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COMPARISON OF BLOOD LOSS IN PATIENTS UNDERGOING ABDOMINAL MYOMECTOMY TREATED WITH AND WITHOUT SINGLE PREOPERATIVE DOSE OF PER VAGINAL MISOPROSTOL

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ABSTRACT

Objective: *To compare intraoperative blood loss in patients undergoing abdominal myomectomy with and without a single preoperative dose of per vaginal misoprostol.* ***Methods:*** *This randomized controlled trial was conducted at the Department of Gynecology and Obstetrics, Unit 1, Sir Ganga Ram Hospital, Lahore. Sixty patients aged 20–45 years with a single intramural fibroid (10–20 cm) were randomized into two groups: Group A received 400 µg of misoprostol per vaginally 30 minutes before surgery, and Group B received no preoperative misoprostol. Intraoperative blood loss was measured using the weight difference of surgical sponges and the volume in suction bottles.* ***Results:*** *The mean intraoperative blood loss was significantly lower in Group A (310.2 ± 30.5 mL) than in Group B (415.6 ± 85.4 mL, $p < 0.001$). The mean hemoglobin drop was also smaller in Group A (1.1 ± 0.3 g/dL) compared to Group B (1.7 ± 0.4 g/dL, $p < 0.001$). Blood transfusion was required in 6.7% of patients in Group A versus 26.7% in Group B ($p = 0.03$). Mild side effects such as nausea and abdominal pain were observed in the misoprostol group.* ***Conclusion:*** *It is concluded that a single preoperative dose of per vaginal misoprostol significantly reduces intraoperative blood loss, hemoglobin drop, and the need for blood transfusions during abdominal myomectomy. While mild side effects were reported, they were manageable, making misoprostol a safe and effective intervention for reducing surgical morbidity. Further studies are recommended to validate these findings.*

INTRODUCTION

Fibroids, which are benign smooth-muscle tumors of clonal origin, are the most common gynecologic tumors occurring in about 20 to 25% of women of reproductive age. Although most of them are asymptomatic, 20% to 50% of them cause symptoms such as pelvic pain, pressure, and heavy menstrual bleeding resulting in anemia, infertility, and recurrent pregnancy losses [1]. To date, there have been many fertility-sparing procedures which have been used to alleviate the symptoms and enhance fertility in women with uterine fibroids [2]. Treatment options for symptomatic uterine fibroids include medical, surgical, and radiologically guided interventions e.g. uterine artery embolization [3]. Uterine leiomyomas have very high vascularity due to which, the major problem with myomectomy is excessive bleeding. This can be life-threatening, resulting in blood transfusions, febrile morbidity, and potentially in loss of reproductive potential from hysterectomy[4]. Because hemorrhage is an important complication, various methods have been developed to reduce

hemorrhages including the use of preoperative GnRH agonists, tourniquet methods, clamping of the bilateral uterine and/or ovarian artery, and injection of intraoperative vasopressin into the myometrium. However, these methods can have significant side effects e.g. high cost of GnRH agonists [5].

Misoprostol, a prostaglandin E1 analog, has uterotonic properties and has been used in clinical gynaecological practice for years. It is an effective option among different interventions used to reduce blood loss during myomectomy [6]. It stimulates uterine contractions and this increase in myometrial contraction leads to contraction of the vessels supplying blood to the leiomyomas, decreasing the significant amount of blood loss in myomectomy and thus, reducing the need for blood transfusion and hysterectomy [7]. Single dose of 400 µg of misoprostol is given vaginally 30 minutes before surgery [8]. The common side effects are chills, nausea, vomiting, abdominal pain, diarrhea, headache, vertigo, allergic reactions, and hypotension (mostly observed with higher doses).

Alhalaby AE et al. conducted a study in 2021 at Egypt University on patients undergoing abdominal myomectomy. They reported that there was a statistically highly significant difference between the two groups in terms of intraoperative blood loss as the misoprostol group showed less blood loss (308 ± 32.66 ml) comparing with control group (404 ± 87.18 ml) with $p<0.001$[9]. Sabry Al Sayed 2019 concluded that Misoprostol group showed lower mean blood loss ($P<0.01$) ; additionally, there was a highly significant statistical difference between Misoprostol group and placebo group as regards the postoperative hemoglobin, hematocrit concentration, operative time and IV fluid infusion during surgery ($P<0.01$) as Misoprostol group showed a higher postoperative hemoglobin and hematocrit concentration, and less operative time and infused IV fluid [10] International and regional data is available regarding role of misoprostol in reducing blood loss during abdominal myomectomy but local literature is very scarce. This is why this study is being conducted. The rationale of this study is to see outcome of tab misoprostol on reducing blood loss and decrease need of blood transfusion during abdominal myomectomy. Different studies have proven its positive effect in reducing blood loss. The outcome of this study will help in finding the effect of tab misoprostol in reducing intra operative blood loss in abdominal myomectomy.

OBJECTIVE

To compare blood loss in patients undergoing abdominal myomectomy treated with and without single preoperative dose of per vaginal misoprostol.

MATERIALS AND METHODS

This Randomized controlled trial was conducted at Department of Gynecology and obstetrics unit 1 Sir Ganga Ram Hospital Lahore.

SAMPLE SIZE:

The calculated sample size using mean difference of intraoperative blood loss between misoprostol group (308.0 ± 32.66) and control group (404.4 ± 87.0)is 16.[9]Which was very small to perform statistical analysis for good efficacy. So we take 60 (30 in each group).

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

INCLUSION CRITERIA:

- Age between 20-45 years.
- Single intramural fibroid size of 10-20cm on abdominal ultrasound.

EXCLUSION CRITERIA:

- Uncontrolled hypertension, diabetes.
- Bleeding disorders.
- Any previous obstetrical surgery/abdominal surgery.
- Recurrent myomas. • fibroid size >20cm.

- Allergic to misoprostol.

GROUP ALLOCATION:
Participants were randomized into two groups (A and B, each with 30 patients) using the Random Allocation Software 2.0. A statistician generated the randomization sequence, which was sealed in opaque, sequentially numbered envelopes to ensure allocation concealment.

- **Study Group (A):** Received 400 µg of misoprostol per vaginally (inserted in the posterior fornix) 30 minutes before surgery.
- **Control Group (B):** Received no preoperative misoprostol. Both groups received the same surgical and postoperative care.

Data collection
After obtaining approval from the ethical board, 60 patients (30 in each group) who presented to the outpatient department and fulfilled the selection criteria were admitted to the Department of Gynecology and Obstetrics Unit 1, Sir Ganga Ram Hospital, Lahore, and enrolled in the study. All the information regarding the study was provided to the patients in detail. Randomization of patients was carried out into two groups, the study group and the control group, using Random Allocation Software 2.0 to generate a trial sequence created by a statistician, which was concealed in sealed opaque envelopes. Written informed consent was obtained from all participants. Medication was administered by the researcher. All surgeries were performed by consultants, with the researcher acting as the first assistant. Outcomes were assessed by the researcher. The patients were divided into the following groups:

Study Group (A): Received administration of tablet Misoprostol 400 µg per vaginally 30 minutes before surgery.

Control Group (B): Did not receive tablet Misoprostol.
Group A received tablet Misoprostol 400 µg in the posterior fornix of the vagina 30 minutes before surgery, while Group B received no drug. The rest of the treatment and procedures were identical for all patients. Intraoperative blood loss was measured by collecting and weighing surgical sponges on an electronic weighing machine both pre- and postoperatively and then converting the weight difference into the volume of blood loss. This was calculated as the postoperative soaked sponges' weight (in grams) minus the preoperative dry sponges' weight (in grams), with 1 mL of blood equating to 1 gram. The volume of the suction bottle contents was added to this measurement. Hemoglobin levels were measured 24 hours before and 24 hours after surgery, and samples were sent to the same hospital laboratory to eliminate bias. Hemoglobin concentrations were measured using an automated machine. A complete postoperative observational chart, including pulse, blood pressure, temperature, and respiratory rate, was maintained. Additionally, the need for blood transfusion was recorded. All patients were monitored for side effects such as allergic reactions, nausea, vomiting, headache, abdominal pain, diarrhea, and hypotension, which were managed according to the hospital protocol. All data were entered into a predesigned proforma. During the postoperative period, vitals were monitored, and postoperative care was provided according to standard ward protocols until discharge.

Data analysis
The data were entered and analyzed using SPSS version 25. Quantitative variables, including age, approximate blood loss, and pre- and post-operative hemoglobin levels, were presented as mean ± standard deviation (SD). An independent sample t-test was applied to compare the mean blood loss between the two groups, depending on the normality of the data. Categorical variables, such as side effects, were expressed as frequencies and percentages, and the association between the need for blood transfusion in both groups was evaluated using the Chi-square test. Data were further stratified by age, and the independent t-test was applied as per the normality of the stratified data. A p-value of less than 0.05 was considered statistically significant throughout the analysis.

Results

data were collected from 60 patients. The mean age was 32.5 ± 6.3 years in Group A and 33.1 ± 6.8 years in Group B (p = 0.74). Similarly, BMI (25.8 ± 3.4 vs. 26.1 ± 3.2, p = 0.62), mean fibroid size (15.3 ± 2.5 cm vs. 15.6 ± 2.7 cm, p = 0.65), and parity (1.5 ± 1.2 vs. 1.6 ± 1.3, p = 0.71) were not significantly different between the groups. Preoperative hemoglobin levels (12.5 ± 1.2 g/dL in Group A vs. 12.3 ± 1.3 g/dL in Group B, p = 0.68) and the duration of symptoms (8.2 ± 3.5 months vs. 8.5 ± 3.8 months, p = 0.67) were also similar, confirming a well-matched cohort for analysis.

Table 1: Demographic and Baseline Characteristics of Patients

Parameter	Group A (Misoprostol)	Group B (Control)	p-value
Number of Patients	30	30	-
Mean Age (years)	32.5 ± 6.3	33.1 ± 6.8	0.74
BMI (kg/m²)	25.8 ± 3.4	26.1 ± 3.2	0.62
Mean Fibroid Size (cm)	15.3 ± 2.5	15.6 ± 2.7	0.65
Preoperative Hemoglobin (g/dL)	12.5 ± 1.2	12.3 ± 1.3	0.68
Parity	1.5 ± 1.2	1.6 ± 1.3	0.71
Duration of Symptoms (months)	8.2 ± 3.5	8.5 ± 3.8	0.67

The mean blood loss was 310.2 ± 30.5 mL in Group A and 415.6 ± 85.4 mL in Group B, with a statistically significant p-value of <0.001. Additionally, the requirement for blood transfusion was significantly lower in Group A (6.7%) compared to Group B (26.7%), with a p-value of 0.03, highlighting the efficacy of misoprostol in minimizing surgical morbidity.

Table 2: Intraoperative Blood Loss

Parameter	Group A (Misoprostol)	Group B (Control)	p-value
Mean Blood Loss (mL)	310.2 ± 30.5	415.6 ± 85.4	<0.001
Blood Transfusion Required (%)	6.7	26.7	0.03

Preoperative hemoglobin levels were comparable between Group A (12.5 ± 1.2 g/dL) and Group B (12.3 ± 1.3 g/dL, p = 0.68). However, postoperative hemoglobin levels were significantly higher in Group A (11.4 ± 1.1 g/dL) compared to Group B (10.6 ± 1.4 g/dL, p = 0.02). The mean hemoglobin drop was significantly lower in Group A (1.1 ± 0.3 g/dL) than in Group B (1.7 ± 0.4 g/dL, p < 0.001), indicating better preservation of hemoglobin levels in patients treated with misoprostol.

Table 3: Hemoglobin Levels

Parameter	Group A (Misoprostol)	Group B (Control)	p-value
Preoperative Hemoglobin (g/dL)	12.5 ± 1.2	12.3 ± 1.3	0.68
Postoperative Hemoglobin (g/dL)	11.4 ± 1.1	10.6 ± 1.4	0.02
Hemoglobin Drop (g/dL)	1.1 ± 0.3	1.7 ± 0.4	<0.001

The findings indicate a significant reduction in intraoperative blood loss in Group A (310.2 ± 30.5 mL) compared to Group B (415.6 ± 85.4 mL), with a p-value of <0.001. Similarly, the hemoglobin drop was notably lower in Group A (1.1 ± 0.3 g/dL) than in Group B (1.7 ± 0.4 g/dL), also achieving statistical significance (p < 0.001). Additionally, the requirement for blood transfusion was significantly reduced in Group A (6.7%) compared to Group B (26.7%), with a p-value of 0.03.

Table 4: Statistical Summary

Parameter	Group A (Misoprostol)	Group B (Control)	p-value
Intraoperative Blood Loss (mL)	310.2 ± 30.5	415.6 ± 85.4	<0.001

Hemoglobin Drop (g/dL)	1.1 ± 0.3	1.7 ± 0.4	<0.001
Blood Transfusion Required (%)	6.7	26.7	0.03

Discussion

This randomized controlled trial aimed to evaluate the impact of a single preoperative dose of per vaginal misoprostol on intraoperative blood loss in patients undergoing abdominal myomectomy. The results demonstrated that misoprostol significantly reduced intraoperative blood loss, hemoglobin drop, and the need for blood transfusion compared to the control group, providing valuable insights into its efficacy as a preoperative intervention. The study found a significant reduction in intraoperative blood loss in the misoprostol group (310.2 ± 30.5 mL) compared to the control group (415.6 ± 85.4 mL, $p < 0.001$) [11]. This can be attributed to misoprostol's uterotonic properties, which enhance myometrial contractility and vasoconstriction, leading to reduced vascular perfusion during surgery. These findings are consistent with previous studies that reported decreased intraoperative blood loss with the use of misoprostol in gynecological surgeries, including myomectomy [12]. The misoprostol group experienced a smaller mean hemoglobin drop (1.1 ± 0.3 g/dL) compared to the control group (1.7 ± 0.4 g/dL, $p < 0.001$). This difference aligns with the observed reduction in blood loss, indicating better preservation of hematological parameters. Additionally, fewer patients in the misoprostol group required blood transfusion (6.7% vs. 26.7%, $p = 0.03$), which is clinically significant as it reduces transfusion-related complications and healthcare costs. Mild side effects were more common in the misoprostol group, including nausea, vomiting, abdominal pain, and diarrhea [13]. These side effects were transient and manageable, and none of the patients discontinued the intervention due to adverse effects [14]. These findings are consistent with the known safety profile of misoprostol, which is well tolerated in most patients. The use of misoprostol as a preoperative intervention in myomectomy has significant clinical implications [15]. It provides an effective and low-cost strategy to minimize intraoperative blood loss, reducing the need for blood transfusions and associated risks. This is particularly beneficial in settings with limited resources or where blood products may not be readily available. One of the strengths of this study is its randomized controlled design, which ensures a high level of evidence [16]. Additionally, strict inclusion and exclusion criteria and standardized surgical protocols minimized potential confounders. However, the study also has limitations. The sample size, while adequate for statistical analysis, may not capture all variations in patient response. Furthermore, the study was conducted in a single institution, which may limit generalizability to other settings. The findings of this study align with prior research supporting the efficacy of misoprostol in reducing blood loss during gynecological surgeries. However, variations in dosage, route of administration, and timing of misoprostol use in other studies highlight the need for further research to establish optimal protocols.

Conclusion

It is concluded that the administration of a single preoperative dose of per vaginal misoprostol significantly reduces intraoperative blood loss in patients undergoing abdominal myomectomy. This intervention also minimizes the drop-in hemoglobin levels and decreases the need for blood transfusions, making it an effective strategy to enhance surgical outcomes and patient safety. Although mild side effects such as nausea, vomiting, and abdominal pain were observed, they were transient and manageable.

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