

## Original Research Article

# Towards zero bleeding after laparoscopic sleeve gastrectomy: investigating the impact of prophylactic tranexamic acid

Owaid M. Almalki<sup>1,2\*</sup>

<sup>1</sup>Department of Surgery, College of Medicine, Taif University, Taif, Saudi Arabia

<sup>2</sup>Department of Surgery, Alhada Military Hospital, Taif, Saudi Arabia

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### \*Correspondence:

Dr. Owaid M. Almalki,

E-mail: oalmalki@gmail.com

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## ABSTRACT

**Background:** Laparoscopic sleeve gastrectomy (LSG) is a prevalent bariatric procedure known for its efficacy in weight loss and amelioration of obesity-related comorbidities. However, postoperative bleeding from the staple line remains a significant complication, necessitating strategies for effective hemostasis. Tranexamic acid (TXA) has shown promise in reducing bleeding complications in various surgical contexts, yet its role in LSG remains underexplored due to concerns about thromboembolic risks.

**Methods:** This retrospective comparative analysis examines the impact of prophylactic TXA administration on perioperative bleeding in LSG patients. Two cohorts of 100 patients each, undergoing LSG before and after TXA implementation, were analyzed. Demographic, clinical, and outcome data were collected and statistically analyzed.

**Results:** In our study, 100 patients received TXA with a mean age of  $36.8 \pm 12.18$  years, while another 100 formed the non-TXA group with a mean age of  $37.2 \pm 11.81$  years. Pre-surgery, clinical characteristics and hemodynamic parameters did not significantly differ between groups. However, post-surgery, TXA patients showed significantly elevated hemoglobin levels ( $p=0.019$ ), increased hematocrit ( $p<0.001$ ), higher prothrombin activity ( $p=0.002$ ), decreased INR values ( $p=0.012$ ), and higher fibrinogen levels ( $p=0.014$ ) compared to non-TXA patients. Three non-TXA patients experienced post-operative bleeding requiring ICU admission and transfusions. The mean length of stay was  $2.1 \pm 0.5$  days for TXA patients and  $2.2 \pm 0.03$  days for non-TXA patients. No venous thromboembolism (VTE) or deaths occurred in either group.

**Conclusions:** The integration of prophylactic TXA into perioperative protocols for LSG holds promise in optimizing hemostasis and enhancing patient outcomes. TXA serves as a valuable adjunctive strategy towards minimizing bleeding events and bolstering safety in LSG procedures.

**Keywords:** Tranexamic acid, TXA, Laparoscopic sleeve gastrectomy, Gastric sleeve surgery, Complications, Staple line bleeding, Postoperative bleeding

## INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) has emerged as a primary operation for obesity due to its efficacy in weight loss and improvement of obesity-related comorbidities, making it the most prevalent bariatric procedure worldwide.<sup>1-4</sup> However, despite its safety profile compared to other procedures, bleeding from the staple line remains a significant complication, with rates ranging from 1% to 10%.<sup>5-7</sup> This complication not only increases the need

requirement for transfusions and length of stay, but it also raises the likelihood of reoperation and readmission.<sup>8</sup>

Achieving effective hemostasis during LSG is crucial to minimize bleeding complications. While traditional methods such as meticulous surgical technique and the use of hemostatic clips and energy devices are generally effective, challenges persist due to the intrinsic vascularity of the gastric fundus and staple line oozing.<sup>9</sup> Various strategies have been developed to address staple-line

bleeds, including staple-line reinforcement, bougie sizing variations, and intraoperative tranexamic acid (TXA) administration.<sup>5,7-10</sup>

TXA has emerged as a promising adjunctive strategy to optimize hemostasis and reduce bleeding complications in various surgical procedures by promoting clot stability and reducing blood loss, its efficacy has been well-established in orthopedic, cardiac, and gynecological surgeries.<sup>11-13</sup> However, its use in bariatric surgeries remains uncommon, and there is still uncertainty about whether TXA may be associated with an increased risk of venous thromboembolism, which limits its widespread use.<sup>8</sup>

Recent studies have shown encouraging results with prophylactic TXA administration during LSG, demonstrating reduced bleeding and shorter operation durations.<sup>8,14</sup> Despite these promising findings, uncertainties persist regarding the morbidity and mortality implications of TXA use in LSG patients.

While initial studies suggest TXA might be beneficial in LSG, questions remain regarding its long-term safety profile. This study aims to comprehensively evaluate TXA's role in LSG, exploring optimal dosage, timing, and patient-specific factors that might influence its effectiveness. By addressing these uncertainties, we hope to pave the way for safe and effective TXA use in LSG, ultimately leading to improved patient outcomes and faster recovery times.

## **METHODS**

### *Study design*

This study employs a retrospective comparative analysis to assess the effects of prophylactic doses of TXA on perioperative bleeding in patients undergoing LSG in a high-volume bariatric centre in Alhada Military Hospital, Taif, Saudi Arabia.

### *Study population*

The study analyzed two cohorts of 100 patients each who underwent primary LSG. The "non-TXA" cohort underwent surgery between January 2022 and June 2022, before the institutional protocol adopted prophylactic TXA. The "TXA" cohort underwent surgery between July 2022 and December 2022, following the implementation of TXA in the standard perioperative protocol (non-TXA group versus TXA group).

### *Inclusion criteria*

Include all adult patients (age >18 years) with an American Society of Anaesthesiologists (ASA) physical status score of II or III, who have undergone primary LSG for obesity class II and more. In order to minimize bias resulting from differences in learning curve, surgical experience, and

treatment length, participants had to have undergone surgery conducted by the same team of surgeons.

### *Exclusion criteria*

Patients with previous bariatric surgery, known bleeding disorders, history of use of anticoagulants, contraindications to TXA (e.g., renal dysfunction, history of thromboembolic events), arterial and/or severe iatrogenic bleeding during surgery, or incomplete medical records were excluded.

### *Prophylactic TXA and thrombolytic regimen*

In the "TXA" cohort, according to our bariatric protocol, 1 g of intravenous TXA (Exacyl®) was routinely administered at the end of the procedure before reversal of anaesthesia to all LSG patients followed by two doses postoperatively every 8 hours.

On the other hand, our venous thromboembolic (VTE) prophylaxis protocol involved administering 60 mg of low molecular weight heparin (Clexane®) subcutaneously on call to surgery, then once every 24 hour in obesity class II and III (body mass index (BMI) below 50 kg/m<sup>2</sup>) or BID twice daily in obesity class IV and V (BMI ≥50 kg/m<sup>2</sup>). Prophylaxis dose of 60 mg once daily will continue for 2 weeks' post-operative as home medication.

### *Surgical technique*

All LSGs were conducted using a three-port approach, consisting of two 5 mm ports and one 12 mm port. The procedure utilized a sealing device (Ligasure™, Medtronic, Covidien, Inc.), along with a bougie size of 36-F.

The gastric reservoir was formed with the ECHELON FLEX™ Powered Staplers (Ethicon Endo-Surgery, Inc.) with a 60 mm cartridge, which was chosen based on the thickness of the stomach. There was no utilization of staple line reinforcement or buttressing. Once the specimen was retrieved, the abdomen was depressurized, and the blood pressure was elevated to a systolic level over 140 mmHg for a duration of 4-5 minutes. Pneumoperitoneum was reestablished again and in the event of bleeding, clips were placed on bleeding points of staple line. The use of intra-abdominal drainage was omitted.

### *Data collection*

Electronic medical records were reviewed to extract relevant data for both cohorts using a standardized data collection form. The following information gathered for each patient: demographic characteristics: age, gender, BMI; comorbidities: diabetes mellitus type 2, arterial hypertension; laboratory values: hemoglobin levels, coagulation profile, and any, collected preoperative and 24 hours postoperatively.

**Outcomes**

Primary outcome was the number of hemorrhagic events on post-operative day one based on clinical pictures, hemoglobin drops more than 2 mg/dl and the presence of substantial free fluid as detected by abdominal ultrasonography.

Postoperative bleeding requires blood transfusion, intensive care unit (ICU) admission and reoperation were obtained.

Secondary outcomes included operating time, length of hospital stay, the occurrence of 30-day complications, and venous thromboembolism within 3 months after surgery.

**Statistical analysis**

We used descriptive statistics to summarize the demographic and clinical characteristics. We presented categorical variables as frequencies and percentages, and, depending on the distribution, expressed continuous variables as means with standard deviations or medians with interquartile ranges. We conducted comparative analyses between the studied groups using appropriate statistical tests, such as chi-square tests for categorical variables and t-tests for continuous variables.

A p value of <0.05 was considered statistically significant. IBM statistical package for the social sciences (SPSS) statistics software (version 25; IBM Corp., Armonk, NY, USA) was used for conducting the statistical analysis.

**RESULTS**

In the study, 100 patients were allocated to the TXA group with a mean age of 36.8±12.18 years, while another 100 were assigned to the non-TXA group, with a mean age of 37.2±11.81 years. The male-to-female ratio was 73:27 in the TXA group and 83:17 in the non-TXA group. The clinical characteristics of the patients, including Diabetes Mellitus, Hypertension, Previous Surgeries, and ASA II, did not show significant differences between the two groups. Similarly, factors such as BMI, ASA grade, and duration of surgery were not significantly different between the groups as indicated in (Table 1).

The hemodynamic parameters and hematological profiles showed no significant differences among the groups prior to surgery (Table 2).

Following surgery, patients in the TXA group exhibited elevated hemoglobin levels (p=0.019), increased hematocrit (p<0.001), higher prothrombin activity (p=0.002), decreased INR values (p=0.012) and higher fibrinogen levels (p=0.014) compared to those in the non-TXA group (Table 3).

In the non-TXA group, three patients experienced post-operative bleeding that did not necessitate intervention. These patients were admitted to the ICU and received blood transfusions. The mean length of stay was 2.1±0.5 days in the TXA group and 2.2±0.03 days in the non-TXA group, with a statistically non-significant difference (p=0.04\*). There were no instances of venous thromboembolism (VTE) or deaths recorded in either group (Table 4).

**Table 1: Clinical characteristics of patients.**

Variables	Group TXA	Non-TXA group	P value
<b>Age (years)</b>			
Mean±SD	36.8±12.18	37.2±11.81	0.81
<b>Gender</b>			
Female	73 (73)	83 (83)	0.08
Male	27 (27)	17 (17)	
<b>Diabetes mellitus</b>			
Yes	21 (21)	23 (23)	0.73
No	79 (79)	77 (77)	
<b>Hypertension</b>			
Yes	46 (46)	42 (42)	0.56
No	53 (53)	57 (57)	
<b>Previous surgeries</b>			
Yes	60 (60)	61 (61)	0.88
No	40 (40)	39 (39)	
<b>ASA II</b>			
Yes	34 (34)	38 (38)	0.55
No	66 (66)	62 (62)	
<b>BMI (kg/m<sup>2</sup>), mean±SD</b>	42.1±5.3	40.9±3.5	0.06
<b>Length of surgery (minutes), mean±SD</b>	69.3±17.5	71.6±19.1	0.37

TXA: Tranexamic acid, BMI: body mass index; BP: blood pressure; ASA: American Society of Anesthesiologists physical status classification system II.

**Table 2: Comparison of hemodynamic variables and hematological data in the preoperative period between the groups evaluated.**

Variables	Group TXA	Non-TXA group	P value
Heart rate (bpm)	74.1±2.2	74.7±2.7	0.08
Systolic BP (mmHg)	118±30	120±28	0.62
Diastolic BP (mmHg)	74±27	75±25	0.78
Hemoglobin (g/dl)	12.8±0.9	12.3±2.1	0.029
Hematocrit (V/V) (%)	37.6±2.5	36.5±2.9	0.79
Platelets	247±51	250.5±40	0.58
Prothrombin time (s)	14.3±0.5	14.4±0.4	0.11
Prothrombin activity (%)	85±6	83±7	0.03
INR	1.11±0.5	1.12±0.9	0.92
Fibrinogen (mg/dl)	301±40.9	283±57.9	0.01

TTPa: Activated partial thromboplastin time, RTTPa: activated partial thromboplastin time ratio, INR: international normalized ratio, \*significant p≤0.05.

**Table 3: Comparison of hematological data in the postoperative period between the groups evaluated.**

Variables	Group TXA	Non-TXA group	P value
Hemoglobin (g/dl)	13.1±1.4	12.3±3.1	0.019*
Hematocrit (V/V) (%)	38.5±3.5	37.9±3.9	0.001*
Platelets	249±40	254±30	0.31
Prothrombin time (s)	14.5±1.4	14.6±1.1	0.57
Prothrombin activity (%)	82.5±3.6	81.3±6.4	0.002*
INR	1.11±0.4	1.16±0.7	0.012*
Fibrinogen (mg/dl)	317±39.1	301±52.1	0.014*

TTPa: Activated partial thromboplastin time, RTTPa: activated partial thromboplastin time ratio, INR: international normalized ratio, \*significant p≤0.05.

**Table 4: Adverse events reported within 3 months among patients who underwent laparoscopic sleeve gastrectomy.**

Adverse events	TXA group, N (%)	Non-TXA group, N (%)	P value
Postoperative bleed	0 (0)	3 (3)	0.31
Length of hospital stay	2.1±0.5	2.2±0.03	0.04
PE/DVT	0 (0)	0 (0)	-
Anastomotic leak	0 (0)	0 (0)	-
Death	0 (0)	0 (0)	-

TXA: Tranexamic acid, N: number of patients, PE: pulmonary embolism, DVT: deep vein thrombosis, \*significant p≤0.05.

## DISCUSSION

The present study contributes to the growing body of evidence regarding the efficacy and safety of prophylactic TXA administration in LSG. Our findings underscore the importance of exploring adjunctive strategies to minimize bleeding complications, a common concern in bariatric surgery.

The introduction of laparoscopic techniques revolutionized bariatric surgery, with LSG emerging as a primary option due to its favorable outcomes in weight loss and comorbidity improvement.<sup>15</sup>

However, staple line bleeding remains a significant challenge. This complication not only prolongs hospital stay but also rises the chances of reoperation and

readmission, imposing a burden on both patients and healthcare systems.<sup>16</sup>

Orthopedic, cardiac, and gynecological surgeries have firmly established the effectiveness of TXA in enhancing clot stability and minimizing blood loss.<sup>17</sup> However, concerns about thromboembolic events have somewhat restricted its use in bariatric surgery.<sup>18</sup> Even with these concerns, recent studies, including ours, have shown that giving TXA as a preventative measure in LSG has positive results. There have been no reports of venous thromboembolism or death being linked to TXA use.

The first report of the use of TXA in the prophylaxis of LSG was described by Chakravatty et al.<sup>8</sup> They compared 25 patients who received 1 g of TXA intravenously as induction with the control group. They noticed that the introduction of TXA significantly decreases intraoperative bleeding, which is consistent with our observations.

Among our sample of 200 patients, we noted a reduction in the occurrence of post-operative bleeding events in the TXA group compared to the non-TXA group (3 patients versus none). Despite the lack of statistical significance, it indicates that the administration of TXA may be useful in lowering post-operative bleeding after LSG.

Similar to our results, previous studies also reported a decrease in post-operative bleeding events.<sup>19,20</sup> This strengthens the emerging evidence supporting TXA's role in reducing bleeding complications associated with LSG.

TXA functions by impeding the degradation of fibrin clots that are generated during the process of clotting. Fibrin clots play a crucial role in hemostasis by forming a tangible obstruction at the site of injury, thereby halting bleeding.

It decreases bleeding by preventing the enzymatic degradation of fibrin blood clots (fibrinolysis). The liver produces plasminogen, which is then transformed into the fibrinolytic enzyme plasmin by tissue plasminogen activator (tPA). Plasminogen and tPA attach to lysine residues at the end of fibrin, causing the synthesis of plasmin in a specific area and the breakdown of fibrin.<sup>21</sup>

TXA is a chemical compound that is similar to lysine at the molecular level. It works by competing with fibrin, a protein involved in clot formation, for the binding sites on plasminogen. Additionally, it prevents plasminogen and plasmin from attaching to fibrin, thereby shielding blood clots from plasmin's breakdown.<sup>22</sup> By preventing their dissolution, TXA has the ability to extend the effectiveness of blood clots and decrease blood loss during and after surgery.

Patients in the TXA group displayed significantly elevated post-operative hemoglobin levels and hematocrit compared to those in the non-TXA group, indicating a potential reduction in blood loss with TXA prophylaxis. The observed decrease in bleeding events in the TXA group likely translates to overall lower blood loss. This effect may help sustain higher hemoglobin levels post-operatively. Moreover, TXA could potentially mitigate blood loss from smaller vessels or oozing, which might not manifest as visible bleeding events but could still contribute to decreased hemoglobin levels.

Furthermore, TXA administration positively influenced coagulation parameters such as prothrombin activity, international normalized ratio (INR), and fibrinogen levels. These favorable changes suggest that TXA may enhance clot formation and stability, further contributing to reduce bleeding. These findings are consistent with prior research conducted by Chakravarty et al and Brito et al.<sup>8,23</sup>

While previous literature has expressed concerns about thromboembolic risks associated with TXA, our study found no instances of venous thromboembolism or other

significant adverse events related to TXA administration during the 3-month follow-up period after LSG.<sup>24</sup> This finding aligns with similar results from previous studies that followed up patients for 30 days–6 months.<sup>8,19,20,23,25</sup> These findings suggest that prophylactic TXA use in LSG may be safe for appropriately selected patients.

The TXA group demonstrated a statistically shorter hospital stay compared to the non-TXA group, likely influenced by several factors related to TXA use. Firstly, reduced bleeding events may have contributed, as patients experiencing bleeding complications often necessitate prolonged hospital stays for observation, blood product transfusions, or additional interventions. Second, the TXA group had better blood clotting parameters, such as higher hemoglobin and other clotting factors. This suggests that they will recover faster and have a lower risk of bleeding complications, which could make it easier for them to go home sooner. This observation highlights the potential economic benefits of TXA in LSG, as shorter hospital stays can lead to cost savings and better resource utilization.

Our finding of a reduced length of stay in the TXA group aligns with studies by Brito et al, which also reported similar reductions following LSG with TXA administration.<sup>18,23</sup> This consistency suggests that TXA may indeed contribute to expedited patient recovery and discharge.

In our protocol, we administered 1 gram of intravenous TXA at the end of the procedure, as laparoscopy allows for the identification and management of intraoperative bleeding with hemostatic clips if necessary. Following this, we provided two postoperative doses every 8 hours, taking into account the approximate half-life of TXA, which is around 3 hours. Notably, Lech et al adhered to a similar protocol, administering TXA at induction, followed by three additional doses every 8 hours.<sup>19,20</sup> Conversely, other studies administered TXA at the induction of anesthesia.<sup>8,18,25</sup> Hence, determining the optimal regimen for TXA administration in LSG requires further investigation.

While our study offers valuable insights into TXA's role in LSG, it is imperative to acknowledge several limitations. Being a retrospective analysis, our study is prone to inherent biases such as selection bias and confounding variables. Moreover, the relatively small sample size restricts the generalizability of our findings. It is crucial to conduct further prospective studies with larger cohorts of participants and longer periods of follow up to confirm our findings and get a deeper understanding of the best way to use TXA in LSG procedures.

## CONCLUSION

Ultimately, our research confirms the efficacy and safety of prophylactic TXA in LSG procedures. TXA exhibits a notable decrease in postoperative bleeding occurrences

without increasing the likelihood of thromboembolic complications, therefore improving patient outcomes, and perhaps reducing healthcare costs.

Integration of TXA into perioperative protocols holds promise for shorter hospital stays and enhanced outcomes in LSG patients. However, further research is essential to fine-tune TXA protocols and address lingering uncertainties, ultimately refining hemostasis optimization and bolstering the safety profile of LSG procedures.

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