

ORIGINAL RESEARCH

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Evaluation of the Effect of Intraoperative Tranexamic Acid on Bleeding in Myomectomy Operations

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ABSTRACT Objective: To evaluate the effects of intraoperative administration of tranexamic acid on perioperative and postoperative bleeding, the need for blood transfusion, the duration of the operation, and the length of hospital stay in patients undergoing myomectomy. **Material and Methods:** This case-control study involved 56 patients who underwent laparotomic myomectomy at our hospital between March 2023-January 2024. Intraoperatively, 28 patients who were administered tranexamic acid and 28 control groups who did not receive tranexamic acid were included in the study. Demographic characteristics, platelet count, prothrombin time, characteristics of fibroids, need for erythrocyte suspension (ES), and pre-postoperative hemoglobin values were compared between the groups. The criteria for administering ES are patients with a shock index above 1. **Results:** There was no statistically significant difference between the 2 groups in terms of demographic characteristics, platelet count, international normalized ratio, activated partial thromboplastin time test, and fibroid parameters ($p>0.05$). No statistically significant difference between postoperative 2nd and 6th hour hemoglobin values ($p=0.225$, $p=0.159$ respectively). No statistically significant difference between postoperative 2nd and 6th hour hematocrit values ($p=0.225$, $p=0.178$ respectively). ES transfusion was statistically significantly lower in the tranexamic acid group than in the control group ($p=0.049$). **Conclusion:** Tranexamic acid was effective in bleeding control by reducing the need for ES, but its antifibrinolytic effect was limited due to the low amount of bleeding. In the comparison between cases that did not receive ES transfusion and the control group, there was no statistically significant difference between the hemoglobin and hematocrit values. In the group of cases that did not undergo ES transfusion, the low amount of bleeding resulted in a low amount of fibrin, which limited the effect of tranexamic acid.

Keywords: Bleeding; myomectomy; tranexamic acid

The most common benign solid mass in the uterus in women is leiomyomas. Leiomyoma is a benign mass that can cause urinary symptoms, constipation or infertility due to abnormal uterine bleeding, pelvic pain, and pressure.¹ Leiomyomas are most common between the ages of 30-55. Many symptomatic leiomyomas are indicated for surgical removal for these reasons.² Leiomyomas can be surgically removed with abdominal or laparoscopic myomectomy. Intraoperative bleeding occurs during

myomectomy. Anemia may be seen due to intraoperative bleeding, blood transfusion is required, operation times and hospital stay are prolonged.³ Studies are aimed at reducing intraoperative bleeding during myomectomy. One of these studies was the use of intraoperative tranexamic acid. Tranexamic acid is an artificial compound structurally related to the amino acid lysine. It works by attaching to lysine-binding sites on plasminogen, which blocks its conversion into plasmin.⁴ Today, it is used to reduce bleeding in

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gynecological and obstetric diseases. Research has demonstrated that tranexamic acid decreases blood loss during myomectomy.^{5,6} (Since tranexamic acid binds to plasminogen and inhibits plasmin activation during the myomectomy operation, the destruction of fibrinogen and fibrin by plasmin is prevented and the destruction of fibrin clots is prevented. In this way, the coagulation pathway is not disrupted and bleeding is reduced.⁷ The intraoperative dosing and delivery method of tranexamic acid, whether oral or intravenous (IV), has been extensively studied in the context of myomectomy. Administration as an IV infusion appeared to have the highest plasma concentration. There is also no clear consensus on the dose of administration.⁶ Therefore, in our study, we divided the patients who underwent laparotomic myomectomy in our clinic into 2 groups: those who were given tranexamic acid infusion and those who were not. The aim of our study was to evaluate the effects of intraoperative tranexamic acid administration on the amount of perioperative and postoperative bleeding, the need for blood transfusion, the duration of operation, and the length of hospital stay.

MATERIAL AND METHODS

Our study was designed as a prospective case-control study. The study was planned in accordance with the Declaration of Helsinki and informed consent forms were obtained from all patients. The study was initiated after the approval of the hospital Clinical Research Ethics Committee dated March 15, 2023 and numbered 2023/50. Between March 2023-January 2024, 56 patients who applied to the Gynecology and Obstetrics Clinic of Gülhane Training and Research Hospital and underwent myomectomy with laparotomy were included in our study. Women included in the study were randomized into 2 groups according to the status of intraoperative administration of tranexamic acid. Group 1 consisted of women who were administered intraoperative tranexamic acid (n=28), while Group 2 consisted of women who were not administered tranexamic acid (n=28). Patients older than >18 years who underwent laparotomic myomectomy were included in the study. Patients with liver failure, renal insufficiency, and additional comorbidities were excluded from the study because of

diseases that may have an effect on coagulation and bleeding amount and disrupt homogeneity in the study group. In addition, patients with anticoagulant drug use, history of thromboembolic disease, and allergy to tranexamic acid were excluded from the study because of contraindications. In the case group, 28 patients were given 1 g tranexamic acid in 100 cc saline for 15 minutes IV intraoperatively. Tranexamic acid was administered before starting to cut the myoma capsule. In the control group, 28 patients received only 100 cc of physiological saline to ensure a double-blind study design, with all surgeries performed by a single surgeon. The criteria for administering erythrocyte suspension (ES) are patients with a shock index above 1. The shock index is a parameter used to quickly and practically assess the hemodynamic status of a patient. The shock index is a parameter that can be measured immediately and assists in rapid clinical decision-making. Especially in cases of sudden volume loss (massive bleeding), it allows for prompt intervention without waiting for blood gas analysis or complete blood count results. In contrast, changes in hemoglobin (Hb) levels appear more slowly and reflect a delay in blood loss. In cases of acute hemorrhage, Hb levels may initially remain high before complete hemodilution occurs in the body. It is calculated by dividing the pulse rate (heartbeats per minute) by the systolic blood pressure (mmHg). In a normal adult, the shock index is between 0.5-0.7. If the value exceeds 1, it indicates that the patient may have severe hypovolemia, bleeding, or cardiovascular failure.⁸ The parameters evaluated in the study were the demographic characteristics of the patients (age, body weight, height), preoperative and postoperative 2nd and 6th hour Hb and hematocrit values, preoperative platelet, international normalized ratio and activated partial thromboplastin time test values, type of fibroids, number of fibroids and largest fibroid size, and intraoperative and postoperative ES transfer requirement, respectively. The patient was examined at 2 h postoperatively to detect early bleeding. The patient was examined at 6 h to assess hemodynamic balance and evaluate the effect of administered fluids and possible blood loss on circulation. In our study, in the comparison of the differences between the preoperative value of Hb and

the postoperative 2nd and 6th hour values, the patients who received ES transfusion had a direct effect on the Hb value. Therefore, 1 case who received ES replacement in the case group and 7 cases who received ES replacement in the control group were excluded. The results of 48 cases were evaluated, including 27 patients who received intraoperative tranexamic acid during laparotomic myomectomy and 21 control groups who did not receive tranexamic acid during laparotomic myomectomy.

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS version 27.0 (IBM Corp., Chicago, IL, USA). A 95% confidence interval was applied for interpretation, and statistical significance was defined as $p < 0.05$. Categorical variables were described using frequencies and percentages, whereas continuous variables were expressed as means, standard deviations, and minimum-maximum ranges. The chi-square test and Fisher's exact test were employed for analyzing the categorical data. The distribution of the numerical data was assessed using the Shapiro-Wilk test to determine normality. Based on the outcome, normally distributed variables were compared using the independent samples t-test, while the Mann-Whitney U test was used for variables not following a normal distribution.

RESULTS

The demographic variables showed no statistically significant variation between the groups ($p > 0.05$) (Table 1).

In our study, the comparison of coagulation parameters showed no statistically significant variation between the groups ($p > 0.05$) (Table 1).

In our study, there was no significant statistical difference in fibroid parameters between the groups ($p > 0.05$) (Table 1).

The risk of bleeding is higher in the removal of submucosal fibroids (International Federation of Gynecology and Obstetrics Type 0, Type 1, and Type 2 fibroids). In our study, statistical analysis showed no significant variation in the number of submucosal fibroids between the groups ($p > 0.05$) (Table 2).

TABLE 1: Comparison of demographic characteristics, coagulation parameters and fibroid characteristics between groups

Parametres	Case (n=28) X±SD	Control (n=28) X±SD	p value
Age (years)	37.14±5.02	37.25±6.96	0.948
Weight (kg)	67.50±11.53	69.13±10.06	0.636
Height (cm)	164.35±4.82	164.25±4.36	0.960
PLT (10 ⁹ /l)	295.04±45.10	295.50±72.04	0.977
INR	1.00±0.06	1.00±0.07	0.686
aPTT (sn)	26.20±2.12	25.74±1.37	0.738
Number of fibroids (pcs)	1.79±1.55	1.79±1.10	0.532
Myoma diameter (cm)	7.43±2.56	7.36±1.79	0.727

*In the comparison between the groups, independent sample comparisons were made using the t-test. The results were summarized with mean±standard deviation values. SD: Standard deviation; PLT: Platelet; INR: International normalized ratio; aPTT: Activated partial thromboplastin time test

TABLE 2: Comparison of the number of submucosal fibroids between groups

Myoma group	Case n (%)	Control n (%)	Total n (%)	p value
Type (1-2)	6 (42.8)	8 (57.2)	14 (100)	0.537
Type (other)	22 (52.3)	20 (47.7)	42 (100)	
Sum	28	28	56	

*In the comparison between the groups; The data were analyzed using the Chi-square test. The results were summarized with mean±standard deviation values.

ES transfusion is thought to affect the Hb and hematocrit (Htc) values. For this reason, one participant from the ES transfusion group and 7 participants from the control group were excluded from the study before comparing the Hb and Htc values at 2 and 6 h before and after surgery. The difference between the Hb and Htc values before and 2 h after the operation was not statistically significant between the case and control groups ($p > 0.05$). When the patients who received intraoperative tranexamic acid infusion during laparotomic myomectomy (case group) and those who did not (control group) were compared, a less downward trend was observed in the preoperative Hb and Htc values in the group using tranexamic acid. However, this difference was not statistically significant. There was no statistically significant difference between the group (case) that received intraoperative tranexamic acid infusion during laparotomic myomectomy and the group that did not receive intraoperative tranexamic acid infusion (control) in terms

of the difference in Hb and Htc values before and 6 h after the operation ($p>0.05$). However, in the case group, the difference in Hb and Htc values before and 6 h after surgery was found to be lower than in the control group. In the case group, which was given tranexamic acid, a less downward trend was observed in preoperative Hb and Htc values (Table 3).

In our study, the differences between the preoperative Hb levels of the patients in the control group and the postoperative 2nd and 6th hour analyses were 1.58 gr/dL and 1.8 gr/dL, respectively, and the differences between the preoperative Hb level and the Htc values at the postoperative 2nd and 6th hours were

TABLE 3: Comparison of the differences between the preoperative Hb and Hct values and the postoperative 2nd and 6th hour values between the groups

Parameters	Case (n=27) $\bar{X}\pm SD$	Control (n=21) $\bar{X}\pm SD$	p value
Hemoglobin (g/dL)			
Postop 2 nd hour (difference)	1.3 \pm 0.80	1.58 \pm 0.67	0.225
Postop 6 th hour (difference)	1.4 \pm 0.91	1.80 \pm 0.79	0.159
Hct (%)			
Postop 2 nd hour (difference)	3.85 \pm 2.56	4.72 \pm 2.20	0.225
Postop 6 th hour (difference)	4.44 \pm 2.83	5.52 \pm 2.57	0.178

*In the comparison between the groups, t-test was used for independent samples. The results were summarized with mean \pm standard deviation values. Hb: Hemoglobin; Hct: Hematocrit; SD: Standard deviation

shown in Figure 1 as 1.3 gr/dL and 1.4 gr/dL, respectively, in the case group receiving tranexamic acid.

In our study, the differences between the preoperative Htc levels and the postoperative 2nd and 6th hour values in the control group were 4.72% and 5.52%, respectively. In the case group receiving tranexamic acid, these differences were 3.85% and 4.44%, respectively, as illustrated in Figure 2.

Our study revealed a significant statistical difference between the groups regarding ES transfusion ($p<0.05$). The probability of ES replacement was 88.9% (1-0.111) lower in the group given tranexamic acid (case group) than in the control group. ES replacement was performed less frequently in the case group than in the control group. Patients with a shock index above 1 underwent ES transfusion replacement (Table 4).

When we looked at the distribution of the cases who underwent ES replacement in our study, 13% were in the case group receiving tranexamic acid, while 87% were in the control group (Figure 2).

DISCUSSION

Although numerous studies on tranexamic acid exist in the literature, there are limited publications re-

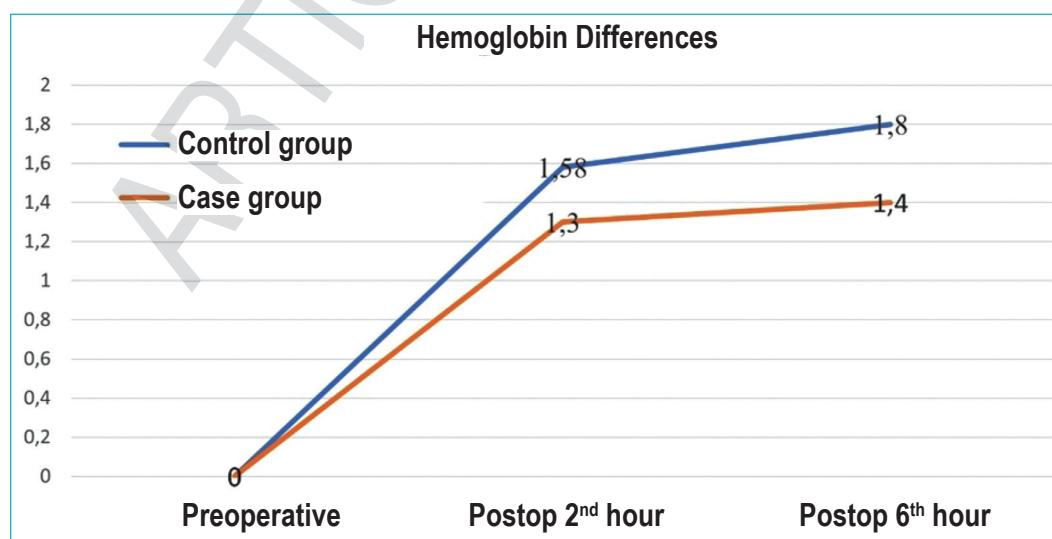


FIGURE 1: The course of the hemoglobin difference between the groups

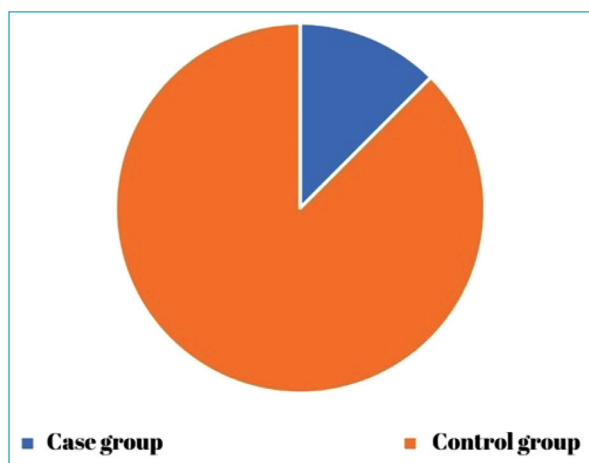


FIGURE 2: Graphical representation of ES replacement between groups
ES: Erythrocyte suspension

TABLE 4: Comparison of ES transfusion between groups

Parameters	Yes/No	Case (n=28)	Control (n=28)	p value
		n (%)	n (%)	
ES transfusion	Yes	1 (3.6)	7 (25.0)	0.049
	No	27 (96.4)	21 (75.0)	
	Sum	28 (100.0)	28 (100.0)	

*In the comparison between the groups; Chi-square test was used. The results were summarized with mean±standard deviation values. ES: Erythrocyte suspension

garding its dosage and efficacy. In our study, it was observed that the intraoperative use of tranexamic acid during laparotomic myomectomy resulted in a smaller decline in the preoperative and postoperative Hb and Hct values. However, the statistical analysis showed that the difference was not significant. Nevertheless, the need for ES transfusion was significantly lower in the tranexamic acid group than in the control group ($p < 0.05$).

A randomized controlled study by Abdul et al. included 80 patients undergoing laparotomic myomectomy, with 40 receiving IV tranexamic acid (10 mg/kg) 15 min before the abdominal incision, while the remaining 40 received saline. Both groups had tourniquets applied. The results showed that the mean intraoperative blood loss, intraoperative blood transfusion rates, and mean transfusion units were significantly higher in the control group. The tranexamic acid group experienced a significantly decreased blood loss per 100 g of fibroid tissue extracted.

Tourniquet use has long been a technique to reduce bleeding during myomectomy. Combining tranexamic acid with a tourniquet resulted in a significant reduction in intraoperative blood loss compared with tourniquet use alone.⁹⁻¹⁵ Unlike the study by Abdul et al.,¹⁵ our research did not involve tourniquet application; tranexamic acid was administered solely to the case group.¹⁵ Furthermore, ES transfusion was statistically significantly lower in the case group. Hb and Hct values were not statistically different among patients who did not require ES transfusion, suggesting that the efficacy of tranexamic acid is linked to the extent of bleeding and fibrin formation.

A randomized controlled trial by Devereaux et al. included 9,535 patients undergoing non-cardiac surgery, with 4,757 receiving a 1 g IV bolus of tranexamic acid. The incidence of composite bleeding was significantly lower in the tranexamic acid group (9.1%) than in the placebo group (11.7%).¹⁶ Unlike this multi-center study covering various non-cardiac surgeries, our research focused solely on laparotomic myomectomy in a single center, reducing variability. Although our sample size was smaller, the controlled environment minimized potential confounding factors. The Devereaux study evaluated the composite bleeding effect of tranexamic acid over 30 days, whereas our study specifically demonstrated its role in reducing ES transfusion, supporting Devereaux's findings.¹⁶

In a 2007 study by Caglar et al., the case group received 10 mg/kg of tranexamic acid IV 10 min before incision, followed by 1 mg/kg in 1,000 cc saline over 10 h, while the control group received only saline. A significant difference was found in postoperative blood loss, total blood loss, and operative time between the groups. However, the perioperative blood loss and transfusion requirements were similar. This study concluded that IV tranexamic acid infusion provided no additional benefit in myomectomy. Unlike Caglar et al.'s study, where the dose was calculated per kilogram, our study administered a fixed 1 g dose to all patients. While Caglar et al. reported no difference in transfusion needs between the groups, our study found a statistically significant reduction in ES transfusion in the tranexamic acid group.¹⁷

A prospective randomized study by Shaaban et al. included 132 patients undergoing laparotomic myomectomy, with the study group receiving perioperative tranexamic acid. The tranexamic acid group had significantly lower blood loss (407 mL) than the control group. Blood transfusion was required in 19.7% of the tranexamic acid group compared with 34.8% in the control group. Postoperative day-3 Hb and Hct levels were significantly lower in the control group, confirming the effectiveness of tranexamic acid' in reducing intraoperative and postoperative blood loss. Unlike Shaaban et al., our study used a fixed 1 g dose instead of weight-based dosing. Despite differences in infusion solutions, both studies showed that the effect of tranexamic acid' became more pronounced with increasing blood loss. Our findings were consistent with those of Shaaban et al., showing a significant reduction in transfusion needs.¹⁴

A 2022 systematic review and meta-analysis by Baradwan et al. included 7 randomized controlled trials (571 patients). A significant reduction in intraoperative, postoperative, and total blood loss was observed in the prophylactic tranexamic acid group. Additionally, postoperative Hb and Hct levels were significantly higher in the tranexamic acid group, and hospital stays were shorter. However, no significant differences were found in the operative time or ES transfusion. None of the participants experienced thromboembolic events, confirming the safety of prophylactic tranexamic acid in myomectomy. Unlike Baradwan et al.'s meta-analysis, which found no significant difference in ES transfusion, our study demonstrated a statistically significant reduction in the case group, possibly due to the single-center design and the expertise of the surgeons involved.¹³

A 2019 systematic review and meta-analysis by Fusca et al. included 266 women undergoing laparotomic myomectomy and found that tranexamic acid significantly reduced intraoperative blood loss but did not impact transfusion rates.¹⁸ Conversely, our study observed a significant reduction in transfusion needs, suggesting differences in study design or patient selection.

In a 2020 double-blind randomized controlled trial by Opoku-Anane et al., 60 patients received 15

mg/kg tranexamic acid IV 20 min before surgery. No significant differences were found in operative time or perioperative Hb changes, but no patients in the tranexamic acid group required transfusions, whereas 13.3% of the placebo group did.¹⁹ Our study similarly showed a reduction in the blood transfusion rates.

A randomized controlled trial by Shady et al. divided 105 patients into 3 groups: Group 1 received saline, Group 2 received 1 g IV tranexamic acid, and Group 3 received 2 g of topical tranexamic acid applied to the fibroid bed intraoperatively. Intraoperative and postoperative blood loss were significantly lower with both IV and topical administration of tranexamic acid than in the control group.²⁰ This study highlights the potential efficacy of topical tranexamic acid, which warrants further investigation.

A systematic review and meta-analysis by Kathopoulis et al. included 310 patients, with 155 receiving IV tranexamic acid. The study found a significant reduction in the total estimated blood loss, intraoperative and postoperative blood loss, and operative time. However, no significant effects were observed on the postoperative Htc, Hb changes, or transfusion rates. Unlike our study, which found a significant reduction in blood transfusions, Kathopoulis et al. did not observe this effect.²¹

The strengths of our study include its randomized controlled design, a homogeneous patient group, and the prospective collection of data. The use of the shock index as an objective transfusion criterion enhanced the study's reliability. Additionally, demographic characteristics, Hb and Htc values, and fibroid characteristics were analyzed comprehensively. However, the limitations include the small sample size, single-center design, and exclusion of ES recipients, which may have influenced the full assessment of blood loss. Future studies should consider evaluating postoperative parameters over a longer period to better understand the long-term effects of tranexamic acid.

CONCLUSION

The use of IV tranexamic acid in laparotomic myomectomy only reduces the need for erythrocyte

transfusion. The criterion for giving ES replacement is patients with a shock index above 1, and the antifibrinolytic effect of tranexamic acid occurs because the amount of fibrin produced with the amount of bleeding increases. When statistically the case and control groups of those who did not undergo ES transfusion were compared, the reason why there was no statistically significant difference between Hb and Hct values is understood. Because the bleeding was low in the case group without ES, the effect was limited because the resulting fibrin was low. In future studies on tranexamic acid effects on surgical blood loss, the ideal dose and timing of the drug administration, topical or systemic application method that can reveal clear options and evaluate the results of new studies with more cases and different medical conditions, could be done.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that pro-

vides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Mehmet Emre Peker, Mustafa Ulubay; **Design:** Mehmet Emre Peker, Mustafa Ulubay, Melis Ece Men Peker; **Control/Supervision:** Mustafa Ulubay, Ufuk Atlhan; **Data Collection and/or Processing:** Mehmet Emre Peker, Ufuk Atlhan, Duygu Uçar Kartal; **Analysis and/or Interpretation:** Mehmet Emre Peker, Ufuk Atlhan, Duygu Uçar Kartal; **Literature Review:** Mehmet Emre Peker, Duygu Uçar Kartal; **Writing the Article:** Mehmet Emre Peker, Melis Ece Men Peker; **Critical Review:** Mustafa Ulubay, Ufuk Atlhan, Melis Ece Men Peker, Furkan Kayabaşoğlu; **References and Fundings:** Mehmet Emre Peker, Mustafa Ulubay, Melis Ece Men Peker, Furkan Kayabaşoğlu; **Materials:** Mehmet Emre Peker, Melis Ece Men Peker, Furkan Kayabaşoğlu.

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