

COMPARATIVE STUDY OF EFFICACY OF MISOPROSTOL VS TRANEXAMIC ACID TO REDUCE BLOOD LOSS DURING MYOMECTOMY

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Abstract

Background: Excessive intraoperative blood loss is a major challenge during myomectomy, often leading to hemodynamic instability and increased transfusion requirements.

Objective: To compare the efficacy of misoprostol versus tranexamic acid in reducing intraoperative blood loss during abdominal myomectomy.

Methods: This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Allied Hospital II, Faisalabad, from February 2025 to May 2025. A total of 200 women aged 30–50 years undergoing abdominal myomectomy were randomized into two groups of 100 each. Group A received 400 µg of vaginal misoprostol one hour preoperatively, while Group B received tranexamic acid 15 mg/kg (maximum 1 g) intravenously 20 minutes before skin incision.

Results: Baseline characteristics were comparable between the two groups. Mean intraoperative blood loss was significantly lower in the misoprostol group (298.5 ± 75.2 ml) compared to the tranexamic acid group (356.2 ± 88.9 ml, $p < 0.001$). The mean fall in hemoglobin was also less in the misoprostol group (0.7 ± 0.3 g/dl) than in the tranexamic acid group (1.2 ± 0.4 g/dl, $p < 0.001$). Blood transfusion was required in 7% of patients in the misoprostol group versus 16% in the tranexamic acid group ($p = 0.04$). Operative time was not significantly different between groups (84.5 ± 12.3 vs. 87.1 ± 13.0 minutes, $p = 0.18$).

Conclusion: It is concluded that misoprostol is more effective than tranexamic acid in reducing intraoperative blood loss, minimizing hemoglobin decline, and decreasing transfusion requirements during myomectomy, without increasing operative time.

INTRODUCTION

Uterine fibroids (also known as leiomyomas and myomas) are the most common benign tumours or

neoplasms of the uterus (15–30%) of the female pelvis in the reproductive age group, i.e., one in every

5 women may have fibroids during their childbearing age, commonly seen in women over 30 years [1,2]. Uterine fibroids comprise of smooth muscle cells, fibroblasts and are dense in extracellular matrix (ECM) [1]. They tend to grow in the form of multicellular cell nodules and in whirlpool pattern on the walls of the uterus and are in multiples. Only then they multiply and increase in size after years through estrogen stimulation coupled with progesterone. Fibroids development reason is still unidentified however it is supposed that it is a result of genetic alternations, developmental elements and sex hormones, at the moment of menstrual cycle [3]. Myomas are mostly asymptomatic, and in 20-50 percent of myoma cases, it is symptomatic, and symptoms include: abnormal vaginal bleeding catamenial, predominantly menorrhagia, pelvic pain referred to the back, or UTI like symptoms. The intensity of the symptoms with the tumors will vary according to size, amount and position [4].

Hysterectomy is the definitive treatment of symptomatic leiomyomas, but in women wishing future fertility or uterus preservation, myomectomy is the usual alternative. Myomectomy: Removal of fibroid alone without destroying the rest of the uterus and performed in women under age of 40 who are interested in preserving fertility and a procedure must be surgically appropriate [5]. Myomas can supply their blood most efficiently, and, due to this fact, bleeding is one of the main complications of myomectomy [6]. This may lead to substantial morbidity and mortality and it continues to pose a significant problem to gynecologists even after implementing numerous approaches in an effort to eliminate job over-hemorrhage in the process [7]. Various procedures that reduce blood loss in myomectomy involve GnRH agonist prior to surgery or vasopressin during the surgery, intravenous oxytocin, intra-uterine bupivacaine with epinephrine, tourniquet, and before the surgery uterine artery embolisation and clamping of the uterine and/or ovarian arteries [4]. Tranexamic acid (TXA), a synthetic lysine-analog antifibrinolytic, was first patented in 1957, and its use has been increasing in contrast to aprotinin, a serine protease inhibitor antifibrinolytic. It has been demonstrated to reduce blood loss during surgery. Misoprostol is a synthetic analog of prostaglandin E1, which is found

in nature [8]. It has been shown to reduce intraoperative bleeding in surgical excision of leiomyomas. During myomectomy, misoprostol is thought to work by reducing uterine arterial blood flow and uterine vasoconstriction. Misoprostol acid levels reach their highest point within one hour of administration through the rectal route, where it remains for up to six hours at significantly higher plasma concentrations than when administered orally or sublingually [9]. According to literature, operative time, intra-operative blood loss, postoperative Hb, and need for blood transfusion in pre-operative vaginal use of misoprostol group vs tranexamic acid group were 73.93 ± 5.02 min vs 89 ± 28.9 min, 483.1 ± 50.16 ml vs 413.6 ± 165.6 ml, 10.16 ± 0.76 g/dl vs 9.71 ± 1 g/dl and 2.5% vs 13.3% respectively [10].

Abdominal myomectomy is a common treatment of uterine fibroids and intra-operative blood loss is a frequent complication of abdominal myomectomy. There are many ways to reduce blood loss during surgery, but no one method is preferred. So, this study is conducted to assess the pre-operative use of misoprostol for reducing intra-operative blood loss during abdominal myomectomy. Misoprostol is typically administered rectally, but in this study, it will be delivered via the vagina. It may be suggested during abdominal myomectomy if it proves to be effective in reducing intraoperative blood loss to avoid complications from excessive blood loss.

Objective

To compare the preoperative vaginal use of misoprostol with tranexamic acid in patients undergoing abdominal myomectomy in terms of mean operative time, mean intra-operative blood loss, the mean post-operative Hb and frequency of need for blood transfusion.

Methodology

This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Allied Hospital II, Faisalabad, from February 2025 to May 2025. The sample size was calculated using the WHO sample size calculator for two proportions, taking $P_1 = 2.5\%$, $P_2 = 13.3\%$, level of significance = 5%, and study power = 80%. The calculated sample size was 200 patients, with 100 participants allocated

to each group. Non-probability consecutive sampling was employed to recruit eligible participants. Women aged 30–50 years undergoing planned abdominal myomectomy were included in the study. Eligible participants had a mean uterine fibroid size between 5–15 cm and were symptomatic, presenting with abnormal uterine bleeding, dull lower abdominal pain, subfertility, or recurrent miscarriages. Only women with fewer than five fibroids were considered for enrollment. Women were excluded if they had a history of previous pelvic or abdominal surgery (laparotomy), endometriosis, or pelvic infection. Patients with known hypersensitivity to either misoprostol or tranexamic acid, or those with significant medical comorbidities such as uncontrolled hypertension, diabetes mellitus, renal dysfunction, or hepatic disease, were also excluded. Additionally, pregnancy, use of preoperative hormonal therapy including GnRH analogues or oral contraceptives, and the presence of more than five fibroids were considered exclusion criteria.

Data Collection Procedure

Ethical approval was obtained from the Institutional Review Board before the commencement of the study. After obtaining informed written consent, eligible patients were recruited from the outpatient department. Participants were randomly assigned to two groups using a computer-generated randomization table. Group A received 400 µg of vaginal misoprostol administered one hour before surgery, while Group B received tranexamic acid (TXA) at a dose of 15 mg/kg intravenously (maximum 1 g) as a bolus over 10 minutes, given 20 minutes before skin incision. All surgical procedures were performed by senior gynecologists using a standardized transverse lower abdominal incision without the application of a tourniquet. The primary outcomes assessed were intraoperative blood loss, changes in hemoglobin levels (preoperative and

within 24 hours postoperative), and the requirement for blood transfusion. Secondary outcomes included operative time. Hemoglobin levels were measured by the hospital pathology laboratory, and all relevant clinical data were recorded on a structured proforma.

Data Analysis

Data were analyzed using SPSS version 25. Quantitative variables, including age, body mass index (BMI), parity, number and site of fibroids, size of the largest fibroid, operative time, intraoperative blood loss, and hemoglobin levels, were expressed as mean ± standard deviation (SD). Qualitative variables, such as the need for blood transfusion, were reported as frequencies and percentages. For comparison between the two groups, independent sample t-tests were applied to continuous variables, while the chi-square test was used for categorical outcomes. Effect modifiers, including age, BMI, parity, number and site of fibroids, and size of the largest fibroid, were controlled by stratification, followed by post-stratification application of chi-square and t-tests. A p-value ≤ 0.05 was considered statistically significant.

Results

Data were collected from 200 patients. The mean age of patients was 38.6 ± 5.2 years in the misoprostol group and 39.1 ± 5.4 years in the tranexamic acid group. Mean BMI was 26.8 ± 3.2 kg/m² versus 27.1 ± 3.5 kg/m², and mean parity was 2.1 ± 1.2 compared to 2.0 ± 1.3, respectively. The average number of fibroids per patient was 2.3 ± 0.9 in the misoprostol group and 2.4 ± 1.0 in the tranexamic acid group, while the mean size of the largest fibroid was 9.8 ± 2.1 cm and 10.1 ± 2.3 cm, respectively. None of these differences were statistically significant (p > 0.05).

Table 1. Baseline Demographic and Clinical Characteristics of Patients (n = 200)

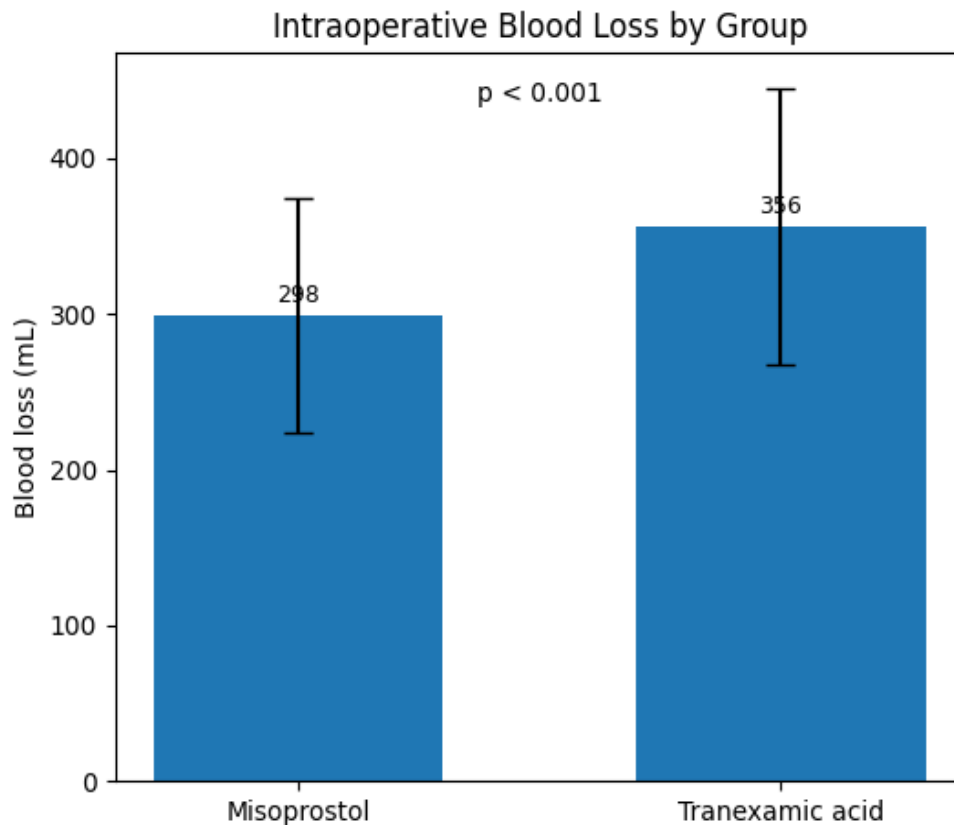
Variable	Misoprostol Group (n=100)	Tranexamic Acid Group (n=100)
Age (years), mean ± SD	38.6 ± 5.2	39.1 ± 5.4
BMI (kg/m ²), mean ± SD	26.8 ± 3.2	27.1 ± 3.5
Parity (mean ± SD)	2.1 ± 1.2	2.0 ± 1.3
Number of fibroids	2.3 ± 0.9	2.4 ± 1.0
Largest fibroid size (cm)	9.8 ± 2.1	10.1 ± 2.3

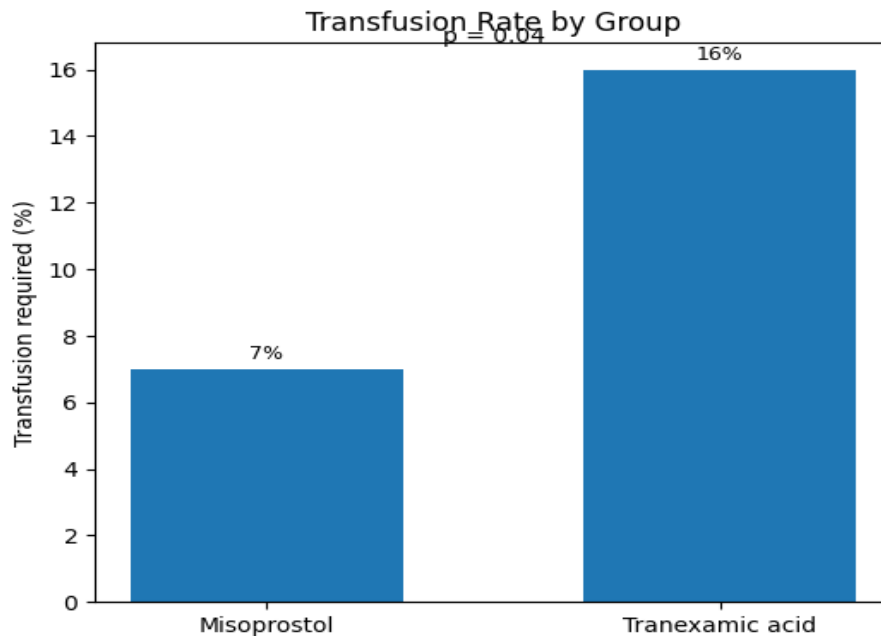
Operative outcomes showed no significant difference in operative time, with a mean duration of 84.5 ± 12.3 minutes in the misoprostol group and 87.1 ± 13.0 minutes in the tranexamic acid group ($p = 0.18$). Intraoperative blood loss, however, was significantly lower in the misoprostol group (298.5 ± 75.2 ml) compared to the tranexamic acid group (356.2 ± 88.9 ml, $p < 0.001$). Preoperative hemoglobin was nearly identical (11.6 ± 1.1 g/dl vs. 11.7 ± 1.2 g/dl, $p = 0.63$), but postoperative

hemoglobin was significantly higher in the misoprostol group (10.9 ± 1.0 g/dl) compared to the tranexamic acid group (10.5 ± 1.1 g/dl, $p = 0.01$). The mean fall in hemoglobin was 0.7 ± 0.3 g/dl in the misoprostol group versus 1.2 ± 0.4 g/dl in the tranexamic acid group ($p < 0.001$). Blood transfusion was required in only 7 patients (7.0%) in the misoprostol group compared to 16 patients (16.0%) in the tranexamic acid group, a significant difference ($p = 0.04$).

Table 2. Intraoperative and Postoperative Outcomes

Outcome	Misoprostol Group (n=100)	Tranexamic Acid Group (n=100)	p-value
Operative time (minutes)	84.5 ± 12.3	87.1 ± 13.0	0.18
Intraoperative blood loss (ml)	298.5 ± 75.2	356.2 ± 88.9	<0.001
Pre-op Hb (g/dl), mean $\pm$ SD	11.6 ± 1.1	11.7 ± 1.2	0.63
Post-op Hb (g/dl), mean $\pm$ SD	10.9 ± 1.0	10.5 ± 1.1	0.01
Fall in Hb (g/dl), mean $\pm$ SD	0.7 ± 0.3	1.2 ± 0.4	<0.001
Blood transfusion required, n (%)	7 (7.0%)	16 (16.0%)	0.04





Age-based stratification showed consistent superiority of misoprostol. In women aged 30–39 years, intraoperative blood loss averaged 285.4 ± 70.6 ml with misoprostol versus 342.7 ± 82.1 ml with tranexamic acid ($p = 0.002$), and the fall in hemoglobin was 0.6 ± 0.3 g/dl versus 1.1 ± 0.4 g/dl

($p < 0.001$). Among women aged 40–50 years, blood loss was 310.7 ± 78.9 ml in the misoprostol group and 367.5 ± 90.3 ml in the tranexamic acid group ($p = 0.004$), while the hemoglobin decline was 0.8 ± 0.3 g/dl versus 1.3 ± 0.5 g/dl, respectively ($p < 0.001$).

Table 3. Comparison of Blood Loss and Hb Fall by Age Group

Age (years)	Group	Outcome	Misoprostol (n=100)	Group	Tranexamic Acid Group (n=100)	p-value
30–39		Blood loss (ml), mean $\pm$ SD	285.4 ± 70.6		342.7 ± 82.1	0.002
		Hb fall (g/dl), mean $\pm$ SD	0.6 ± 0.3		1.1 ± 0.4	<0.001
40–50		Blood loss (ml), mean $\pm$ SD	310.7 ± 78.9		367.5 ± 90.3	0.004
		Hb fall (g/dl), mean $\pm$ SD	0.8 ± 0.3		1.3 ± 0.5	<0.001

When stratified by fibroid size, patients with smaller fibroids (5–10 cm) had significantly less blood loss with misoprostol (272.1 ± 65.4 ml) compared to tranexamic acid (325.6 ± 70.8 ml, $p < 0.001$), and a smaller fall in hemoglobin (0.6 ± 0.2 g/dl vs. 1.0 ± 0.3 g/dl, $p < 0.001$). In patients with larger fibroids (>10–15 cm), blood loss was again significantly reduced in the misoprostol group (335.9 ± 82.7 ml) compared to the tranexamic acid group (392.4 ± 95.5 ml, $p = 0.003$). The mean hemoglobin fall was 0.9 ± 0.3 g/dl in the misoprostol group versus 1.4 ± 0.5

g/dl in the tranexamic acid group ($p < 0.001$). In women with two or fewer fibroids, blood loss was 280.5 ± 72.3 ml with misoprostol compared to 338.7 ± 79.2 ml with tranexamic acid ($p = 0.001$), with hemoglobin fall of 0.6 ± 0.2 g/dl and 1.0 ± 0.3 g/dl, respectively ($p < 0.001$). Among women with three to four fibroids, blood loss was 322.8 ± 80.5 ml in the misoprostol group and 376.1 ± 92.0 ml in the tranexamic acid group ($p = 0.005$). The hemoglobin fall was 0.8 ± 0.3 g/dl compared to 1.3 ± 0.4 g/dl, respectively ($p < 0.001$).

Table 4. Comparison of Blood Loss and Hb Fall by Largest Fibroid Size

Fibroid Size (cm)	Outcome	Misoprostol Group (n=100)	Tranexamic Acid Group (n=100)	p-value
5-10	Blood loss (ml), mean $\pm$ SD	272.1 $\pm$ 65.4	325.6 $\pm$ 70.8	<0.001
	Hb fall (g/dl), mean $\pm$ SD	0.6 $\pm$ 0.2	1.0 $\pm$ 0.3	<0.001
>10-15	Blood loss (ml), mean $\pm$ SD	335.9 $\pm$ 82.7	392.4 $\pm$ 95.5	0.003
	Hb fall (g/dl), mean $\pm$ SD	0.9 $\pm$ 0.3	1.4 $\pm$ 0.5	<0.001
Number of Fibroids				
≤ 2	Blood loss (ml), mean $\pm$ SD	280.5 $\pm$ 72.3	338.7 $\pm$ 79.2	0.001
	Hb fall (g/dl), mean $\pm$ SD	0.6 $\pm$ 0.2	1.0 $\pm$ 0.3	<0.001
3-4	Blood loss (ml), mean $\pm$ SD	322.8 $\pm$ 80.5	376.1 $\pm$ 92.0	0.005
	Hb fall (g/dl), mean $\pm$ SD	0.8 $\pm$ 0.3	1.3 $\pm$ 0.4	<0.001

Discussion

This randomized controlled trial compared the efficacy of misoprostol and tranexamic acid in reducing intraoperative blood loss during myomectomy. In our results, we found out that misoprostol is better as a prophylaxis compared to tranexamic acid when it comes to reducing blood loss, limiting the postoperative decrease of hemoglobin, and decreasing blood transfusion. The duration of operative time was similar in both groups; hence the observed hemostatic benefit of misoprostol did not increase operative time [11]. Blood loss reduction we achieved using misoprostol corresponds to the previous studies that reveal that misoprostol has a potent uterotonic effect by increasing myometrial contractility and decreasing uterine perfusion in the obstetric and gynecologic practice. Comparatively, tranexamic acid, which is efficient in antifibrinolytic drug, has the main effect of stabilizing active clots with minimal effect on uterine tone. Such a difference in mechanism can perhaps cause the better performance of misoprostol in our trial [12].

Mean intraoperative blood loss of 298 ml in the misoprostol group was significantly less than 356 ml in the tranexamic acid group mirroring the results

of past clinical trials indicating that prostaglandin analogues have the potential to decrease surgical bleeding up to 2025%). In a similar manner, the decrease in hemoglobin was not marked as in the misoprostol group implying that the hemostatic advantage increased the perioperative hematologic stability [13]. Notably, the transfusion need in our analysis was twice as high in the tranexamic acid arm and the misoprostol arm and hence the clinical importance of this observation. The findings of our study lay emphasis on the fact that both agents are effective in varied surgical and obstetric indications, but misoprostol might be more ideal to achieve myomectomy, especially in low-resource settings with limited availability of blood products [14-16]. The benefits of misoprostol are that it is easy to administer, cheap, has stability at room temperature, and it has good safety profile. Tranexamic acid, which has been proven safe and used common in surgical practice, has found to be potentially more useful as adjuvant than stand-alone therapy during myomectomy [17]. The study also affirmed that parity, number of fibroids, size of the largest fibroid, age, were factors influencing the amount of blood loss at the baseline characteristics. Stratified analysis revealed that individuals with large

fibroids (> 10 cm) or with multiple fibroids (ie 3 or more) had more blood loss irrespective of the drug. Nevertheless, misoprostol was systematically more effective in every subset, which confirms its applicability. Guided by the results of the presented study, it is proposed that an intervention with misoprostol must be included in the perioperative regimen of women who undergo myomectomy in order to mitigate intraoperative resuscitation and prevent transfusion demand as effectively as possible [18]. Tranexamic acid can continue to be considered as a choice in adjunctive therapy in patients who have certain indications, but misoprostol must take precedence, particularly in a resource-poor situation. Multi-center randomized controlled trials with additional sample size and extended follow-up are warranted to confirm these findings, determine long-term effects and safety of combining misoprostol with other hemostatic interventions to optimize surgical outcomes [19,20]. Some limitations are to be noted First, the research process was at one center, which complicates the external validation of the study. Second, blood loss was measured and not calculated using gravimetric or photo electric methods that may have added variability. Third, the postoperative period was only up to immediate, and long-term outcomes like recurrence or development of late complications was not evaluated. Besides these limitations, the study has presented ample evidence in support of the use of misoprostol as an effective agent compared to tranexamic acid in reducing blood loss during myomectomy.

Conclusion

It is concluded that misoprostol is more effective than tranexamic acid in reducing intraoperative blood loss during myomectomy. Patients receiving misoprostol experienced a significantly lower mean blood loss, a smaller postoperative decline in hemoglobin, and a reduced requirement for blood transfusion compared to those given tranexamic acid. Operative time was not significantly different between the two groups, indicating that misoprostol provides superior hemostatic benefit without prolonging surgery.

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