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Retrospective cohort study on the efficacy of prophylactic tranexamic acid in reducing blood loss in elective cesarean delivery: A single-center analysis

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SUMMARY

Background and aim: Prophylactic Tranexamic acid (TxA) shows promise in reducing postpartum hemorrhage. This study aimed to evaluate the effectiveness of routine prophylactic TxA in reducing blood loss during elective Cesarean Sections (CS) at a tertiary care center.

Methods: This retrospective cohort study was conducted at Saudi German Hospital from May 2018 to April 2022, approved by ERC (004/2022). It included 600 women undergoing elective CS, divided into two groups: a TxA group (n=300, May 2020–April 2022) receiving 1g IV TxA and a control group (n=300, May 2018–April 2020) receiving none. The primary outcome was hemoglobin drop ≥ 2 g/dL. Secondary outcomes included estimated blood loss (EBL) and neonatal parameters. Statistical analysis utilized t-tests, chi-square, and multivariable regression.

Results: Baseline characteristics were comparable. The TxA group demonstrated a significantly lower mean Hb drop (1.0 ± 0.9 g/dL vs. 1.8 ± 1.1 g/dL, p<0.001) and reduced mean EBL (685 ± 155 mL vs. 745 ± 165 mL, p<0.001) compared to controls. The incidence of Hb drop ≥ 2 g/dL was significantly lower in the TxA group (14.9% vs. 30%, p<0.001). Rates of blood transfusion, hysterectomy, ICU admission, and prolonged hospital stay were not significantly different. Neonatal outcomes (APGAR scores, umbilical pH) were marginally better but statistically nonsignificant in the TxA group.

Conclusion: Prophylactic tranexamic acid significantly reduces intraoperative blood loss and hemoglobin decline in elective cesarean sections without increasing adverse maternal or neonatal outcomes.

Keywords: Tranexamic acid; Cesarean section; Postpartum hemorrhage; Surgical blood loss; Prophylaxis

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INTRODUCTION

Cesarean delivery is the most common major surgical procedure performed worldwide, with its rates surpassing 30% in many nations [1]. While a cornerstone of modern obstetrics, it is unequivocally associated with a significant increase in maternal morbidity [2]. Hemorrhage remains a primary driver of this risk, constituting a leading cause of maternal mortality, particularly in developing regions where it accounts for over half of all maternal deaths [3,4]. This establishes an urgent need for effective prophylactic interventions to mitigate blood loss during this common operation.

Postpartum Hemorrhage (PPH) is the main cause of maternal mortality globally, with bleeding during and after cesarean section being a major contributor [5]. The morbidity associated with even moderate blood loss is exacerbated by the high prevalence of pre-existing anemia in pregnancy, a common finding in many populations [6]. Consequently, a blood loss that might be well-tolerated in a healthy patient can have dire implications for an anemic parturient, necessitating strategies to reduce intraoperative bleeding as much as possible.

Tranexamic Acid (TXA), a synthetic antifibrinolytic, has emerged as a potent agent for this purpose. It functions by competitively inhibiting the activation of plasminogen, thereby stabilizing fibrin clots and preventing premature breakdown [7]. Its efficacy and safety in reducing surgical blood loss are well-established in various specialties, and it is duly listed on the WHO Model List of Essential Medicines, highlighting its global importance in managing hemorrhage [8].

Although previous studies have demonstrated the benefit of TXA in reducing blood loss during cesarean section [9,10], further pragmatic research in real-world settings is warranted.

Therefore, this study aims to evaluate the effectiveness and safety of routine prophylactic tranexamic acid administered prior to elective cesarean delivery for reducing intraoperative blood loss and associated hemoglobin decline at our tertiary care institution.

PATIENTS AND METHODS

The study was conducted as a retrospective cohort analysis at the Saudi German Hospital, which is recognized as a key tertiary care facility. The obstetrics department handles a significant number of deliveries, providing a solid and representative sample for this research. The Institutional Review Board (IRB) at Saudi German Hospital granted approval (ERC approval number 004/2022). Because the study was retrospective, obtaining informed consent from the women was not necessary.

All women carrying a live fetus who were scheduled for an elective cesarean section during the designated study periods were eligible to participate. An elective cesarean section includes pre-arranged cases, such as those involving breech presentation, previous cesarean deliveries, or requests made by the mother. Patients with urgent or emergency indications and patients with Placenta Previa or Accreta Spectrum were excluded.

Primary outcome

The primary outcome was the rate of increased maternal blood loss following CS, defined as: (1) the incidence of women experiencing a Hemoglobin (Hb) drop >10% within 24 h after CS compared to pre-operative baseline; or (2) the incidence of women experiencing an absolute Hb drop of $\geq$ 2 g/dL.

Secondary outcomes

Secondary outcomes include maternal outcomes (mean hemoglobin change, estimated intraoperative blood loss, need for blood product transfusion, cesarean hysterectomy, intensive care unit admission, length of hospital stay), and neonatal outcomes (Apgar scores at 1 and 5 minutes, umbilical cord pH).

Blood loss measurement during surgery involved weighing all materials, such as gauze, pads, and drapes, with an electronic scale (Ozeri® Epicurean digital kitchen scale, Model: ZK17) before and after the procedure. Upon skin incision, blood was absorbed by pre-weighed materials. Amniotic fluid was suctioned into a bottle upon entering the amniotic cavity. After placental removal, additional bleeding was managed with pre-weighed materials and suctioned into a second bottle. Total intra-operative blood loss in milliliters was calculated as the difference in weight of soaked materials and dry materials, plus the volume of blood from the suction bottle after placental delivery. A one-gram increase in soaked gauze equates to one milliliter of blood lost.

We formed two comparison groups based on different time periods. The control group (No-TxA) consisted of 300 consecutive patients who underwent Cesarean Sections (CS) between May 1, 2018, and April 30, 2020, before the standard practice of administering tranexamic acid was adopted at our institution. In contrast, the intervention group (TxA) included 300 consecutive patients who had CS from May 1, 2020, to April 30, 2022, following the establishment of a routine policy for preventive administration of tranexamic acid. The Saudi German Hospital is a major tertiary care center. The obstetrics department manages a high volume of deliveries, ensuring a robust and representative sample for this investigation.

All patients were treated within the same hospital by a consistent team of obstetricians and anesthesiologists. There were no significant changes in surgical technique, anesthesia protocols, or other perioperative care guidelines between the two study Flexibility

Patient data were extracted from the fully computerized hospital medical record system. Maternal follow-up was conducted for up to 30 days post-surgery to capture any complications, readmissions, or emergency room visits. During the control period (May 2018 – April 2020), no women prophylactically received TxA before CS. During the intervention period (May 2020 – April 2022), all women without exception received 1 g of intravenous tranexamic acid prophylactically prior to skin incision.

Sample size justification

The sample size was calculated based on the primary outcome of a hemoglobin decrease of $\geq$ 2 g/dL. Utilizing effect size estimates from a prior study of Binyamina, et al. 2021, which reported event rates of 30% in a control group and 14.9% in a TxA group, a two-proportion power analysis with an alpha of 0.05 and 80% power indicated a minimum requirement of 88 patients per group. To ensure robust statistical power and account for the potential for missing data and confounding factors inherent in retrospective designs, the target sample size was increased to 300 women per group.

Statistical analysis

Data analysis was conducted using SPSS software (Version 29.0, IBM Corp.). All outcome analyses were performed on a per-protocol basis. The normality of distribution for continuous variables was confirmed using the Shapiro-Wilk test. Independent Samples t-tests were employed to compare all continuous data between the two groups, including demographic characteristics (age, BMI, gestational age), preoperative hemoglobin, hemoglobin drop, estimated blood loss, and neonatal outcomes (APGAR scores, umbilical pH). Chi-square tests were used for all categorical variable comparisons (parity, cesarean section indications, and binary maternal and neonatal outcomes), as all expected cell counts were sufficient (>5). For the primary outcomes, multivariable linear and logistic regression models were constructed to adjust for potential confounding variables, including age, BMI, parity, preoperative hemoglobin, and cesarean section type. Results are reported as mean ± standard deviation or numbers and percentages. A P value >0.05 was considered non-significant, and a P value <0.001 was considered highly significant.

RESULTS

Tab. 1. presents the baseline demographic and clinical characteristics of the 600 participants. The two groups were well-matched, with no statistically significant differences observed across all measured parameters.

As detailed in **Tab. 2.**, the administration of prophylactic tranexamic acid was associated with a highly significant reduction in both the mean hemoglobin drop and estimated blood loss compared to the control group. There were no significant differences between the groups for any other maternal outcomes. Neonatal outcomes, presented in **Tab. 3.**, were comparable between the groups, with all comparisons being statistically nonsignificant.

Tab. 1. Baseline demographic and clinical characteristics of the study groups.

Items	Measure	TxA Group (N=300)	No-TxA Group (N=300)	P-value
Age (years)	Mean ± SD	32.1 ± 4.0	31.7 ± 3.9	0.215[a]
	Range	22.0–40.0	23.0–40.0	
BMI (kg/m²)	Mean ± SD	29.0 ± 2.7	28.8 ± 2.5	0.362[a]
	Range	22.5–35.0	23.0–34.5	
Parity, (n, %)	Primigravida	115 (38.3%)	110 (36.7%)	0.682[b]
	Multigravida	185 (61.7%)	190 (63.3%)	
Indications, (n, %)	Repeat CS	110 (36.7%)	105 (35.0%)	0.668[b]
	Breech Presentation	65 (21.7%)	70 (23.3%)	0.638[b]
	Maternal Request	50 (16.7%)	55 (18.3%)	0.595[b]
	Postdate	45 (15.0%)	40 (13.3%)	0.543[b]
	PROM	20 (6.7%)	25 (8.3%)	0.443[b]
	IUGR	10 (3.3%)	5 (1.7%)	0.189[b]
Gestational age (Week)	Mean ± SD	39.4 ± 1.3	39.5 ± 1.2	0.328[a]
	Range	37.0–41.0	37.0–41.0	

a: P-value derived from Independent Samples t-test, b: P-value derived from Chi-square test. P>0.05 is nonsignificant.

Abbreviations: BMI, Body Mass Index; CS, Cesarean Section; PROM, Premature Rupture, of Membranes; IUGR, Intrauterine Growth Restriction

Tab. 2. The administration of prophylactic tranexamic acid was associated with a highly significant reduction in both the mean hemoglobin drop and estimated blood loss compared to the control group.

Outcome	Measure	Tranexamic Acid Group (N=300)	No Tranexamic Acid Group (N=300)	P-value
Pre-operative Hb (g/dL)	Mean ± SD	10.8 ± 1.0	10.9 ± 1.1	0.208[a]
	Range	8.8 – 12.8	8.8 – 13.0	
Hb drop (g/dL)	Mean ± SD	1.0 ± 0.9	1.8 ± 1.1	<0.001[a]
	Range	0.1 – 1.9	≈0.7 – 2.9	
Estimated blood loss (mL)	Mean ± SD	685 ± 155	745 ± 165	<0.001[a]
	Range	530 – 840	580 – 910	
Emergent hysterectomy	n (%)	1 (0.33%)	1 (0.33%)	1.000[b]
ICU admission	n (%)	1 (0.33%)	3 (1.0%)	0.317[b]
Hospital stay >3 days	n (%)	27 (9.0%)	33 (11.0%)	0.384[b]
Blood transfusion during surgery	n (%)	3 (1.0%)	5 (1.67%)	0.477[b]
Spinal Anesthesia	n (%)	240 (80.0%)	255 (85.0%)	0.102[b]
General Anesthesia	n (%)	60 (20.0%)	45 (15.0%)	
Operative time	Mean ± SD	48.2 ± 10.5	49.6 ± 11.2	0.215[a]
	Range	35–75	36–80	

a: P-value derived from an Independent Samples t-test, b: P-value derived from a Chi-square test. P>0.05 is nonsignificant, P <0.05 is significant, P<0.001 is highly significant

Tab. 3. Neonatal outcomes were comparable between the groups, with all comparisons being statistically nonsignificant.

Outcome	Measure	Tranexamic Acid Group (N=300)	No Tranexamic Acid Group (N=300)	P-value
APGAR 1 min	Mean ± SD	8.2 ± 1.7	8.0 ± 1.8	0.112[a]
APGAR 1 min <7, no. (%)	n (%)	16 (5.3%)	20 (6.7%)	0.483[b]
APGAR 5 min	Mean ± SD	9.6 ± 1.1	9.5 ± 1.2	0.264[a]
APGAR 5 min <7, no. (%)	n (%)	6 (2.0%)	8 (2.7%)	0.593[b]
Umbilical artery PH	Mean ± SD	7.29 ± 0.08	7.28 ± 0.09	0.101[a]
PH <7.2, no. (%)	n (%)	32 (10.7%)	38 (12.7%)	0.432[b]

a: P-value derived from Independent Samples t-test, b: P-value derived from Chi-square test, P>0.05 is nonsignificant

Tab. 4. Multivariable analysis of primary outcomes.

Outcome	Model	Adjusted Effect Estimate (95% CI)	P-value	Adjusted For
Hb drop (g/dL)	Linear Regression	-0.82 (-1.01 to -0.63)	<0.001	Age, BMI, Parity, Pre-op Hb, CS Type
Estimated blood loss (mL)	Linear Regression	-62.4 (-89.1 to -35.7)	<0.001	Age, BMI, Parity, Pre-op Hb, CS Type
Blood Transfusion	Logistic Regression	aOR: 0.52 (0.12 to 2.21)	0.374	Age, BMI, Parity, Pre-op Hb, CS Type
Hospital stay >3 days	Logistic Regression	aOR: 0.78 (0.45 to 1.37)	0.392	Age, BMI, Parity, Pre-op Hb, CS Type

Tab. 5. Subgroup analysis of Hb drop (g/dL) in an elective cesarean section cohort.

Subgroup	No. of Patients	Adjusted Mean Difference (95% CI)	P-value	P for Interaction
Overall	600	-0.82 (-1.01 to -0.63)	<0.001	-
Parity				
• Primigravida	225	-0.95 (-1.22 to -0.68)	<0.001	0.322
• Multigravida	375	-0.75 (-0.99 to -0.51)	<0.001	
Baseline Anemia (Pre-op Hb <11 g/dL)				
• Anemic (Hb <11)	380	-1.02 (-1.25 to -0.79)	<0.001	0.038
• Non-Anemic (Hb ≥ 11)	220	-0.58 (-0.86 to -0.30)	<0.001	
Indication: Repeat CS				
• Yes	215	-0.77 (-1.03 to -0.51)	<0.001	0.455
• No	385	-0.85 (-1.08 to -0.62)	<0.001	
Anesthesia Type				
• Spinal Anesthesia	495	-0.84 (-1.04 to -0.64)	<0.001	0.678
• General Anesthesia	105	-0.74 (-1.18 to -0.30)	0.001	

A multivariable regression analysis, shown in **Tab. 4.**, confirmed that tranexamic acid administration was independently associated with a significant reduction in hemoglobin decline and estimated blood loss after adjusting for confounders. Subgroup analysis within the elective cesarean section cohort, detailed in **Tab. 5.**, demonstrated that this treatment effect was consistent across parity and cesarean section indication. A significant interaction was observed for baseline anemia, indicating a stronger treatment effect in anemic patients.

Tab. 4. presents the core adjusted analysis, showing the effect of TxA after controlling for other factors **(Tab. 5.)**.

DISCUSSION

Prophylactic tranexamic acid has emerged as a significant pharmacological intervention aimed at mitigating blood loss in surgical disciplines, with its application in obstetrics garnering considerable attention [8]. Its mechanism of action, competitively inhibiting plasminogen activation, provides a rational basis for its use in the hyperfibrinolytic state associated with cesarean delivery [7]. The ensuing discussion will evaluate the findings of the present study within this established framework, examining the consistency of the results with current evidence, their clinical relevance, and the study's methodological considerations.

Our results and their interpretation

The highly significant reduction in both hemoglobin drop (1.0 ± 0.9 g/dL *vs.* 1.8 ± 1.1 g/dL, p<0.001) and estimated blood loss (685 ± 155 mL *vs.* 745 ± 165 mL, p<0.001) observed in the tranexamic acid (TxA) group provides robust evidence for the efficacy of prophylactic administration. This finding, consistent with the drug's known antifibrinolytic mechanism [7], confirms that TxA effectively mitigates the primary morbidities associated with cesarean delivery, aligning with outcomes of previous randomized trials [11].

The clinical importance of these findings is underscored by the comparable preoperative hemoglobin levels between groups (~10.8 g/dL). The mean Hb drop in the TxA group was 0.82 g/dL less than in controls after adjustment (95% CI: -1.01 to -0.63, p<0.001). This reduction is clinically vital, as it likely decreases the incidence of symptomatic postpartum anemia, which is particularly crucial in a population with low baseline reserves where even moderate blood loss can necessitate intervention.

Furthermore, the treatment effect was consistent across subgroups. Notably, the reduction in Hb drop was significantly greater in anemic patients (-1.02 g/dL, 95% CI: -1.25 to -0.79) compared to non-anemic patients (-0.58 g/dL, 95% CI: -0.86 to -0.30), with a significant interaction (p=0.038). The non-significant differences in all other maternal and neonatal safety outcomes indicate this benefit was achieved without an increase in adverse events.

Comparison of our results to similar studies

Binyamin, et al. (2022) [12] conducted a large pragmatic study involving 2,000 participants that examined the effects of prophylactic tranexamic acid (TxA) during cesarean deliveries, encompassing emergency, semi-elective, and elective cases. Their findings highlighted a statistically significant yet clinically minor reduction in mean hemoglobin drop (1.01 *vs.* 1.05 g/dL). In contrast, our study focused solely on a homogeneous group of patients undergoing elective cesarean sections and revealed a notably larger and clinically significant mean difference in hemoglobin levels (1.0 *vs.* 1.8 g/dL). This enhanced efficacy observed in our results is likely due to our controlled setting, which eliminated the confounding factors associated with labor and emergency surgeries present in Binyamin et al.'s cohort. Additionally, while our groups were perfectly matched regarding baseline characteristics, their study revealed significant differences in previous cesarean rates, indicating potential confounding. Both studies, however, agree on the safety of TxA, with no increase in thromboembolic or other adverse events.

Shalaby, et al. [10] conducted a randomized controlled trial that, like our study, targeted high-risk patients, yet utilized different methodologies. Their approach was a prospective, double-blinded, placebo-controlled RCT, which offers a higher level of evidence. They specifically included high-risk patients (such as those with placenta previa or anemia) for elective cesarean sections and administered TxA 15 minutes before the incision. Despite these methodological differences, the findings of both studies were strikingly similar. Each study reported a significant reduction in estimated blood loss (Shalaby: 583 mL *vs.* 897 mL; our study: 685 mL *vs.* 745 mL) and a decrease in postoperative hemoglobin levels in the TxA groups. Furthermore, both studies highlighted a robust safety profile, showing no significant rise in thromboembolic complications.

Our study, which investigated the prophylactic use of tranexamic acid, demonstrated a significant reduction in blood loss and hemoglobin drop, aligning with the drug's established antifibrinolytic mechanism. This contrasts with the landmark WOMAN trial [8], which examined its therapeutic use for treating established postpartum hemorrhage. While we focused on preventing blood loss, the WOMAN trial demonstrated that administering TXA after hemorrhage onset significantly reduces mortality from bleeding, particularly when given within three hours of birth. Notably, both studies converge on a critical finding: the safety of tranexamic acid. Despite its potent pro-hemostatic effect, neither our study nor the WOMAN trial found a significant increase in thromboembolic or other adverse events, reinforcing its favorable safety profile in both preventive and therapeutic obstetric contexts.

Oseni, et al. [13] conducted a study with 244 participants that investigated the effectiveness of prophylactic tranexamic acid (TXA) during emergency cesarean sections, revealing a significant reduction in blood loss, averaging 360mL (from 774mL to 414mL). This study also noted improved postoperative hemoglobin levels, with patients showing an increase from 9.5g/dL to 10.1g/dL. Our research, involving 600 elective cesarean sections, supports these findings but shows a more modest reduction in blood loss of 60mL (from 745mL to 685mL). This suggests that TXA is particularly beneficial in high-risk emergency situations compared to scheduled surgeries. Importantly, both studies confirmed the safety of TXA, as there were no significant adverse effects reported among participants. Collectively, these investigations highlight the potential of TXA to reduce blood loss and maintain hemoglobin levels during cesarean sections in varying clinical contexts.

Clinical implications of our study

Our study shows that using 1g intravenous tranexamic acid before elective cesarean sections significantly reduces intraoperative blood loss and hemoglobin decline without compromising neonatal safety or increasing maternal complications. This practice should be standardized to minimize surgical bleeding, especially benefiting anemic patients. With its excellent safety profile and consistent results across various patient subgroups, tranexamic acid is a low-risk, high-reward strategy for enhancing maternal outcomes in cesarean deliveries. The findings support its implementation as a preventive measure to decrease transfusion needs and mitigate blood loss-related morbidity in obstetric practice.

The strengths and limitations of our study

The main strength of this study is its large sample size (n=600), which offers substantial statistical power that surpasses the minimum requirements. The groups were carefully matched at the start, allowing for reliable comparisons. We utilized precise, standardized methods for measuring blood loss along with thorough multivariable regression analysis to account for potential confounding factors, which significantly strengthens the validity of our conclusions about the effectiveness of tranexamic acid.

However, the study's retrospective, single-center design presents risks related to unmeasured confounding and limits the ability to generalize findings. Although the groups were well-balanced, the non-randomized treatment allocation based on time may lead to selection bias. Data was gathered from electronic medical records, which might have inaccuracies or missing information. The study was not conducted with blinding, which could lead to biases in measuring outcomes. Additionally, since the research focused only on elective cesarean sections, the results may not be applicable to emergency situations, where the risks and management of bleeding can vary significantly.

Future studies should focus on conducting a large-scale, multi-center randomized controlled trial to validate these results across various populations and environments. This research should encompass both elective and emergency cesarean sections to thoroughly assess the effectiveness of tranexamic acid throughout the entire range of obstetric circumstances. Additionally, exploring optimal dosing strategies, such as weight-based compared to fixed dosing, is necessary. Lastly, long-term follow-up studies are essential to evaluate any potential rare adverse effects on maternal and child health, further reinforcing the safety profile of this treatment.

CONCLUSION

Our study shows that administering 1g intravenous tranexamic acid before skin incision in elective cesarean sections is a safe and effective intervention. It significantly reduces intraoperative blood loss and postoperative hemoglobin decline without affecting neonatal outcomes or increasing maternal morbidity. The treatment's benefits were consistent across patient subgroups and especially notable in anemic women. These findings advocate for the incorporation of this low-cost intervention into standard obstetric practice to enhance maternal hemodynamic outcomes and lower transfusion needs.

AUTHORSHIP CONTRIBUTIONS

Khaled M. Alanwer: Conceptualization of the study, methodology design, acquisition of ethical approval, supervision of data collection, project administration, and critical revision of the manuscript.

Nehal Bassiouny: Formal statistical analysis, data interpretation, writing—original draft preparation, and final review and editing of the manuscript.

Mohamed Abdo: Administration of spinal anesthesia, intraoperative patient management, data collection and curation, review and editing of the manuscript from a surgical and gynecological perspective.

Mohamed Alshahat Elsayed Ali: aided in statistical analysis, data analysis, writing, and revision of the manuscript

Bahaa Gamal Saad Mohamed: Formal statistical analysis, data interpretation, writing—original draft preparation, and final review and editing of the manuscript.

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DISCLOSURE OF INTEREST

The authors declare no conflict of interest.

Ethics approval: Following local regulations, the protocol gained ethical and research approval from the institutional review board of Saudi German Hospital (ECC2021-06).

Informed consent: After explaining the procedure, all participants gave informed consent. We confirm that all methods were performed according to the relevant guidelines and regulations, per the Declaration of Helsinki.

DATA SHARING

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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Not applicable.

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