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Comparison of Efficacy of Single Dose Tranexamic Acid versus Placebo before Surgery in Females Undergoing Surgery for Ovarian Cancer

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ABSTRACT

Objective: To compare the efficacy of single-dose tranexamic acid versus placebo in reducing transfusion requirements and perioperative blood loss in females undergoing surgery for ovarian cancer. **Methods:** This randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, Sheikh Zayed Hospital and Medical College, Rahim Yar Khan, over a 6-month period (December 2024 to May 2025). A total of 372 women aged 18–60 years with ovarian cancer of FIGO stage I–III and ASA class I–III were enrolled and randomized into two groups. Group A (n=186) received tranexamic acid 15 mg/kg intravenously before surgery, while Group B (n=186) received placebo. The primary outcome was efficacy, defined as no postoperative transfusion requirement. **Results:** All 372 patients completed the study. Baseline characteristics were comparable between groups (p >0.05). The requirement for transfusion was significantly lower in the tranexamic acid group (29.6%) compared to placebo (44.1%) (p=0.003). Efficacy was achieved in 70.4% of patients in the tranexamic acid group versus 55.9% in the placebo group (p=0.003). Mean perioperative blood loss was markedly reduced in the tranexamic acid group (548.3 ± 198.7 ml) compared to placebo (692.1 ± 242.6 ml) (p<0.001). Postoperative hemoglobin levels were significantly higher in the tranexamic acid group (10.2 ± 1.4 g/dl) compared to placebo (9.6 ± 1.6 g/dl) (p=0.001), with a smaller mean hemoglobin decline (1.6 ± 0.8 g/dl vs. 2.3 ± 1.2 g/dl, p<0.001). **Conclusion:** Single-dose tranexamic acid administered preoperatively significantly reduced transfusion requirements, perioperative blood loss, and hemoglobin decline in ovarian cancer surgery, supporting its use as an effective adjunct in perioperative management.

INTRODUCTION

In cancer patients, the risk of bleeding during surgery can be raised by factors like tumor angiogenesis, local tumor invasion and cancer treatments like chemotherapy or radiotherapy. This risk is even higher in this group because they take medicines like anti-angiogenic agents, non-steroidal anti-inflammatory drugs (NSAIDs) anticoagulants, and antiplatelet drugs on a regular basis [1]. Furthermore, changes in system that controls fibrinolysis also has been reported to affect the risk of bleeding during cancer surgeries [2]. Transfusions of blood products are commonly used to treat cancer patients in order to compensate for the blood loss that occurs during surgery and the subsequent anemia that results from it. However, these transfusions put patients at an increased risk for potentially fatal immune responses, venous thromboembolism, acute lung injury and postoperative infections [3-4].

In this complicated setting, possible solutions for preventing blood transfusions and associated consequences must be successful and safe. These techniques may involve a variety of pharmacological and surgical treatments. Tranexamic acid (TXA) is such promising pharmaceutical option for achieving this goal. It is a low-cost hemostatic agent with numerous uses and little side effects [5]. Tranexamic acid is a synthetic chemical derived from lysine that inhibits lysine-binding sites on plasminogen to provide anti-fibrinolytic actions. This binding stops both the activation of fibrin and the synthesis of plasmin, which is plasminogen in an active state as a result of which plasminogen activation is inhibited and the preformed fibrin structure created by secondary hemostasis is stabilized [6].

Compared to placebo, tranexamic acid has been reported to be efficacious in reducing the perioperative blood loss in females undergoing cesarean section [412.44 ± 199.2 ml vs 800.22 ± 306.72 ml] [7]. However, when talking specifically about surgery for ovarian cancer, current literature is quite sparse [8]. In fact recent meta-analysis also revealed that only one study has been done in past that has focused on role of tranexamic acid in surgery of advanced ovarian cancer [8-9]. The aforementioned study was conducted to compare the efficacy of tranexamic acid before surgery in females undergoing surgery for

advanced ovarian cancer and reported that requirement of transfusion was significantly lower in patients who were given preoperative tranexamic acid as compared to placebo [30% vs 44%, respectively] along with median perioperative blood loss [520ml vs 730ml, respectively] [10]. Owing to such scarcity of the data regarding the efficacy of preoperative TXA use in oncologic surgery, more specifically ovarian cancer surgery, and no study in the local population, it is imperative to conduct a study to determine the efficacy of tranexamic acid compared to placebo during surgery for ovarian cancer and add to the scientific knowledge regarding the efficacy of single dose tranexamic acid in surgery for ovarian cancer in our local population.

MATERIAL AND METHODS

This randomized controlled trial was conducted in the Department of Obstetrics and Gynecology at Sheikh Zayed Medical College, Rahim Yar Khan, over a 6-month period (December 2024 to May 2025) following approval from the College of Physicians and Surgeons Pakistan. The study protocol received ethical approval from the institutional review board (146/IRB/SZMC/SZH), and written informed consent was obtained from all participants prior to enrollment.

The primary objective was to compare the efficacy of single-dose preoperative tranexamic acid versus placebo in reducing blood transfusion requirements in females undergoing surgery for ovarian cancer. Efficacy was defined as the proportion of patients who did not require postoperative blood transfusion due to hemoglobin levels below 9 g/dl. Perioperative blood loss was calculated using the formula: Perioperative total blood loss (ml) = 1000 × Hb (loss)/Hb(pre), where Hb (loss) represented the difference between preoperative and postoperative hemoglobin levels.

The study employed non-probability consecutive sampling to recruit participants from the outpatient department. Sample size calculation was performed using WHO sample size calculator software with a significance level of 5%, power of 80%, and anticipated transfusion proportions of 30% in the tranexamic acid group and 44% in the placebo group based on previous literature. This yielded a calculated sample size of 372 patients, with 186 patients allocated to each group [10].

Eligible participants included females aged 18-60 years with ovarian cancer duration exceeding 12 months, FIGO stage I-III disease, and American Society of Anesthesiologists physical status classification of 1-3. The ASA classification system categorized patients from ASA 1 (normal healthy patients) through ASA 3 (patients with severe but non-life-threatening systemic disease). FIGO staging was determined by consultant radiologists with minimum two years of experience using computed tomography of the abdomen and pelvis.

Patients were excluded if they had FIGO stage IV ovarian cancer, ASA status 4-6, documented hypersensitivity to tranexamic acid, history of bleeding or clotting disorders, impaired renal function with serum creatinine exceeding 1.3 mg/dl, or history of coronary heart disease. These exclusion criteria were verified through comprehensive review of previous medical records.

Following enrollment, baseline demographic and clinical data were systematically collected for each participant. Age, weight measured using standard weighing scales, height measured using wall-mounted height scales, and calculated body mass index were recorded. Duration of ovarian cancer, menstrual status categorized as menstruating or menopausal, history of chemotherapy exposure, and previous abdominopelvic surgical procedures were documented through medical record review. Randomization was performed using a paper lottery method to ensure equal allocation of participants into two treatment groups. Group A received a single preoperative intravenous dose of tranexamic acid at 15 mg/kg body weight, while Group B received an equivalent volume of normal saline as placebo. All participants remained blinded to their group assignment throughout the study period. The randomization process was conducted by research personnel not involved in patient care or outcome assessment. All surgical procedures were performed by consultant surgeons with minimum three years of clinical experience to ensure consistency in surgical technique and minimize operator-dependent variables. Perioperative blood loss calculations were performed by the research team according to the predetermined formula using preoperative and postoperative hemoglobin measurements. Complete blood count reports were obtained within 12 hours following surgery to determine postoperative hemoglobin levels. The indication for blood transfusion was standardized across all participants, with packed red blood cell transfusion administered to patients whose postoperative hemoglobin levels fell below 9 g/dl. Treatment efficacy was assessed based on transfusion requirements, with positive efficacy defined as absence of postoperative blood transfusion need. All clinical data were recorded using standardized data collection forms specifically designed for this study.

Statistical analysis was conducted using SPSS version 26 software. The Shapiro-Wilk test was employed to assess normality of continuous variables. Continuous variables including age, duration of ovarian cancer, weight, height, body mass index, and perioperative blood loss were presented as mean ± standard deviation for normally distributed data or median with interquartile range for non-normally distributed data. Categorical variables including menstrual status, chemotherapy exposure history, previous abdominopelvic surgery, ASA classification, FIGO stage, transfusion requirements, and treatment efficacy were expressed as frequencies and percentages.

Between-group comparisons for transfusion requirements were performed using Chi-square test or Fischer exact test as appropriate based on expected cell frequencies. Perioperative blood loss comparisons between groups were conducted using Student t-test for normally distributed data or Mann-Whitney U-test for non-parametric data. Stratified analysis was performed to control for potential effect modifiers including age, body mass index, duration of ovarian cancer, menstrual status, chemotherapy exposure, previous abdominopelvic surgery history, ASA classification, and FIGO stage. Post-stratification statistical comparisons utilized Chi-square

test or Fischer exact test with statistical significance defined as p-value ≤ 0.05.

RESULTS

The baseline demographic and clinical characteristics of the study participants are presented in Table 1. The mean age of participants was 47.2 ± 11.4 years in the tranexamic acid group and 48.6 ± 10.8 years in the placebo group (p = 0.204). No statistically significant differences were observed between groups regarding age, weight, height, BMI, menstrual status, exposure to chemotherapy, previous abdominopelvic surgery, ASA classification, or FIGO staging.

Table 1

Baseline Characteristics of Study Participants

Variable		Tranexamic Acid Group (n=186)	Placebo Group (n=186)	p-value
Age (years)		47.2 ± 11.4	48.6 ± 10.8	0.204
Weight (kg)		68.4 ± 12.3	67.9 ± 11.8	0.677
Height (m)		1.58 ± 0.07	1.59 ± 0.06	0.142
BMI (kg/m^2)		27.3 ± 4.2	26.8 ± 3.9	0.233
Menstrual Status	Menstruating	89 (47.8%)	93 (50.0%)	0.612
	Menopausal	97 (52.2%)	93 (50.0%)	
Exposure to Chemotherapy	Yes	142 (76.3%)	138 (74.2%)	0.534
	No	44 (23.7%)	48 (25.8%)	
Previous Abdominopelvic Surgery	Yes	78 (41.9%)	81 (43.5%)	0.778
	No	108 (58.1%)	105 (56.5%)	
ASA Classification	ASA 1	52 (28.0%)	48 (25.8%)	0.456
	ASA 2	98 (52.7%)	107 (57.5%)	
	ASA 3	36 (19.4%)	31 (16.7%)	
FIGO Stage	Stage I	64 (34.4%)	69 (37.1%)	0.623
	Stage II	78 (41.9%)	73 (39.2%)	
	Stage III	44 (23.7%)	44 (23.7%)	
Pre-operative Hemoglobin (g/dl)		11.8 ± 1.6	11.9 ± 1.4	0.524

The primary efficacy outcome, defined as the proportion of patients not requiring postoperative blood transfusion, demonstrated a statistically significant difference between groups. In the tranexamic acid group, 131 patients (70.4%) did not require transfusion compared to 104 patients (55.9%) in the placebo group (p = 0.003). Consequently, 55 patients (29.6%) in the tranexamic acid group required transfusion versus 82 patients (44.1%) in the placebo group.

Table 2

Primary Efficacy Outcomes

Outcome		Tranexamic Acid Group (n=186)	Placebo Group (n=186)	p-value
Transfusion Required	Yes	55 (29.6%)	82 (44.1%)	0.003
	No	131 (70.4%)	104 (55.9%)	
Efficacy (No Transfusion)		131 (70.4%)	104 (55.9%)	0.003

Mean perioperative blood loss was significantly lower in the tranexamic acid group compared to the placebo group (548.3 ± 198.7 ml vs 692.1 ± 242.6 ml, respectively; p < 0.001). The median blood loss was 520.0 ml (IQR: 420.0-680.0) in the tranexamic acid group and 670.0 ml (IQR: 510.0-850.0) in the placebo group.

Table 3

Perioperative Blood Loss Comparison

Blood Loss Measurement	Tranexamic Acid Group (n=186)	Placebo Group (n=186)	p-value
Mean ± SD (ml)	548.3 ± 198.7	692.1 ± 242.6	<0.001
Median (IQR) (ml)	520.0 (420.0-680.0)	670.0 (510.0-850.0)	<0.001
Range (ml)	280-1150	320-1380	

Table 4

Stratified Analysis of Efficacy by Baseline Characteristics

Stratification Variable		Tranexamic Acid Efficacy	Placebo Efficacy	p-value
Age Groups	≤45 years	45/72 (62.5%)	32/69 (46.4%)	0.046*
	>45 years	86/114 (75.4%)	72/117 (61.5%)	0.021*
BMI Categories	<25 kg/m^2	42/58 (72.4%)	31/62 (50.0%)	0.013*
	25-30 kg/m^2	67/92 (72.8%)	52/86 (60.5%)	0.084
	>30 kg/m^2	22/36 (61.1%)	21/38 (55.3%)	0.600
Menstrual Status	Menstruating	64/89 (71.9%)	48/93 (51.6%)	0.006*
	Menopausal	67/97 (69.1%)	56/93 (60.2%)	0.218
Chemotherapy Exposure	Yes	98/142 (69.0%)	76/138 (55.1%)	0.019*
	No	33/44 (75.0%)	28/48 (58.3%)	0.102
Previous Surgery	Yes	52/78 (66.7%)	43/81 (53.1%)	0.092
	No	79/108 (73.1%)	61/105 (58.1%)	0.024*
ASA Classification	ASA 1	39/52 (75.0%)	28/48 (58.3%)	0.084
	ASA 2	71/98 (72.4%)	58/107 (54.2%)	0.008*
	ASA 3	21/36 (58.3%)	18/31 (58.1%)	0.982
FIGO Stage	Stage I	48/64 (75.0%)	42/69 (60.9%)	0.085
	Stage II	57/78 (73.1%)	43/73 (58.9%)	0.073
	Stage III	26/44 (59.1%)	19/44 (43.2%)	0.127

*Statistically significant (p < 0.05)

The postoperative hemoglobin levels were significantly higher in the tranexamic acid group (10.2 ± 1.4 g/dl) compared to the placebo group (9.6 ± 1.6 g/dl, p = 0.001). The mean decrease in hemoglobin levels was significantly less in the tranexamic acid group (1.6 ± 0.8 g/dl) compared to the placebo group (2.3 ± 1.2 g/dl, p < 0.001).

DISCUSSION

The present randomized controlled trial evaluated the efficacy of single-dose tranexamic acid (TXA) in reducing transfusion requirements and perioperative blood loss in females undergoing surgery for ovarian cancer. The findings demonstrated that TXA significantly reduced the proportion of patients requiring blood transfusion, lowered perioperative blood loss, and resulted in less pronounced postoperative hemoglobin decline compared to placebo.

The reduction in transfusion requirements observed in this study (29.6% in the TXA group vs. 44.1% in the placebo group) aligns with the findings of Lundin et al., who first reported that TXA significantly reduced transfusion needs in patients undergoing cytoreductive surgery for advanced ovarian cancer [10]. Similarly, a meta-analysis on antifibrinolytics in oncological surgery concluded that TXA consistently reduced transfusion rates without increasing thromboembolic risk [11]. These consistent outcomes across different populations support the robustness of TXA's effect in gynecologic oncology surgery.

In the present study, perioperative blood loss was significantly reduced in the TXA group (mean 548.3 ml vs. 692.1 ml in placebo; $p < 0.001$). Comparable reductions in blood loss have been reported in non-gynecologic oncologic surgeries. A Cochrane review analyzing 82 trials across various surgical disciplines confirmed that TXA reduces mean blood loss by approximately 30% [12]. Studies specifically in gynecological surgery, including myomectomy and hysterectomy, also demonstrated significant reductions in intraoperative blood loss with TXA administration [13,14]. Thus, the results of this study reaffirm TXA's applicability in oncologic gynecological procedures, extending beyond obstetric settings where its efficacy is already well established [7].

The postoperative hemoglobin decline was also significantly less pronounced in patients receiving TXA (1.6 g/dl vs. 2.3 g/dl). Similar outcomes have been described in gynecologic and gastrointestinal oncologic surgery [15,16]. Preservation of hemoglobin is clinically relevant as it reduces perioperative anemia and the associated risk of delayed recovery, infection, and need for transfusion.

The anti-fibrinolytic action of TXA underlies its protective effect. In ovarian cancer, increased fibrinolytic activity due to tumor angiogenesis and vascular invasion predisposes to higher intraoperative blood loss [1,2]. By blocking lysine-binding sites on plasminogen, TXA stabilizes fibrin clots and prevents premature lysis [6]. The magnitude of benefit observed in this study suggests that a single preoperative intravenous dose is sufficient to modulate the fibrinolytic response in oncologic surgery, reducing both acute intraoperative bleeding and subsequent hemoglobin decline. Blood transfusion is associated with significant risks, including immunomodulation, venous thromboembolism, and increased postoperative morbidity [3,4,17]. Reducing transfusion exposure is therefore a critical perioperative goal. The reduced transfusion requirements observed in the TXA group translate into potential clinical benefits, including reduced postoperative infection rates, lower thrombotic complications, and improved overall survival in cancer patients [18].

Stratified analyses confirmed the consistency of TXA's efficacy across most patient subgroups. Younger patients and those with lower BMI demonstrated particularly pronounced benefit, possibly due to fewer comorbidities and better physiological reserve. Patients with ASA II status also derived significant benefit, whereas efficacy was less pronounced in ASA III patients, reflecting the impact of more advanced systemic disease on perioperative hemostasis. The lack of statistical significance in certain subgroups (e.g., FIGO stage III) may relate to sample size limitations within strata rather than absence of effect. These findings suggest that TXA can be broadly effective across different clinical profiles, though the magnitude of benefit may vary according to baseline risk factors.

Evidence from other surgical specialties supports the current findings. In orthopedic surgery, TXA has consistently demonstrated efficacy in reducing perioperative blood loss and transfusion needs in hip and knee arthroplasty [19]. Similarly, in cardiac surgery, prophylactic TXA significantly reduced transfusion rates without increasing thrombotic events [20]. In oncologic surgery beyond gynecology, including gastrointestinal and hepatic resections, TXA use was also associated with reduced blood loss and transfusion requirements [21,22]. The parallel results across diverse surgical fields highlight the broad applicability of TXA and strengthen the external validity of the present findings.

Although the present study did not specifically evaluate adverse events, safety remains a central concern when using antifibrinolytic agents in cancer patients who already carry elevated risks for venous thromboembolism (VTE). However, multiple large-scale studies and meta-analyses have reported no significant increase in thromboembolic complications associated with TXA [11,12,23]. For example, the WOMAN trial, which included over 20,000 obstetric patients, confirmed the absence of excess thromboembolic events despite widespread TXA use [24]. In oncologic surgery, a systematic review similarly reported no increase in VTE incidence with TXA administration [25]. Collectively, these data suggest that TXA, when administered as a single perioperative dose, is both efficacious and safe in this high-risk population.

A key strength of the present study is the randomized controlled design with a relatively large sample size, which increases the reliability and generalizability of findings. Rigorous stratified analyses further enhance the interpretability of subgroup effects. Additionally, the study addresses a critical gap in the literature, as few prior trials have specifically focused on TXA use in ovarian cancer surgery. The study did not include long-term follow-up to assess thromboembolic events or survival outcomes, which remain important considerations in oncology patients. Furthermore, only a single dosing regimen was evaluated, and dose-response effects were not explored. Future research should therefore address long-term safety outcomes, optimal dosing strategies, and cost-effectiveness analyses in oncologic surgery. The findings of this study hold important clinical implications. Single-dose TXA administration prior to ovarian cancer surgery significantly reduces perioperative blood loss and transfusion requirements, supporting its routine use as an adjunct to perioperative management. Given the global emphasis on patient blood management, TXA offers a cost-effective and easily implementable strategy to reduce transfusion exposure and associated morbidity

CONCLUSION

This study provides robust evidence that a single preoperative dose of tranexamic acid significantly reduces transfusion requirements, perioperative blood loss, and postoperative hemoglobin decline in patients undergoing surgery for ovarian cancer. These findings support the incorporation of TXA into perioperative management protocols in gynecologic oncology surgery, offering a safe and effective strategy to improve surgical outcomes and reduce transfusion-related risks.

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