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Indian Journal of Clinical Anaesthesia

Journal homepage: www.ijca.in

Original Research Article

# Effect of prophylactic oral tranexamic acid on blood loss during laparoscopic myomectomy under general anaesthesia: A randomised controlled trial

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## Abstract

**Background:** Myomas are commonly associated with heavy menstrual bleeding, and myomectomy is the preferred treatment for fibroids in women of reproductive age. Effective control of bleeding during surgery is crucial to ensure proper dissection and to minimize the need for blood transfusions and hysterectomies. This study aimed to evaluate the impact of a single preoperative dose of oral tranexamic acid (TXA) 1g on intraoperative blood loss during laparoscopic myomectomy.

**Materials and Methods:** This prospective, randomized, double-blinded study included 36 female patients undergoing laparoscopic myomectomy. Participants were randomly assigned into two equal groups (C and D) using the closed envelope technique for concealment. Group C received a placebo, while Group D received 1g of oral TXA two hours before surgery. Both groups followed a standard anesthesia protocol. Intraoperative blood loss, surgical drain loss, and postoperative hemoglobin changes were measured. The incidence of any adverse drug-related events was also recorded.

**Results:** Demographic characteristics and anesthesia times were comparable between the two groups. Preoperative and postoperative hemoglobin levels were similar. However, the change in hemoglobin was significantly lower in Group D compared to Group C (1.11 ± 0.83 vs. 1.83 ± 1.04, p = 0.028). The mean intraoperative blood loss was significantly lower in Group D (236.11 ± 90.69 mL vs. 400 ± 224.26 mL, p = 0.009), while intraoperative blood transfusion rates were comparable. Postoperative hemoglobin levels were similar between the two groups.

**Conclusion:** Administration of a single preoperative dose of oral TXA significantly reduces intraoperative blood loss during laparoscopic myomectomy without causing significant complications. Further studies with larger sample sizes are warranted to confirm these findings.

**Keywords:** Blood loss, Fibroids, Laparoscopic, Myomectomy, Tranexamic acid.

**Received:** 17-01-2025; **Accepted:** 19-04-2025; **Available Online**: 15-07-2025



## 1. Introduction

Myomas are commonly associated with heavy menstrual bleeding, and laparoscopic myomectomy is a standard treatment for fibroids in women of reproductive age. The first successful myomectomy was performed by Amussat in 1840, and the technique involves resection, curettage, and suturing (myomucous, myometrial, and myoserous).[1] In the early days, most myomectomies were converted to hysterectomy due to excessive bleeding. Effective control of bleeding is essential, as it helps the surgeon to reach the correct plane of dissection, thus preventing unnecessary blood transfusions and hysterectomies. Various surgical methods, such as blocking uterine vessels, are used to reduce bleeding during myomectomy.[2.]

Laparoscopic and open myomectomies both involve significant intraoperative blood loss, though laparoscopic myomectomy, despite a longer operating time, has superior results when compared to open myomectomy.[3] In the presence of pre-existing anaemia, further blood loss may be life-threatening and may require emergency blood transfusions. Several techniques, including vasopressin or adrenaline injections into the myoma and uterine artery

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https://doi.org/10.18231/j.ijca.2025.072

embolization, are employed to reduce intraoperative bleeding.[4-6]

Oral tranexamic acid (TXA), a medication commonly used to treat menorrhagia, has been suggested as a potential option for reducing bleeding during surgical procedures. However, there are no studies specifically assessing the prophylactic use of oral TXA to reduce blood loss during myomectomy surgeries. The objective of this study is to evaluate the effect of a single, preoperative dose of oral TXA (1g) on decreasing intraoperative blood loss during laparoscopic myomectomy. We hypothesised that oral TXA will be more effective than a placebo in reducing blood loss in patients undergoing laparoscopic myomectomy. The primary objective of this study was to compare intraoperative blood loss, while secondary objectives include comparing the drop in postoperative haemoglobin levels, the requirement for blood transfusions, and any adverse outcomes associated with the use of TXA.

## 2. Materials and Methods

This randomized, double-blinded trial was done following approval from the hospital ethical committee (IEC-AIMS-2023-ANES-099), clinical trials registry- India (CTRI/2023/04/052073) clearance, and informed written consent from patients. Female patients aged 18–50 years, of the American Society of Anaesthesiologists (ASA) physical status 1 and 2, undergoing laparoscopic or open myomectomy surgeries were included in this study. Parturient, nursing mothers, hormonal contraception, on drugs affecting coagulation (factor IX concentrates, trans-retinoic acid and anti-inhibitor coagulant concentrates) and hypersensitivity to tranexamic acid, patients with history of thromboembolic disease, ischemic heart disease, cancer, haematuria, liver/kidney disease, or subarachnoid haemorrhage were excluded from the study.

Preoperative haemoglobin, number and size of myomas were noted during the pre-anaesthesia visits. To achieve minimum haemoglobin of 10gm/dL before surgery, packed red blood cell concentrate was transfused 48 hours preoperatively in anaemic patients. The haemoglobin measurements were repeated on the previous day of surgery in the hospital laboratory. The participants were randomly assigned into two equal groups, C and D, selected on the basis of a computer-generated random sequence of numbers.

Group C patients received oral placebo and group D patients received oral tranexamic acid (TXA) 1gm, 2 hours prior to surgery. Concealment was achieved by the closed envelope technique. Standard anaesthesia protocol was followed in both groups. Patients received premedication of oral pantoprazole 40mg, metoclopramide 10mg, and alprazolam 0.25mg on the night before surgery and oral pantoprazole 40mg, metoclopramide 10 mg, and TXA 1gm 2 hours before surgery.

In the operation theatre, a wide bore intravenous cannula was inserted and monitoring with electrocardiography, non-invasive blood pressure monitor, and pulse oximeter was done. Standard anaesthesia protocol was performed and laparoscopic myomectomy was performed under general anaesthesia. If the bleeding exceeded the allowable blood loss for the given patient, and haemoglobin drops below 8gm as assessed by arterial blood gas sample, blood was transfused. Intraoperative blood loss was calculated by measuring the volume in the suction apparatus and weighing the surgical swabs by gravimetric method. Drapes, sponges, and abdominal pads were weighed beforehand and again at the end of the surgery in an electronic weighing machine. The difference in weight was noted. A rise in 1mg weight was taken as equivalent to 1ml of blood. The placement and amount of blood in postoperative drains if inserted was noted.

Following surgery, the patients were transferred to postoperative recovery for further observation. Postoperative haemoglobin was determined 6 hours after surgery in both groups. Need for blood transfusion, duration of the operative procedure, the incidence of postoperative thromboembolic events (deep venous thrombosis, pulmonary embolism, myocardial infarction, and stroke) and incidence of other drug related adverse events **(**headache, seizure, visual disturbances, nausea/vomiting, diarrhoea) were noted.

### *2.1. Statistical analysis*

As there were no existing studies comparing intraoperative blood loss with the prophylactic use of oral tranexamic acid (TXA), a pilot trial was conducted with 10 samples in each group. Based on the mean and standard deviation of blood loss from the pilot study, Group D (TXA) had a mean of 225.0 ± 101.32 mL, while Group C (placebo) had a mean of 540 ± 228.29 mL. Using these values, along with a 95% confidence interval and 90% power, the minimum sample size calculated was 7 patients per group.

To test the statistical significance of the differences in the mean blood loss and the postoperative drop in haemoglobin between the two groups (TXA vs. placebo), the independent sample t-test was used for normally distributed data and the Mann-Whitney U test was used for skewed data. The chi-square test was employed to assess the statistical significance of differences in the proportions of blood transfusion requirements and any complications between the two groups. For comparing the mean values of numerical variables between groups, one-way ANOVA was applied. A p-value of $< 0.05$ was considered statistically significant.

## 3. Results

A total of 36 individuals were included in this prospective, randomised, double-blinded study (**Figure 1**). The participants were divided into two groups: Group C and Group D, each consisting of 18 participants. The mean age in Group C was 35.44 ± 6.74 years, while Group D had a mean

age of 37.11 ± 6.39 years. There was no statistically significant difference in age between the groups (p = 0.452). The mean weight of Group C was 63.72 ± 6.74 kg, and that of Group D was 62.67 ± 4.32 kg, which was comparable (p = 0.640). The mean height in Group C was 158.17 ± 5.50 cm, and in Group D, it was 159.22 ± 7.51 cm, with no significant difference (p = 0.634). The mean anaesthesia time for Group C was 164.44 ± 15.99 minutes, while for Group D, it was 165.28 ± 13.77 minutes, showing no statistically significant difference between the groups (p = 0.868).(**Table 1**)

The mean preoperative haemoglobin (Hb) levels in Group C were 12.06 ± 1.55 g/dL and in Group D, 11.67 ± 1.57 g/dL, with no significant difference (p = 0.460). Postoperative Hb levels in Group C were 9.94 ± 1.35 g/dL and in Group D, 10.50 ± 1.20 g/dL, which was also not statistically significant (p = 0.201). However, the mean change in Hb in Group C was 1.83 ± 1.04 g/dL, compared to 1.11 ± 0.83 g/dL in Group D, which was statistically significant (p = 0.028).(**Table 2**)

The mean preoperative blood transfusion requirements for Group C were 0.11 ± 0.47 units, and for Group D, 0.06 ± 0.24 units, showing no statistically significant difference between the groups (p = 0.658). The mean intraoperative blood transfusion in Group C was 0.28 ± 0.58 units, while for Group D, it was 0.11 ± 0.32 units. This difference was not statistically significant (p = 0.293).(**Table 3**)

The mean number of myomas in both Group C was 1.28 ± 0.58 and in group D was 1.14±0.39, which was comparable (p = 0.401). The mean intraoperative blood loss in Group C was 400.00 ± 224.26 mL, while in Group D, it was 236.11 ± 90.69 mL, showing a statistically significant reduction in Group D (p = 0.009) (**Figure 2**). The mean surgical drain loss in Group C was 0.00 ± 0.00 mL, and in Group D, it was 2.78 ± 11.79 mL, but this difference was not statistically significant (p = 0.331).(**Table 4**)

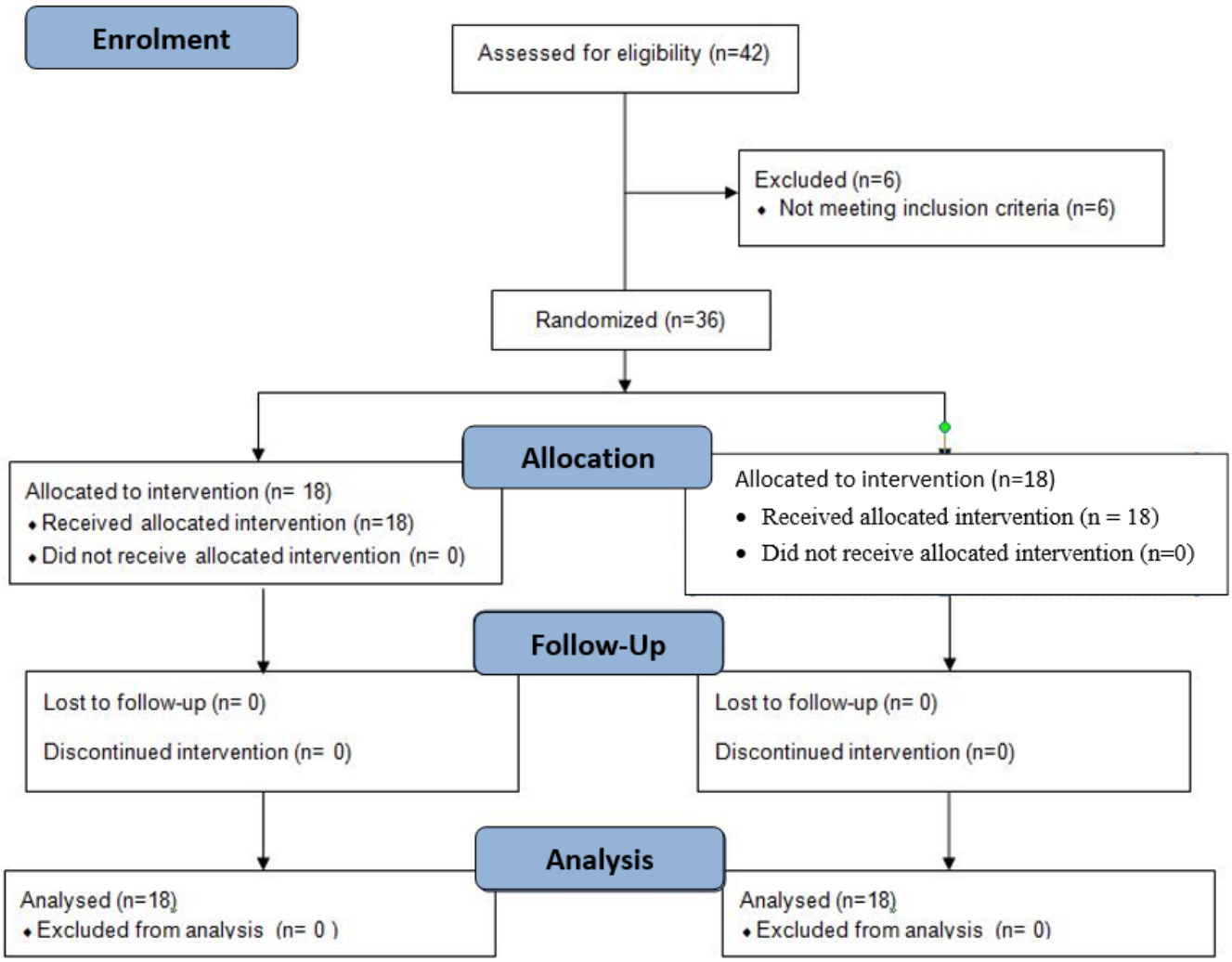


**Figure 1:** Consort flow diagram

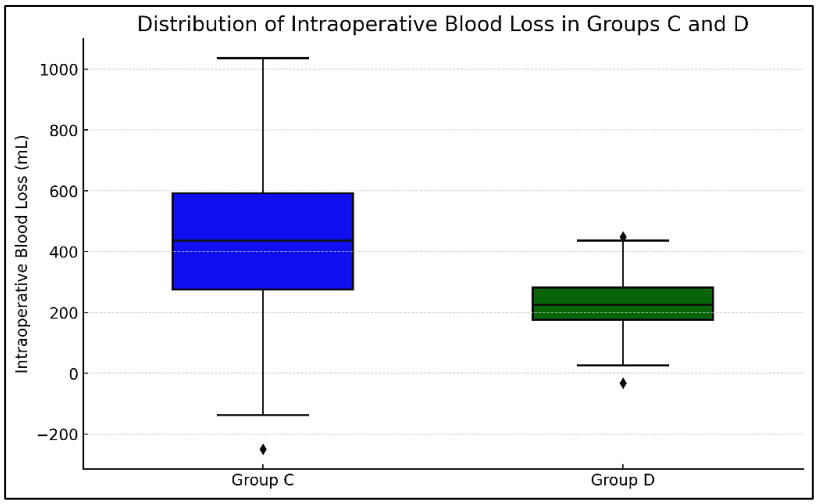


**Figure 2:** Comparison of intraoperative blood loss (in ml) between groups

**Table 1:** Comparison of demographic data and anaesthesia time

| Variable | Group C | Group D | *p*-value |
|---|---|---|---|
| **Age(years)** | 35.44±6.74 | 37.11±6.39 | 0.452 |
| **Weight( kg)** | 63.72±6.74 | 62.67±6.69 | 0.640 |
| **Height (cm)** | 158.17±5.50 | 159.22±7.51 | 0.634 |
| **Anaesthesia time (min)** | 164.44±15.99 | 165.28±13.77 | 0.868 |

**Table 2:** Comparison of perioperative haemoglobin

| Variable | Group C | Group D | *p*-value |
|---|---|---|---|
| **Preop Hb(g/d L)** | 12.06±1.55 | 11.67±1.57 | 0.460 |
| **Postop Hb(g/d L)** | 9.94±1.35 | 10.50±1.20 | 0.201 |
| **Change in Hb(g/d L)** | 1.83±1.04 | 1.11±0.83 | 0.028 |

**Table 3:** Comparison of perioperative blood transfusion

| Variable | Group C | Group D | *p*-value |
|---|---|---|---|
| **Preop blood transfusion** | 0.11±0.47 | 0.06±0.24 | 0.658 |
| **Intra op blood transfusion** | 0.28± 0.58 | 0.11± 0.32 | 0.293 |

**Table 4**: Comparison of myomas and blood loss

| Variable | Group C | Group D | *p*-value |
|---|---|---|---|
| **No. of myomas** | 1.28± 0.58 | 1.14±0.39 | 0.401 |
| **Intra op blood loss** | 400.00± 224.26 | 236.11± 90.69 | 0.009 |
| **Postop drain loss** | 0.00±0.00 | 2.78±11.79 | 0.331 |

## 4. Discussion

The effectiveness of oral tranexamic acid (TXA) as a premedication to reduce intraoperative blood loss during laparoscopic myomectomy has not been previously studied. While intravenous TXA has proven to be safe and effective in reducing blood loss during orthopaedic, myomectomy, and cardiovascular procedures,[7,8] this study demonstrates that a single dose of oral TXA prior to laparoscopic myomectomy significantly reduced intraoperative blood loss compared to placebo. Additionally, patients who received TXA showed more favourable haemoglobin changes postoperatively compared to the control group. Importantly, no adverse effects directly associated with oral TXA were reported in the study.

The ability of TXA to reduce blood loss may be related to the dose administered. Some studies have observed that intravenous TXA at a lower dose (10 mg/kg) and continuous infusion does not significantly decrease blood loss or transfusion requirements. However, higher doses of intravenous TXA (20 mg/kg) have been linked to a notable

reduction in intraoperative blood loss and transfusion requirements.[2,9,1010] It is worth mentioning that we did not assess the impact of varying TXA dosages in this study, as we focused on a single preoperative dose of 1g.

Vasopressin injections into the myoma were administered to every patient in our trial group, which might have assisted in lowering the total transfusion rate. The blood transfusion in the TXA group was lower than in the control group, but this difference was not statistically significant. Transfusions were given as soon as the maximum allowable blood loss was reached, and the overall transfusion rate in our study was 11.7%. This finding is consistent with transfusion rates reported in other related studies, which were 5.8% for Vargas *et al*.,[11] 27.3% for Shaaban *et al*.,[12] 18.1% for Sinha *et al*.,[13] 5.7% for Zhao *et al*.[14] and 6.7% for Singh *et al.*[15]

The use of TXA was found to shorten anaesthesia duration, possibly due to reduced time spent on achieving haemostasis and cleaning laparoscopic instruments, which enhanced visibility.[2] However, in our study, anaesthesia duration was similar between the TXA and placebo groups. Additionally, surgical drain insertion was not routinely performed in our institution for laparoscopic myomectomy unless the surgeon was unsatisfied with the degree of haemostasis. In our study, only one patient in the control group required a surgical drain, while none in the TXA group required drain.

TXA prevents plasminogen from being activated by plasminogen activator and thus prevents plasminogen from attaching to fibrin through its lysine-binding sites. One possible explanation for the lower intraoperative blood loss observed with TXA could be the inhibition of normal plasminogen activator increase seen during surgery. In gynaecology practice, oral TXA is used to lessen heavy menstrual bleeding. Patients tolerate oral TXA well.[16] Intravenous TXA has proven to be a viable treatment for obstetric bleeding caused by placental abruption and placenta previa. Oral TXA therapy has also been reported to be beneficial for patients undergoing surgical cervix conization.[17] It is strongly recommended to use TXA in the treatment of postpartum haemorrhage.

Perioperative blood loss can be influenced by various factors, including patient characteristics, the surgeon's experience, the size and number of myomas, the duration of the procedure, and the anaesthetic technique. In this study, patient demographics, procedure duration, the number of myomas, and the preoperative blood transfusions required to elevate haemoglobin levels to 10 g/dL were comparable across both groups.

In this study, the use of TXA premedication significantly reduced intraoperative blood loss. Oral TXA administration is rarely associated with side effects. Although antifibrinolytics have previously raised concerns about an increased thrombotic risk, no significant rise in thrombotic events has been reported following its use in multiple centres. TXA is increasingly utilized in procedures where bleeding is anticipated, to minimize the need for allogeneic blood transfusions and reduce the risk of transfusion-related complications. Notably, no thrombotic complications were observed in any of the participants in this study. Additionally, no supplementary surgical interventions, such as uterine artery ligation or conversion to open myomectomy or hysterectomy, were required to control bleeding.

This study had several strengths, including its randomized, double-blinded, placebo-controlled design, which adhered to the CONSORT guidelines. All operating surgeons were highly trained in laparoscopic techniques, minimizing bias related to surgeon experience. However, there were some limitations also. The location of the myoma and patient characteristics could influence blood loss. For instance, submucous myomas, despite being smaller in size, may bleed more. Additionally, we did not compare the length of hospital stays between the two groups. This study also used a standardized 1g dose of TXA for all patients, regardless of their weight, and did not explore the impact of different dosages. Further randomized controlled trials assessing various dosages and timing of premedication are necessary to strengthen the evidence supporting the use of oral TXA as a premedication in laparoscopic myomectomy procedures.

## 5. Conclusion

Patients undergoing laparoscopic myomectomy experience considerably less intraoperative blood loss with a single dose of oral tranexamic acid as premedication. This reduction in blood loss may contribute to improved surgical outcomes and reduced need for blood transfusions. Moreover, the use of oral tranexamic acid does not result in any significant complications, making it a safe and effective adjunct to myomectomy procedures.

## 6. Sources of Funding

None.

## 7. Conflict of Interest

None.

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**Cite this article:** Belvin S, Puthenveettil N, Nair S, Raja S. Effect of prophylactic oral tranexamic acid on blood loss during laparoscopic myomectomy under general anaesthesia: A randomised controlled trial. *Indian J Clin Anaesth*. 2025;12(3):463–468.