

Original Article



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Efficacy of Tranexamic Acid In Reducing Blood Loss During Myomectomy; An Institutional Experience

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Abstract

Objective: To compare the efficacy of tranexamic acid versus placebo in reducing intraoperative blood loss during myomectomy, assessed by postoperative haemoglobin level.

Methodology: This randomized controlled trial (RCT) was conducted in Gynecology & Obstetrics department of department of Nishtar Medical University, Multan from 01-01-2024 to 31-12-2024. Total 90 patients were divided equally into two groups on the basis, they received injectable tranexamic acid or placebo. The main outcome was measured by checking postoperative haemoglobin levels to ascertain the intraoperative blood loss irrespective of blood transfusions during surgery. Data was analyzed using SPSS version 25. Post stratification t-test for quantitative data and Chi square test for qualitative variables was applied. P-value ≤ 0.05 was considered significant.

Results: Two study groups were similar in demographic characteristics including the age, parity, BMI and change in perioperative Hemoglobin (Hb) levels. Change in Hb in two groups was 0.2 ± 0.2 vs 4.9 ± 1.2 ($p = 0.01$). There was significant difference in need of blood transfusion, 11% vs 44% ($p = 0.04$).

Conclusion: Tranexamic acid significantly reduces myomectomy-associated blood loss, and need for further blood transfusions.

Keywords: Blood loss, Surgical, Gynecologic surgical procedures, Myomectomy, Tranexamic acid, Uterine fibroids



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Introduction

Uterine fibroid are very common benign tumors affecting the female reproductive system.¹ By the age of 50, the cumulative incidence of uterine fibroids reaches up to 70% in white women and over 80% in Black women. While these tumors are often asymptomatic, 20% to 50% of affected individuals experience symptoms such as heavy menstrual bleeding, anemia, pelvic pain, pressure and infertility.² Leiomyomas are classified into four types based on their location; subserous, intramural, submucous, and pedunculated.^{3,4,5} Due to their highly vascular nature, perioperative blood loss during myomectomy is a frequently reported complication, with severe cases requiring urgent blood transfusion.^{6,7} Effective interventions to control bleeding and manage associated complications are essential in reducing morbidity and mortality.⁸

A systematic review reported that interventions such as misoprostol, bupivacaine with epinephrine, vasopressin, tranexamic acid (TXA), and mechanical tourniquets are found more effective in minimizing bleeding compared to placebo or no treatment.⁹ Tranexamic acid (TXA), a non-hormonal synthetic lysine analogue, works by inhibiting plasmin activity and fibrinolysis, thereby reducing hemorrhage risk. TXA stabilizes the fibrin meshwork, exerting anti-hemorrhagic effects. It is a cost-effective, safe treatment with minimal side effects, significantly reducing abnormal menstrual bleeding and increasingly being studied for its role in blood loss control during myomectomy.¹⁰ TXA has a rapid onset of action (5 to 15 minutes), a half-life of approximately 2 hours, and 90% of the drug is excreted within 24 hours. A single dose of 1 gram (15 mg/kg) administered before surgery has been associated with reduced hemorrhage-related mortality rate.^{11,12,13}

Due to its significance in bleeding management, tranexamic acid (TXA) has been added to the list of essential medicines by World Health Organization. The use of TXA has gained widespread popularity in surgical procedures. In a meta-analysis of over 1,000 trauma patients, Ageron has demonstrated the efficacy of TXA in both severely and non-severely injured trauma patients.¹⁴ Additionally, studies have shown that TXA is highly effective in controlling hemorrhage during elective surgeries such as liposuction,¹⁵ sleeve gastrectomy,¹⁶ and hip arthroplasty.¹⁷ Shaaban has further evaluated the efficacy of TXA in 132 women undergoing abdominal myomectomy. The TXA group experienced significantly less blood loss (407 ml vs 677 ml, $p < .01$), reduced need for blood transfusions (19.7% vs 34.8%, $p < .01$), and the control group exhibited lower hemoglobin and hematocrit levels ($p = 0.001$).¹⁸

Extensive international research supports TXA's efficacy in preventing hemorrhage and related complications like need for transfusions, prolonged hospital stays, and increased morbidity even mortality. However, no

local research has been conducted on this topic. This study aims to provide a guidance on the use of TXA as a prophylactic measure to reduce intraoperative blood loss in myomectomy especially in underdeveloped countries where anemic population cannot bear the stress of acute blood loss. Establishing local protocols for TXA use will help improve blood loss, reduce complications, and enhance patient safety and recovery.

Methodology

This Randomized Controlled trial was conducted from 01-01-2024 to 31-12-2024 in the department of Gynecology & Obstetrics, Nishtar Medical University, Multan. Sample techniques was non-probability, convenient sampling and size was 90 i.e. 45 patients in each group

Sample size was calculated using the OpenEpi sample-size calculator for comparing two means, with 95% confidence level and 80% power, giving a total of 90 participants (45 in each arm).^{1,9} Women age between 25 to 40 years having single or multiple fibroids with fibroid size up to 20-week were included in this study.

All those patients who are allergic to drug were excluded from the study. Patient with uncontrolled hypertension, diabetes or anemia ($Hb < 11$ gm/dl), patients having uterine malignancy, patients with previous pelvic surgeries and coagulation disorders were also excluded from the study. Informed consent was taken from all the patients. After admission detailed history, examination, ultrasound abdomen/pelvis and preoperative blood tests were carried out on all patients. Patients were divided in to two equal groups randomly by using lottery technique. Group-A patients received 1g Injection Tranexamic acid intravenously prior to surgical incision and Group-B patients received equal volume of distilled water as placebo and same surgical team conducted procedures to control bias. The main outcome was postoperative haemoglobin level. Preoperative Hb, postoperative Hb, and all other relevant information were recorded on specially designed proforma. Data was analyzed by SPSS v 25.0 to measure mean and standard deviation for variables like age, parity, BMI, preoperative hemoglobin, postoperative hemoglobin and change in hemoglobin while frequency and percentages for characteristics(single, multiple, large and small) of fibroids and need for blood transfusion was made according to postoperative hemoglobin. The main outcome was postoperative hemoglobin levels and further need of blood transfusion. Postoperative mean change in hemoglobin levels in both groups were compared by applying Independent-samples t-test at 95 % CI while taking $P \leq 0.05$ as significant.

Results

The mean age of the patients was 35.2 ± 5.5 years and 33.5 ± 4.4 years in Group-A & B.

The baseline levels of mean Hb preoperatively were 11.0 \pm 0.9 and 12.2 \pm 2.3, while postoperative Hb levels were 10.8 \pm 1.5 and 7.3 \pm 1.1 in both groups respectively on postoperative day 1. There was significant difference for blood transfusion requirements postoperatively in both groups (11% vs 44%). No patient developed any serious complications.

Discussion

In current research, a significant decline in postoperative hemoglobin was noted, reflecting meaningful perioperative blood loss. This pattern corresponds with several earlier reports demonstrating that tranexamic acid (TXA) helps limit surgical bleeding. Zaid et al., showed that TXA lowered intraoperative blood loss, reduced the need for transfusion, and minimized the use of additional hemostatic agents during hysterectomy, which collectively contributed to better preservation of postoperative hemoglobin.⁸ Likewise, the meta-analyses by Dongdong et al., and Heyns et al., found that TXA consistently decreases blood loss and mitigates postoperative hemoglobin drop in various surgical settings.^{10,11} Koh and colleagues also reported a protective effect of TXA on perioperative blood loss in major abdominal procedures, supporting its role in maintaining postoperative hemoglobin levels.¹²

Abdou et al., observed no significant change in postoperative hemoglobin or hemoglobin difference between groups receiving oxytocin versus a regimen combining TXA and ethamsylate.¹ Shady et al. also reported that, despite reduced blood loss, the change in hemoglobin after surgery did not reach statistical significance. Such

variations among studies may be influenced by differences in fibroid size, surgical complexity, TXA dosage and timing, baseline hemoglobin status, or the simultaneous use of other hemostatic medications.⁹

Overall, the significant postoperative hemoglobin reduction seen in current study finding which aligns with the majority of published evidence supporting TXA's ability to reduce surgical bleeding. The heterogeneity observed across the literature highlights the need for standardized TXA protocols and consistent outcome reporting to more accurately assess its impact on perioperative hemoglobin trends.

The complexity of surgery is often associated with longer operation times and increased intraoperative blood loss. Plasminogen activator levels typically rise 30 to 60 minutes after the start of surgery. As surgery progresses, fibrinolytic activity naturally increases, with plasminogen activator levels rising within the first 30–60 minutes. This physiological response can contribute to additional blood loss. In our study, the notable decrease in postoperative blood loss in patients receiving tranexamic acid (TXA) is likely related to its capacity to inhibit plasmin formation and counteract this surgery-induced fibrinolytic surge.

The findings of present research are reinforced by several studies in reference list. Shaaban et al. reported a significant reduction in blood loss during myomectomy in women treated with TXA.¹⁸ Comparable outcomes were also noted by Shady and colleagues, who demonstrated that both intravenous and topical TXA decreased bleeding during open myomectomy. Large meta-analyses conducted by Dongdong et al., and

Table 1. Demographic data of the patient (n=90)

| Variable | Group-A (n=45) | Group-B (n=45) | p-value |
|-------------|------------------------|------------------------|---------|
| Age (Years) | 35.2 \pm 5.5 (25–40) | 33.5 \pm 4.4 (25–40) | 0.15 |
| BMI | 25.5 \pm 1.4 | 25.9 \pm 2.1 | 0.786 |
| Parity | 3 | 4 | 0.09 |

Table 2. Relationship between Study Variables & Use of Tranexamic Acid

| Variable | | Group-A (n=45) | Group-B (n=45) |
|-----------------------------|--------------------------|----------------|------------------------|
| Characteristics of Fibroids | • Small Fibroids | 08(18%) | 18(40%) |
| | • Large Fibroids | 11(24%) | 12(26%) |
| | • Single Fibroids | 20(44%) | 10(23%) |
| | • Multiple Fibroids | 06 (14%) | 05(11%) |
| Hemoglobin | Preoperative Hemoglobin | 11.0 \pm 1.9 | 12.2 \pm 2.3(p=0.24) |
| | Postoperative Hemoglobin | 10.8 \pm 1.5 | 7.3 \pm 1.1 (p<0.01) |
| | Change in Hemoglobin | 0.2 \pm 0.2 | 4.9 \pm 1.2 (p=0.01) |
| Need for Blood Transfusion | | 5 (11%) | 20 (44%) (p= 0.04) |

Heyns et al.^{10,11} further support the consistent benefit of prophylactic TXA in surgeries where substantial hemorrhage is anticipated. Koh et al., also confirmed that TXA lowers blood loss in major abdominal operations without increasing thromboembolic risk.¹² Conversely, Abdou et al., did not observe a significant difference in postoperative hemoglobin changes when TXA was combined with ethamsylate versus oxytocin alone, suggesting that variations in adjunct hemostatic agents, surgical technique, or patient characteristics may influence outcomes.¹ Findings of this investigation revealed that the significant reduction in postoperative blood loss observed in the TXA group may be attributed to the suppression of plasminogen activator activity.

Recent studies and systematic reviews consistently demonstrate that prophylactic use of TXA is both safe and effective in reducing blood loss in procedures where significant hemorrhage is expected, without increasing the risk of thromboembolism.^{18,19,20}

Overall, TXA is an effective and safe intervention that enhances surgical outcomes in myomectomy by minimizing intraoperative bleeding and supporting hemodynamic stability. This study was conducted at a single center with a relatively small sample size may affect the results negatively.

There are many limitations in our study like single-center design with relatively small sample size over short follow-up period and other factors such as surgeon experience, variability in surgical technique, operative time and patient comorbidities (e.g., anemia, BMI) may have influenced blood loss but were not fully controlled or stratified.

Conclusion

In this study, Tranexamic acid was shown to significantly reduce myomectomy- associated blood loss and requirements for blood transfusion.

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Authors' Contribution Statement

HS contributed to the conception, design, acquisition, analysis, interpretation of data, drafting of the manuscript, critical review of the manuscript, and final approval of the version to be published. SS contributed to the design, acquisition, analysis, interpretation of data, drafting of the manuscript, and critical review of the manuscript. SYQ contributed to the design, acquisition, analysis, interpretation of data, drafting of the manuscript, and critical review of the manuscript. AUT contributed to the acquisition, analysis, interpretation of data, and drafting of the manuscript. AA contributed to the acquisition, analysis, interpretation of data, and drafting of the manuscript. AA contributed to the acquisition, analysis, interpretation of data, and drafting of the manuscript. All authors are accountable for their work and ensure the accuracy and integrity of the study.

Conflict of Interest

Authors declared no conflict on interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.