
Oral Tranexamic Acid versus Intravenous Tranexamic Acid in Reducing Intraoperative Blood Loss during Elective Cesarean Section

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Short title

Oral vs IV TXA for reducing bleeding in CS: RCT

Ethics approval and consent to participate.

Ethics Approval:

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. The protocol for this research was reviewed and approved by the Scientific and Ethics Committee of the OBGYN department, Cairo University, under protocol number [MS-272-2023] on [11/11/2023].

Consent to Participate:

Informed consent was obtained from all participants included in the study. Participants were provided with detailed information about the study objectives, procedures, potential risks and benefits, confidentiality measures, and their right to withdraw at any time without consequences. Written consent was obtained from each participant before their inclusion in the study. Additionally, participants' confidentiality was strictly maintained throughout the research process, and all data were anonymized to ensure privacy.

consent for publication.

My manuscript does not contain any individual person's data in any form ((including any individual details, images, or videos).

availability of data and materials

All data generated or analyzed during this study are included in this published article as supplementary information files.

competing interests

The authors declare that they have no competing interests.

Author contributions

Mohamed Bahaa Hussein: Conceptualized the study, designed the methodology, performed data acquisition, and supervised the overall project. Drafted and revised the manuscript. **Ahmed Salah El-Harty:** Contributed to data

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collection, statistical analysis, and interpretation of results. Provided critical revisions for intellectual content. Assisted in data collection, literature review, and preparation of the manuscript draft. Participated in coordinating the project logistics. **Moutaz El Sherbini**: Contributed to the study design, reviewed the manuscript, and provided expert input on clinical implications. **Ahmed Nagy Shaker**: Reviewed and edited the manuscript critically, ensuring the accuracy of the clinical aspects and compliance with ethical standards, conducted data analysis and interpretation. Provided substantial input during manuscript drafting and ensured clarity of scientific content. **Reem husameddin**: Provided senior supervision, revised the manuscript critically for important intellectual content, and approved the final version for submission. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work. All authors actively participated in the preparation of this manuscript, including the cases they performed. They reviewed the completed manuscript and gave their approval for publication.

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Abstract

Background: The cesarean section (CS) rate globally is rising, particularly in Egypt, where it increased from 20% in 2005 to 52% in 2014. While CS can be lifesaving in complicated deliveries, it poses risks such as excessive blood loss and complications in future pregnancies. Obstetric hemorrhage accounts for 27% of maternal deaths worldwide. Tranexamic acid (TXA), an antifibrinolytic agent, effectively reduces surgical bleeding, but the efficacy of oral versus intravenous (IV) TXA in cesarean deliveries is not well-studied.

Objective: This study compares the effectiveness and safety of preoperative oral versus IV TXA in reducing intraoperative blood loss during elective lower segment cesarean sections (LSCS).

Patients and Methods: We randomly assigned 140 women scheduled for LSCS into two groups: the IV TXA group received 1 g of TXA intravenously at anesthesia induction, while the oral TXA group received 2 g orally one hour before surgery. The primary outcome was estimated blood loss (EBL),

with secondary outcomes including excessive blood loss (>1000 mL), blood transfusion needs, uterotonic usage, and side effects.

Results: The oral TXA group experienced significantly higher average blood loss than the IV group, measured through surgical towels, suction containers, and estimation formulas. No significant differences in postpartum hemorrhage rates or transfusion needs were observed, and both TXA forms showed no adverse maternal or fetal outcomes.

Conclusion: Oral TXA led to greater intraoperative blood loss compared to IV TXA, but both methods were equally effective in preventing excessive postpartum bleeding. TXA was safe for mothers and fetuses regardless of administration route.

Keywords: Caesarean section- Postpartum hemorrhage- Tranexamic acid.

Introduction

The global prevalence of cesarean section (CS) is steadily increasing. By 2015, approximately 29.7 million births were delivered via CS, a significant rise from the estimated 16 million in 2000 (1). In Egypt, the rate of CS has also seen a sharp increase, climbing from 20% in 2005 to 52% in 2014, marking the highest incidence in the Eastern Mediterranean Region (2). Cesarean section is a life-saving surgical procedure for both the fetus and the mother, particularly in cases of complications during vaginal delivery. Absolute indications for CS include conditions such as pelvic deformity, abnormal fetal presentation, chorioamnionitis, uterine rupture, placenta previa, umbilical cord prolapse, and eclampsia (3). However, the World Health Organization (WHO, 2015) advises that CS should be limited to cases where it is medically necessary. When CS rates exceed 10%, there is no corresponding improvement in maternal or neonatal outcomes (4). Additionally, CS is associated with various complications, including increased blood loss, or-

gan damage, anesthetic risks, hysterectomy, thromboembolic events, adhesion formation, and chronic pain. Subsequent pregnancies after CS are also at higher risk for complications such as ectopic pregnancy, miscarriage, preterm delivery, infertility, and placental abnormalities (3). Obstetric hemorrhage remains a leading cause of maternal morbidity and mortality, accounting for roughly 27% of all maternal deaths globally. Of these, postpartum hemorrhage (PPH) alone contributes to 19.7% of cases (5). Mortality rates from PPH vary significantly between developed and developing nations, with rates of 8% and 19.7%, respectively (5). Emergency cesarean sections further heighten the risk of severe postpartum hemorrhage (6). The average blood loss during a cesarean section is approximately double that of a vaginal delivery, which often necessitates blood transfusions and exposes mothers to additional risks (7). Effective management strategies are critical to mitigate complications resulting from postpartum bleeding. During labor and delivery, certain physiological mechanisms help control bleeding. After placental separation, the uterine wall undergoes significant changes, including intense uterine contractions, platelet activation, and increased release of coagulation factors, alongside enhanced fibrinolysis. To further minimize bleeding, uterotonic agents such as oxytocin, ergometrine, prostaglandins (E1, F2 α), and carbetocin are routinely administered (8). Other agents, such as tranexamic acid (TXA) and ethamsylate, are also used to promote hemostasis (9). Oxytocin stimulates uterine contractions, with an intravenous dose of 5 IU often sufficient to reduce bleeding postpartum. Tranexamic acid, a lysine analog, inhibits plasminogen activation by binding to lysine receptors, thereby reducing fibrinolysis and minimizing intraoperative and postoperative blood loss (8). The World Maternal Antifibrinolytic (WOMAN) trial, published in *The Lancet* in 2017, provided robust evidence of TXA's safety and efficacy in reduc-

ing maternal mortality due to PPH. However, concerns persist regarding the potential risk of thromboembolic events (10). While intravenous TXA has demonstrated efficacy in treating PPH, its effectiveness in oral form remains uncertain, with limited research exploring its use in this context.

Patients and methods

This study, conducted at Cairo University Hospitals' Obstetrics and Gynecology Department from June 2023 to January 2024, was a double-blinded, randomized comparative trial involving 140 pregnant women aged 18-40 years who were candidates for elective cesarean sections. Women were included if they had a BMI of 18.5-30, singleton pregnancies at ≥ 37 weeks of gestation, preoperative hemoglobin levels ≥ 10 mg/dL, and were undergoing cesarean sections under spinal anesthesia. Exclusion criteria encompassed known allergies to tranexamic acid (TXA) or its excipients, comorbidities (e.g., diabetes mellitus, hypertension, clotting disorders, or renal/cardiac diseases), previous cesarean deliveries exceeding three, prolonged operative time (>2 hours), emergency cesarean sections, high-risk obstetric hemorrhage cases, and known fetal anomalies. Ethical approval was obtained, and informed consent was secured from all participants. Participants were randomized into two groups: an intravenous (IV) TXA group (1 g TXA administered at anesthesia induction) and an oral TXA group (2 g TXA administered 1 hour preoperatively). We selected the 2-gram oral dose of tranexamic acid (TXA) based on evidence from previous studies demonstrating its efficacy and safety in reducing blood loss during surgical procedures, like knee arthroplasty. Research suggests that a 2-gram oral dose achieves therapeutic plasma concentrations comparable to a 1-gram intravenous dose when administered approximately 1-2 hours preoperatively as oral route will pass through hepatic metabolism so effective concentration will decrease. Specifically, studies

such as (Kayupov et al., 2017; Fillingham et al., 2016) (11,12), the timing of 1 hour prior to surgery was chosen to ensure adequate systemic absorption and peak plasma levels at the time of incision, optimizing its antifibrinolytic effects during the critical period of surgery. This timing aligns with pharmacokinetic data indicating that TXA achieves maximum efficacy within this window when administered orally (13). All procedures adhered to a standardized cesarean protocol, including Pfannenstiel incisions, immediate cord clamping (<30 seconds), controlled placental cord traction, and uterine closure in two layers. Blood loss was evaluated using the difference in towel weights, suction contents, and pre- and postoperative hemoglobin levels. Monitoring also included fluid infusion rates, urine output, and complete blood count testing 12 hours postoperatively. The study's primary outcome was estimated blood loss during cesarean delivery. Secondary outcomes included excessive blood loss ($>1,000$ mL), blood transfusion requirements, additional uterotonic use, and maternal or fetal side effects. we employed standard prophylactic uterotonics in all cases. Each participant received 10 IU of oxytocin administered via intravenous infusion immediately after delivery of the fetus, which is in line with established guidelines for minimizing postpartum hemorrhage (PPH) risk during cesarean sections. The parameters for administering additional uterotonics included: intraoperative blood loss, if as ≥ 500 mL, Poor uterine tone, as assessed clinically by the attending surgeon and anesthetist, and hemodynamic instability, including hypotension or tachycardia suggestive of ongoing hemorrhage. In cases where these criteria were met, additional uterotonics such as ergometrine or misoprostol were administered per clinical judgment to ensure adequate uterine contraction and hemostasis.

The calculation of sample size was based on comparing the intraoperative (IO) total blood loss during elective Cesarean sections between women receiving oral tranexamic

acid and those administered IV tranexamic acid. According to earlier research by Wu et al., (14), the average IO blood loss for the IV tranexamic acid group was reported as 886.1 ± 200 ml, while the oral tranexamic acid group had an average of 863.3 ± 272 ml. Assuming a minimal clinically significant difference of 20% in IO total blood loss, and taking the mean of the standard deviations from both groups, a minimum of 70 participants in each group was determined to be necessary to achieve 80% power at a significance level of $\alpha = 0.05$, utilizing Student's t-test for independent samples. The sample size calculation was performed using Stats Direct statistical software version 2.7.2, developed by StatsDirect Ltd. in Cheshire, UK.

Statistical analysis

Continuous variables that follow a normal distribution are presented as means along with their standard deviations, whereas data that do not follow a normal distribution are represented as medians with ranges or interquartile ranges (IQRs). Categorical variables are described in terms of frequencies and percentages. To assess the normality of numerical data, the Kolmogorov-Smirnov test was utilized. Group comparisons were conducted using Student's t-test for variables with a normal distribution and the Mann-Whitney U test for those without. For categorical variables, the chi-square test was used, and Fisher's exact test was applied when the expected frequencies were less than 5. A significance level of $P < 0.05$ was established. All statistical analyses were performed using Microsoft Excel 2016 and IBM SPSS Statistics software (version 22 for Windows).

Results

Table 1: Demographic Characteristics and Previous Cesarean Section Distribution. This table outlines the demographic data and the distribution of prior cesarean sections among

participants in the IV TXA and Oral TXA groups, revealing no significant differences in age, weight, or gestational age ($P > 0.05$). Most participants in both groups had undergone one prior cesarean section (52.9% in the IV TXA group vs. 62.9% in the Oral TXA group). Notably, while none of the Oral TXA group had zero prior cesarean sections, 4.3% of the IV TXA group did. The distribution of previous cesarean sections did not differ significantly ($P = 0.325$), suggesting that baseline obstetric histories were comparable across the groups. **Table 2:** Estimated Blood Loss (EBL) Between Groups. The study evaluated blood loss in the IV TXA and Oral TXA groups by measuring towel weights and suction unit volumes. The IV TXA group showed significantly lower mean postoperative towel weight (555.71 g) compared to the Oral TXA group (615.64 g, $P = 0.04$). Similarly, the towel weight difference was smaller in the IV TXA group (356.50 g vs. 422.14 g, $P = 0.002$). Blood volume in the suction unit was also reduced in the IV TXA group (207.86 ml vs. 293 ml, $P = 0.001$). Preoperative hemoglobin (Hb) and hematocrit (Hct) levels were similar between groups; however, postoperative Hb (10.56 g/dl vs. 10.15 g/dl, $P < 0.001$) and Hct (31.68 vs. 30.88, $P = 0.009$) were significantly higher in the IV TXA group. The overall EBL was lower in the IV TXA group, with a mean of 564.36 ml (median 545 ml) compared to the Oral TXA group, which had a mean of 715 ml (median 652.5 ml). These findings indicate that IV TXA was more effective in minimizing blood loss than oral TXA. **Table 3:** Ecchymotic Use and Postpartum Hemorrhage (PPH). This table demonstrates a significant disparity in the need for additional ecchymotic agents between the groups. The Oral TXA group had a substantially higher proportion of participants requiring additional ecchymotic (54.3%) compared to the IV TXA group (17.1%; $P < 0.001$). However, the occurrence of $PPH > 1000$ ml was low and similar across both groups (1.4% in the IV TXA group vs. 2.9% in the Oral TXA group, $P = 1$). These

results suggest that IV TXA is more effective in reducing the need for additional uterotonic agents, while both forms of TXA are equally effective in preventing severe PPH. The findings across the tables highlight that IV TXA consistently outperformed oral TXA in minimizing blood loss and the requirement for additional ecboic, while maintaining similar effectiveness in preventing significant postpartum hemorrhage.

Discussion

Obstetric hemorrhage is a significant contributor to maternal mortality, accounting for approximately 25% of maternal deaths globally (15). Despite routine prophylaxis, postpartum hemorrhage (PPH) still occurs in 3–10% of deliveries (8). Tranexamic acid (TXA), a synthetic derivative of lysine, functions as an anti-fibrinolytic agent by inhibiting the lysine binding sites on plasminogen. TXA has been shown to significantly reduce postoperative bleeding and the need for blood transfusions following surgery (16). The WOMAN trial demonstrated that administering 1 g of intravenous TXA within three hours of delivery substantially reduced mortality due to PPH, leading to its recommendation by the WHO as a standard treatment for PPH, irrespective of its cause (17).

While the efficacy of intravenous TXA (IV TXA) in managing PPH is well-established, its effectiveness when administered orally remains uncertain. There is currently no data supporting the use of oral TXA as a therapeutic option for PPH. However, studies suggest that oral TXA could be effective in preventing PPH, especially when combined with misoprostol (18). If proven effective, oral TXA could be administered in resource-limited settings by mid- or low-level healthcare providers during home deliveries or when intravenous access is unavailable. This approach could enhance PPH management, particularly in low-resource settings where most maternal deaths from PPH occur (19). One of the challenges with TXA treatment lies in its

need for intravenous administration, which requires trained personnel. Exploring alternative routes, such as intramuscular or oral administration, could improve accessibility and ease of use, especially in settings with limited resources. However, more research is needed to evaluate the pharmacokinetics, pharmacodynamics, and safety of TXA administered through these alternative routes during pregnancy (20).

This randomized controlled trial assessed the effectiveness of oral versus intravenous TXA in reducing blood loss during cesarean sections. A total of 140 patients were enrolled, with 70 receiving 1 g of IV TXA at the time of anesthesia induction and 70 receiving 2 g of oral TXA two hours before surgery. The dosage for oral TXA was based on its previously established safety profile. Our findings showed no significant differences between the two groups in demographic characteristics, such as age, weight, gestational age, and number of previous cesarean sections, indicating proper randomization. However, blood loss was significantly lower in the IV TXA group compared to the oral TXA group. This was demonstrated by differences in towel weight, suction volume, hemoglobin drop, hematocrit drop, and the need for additional uterotonics, all of which were statistically significant ($p < 0.001$). The incidence of PPH and the requirement for blood transfusions were lower in the IV TXA group, though these differences were not statistically significant due to the small sample size. Reported side effects of TXA, such as gastrointestinal symptoms, were not observed in our study. Serious complications, including thrombotic events, were also not reported, likely due to the low, safe doses used.

Our results align with the WOMAN trial, which demonstrated that early administration of IV TXA effectively reduces mortality from PPH (21). Similarly, a systematic review by Wang et al. (2015) confirmed that IV TXA significantly decreases blood loss and the need for transfusions during and af-

ter cesarean sections. Shady et al. evaluated oral TXA combined with buccal misoprostol in vaginal deliveries and found it effective in reducing blood loss compared to misoprostol or oxytocin alone. In contrast, our study focused solely on oral TXA without additional uterotonics, potentially explaining the lesser efficacy compared to IV TXA (22).

Conclusion

intravenous TXA remains superior to oral TXA in reducing blood loss during cesarean sections, minimizing hemoglobin and hematocrit drops, and lowering the need for blood transfusions. Further research is required to optimize the use of oral TXA in obstetrics, particularly in resource-constrained settings, to provide an accessible alternative to intravenous administration.

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Table 1: Demographic Data and Previous Cesarean Sections of Studied Groups

Parameter	IV TXA Group (Mean \pm SD / Count)	Oral TXA Group (Mean \pm SD / Count)	P-Value
Age (years)	28.60 \pm 4.36	27.37 \pm 3.90	0.081*
Weight (kg)	90.49 \pm 9.98	89.73 \pm 10.58	0.664*
Gestational Age (weeks)	38.3 \pm 0.80	38.03 \pm 0.76	0.071*
Previous Cesarean Sections			0.325#
- 0 previous CS	3 (4.3%)	0 (0.0%)	
- 1 previous CS	37 (52.9%)	44 (62.9%)	
- 2 previous CS	24 (34.3%)	20 (28.6%)	
- 3 previous CS	6 (8.6%)	6 (8.6%)	

Values (continuous quantitative data) are given as the means \pm SDs, values (categorical) are given as numbers (percentages). The Kolmogorov–Smirnov test was used to analyze the normality of the data distribution characteristics namely, age, BMI, and GA, or all the study patients.

T test was used for normally distributed continuous quantitative data.

#Chi-square test was used for qualitative (categorical) data

A P value <0.05 was considered to indicate statistical significance, so the P value of the study group was not significant.

Table 2: Blood Loss, Hemoglobin, Hematocrit, and Estimated Blood Loss (EBL) in the IV TXA and Oral TXA Groups

Parameter	IV TXA	Oral TXA	P-Value
Preoperative Towel Weight (gm)	Mean: 199.21 \pm 22.60 (165–225)	Mean: 193.50 \pm 20.77 (180–225)	0.122
Postoperative Towel Weight (gm)	Mean: 555.71 \pm 120.30 (390–1050)	Mean: 615.64 \pm 121.36 (325–900)	0.004
Towel Difference (gm)	Mean: 356.50 \pm 125.87 (210–870)	Mean: 422.14 \pm 116.00 (145–715)	0.002
Suction Blood (ml)	Mean: 207.86 \pm 100.73 (100–690)	Mean: 293.71 \pm 169.48 (100–950)	<0.001
Preoperative Hemoglobin (Hb)	Mean: 11.19 \pm 0.82 (10.20–14.10)	Mean: 11.09 \pm 0.65 (10.20–13.00)	0.444
Preoperative Hematocrit (HCT)	Mean: 33.39 \pm 2.31 (30.50–40.90)	Mean: 33.06 \pm 1.59 (30.00–39.40)	0.331
Postoperative Hemoglobin (Hb)	Mean: 10.56 \pm 0.67 (9.60–12.80)	Mean: 10.15 \pm 0.67 (9.10–12.20)	<0.001
Postoperative Hematocrit (HCT)	Mean: 31.68 \pm 2.03 (28.80–38.50)	Mean: 30.88 \pm 1.51 (27.60–36.50)	0.009
Hemoglobin Difference (g/dL)	Mean: 0.63 \pm 0.36 (0.10–2.00)	Mean: 0.94 \pm 0.31 (0.10–2.10)	<0.001

Hematocrit Difference (%)	Mean: 1.70 ± 0.53 (1.19–4.11)	Mean: 2.19 ± 0.47 (1.40–3.60)	<0.001
EBL (Towels + Suction) (ml)	Median: 535; Mean: 564.36 ± 168.43 (370–1010)	Median: 652.5; Mean: 715.86 ± 194.43 (465–1400)	<0.001
EBL Using Formula (ml)	Median: 379.07; Mean: 412.11 ± 124.06 (284.81–1013.75)	Median: 506.71; Mean: 541.36 ± 141.44 (378.53–1044.12)	<0.001

Values (continuous quantitative data) are given as the means \pm SDs (range),

The Kolmogorov–Smirnov test was used to analyze the normality of the data distribution characteristics of all the study patients.

T test was used for normally distributed continuous quantitative data.

A P value <0.05 was considered to indicate statistical significance, so the P value of the study group was not significant.

Table 3: Ecboic Use and Occurrence of Postpartum Hemorrhage (PPH) Between IV TXA and Oral TXA Groups

Variable	IV TXA (n = 70)	Oral TXA (n = 70)	P-Value
Use of Additional Ecboics			
Yes	12 (17.1%)	38 (54.3%)	< 0.001#
No	58 (82.9%)	32 (45.7%)	
PPH > 1000 ml			
Yes	1 (1.4%)	2 (2.9%)	1#
No	69 (98.6%)	68 (97.1%)	

values (categorical) are given as numbers (percentages).

#Chi-square test was used for qualitative (categorical) data

A P value <0.05 was considered to indicate statistical significance, so the P value of the study group was not significant.