus was closed in two layers with number one vicryl suture. The operating room nurse recorded the time of surgery start and placenta delivery.

Outcome Measures and Data Collection

Primary Outcomes

Intraoperative blood loss (mL): Calculated by summing the volume of blood in the suction canister and the estimated blood in soaked gauzes and laparotomy sponges, then subtracting the volume of amniotic fluid.

Gauze estimation: The weight (in grams) of soaked gauzes and sponges minus their dry weight was converted to volume (mL) by assuming 1 g = 1 mL.

Suction volume: The total fluid volume in the suction canister was measured. Amniotic fluid volume was estimated visually by the obstetrician and subtracted.

Postoperative blood loss (mL): Assessed by measuring blood collected in a graduated drape over the first 24 hours after surgery.

Secondary Outcomes

- The need for additional uterotonic drugs (e.g., additional oxytocin, misoprostol, methylergometrine) during or after surgery.
- Change in hemoglobin (g/dL) and hematocrit (%) levels, measured preoperatively and 24 hours postoperatively.
- Changes in coagulation profile (PT, PTT, INR) preoperatively and 24 hours postoperatively.
- Need for blood transfusion.
- Incidence of adverse effects (e.g., nausea, vomiting, dizziness, thrombosis) within the first 24 hours.
- Duration of surgery (minutes).
- Vital signs (blood pressure, pulse) and renal function tests (BUN, creatinine).

Statistical Analysis

Data were analyzed using SPSS software version 25. The normality of quantitative data was assessed using the Kolmogorov-Smirnov test. Descriptive statistics are presented as mean ± standard deviation (SD) for normally distributed variables, median (interquartile range) for non-normal variables, and frequency (percentage) for categorical variables. Independent samples t-test (or Mann-Whitney U test for non-normal data) was used to compare continuous variables between the two groups. The chi-square test (or Fisher's exact test) was used to compare categorical variables. Within-group comparisons of pre- and post-operative measurements were performed using paired t-tests or Wilcoxon signed-rank tests. A *P* value of less than 0.05 was considered statistically significant.

Results

Participant Flow

A total of 220 women were assessed for eligibility. Fifty women were excluded (30 did not meet inclusion criteria, 20 declined to participate). The remaining 200 women were randomized into two groups (100 per group). All randomized participants received the allocated intervention and were included in the final analysis (Figure 1).

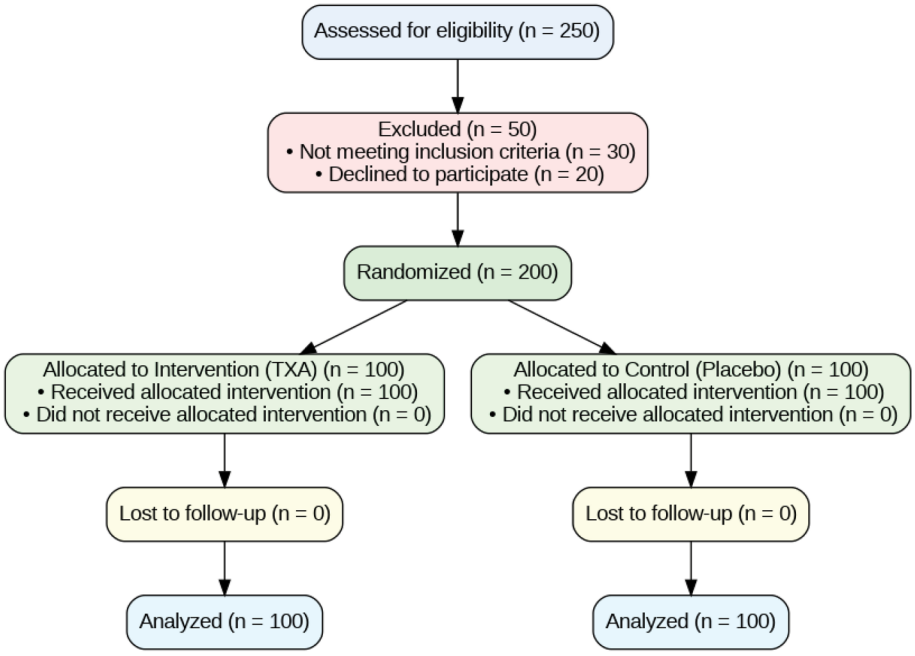

Figure 1. Consort Flow Diagram of the Study.

Baseline Characteristics of Study Participants

The study population consisted of 200 pregnant women. As shown in Table 1, the mean maternal age was 30.5 ± 4.3 years, with no significant difference between groups ($P = 0.72$). The mean gestational age was 38.4 ± 0.4 weeks. There were no significant differences between the two groups in terms of gravidity, parity, number of previous cesarean sections, BMI, or infant weight, indicating that the randomization process was successful.

Primary Outcomes

Amount of Bleeding During and After Cesarean Delivery

As shown in Table 2, there was no statistically significant difference in intraoperative blood loss between the TXA group (466.0 ± 110.5 mL) and the placebo group (491.1 ± 102.1 mL) ($P = 0.18$). Similarly, postoperative blood loss was comparable between the TXA group (505.7 ± 113.1 mL) and the placebo group (507.1 ± 77.3 mL) ($P = 0.81$). The calculated blood loss from gauzes and sponges and the suction volume also showed no significant differences.

The amount of bleeding during cesarean delivery was evaluated using the total blood volume, number of gauzes and Lon gauzes used during the operation, and the volume of suction blood. The results showed that the mean volume of bleeding during cesarean section was 466.00 ± 110.536 mL in the intervention group and 491.101 ± 20.09 mL in the control group, with no statistically significant difference between the two groups ($P = 0.18$). Additionally, there was no significant difference in the mean volume of bleeding after cesarean in the intervention group (505.68 ± 113.13 mL) and in the control group (507.134 ± 77.33 mL) ($P = 0.81$) (Figure 2).

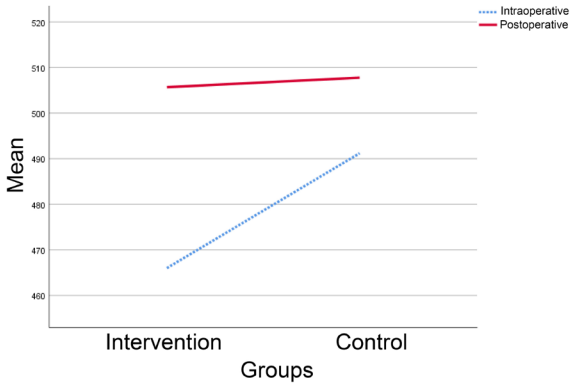

Figure 2. Comparison of the Mean Volume of BLEEDING DURING and After Cesarean Section Between Both Groups.

Hematologic Indices

There were no significant differences in preoperative hemoglobin, hematocrit, PT, PTT, or INR levels between the two groups (Table 3). At 24 hours postpartum, these indices remained comparable between the groups, and the change from baseline (delta) was not significantly different.

Renal Function and Blood Pressure

Blood urea nitrogen (BUN) and creatinine levels before and 24 hours after surgery were similar between groups (All $P > 0.05$) (Data not shown in detail for brevity). Systolic and diastolic blood pressure measurements taken at various time points (preoperatively, before transfer to ward, 24-h postoperatively) were also not significantly different between the TXA and placebo groups (Table 4).

Table 1. Demographic and Obstetric Characteristics of the Intervention and Control Groups

Characteristic	Total (n=200)	TXA group (n=100)	Placebo group (n=100)	*P* value
Maternal age (y)	30.5 ± 4.3	30.8 ± 3.3	30.2 ± 4.3	0.72
Gestational age (wk)	38.4 ± 0.4	38.4 ± 0.4	38.5 ± 0.4	0.14
Gravidity	2.1 ± 0.9	2.0 ± 0.8	2.2 ± 1.0	0.09
Parity	1.5 ± 0.7	1.4 ± 0.7	1.6 ± 0.7	0.28
Number of previous CS	0.6 ± 0.6	0.6 ± 0.6	0.5 ± 0.6	0.10
BMI (kg/m²)	28.7 ± 5.3	28.6 ± 5.3	28.8 ± 5.3	0.86
Infant weight (g)	3250 ± 373	3276 ± 364	3221 ± 382	0.58

Data presented as Mean ± SD. *P* value from Independent T-test or Mann-Whitney U test.

Table 2. Comparison of Intraoperative and Postoperative Blood Loss

Parameter	TXA group (n=100)	Placebo group (n=100)	Mean difference (95% CI)	*P* value
Intraoperative EBL (mL)	466.0 ± 110.5	491.1 ± 102.1	-25.1 (-61.8 to 11.6)	0.18
Postoperative EBL (mL)	505.7 ± 113.1	507.1 ± 77.3	-1.4 (-33.2 to 30.4)	0.81
Blood in suction (mL)	438.1 ± 80.2	456.1 ± 30.3	-18.0 (-36.1 to 0.1)	0.051
Blood in gauzes (mL)	108.6 ± 21.5	133.3 ± 33.3	-24.7 (-32.1 to -17.3)	<0.001*
No. of lap sponges used	4.4 ± 1.0	4.9 ± 1.0	-0.5 (-0.8 to -0.2)	0.001*

EBL = Estimated Blood Loss; Data presented as Mean ± SD. *P* value from Independent T-test.
*Note: While the number of sponges and calculated gauze blood showed a statistical difference, this did not translate to a significant difference in the primary outcome of total intraoperative EBL.

Table 3. Hematologic Indices Before and 24 Hours After Cesarean Section

Parameter	Timepoint	TXA group (n=100)	Placebo group (n=100)	*P* value
Hemoglobin (g/dL)	Preoperative	12.3 ± 1.3	12.2 ± 1.4	0.63
	Postoperative (24h)	11.3 ± 1.3	11.2 ± 1.4	0.62
Hematocrit (%)	Preoperative	37.2 ± 2.5	36.9 ± 2.6	0.16
	Postoperative (24h)	34.2 ± 2.5	33.9 ± 2.6	0.16
PT (s)	Preoperative	12.9 ± 0.6	12.9 ± 0.7	0.87
	Postoperative (24h)	13.0 ± 0.8	13.1 ± 0.6	0.48
PTT (s)	Preoperative	31.5 ± 4.5	31.5 ± 4.5	0.51
	Postoperative (24h)	32.6 ± 4.3	33.3 ± 4.8	0.21
INR	Preoperative	1.00 ± 0.03	1.00 ± 0.03	0.65
	Postoperative (24h)	1.01 ± 0.03	1.01 ± 0.03	0.70

Data presented as mean ± SD. P value from independent t-test for between-group comparisons at each timepoint.

Table 4. BUN and Creatinine Levels Before and 24 Hours After Cesarean Section in the Intervention Group Compared to the Control Group

	Parameters	Intervention group (mean ± SD)	Control group (mean ± SD)	*P* value*
Before cesarean section	Blood urea nitrogen (mg/dL)	118.4±90.17	117.4±79.03	0.16
	Creatinine (mg/dL)	79.5±16.45	78.5±91.58	0.91
24 hours after cesarean section	Blood urea nitrogen (mg/dL)	112.5±90.67	112.5±94.91	0.79
	Creatinine (mg/dL)	75.5±15.68	74.5±97.44	0.64

**P* value was determined using the Mann-Whitney U test. *P* value less than 0.05 considered significant.

Blood Pressure of Women Undergoing Cesarean Section

To evaluate the blood pressure of women undergoing cesarean delivery, we measured systolic and diastolic blood pressure in both groups before cesarean section, before transfer to the ward, and 24 hours after cesarean section. Our results showed that there was no statistically significant difference in systolic and diastolic blood pressure between the intervention group and the control group (All *P* values > 0.05) (Table 5).

Secondary Outcomes

Duration of Surgery and Additional Interventions

The average duration of cesarean section was similar between the TXA group (32.7 ± 8.5 minutes) and the placebo group (32.8 ± 6.7 minutes) ($P = 0.62$). No patients in either group required a blood transfusion.

Need for Additional Uterotonics

A total of 63 women (31.5%) required additional uterotonic agents. This need was not significantly different between the TXA group (26 women, 26%) and the placebo group (37 women, 37%) ($P = 0.09$).

Adverse Effects

Thirteen women (6.5%) reported transient gastrointestinal side effects (nausea, vomiting). The incidence was higher in the TXA group (9%) than in the placebo group (4%), but this difference was not statistically significant ($P = 0.15$). No cases of thromboembolic events (e.g., DVT, PE) were observed in either group within the study period.

Discussion

This randomized, double-blind, placebo-controlled trial investigated the prophylactic use of intravenous TXA in addition to oxytocin in 200 low-risk women undergoing elective cesarean delivery. The primary finding is that a 1-gram dose of TXA administered 20 minutes before surgery did not result in a statistically or clinically

Table 5. Comparison of Systolic and Diastolic Blood Pressure in Both Groups Before Cesarean Section, Before Transfer to the Ward, and 24 Hours After Cesarean Section Between Two Groups

	Parameters	Intervention group (mean ± SD)	Control group (mean ± SD)	*P* value*
Before cesarean section	Systolic blood pressure (mm Hg)	118.4±90.17	117.4±79.03	0.168
	Diastolic blood pressure (mm Hg)	79.5±16.45	78.5±91.58	0.917
Before transfer to the ward	Systolic blood pressure (mm Hg)	112.5±90.67	112.5±94.91	0.797
	Diastolic blood pressure (mm Hg)	75.5±15.68	74.5±97.44	0.645
24 hours after cesarean section	Systolic blood pressure (mm Hg)	119.2±39.12	119.2±15.52	0.895
	Diastolic blood pressure (mm Hg)	79.4±96.46	55±55	0.616

**P* value was determined using the Mann-Whitney U test. *P* value less than 0.05 considered significant.

significant reduction in intraoperative or postoperative blood loss compared to placebo. Furthermore, TXA administration did not lead to significant differences in changes in hemoglobin levels, the need for additional uterotonic agents, or other hematologic parameters.

Bleeding during childbirth is unpredictable and the only way to help is to use preventive measures (14). Since PPH is the main cause of mortality in developing countries and the cause of half of hysterectomies during childbirth in developed countries (15), the present work aimed to investigate the effect of TXA in reducing the volume of blood lost during and after cesarean section.

The main findings of this study are that intravenous injection of 1 gram of TXA before cesarean section did not significantly reduce bleeding during and after elective cesarean section in low-risk women, and that the use of TXA did not lead to any significant changes in hemoglobin, hematocrit, or blood clotting factors.

The results of this study demonstrate that the antifibrinolytic properties of TXA, which are intended to mitigate bleeding, were not effective in reducing bleeding during and after delivery in low-risk women. This finding is consistent with the timing of the drug's administration, as the intravenous injection of TXA prior to delivery would not allow for its therapeutic effects to be manifest during the postpartum bleeding episode. Therefore, the data suggest that TXA does not exhibit a protective or therapeutic effect on bleeding in low-risk women undergoing cesarean delivery.

The findings of this study indicate that the mean blood loss during cesarean section and postpartum period was less than 500 mL, suggesting that the study population did not exhibit significant postpartum bleeding. This observation has important implications for the use of TXA in low-risk patients. Specifically, it suggests that the addition of this antifibrinolytic agent in patients who are not at risk of bleeding or at low risk of PPH is unlikely to have a significant therapeutic effect. As such, our results highlight the importance of considering the risk-benefit profile of TXA in low-risk patients, where the potential benefits may be outweighed by the potential risks and costs.

Several studies have investigated the potential lack of effect of TXA on bleeding volume, yielding similar findings to our study. Shariatnia et al reported that the mean urine output in the control group was significantly higher than that in the intervention group, but no significant correlation was observed (16). Ferrer et al. found that there was insufficient evidence to support the efficacy of TXA in reducing bleeding after childbirth, suggesting that further research is necessary to confirm its effectiveness (17). Similarly, McClure et al concluded that the drug's effect on reducing the risk of postpartum bleeding was modest, with a relative reduction of only 2% (18). These studies collectively underscore the need for further investigation into the efficacy and potential benefits of TXA in reducing bleeding in low-risk patients.

In contrast to our study, other research has explored the effectiveness of TXA in controlling bleeding during and after cesarean section. Stortroen et al. found that prophylactic administration of TXA reduced blood loss volume and the number of uterotonics required in high-risk patients undergoing cesarean delivery (2). This finding is consistent with other studies (19-21), and suggests that TXA may be effective in reducing bleeding complications in high-risk patients.

The difference in results between these studies and our own can be attributed to the patient populations. The studies mentioned involved high-risk patients with a history of PPH, whereas our study did not involve any patients with PPH.

One of the strengths of our study is that we investigated the effect of TXA on various factors related to bleeding, in addition to measuring blood loss volume. Our results showed that TXA did not alter the levels of hemoglobin, hematocrit, PT, PTT, and INR compared to the control group. Although we did not find a statistically significant difference in blood loss volume or bleeding-related factors before and after cesarean section, our findings suggest that TXA may not be necessary in low-risk patients. This implies that healthcare providers may not need to inject TXA during cesarean section for low-risk patients, which can help prevent unnecessary medication use.

Stortroen et al (2), found that TXA does not affect hemoglobin levels after surgery, which is consistent with our findings and those of Sahahf et al (22). In contrast, Sanad et al. reported a significant decrease in hemoglobin and hematocrit levels in the control group compared to the group receiving TXA (23). However, it is important to note that these studies differ from ours in terms of the dose, timing, and dilution of TXA administration.

The present study found that mean systolic and diastolic blood pressure, BUN, and creatinine levels were similar in the TXA and control groups. This study was one of the few to investigate the effect of TXA on blood pressure in women undergoing cesarean section, making it difficult to compare the results with other researches. Various studies have shown that TXA has antioxidant and anti-inflammatory properties, which in turn reduce damage caused by bleeding and prevent bleeding (24, 25). Some studies have reported that anti-oxidative and anti-inflammatory properties, leading to reduced damage to the reproductive system and protection of these tissues against inflammatory damage (11, 26, 27).

Another key finding of this study is that TXA did not reduce the duration of cesarean delivery. Although the study found a slight reduction in cesarean section duration, it was not statistically significant and did not create a significant difference between the two groups.

The overall result of our study on the side effects of intravenous TXA injection was that it did not cause any significant side effects in the mother. Although nausea,

vomiting, and dizziness were reported 2.2 times more frequently in the treatment group, these side effects were not statistically significant and may have been attributed to the anesthetic drugs used. This finding is consistent with a similar study by Qayum et al (28), and Sentürk et al (29), which also found that minor gastrointestinal side effects were common but not significant.

Another aim of this study was to investigate the effect of TXA on the need for anticoagulants and additional treatments in cases of bleeding. The results showed that the need for anticoagulants and additional treatments, including Methergin ampoules, misoprostol suppositories, and combinations of these drugs, did not differ between the two groups. This finding contrasts with the results of Gungorduk et al's study (3), which found that more women in the placebo group required additional drugs compared to the TXA group.

The antifibrinolytic property of TXA is due to its ability to block the binding site of lysine on plasminogen, thereby reducing its fibrinolytic effect and slowing the spread of bleeding (30). This finding provides a foundation for future studies on the effect of TXA in other women's surgeries, such as hysterectomy or uterosection during cesarean section.

The demographic characteristics of mothers in the TXA and control groups were matched and did not differ significantly in terms of basic characteristics, including age, gestational age, parity, gravidity, number of previous cesarean sections, body mass index, and infant weight. This suggests that confounding factors were minimized, allowing for a more accurate comparison of the two groups.

Limitations of Study

Our study has several limitations that must be acknowledged. First, the method of blood loss measurement, while standardized and involving quantitative assessment of suction canister volume and weighed sponges, still contains an element of estimation and is subject to error. However, this method was applied consistently across both groups, minimizing the potential for bias. Second, our strict inclusion criteria, while necessary to create a homogeneous low-risk cohort, limit the generalizability of our findings to the broader obstetric population, particularly to high-risk patients or those undergoing emergency cesarean delivery. Finally, the study was powered to detect a difference in blood loss and may be underpowered to detect very rare adverse outcomes like thrombosis.

Conclusion and Clinical Implications

In conclusion, the findings of this study demonstrate that prophylactic intravenous TXA does not reduce bleeding during or after elective cesarean section in low-risk women. Therefore, we do not recommend its routine use in this specific patient population. This aligns with a prudent approach to pharmacotherapy, avoiding intervention where the risk-benefit ratio is not favorable. Future research should continue to focus on identifying which patient subgroups—particularly those with specific risk factors for hemorrhage or fibrinolysis—stand to benefit most from TXA prophylaxis, ensuring this valuable drug is used effectively and efficiently.

Authors' Contribution

Conceptualization: Ramesh Baradaran Bagheri.
Data curation: Zahra Sadat Khonsarian, Shima Mohammadian.
Formal analysis: Zahra Sadat Khonsarian.
Funding acquisition: Ramesh Baradaran Bagheri.
Investigation: Ramesh Baradaran Bagheri.
Methodology: Ramesh Baradaran Bagheri, Shima Mohammadian.
Project administration: Ramesh Baradaran Bagheri.
Resources: Ramesh Baradaran Bagheri.
Software: Shima Mohammadian.
Supervision: Ramesh Baradaran Bagheri.
Validation: Ramesh Baradaran Bagheri.
Visualization: Ramesh Baradaran Bagheri.
Writing–original draft: Ramesh Baradaran Bagheri, Shima Mohammadian.
Writing–review & editing: Ramesh Baradaran Bagheri, Shima Mohammadian.

Conflict of Interests

Authors have no conflict of interest.

Declaration of AI-Assisted Tools in the Writing Process

The authors used DeepSeek (V3) AI tool for editing in order to enhance the quality of this manuscript. All content was checked by the authors, who accept full responsibility for its accuracy.

Financial Support

This study was supported by a grant from the Vice-Chancellor for Research of Alborz University of Medical Sciences (grant number: 59906).

Acknowledgments

The authors would like to express their sincere gratitude to the dedicated staff and nurses of the Obstetrics and Gynecology Department and operating rooms at Kamali Hospital for their invaluable assistance and cooperation throughout the data collection process. We are also deeply thankful to the hospital's pharmacy department for their meticulous preparation and blinding of the study medications.

We extend our heartfelt thanks to the statisticians at Alborz University of Medical Sciences for their expert guidance in the study design and statistical analysis.

We also extend our gratitude to the Clinical Research Development Unit of Tabriz Valiasr Hospital for their technical and logistical support throughout the study.

References

1. Derman RJ, Kodkany BS, Goudar SS, et al. Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. Lancet. 2006;368(9543):1248-1253. doi:10.1016/S0140-6736(06)69522-6
2. Stortroen NE, Tubog TD, Shaffer SK. Prophylactic tranexamic acid in high-risk patients undergoing cesarean delivery: a systematic review and meta-analysis of randomized controlled trials. AANA J. 2020;88(4):273-281.
3. Gungorduk K, Yıldırım G, Asıcıoğlu 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. Am J Perinatol. 2011;28(3):233-240. doi:10.1055/s-0030-1268244
4. Feitsma A, Kanhai H, eds. Misoprostol in the Management of Postpartum Haemorrhage. Elsevier; 2005. International Congress Series.
5. Othman ER, Fayez MF, Abd El Aal DEM, Mohamed HSE-D, Abbas AM, Ali MK. Sublingual misoprostol versus intravenous oxytocin in reducing bleeding during and after cesarean delivery: a randomized clinical trial. Taiwan J Obstet Gynecol. 2016; 55(6):791-795. doi:10.1016/j.tjog.2016.07.008
6. Ducloy-Bouthors AS, Jude B, Duhamel A, et al. High-dose tranexamic acid reduces blood loss in postpartum haemorrhage. Crit Care. 2011;15(2):R117. doi:10.1186/cc10143
7. Gandhi R, Evans HM, Mahomed SR, Mahomed NN. Tranexamic acid and the reduction of blood loss in total knee and hip arthroplasty: a meta-analysis. BMC Res Notes. 2013;6:184. doi:10.1186/1756-0500-6-184
8. Hutton B, Joseph L, Fergusson D, Mazer CD, Shapiro S, Tinmouth A. Risks of harms using antifibrinolytics in cardiac surgery: systematic review and network meta-analysis of randomised and observational studies. BMJ. 2012;345:e5798. doi:10.1136/bmj.e5798
9. Ker K, Roberts I, Shakur H, Coats TJ. Antifibrinolytic drugs for acute traumatic injury. Cochrane Database Syst Rev. 2015;2015(5):CD004896. doi:10.1002/14651858.CD004896.pub4
10. Heesen M, Böhmer J, Kloehr S, et al. Prophylactic tranexamic acid in parturients at low risk for post-partum haemorrhage: systematic review and meta-analysis. Acta Anaesthesiol Scand. 2014; 58(9):1075-1085. doi:10.1111/aas.12341
11. Bagheri RB, Chavoshinezhad N, Barghi B, et al. Effects of Cornus mas extract (anthocyanin) and treadmill exercise on hormonal and histological effects in the rat model of polycystic ovary syndrome. Int J Womens Health Reprod Sci. 2025;13(1).
12. Bryant-Smith AC, Lethaby A, Farquhar C, Hickey M. Antifibrinolytics for heavy menstrual bleeding. Cochrane Database Syst Rev. 2018;2018(4):CD000249. doi:10.1002/14651858.CD000249.pub2
13. Peitsidis P, Kadir RA. Antifibrinolytic therapy with tranexamic acid in pregnancy and postpartum. Expert Opin Pharmacother. 2011; 12(4):503-516. doi:10.1517/14656566.2011.545819
14. Wasserloos A, Thomassen M, Costa S, et al. Effect of blood loss during caesarean section on coagulation parameters. Thromb Res. 2021;202:84-89. doi:10.1016/j.thromres.2021.03.015
15. Gillissen A, Henriquez DDCA, van den Akker T, et al. The effect of tranexamic acid on blood loss and maternal outcome in the treatment of persistent postpartum hemorrhage: a nationwide retrospective cohort study. PLoS One. 2017;12(11):e0187555. doi:10.1371/journal.pone.0187555
16. Shariatinia F, Malekzadeh J, Alizadeh M, Ghaffari P. Investigating and comparing the therapeutic effect of tranexamic acid and oxytocin in control of postpartum hemorrhage following uterine atony after cesarean section: a randomized clinical trial. J Mazandaran Univ Med Sci. 2023;33(225):94-102.
17. Ferrer P, Roberts I, Sydenham E, Blackhall K, Shakur H. Anti-fibrinolytic agents in post partum haemorrhage: a systematic review. BMC Pregnancy Childbirth. 2009;9:29. doi:10.1186/1471-2393-9-29
18. McClure EM, Jones B, Rouse DJ, et al. Tranexamic acid to reduce postpartum hemorrhage: a MANDATE systematic review and analyses of impact on maternal mortality. Am J Perinatol. 2015; 32(5):469-474. doi:10.1055/s-0034-1390347
19. Hassan NE, Elghareeb NAM, Zaki FM. Efficacy of oxytocin infusion versus tranexamic acid infusion in controlling blood loss during elective lower segment caesarean section. Egypt J Hosp Med. 2020;81(4):1822-1827.
20. Ker K, Roberts I, Chaudhri R, et al. Tranexamic acid for the prevention of postpartum bleeding in women with anaemia: study protocol for an international, randomised, double-blind, placebo-controlled trial. Trials. 2018;19:712. doi:10.1186/s13063-018-3081-7
21. Ahmadzia HK, Phillips JM, Katler QS, James AH. Tranexamic acid for prevention and treatment of postpartum hemorrhage: an update on management and clinical outcomes. Obstet Gynecol Surv. 2018;73(10):587-594. doi:10.1097/OGX.0000000000000596
22. Sahhaf F, Abbasalizadeh S, Ghojazadeh M, et al. Comparison effect of intravenous tranexamic acid and misoprostol for postpartum haemorrhage. Niger Med J. 2014;55(4):348-353. doi:10.4103/0300-1652.137224
23. Gomaa AM, Hamza HA, Elsalamony HH, Ellakwa HE, Sanad ZF. Effect of tranexamic acid in reducing blood loss during and after cesarean delivery. Menoufia Med J. 2020;33(4):1270-1275.
24. de Moraes FM, Philippi JV, Belle F, et al. Iota-carrageenan/xyloglucan/serine powders loaded with tranexamic acid for simultaneously hemostatic, antibacterial, and antioxidant performance. Biomater Adv. 2022;137:212805. doi:10.1016/j.bioadv.2022.212805
25. Zulfiqar A, Ahmed D. Solvent-free mechanochemical green synthesis of Schiff bases of tranexamic acid and study of their urease inhibitory and antioxidant activities. Asian Journal of Green Chemistry. 2022;6(1):40-47. doi:10.22034/ajgc.2022.1.4
26. Bagheri RB, Khaki AA. Effects of carvacrol on hormonal and biochemical blood factors related to diabetes in diabetic adult rats induced by streptozocin. Medical Journal of Tabriz University of Medical Sciences. 2024;46(2):136-144.
27. Bagheri RB, Salami SS, Boukani LM, Khaki AA. The regulatory effect of eugenol on FSHR, LHCGR, and ER expression during follicular development in female rats with ovarian torsion. Int J Womens Health Reprod Sci. 2023;11(2):138–144. doi:10.15296/ijwhr.2023.24.
28. Qayum M, Ali W, Waheed N. Post partum hemorrhage prevention with tranexamic acid is effective and safe in comparison to placebo: PPH prevention with tranexamic acid. Pak Armed Forces Med J. 2018;68(4):908-913.
29. Sentürk MB, Cakmak Y, Yildiz G, Yildiz P. Tranexamic acid for cesarean section: a double-blind, placebo-controlled, randomized clinical trial. Arch Gynecol Obstet. 2013;287:641-645. doi:10.1007/s00404-012-2598-4
30. Saccone G, Della Corte L, D'Alessandro P, et al. Prophylactic use of tranexamic acid after vaginal delivery reduces the risk of primary postpartum hemorrhage. J Matern Fetal Neonatal Med. 2020;33(19):3368-3376. doi:10.1080/14767058.2019.1571576