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Comparative Study of Preoperative Misoprostol versus Intraoperative Hemostatic Uterine Artery Ligation in Reducing Blood Loss in Cases of Myomectomy

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ABSTRACT

Article info Received: Accepted:	rmation 16-09-2023 28-11-2023	 Background: Myomectomy is a common surgical intervention for the remove of uterine fibroids. Excessive blood loss during the procedure remains concern. However, there is currently no agreement on the optimal meth for minimizing blood loss during myomectomy procedures. Aim of the Work: This comparative study aimed to assess the efficacy of two approaches, namely preoperative misoprostol administration a intraoperative cervical hemostatic uterine artery ligation, in reduci intraoperative blood loss. 				
DOI: 10.21608/IJMA.2023.209653.1681.		Patients and Methods: A prospective randomized controlled trial was conducted, including a total of 80 patients undergoing myomectomy for symptomatic uterine fibroids. These patients were divided into two groups:				
*Corresponding author Email: mohamedmostafaa327@gmail.com Citation: NorEldien MMM, Gebreel MM, Marai AA. Comparative Study of Preoperative Misoprostol versus Intraoperative Hemostatic Uterine Artery Ligation in Reducing Blood Loss in Cases of Myomectomy. IJMA 2023 October; 5 [10]: 3734-3741. doi: 10.21608/IJMA.2023.209653.1681.		 Group A [40 patients] received preoperative misoprostol and Group B [40 patients] underwent intraoperative cervical hemostatic uterine artery ligation. The primary outcome measure was the difference in blood loss between the two groups. Secondary outcomes included operation time, postoperative hemoglobin levels and transfusion rates. Results: The findings revealed that the amount blood loss was significantly less in Uterine Artery Ligation group. The mean blood loss in Group A was 440.0±78.1 ml, while in Group B, it was 375.0±96.3 ml [p 0.006]. Furthermore, Group B demonstrated a lower transfusion rate and higher postoperative hemoglobin levels compared to Group A. Conclusion: Intraoperative cervical hemostatic uterine artery ligation was found to be more effective than preoperative misoprostol administration in reducing blood loss during myomectomy procedures. This technique shows promise in improving surgical outcomes, minimizing blood loss, and potentially reducing the need for blood transfusion, but further research and long-term follow-up studies are needed for validation and to determine its clinical significance. 				

Keywords: Leiomyoma; Misoprostol; Uterine Artery; Uterine Myomectomy; Surgical Blood Loss.



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INTRODUCTION

Uterine leiomyomas, also known as fibroids or myomas, are non-cancerous growths of smooth muscle in the uterus ^[1]. Uterine leiomyomas are common benign tumors in women. While many cases are symptomless and discovered incidentally, 20% to 50% can cause issues like heavy menstrual bleeding, pelvic pain, pressure symptoms, as well as problems in the colorectal and urinary systems ^[2].

Treatment of women with uterine leiomyomas depend on number and size and location of fibroid and desire to preserve fertility. Symptomatic uterine fibroid may be treated medically, surgically, or with combination of both ^[3].

Medical treatments for managing symptoms of uterine leiomyomas and reducing their size include oral contraceptives, progestins/levonorgestrel intrauterine system, GnRH agonists, GnRH antagonists, Danazol, and aromatase inhibitors^[4].

The standard treatment for symptomatic leiomyomas is myomectomy, which can be performed through laparotomy, laparoscopy, or hysteroscopy. Laparotomy involves surgically removing the fibroids through an abdominal incision, while laparoscopic myomectomy is an option for cases with a small number of subserous or intramural myomas and a uterine size less than 16 weeks gestation ^[5]. During myomectomy, blood loss can occur either during the surgery or in the postoperative period, sometimes leading to hematoma formation. Dissecting large fibroids can result in significant blood loss, making myomectomy a more difficult procedure compared to hysterectomy. In cases of heavy and uncontrollable bleeding or when it's not feasible to reconstruct the uterus due to multiple myoma removal, myomectomy may be converted to hysterectomy intraoperatively ^[6].

Many techniques are used to reduce blood loss during myomectomy; preoperative measures such as correction of preoperative anemia associated with menorrhagia may be treated with iron supplementation, use of gonadotropin [GHC] triggers prior to surgery. Intra-operative measures as use of tourniquet around the uterus during the operation, injections of vasopressin or other vasopressors as epinephrine in the uterine muscle and use of ecbolic [misoprostol, oxytocin, etc.]. In situations where heavy bleeding is expected or occurs during myomectomy, alternative techniques such as uterine artery ligation [UAL], embolization, or internal iliac artery ligation may be employed to prevent the need for a hysterectomy ^[7].

Misoprostol is a synthetic substance that mimics the effects of prostaglandin E1. Prostaglandins enhance contractions of the uterine muscle and help reduce excessive bleeding from the uterine lining ^[8]. Misoprostol is a valuable drug in obstetrics and gynecology due to its ability to induce uterine contractions and promote cervical ripening. Notably, it is affordable, readily accessible, and remains stable at room temperature. In obstetrics, misoprostol is utilized to treat and prevent postpartum hemorrhage and may also reduce intraoperative bleeding during myomectomies ^[9].

Bilateral ascending UAL can be a preferred option in abdominal myomectomy due to its advantages of being simpler, faster, more costeffective, and not requiring specialized surgical skills. Several researchers have indicated the potential long-term benefits of UAL for fertility and pregnancy outcomes. It has been observed to completely resolve excessive menstrual bleeding associated with fibroids and has the potential to prevent fibroid recurrence. Furthermore, UAL doesn't seem to have a negative impact on fertility, which is crucial as preserving fertility is a primary consideration for women opting for myomectomy over hysterectomy ^[10]. Research has also demonstrated that the presence of very small fibroids that are not removed during the surgery tends to decrease in size, effectively reducing the likelihood of new fibroid formation^[11].

The management of blood loss during myomectomy is crucial to minimize perioperative complications and optimize patient outcomes. Various techniques have been explored to reduce blood loss, including preoperative administration of misoprostol and intraoperative cervical hemostatic uterine artery ligation. While these approaches have shown promise individually, there is a notable gap in the literature regarding a direct comparison between these two strategies. Understanding the comparative efficacy of preoperative misoprostol versus intraoperative cervical hemostatic uterine artery ligation in reducing blood loss during myomectomy is essential to guide clinical decision-making and optimize surgical outcomes. Therefore, this study aims to address this knowledge gap by conducting a comparative analysis of these two techniques, evaluating their effectiveness in reducing blood loss and providing valuable insights for improving the management of myomectomy procedures.

PATIENTS AND METHODS

After ethical committee approval and informed consent from the patients, this randomized controlled study was performed on total of 80 women suffering from symptomatic uterine myoma and scheduled to undergo myomectomy at Al-Hussein University Hospital, Obstetrics and Gynecology Department starting from October 2021 till March 2022.

All patients were randomly [using a computer-based program] divided into two equal groups: Group A: was given 400 ug of misoprostol [Misotac 200 ug 2 tab made by Sigma company] intravaginally one hour before the operation, and group B: [uterine artery ligation group] was subjected to bilateral uterine artery ligation during the procedure to reduce intraoperative blood loss.

Inclusion criteria: Age of women between 30 to 45 years old, symptomatic of uterine myoma, and uterine size less than 24 weeks pregnancy.

Exclusion criteria: Pregnancy, adenomyosis, patients who have bleeding disorder, hemoglobin <10 mg%, hypertension, cardiac and pulmonary disease, chronic endocrine and metabolic disease as diabetes, obesity [BMI $>30 \text{ kg/M}^2$], history of previous myomectomy and patients received pre-operative, hormonal therapy and oral contraceptive pill.

2D Ultrasonography was carried out transvaginal using to confirm the exact site, size and number of uterine fibroids and to exclude any associated pelvic pathology.

Myomectomy Procedure

All procedures were performed under general anesthesia. All the patients involved in the study underwent myomectomy with pfannenstiel skin incision and vertical uterine incision type.

In group B. During the laparotomy procedure, uterine artery ligation was conducted. The lower portion of the broad ligament was exposed by pulling up the uterus. Near the junction of the body and the cervix, the beating of the uterine artery was detected. Using Vecryl 0, a suture was threaded around the artery and through around 1–2 cm of the myometrium at the location where an incision at the level of

internal os would be made in the lower uterine segment. This process was replicated on the opposite side. A single midline anterior incision was made on the uterus initially, followed by creating a small opening in an area without blood vessels. There was a fibroid located in the broad ligament on both sides of the uterine isthmus, positioned just beside the uterine vessels.

The blood loss was assessed by measuring the volume of blood in the suction container after each procedure. Additionally, the amount of blood absorbed by the laparotomy mop packs, which were initially dry before being placed in the abdomen after opening the parietal peritoneum, was determined by weighing them.

Post-operative observation included clinical assessment of vital sign pulse, blood pressure, temperature, hemoglobin, hematocrit value, vaginal bleeding.

Follow-up postoperative laboratory analysis for complete blood count, hemoglobin and hematocrit.

To prevent inaccurate results caused by intravenous fluid-induced hemodilution within the initial 24 hours, hemoglobin and hematocrit levels were obtained from post-operative venous blood samples of patients after a 24-hour period.

Primary outcome: Estimated blood loss [the percentage of haemoglobin drop between preoperative and Postoperative CBC and haematocrit levels] and operative time

Secondary outcome: Duration of operation, duration of hospital stay and need for blood transfusion.

Statistical Analysis

Continuous data was summarized using the mean and standard deviation, while qualitative data was presented as percentages. The Student's t-test was employed to compare continuous data between two independent groups, whereas the Chi-square test was used for analyzing qualitative data. Paired t test was used to compare pre and post-operative data. A significance level of 0.05, indicating the smallest acceptable value, was chosen. The statistical analysis was conducted using IBM® SPSS® Statistics Version 22 for Windows.

RESULTS

Table [1] shows that there were no significant variations in tumor number, type, site, and size between the studied groups.

Vital data and preoperative hemoglobin also did not exhibit any significant differences [Table 2].

Uterine size did not significantly differ among the groups [Table 3].

In terms of operation duration, the Uterine Artery Ligation group had a significantly shorter duration compared to the misoprostol group. The Uterine Artery Ligation group had significantly less blood loss and a lower frequency of blood transfusion [Table 4].

Regarding hemoglobin levels, there were no significant differences observed in preoperative levels, but postoperative hemoglobin was significantly higher in the UAL group. Additionally, the UAL group experienced a lower drop in hemoglobin levels compared to the other group [Table 5].

Postoperative hematocrit did not significantly differ in preoperative levels, but was significantly higher in the UAL group. Similar to hemoglobin, the UAL group showed a lower drop in hematocrit levels and both groups experienced a significant decrease postoperatively [Table 6].

Variables	Measures	Group A [N=40]	Group B [N=40]	P-value
Number	Single	24 [60%]	28 [70%]	0.260
	Multiple	16 [40%]	12 [30%]	
Туре	Intramural	9 [22.5%]	13 [32.5%]	0.492
	Subserosal	20 [50.0%]	17 [42.5%]	
	Both	11 [27.5%]	10 [25.0%]	
Site	Anterior	16 [40.0%]	18 [45.0%]	0.244
	Posterior	14 [35.0%]	16 [40.0%]	
	Both	10 [25.0%]	6 [15.0%]	
Tumor size [cm ²]	Mean±SD	64.0±16.7	62.7±20.0	0.784
	Range	26.5-89.5	28.9-105.9	

Table [1]: Comparison between the studied groups regarding ultrasound findings

 Table [2]: Comparison between the studied groups regarding preoperative laboratory findings and vital data

Time	Measures	Group A [N=40]	Group B [N=40]	P-value [groups]	
Systolic blood pressure [mmHg]	Mean±SD	121.0±7.0	119.0±6.7	0.264	
	Range	105.0-130.0	110.0-130.0		
Diastolic blood pressure [mmHg]	Mean±SD	75.7±6.3	74.0±7.2	0.344	
	Range	60.0–90.0	60.0-80.0		
Mean blood pressure [mmHg]	Mean±SD	90.6±6.3	88.9±6.9	0.302	
	Range	74.9–103.2	76.5–96.5		
Heart rate [beat/minute]	Mean±SD	80.7±2.7	79.3±5.2	0.209	
	Range	75.0-85.0	70.0-85.0		
Temperature [°C]	Mean±SD	36.9±0.1	36.9±0.1	0.325	
	Range	36.8-37.0	36.8-37.0		
Hemoglobin [gm/dL]	Mean±SD	$11.8{\pm}1.0$	11.8±0.9	0.829	
	Range	10.2-14.7	10.5-13.8		
Hematocrit [%]	Mean±SD	36.0±2.1	36.1±2.3	0.753	
	Range	30.9-41.2	32.0-41.8		

Table [3]: Comparison between the studied groups regarding surgical operation findings

Variables	Measures	Group A [N=40]	Group B [N=40]	P-value
Uterine size [weeks]	Mean±SD	13.3±1.4	13.2±1.2	0.848
	Range	12.0-16.0	12.0–16.0	

Table [4]: Comparison between the studied groups regarding operation duration, blood loss and blood transfusion

		Group A [N=40]	Group B [N=40]	P-value	<u>Effect size</u> Mean±SE 95% CI
Operation duration	Mean±SD	53.0±6.9	47.5±4.7	0.001	-5.5±1.5
[minutes]	Range	45.0-60.0	45.0-60.0		-8.5-2.5
Blood loss [mL]	Mean±SD	440.0 ± 78.1	375.0±96.3	0.006	-65.0±22.6
	Range	300.0-600.0	200.0-600.0		-110.319.7
Blood transfusion	Needed	8 [20%]	2 [5%]	0.038	0.25
	Not needed	32 [80%]	38 [95%]		0.06-1.08

 Table [5]: Comparison between the studied groups regarding hemoglobin [gm/dL]

Time	Measures	Group A [N=40]	Group B [N=40]	P-value [groups]	<u>Effect size</u> Mean±SE 95% CI
Preoperative	Mean±SD	11.8±1.0	11.8±0.9	0.829	-0.1±0.2
	Range	10.2-14.7	10.5-13.8		-0.5–0.4
Postoperative	Mean±SD	10.1±0.9	10.6±1.0	0.033*	0.5±0.2
_	Range	8.6-12.8	9.2–12.4		0.0–1.0
Change	Mean±SD	-1.7±0.6	-1.1±0.5	<0.001*	0.6±0.1
[post-pre]	Range	-3.10.8	-2.00.1		0.3–0.9
P-value [Times]		<0.001*	<0.001*		

 Table [6]: Comparison between the studied groups regarding hematocrit [%]

Time	Measures	Group A [N=40]	Group B [N=40]	P-value [groups]	<u>Effect size</u> Mean±SE 95% CI
Preoperative	Mean±SD	36.0±2.1	36.1±2.3	0.753	0.2±0.6
	Range	30.9-41.2	32.0-41.8		-0.9–1.3
Postoperative	Mean±SD	32.2±2.4	33.7±2.6	0.033*	1.5±0.6
	Range	27.3-37.0	28.2-38.5		0.2–2.8
Change	Mean±SD	-3.7±1.4	-2.4±1.5	0.001*	1.3±0.4
[post-pre]	Range	-6.91.9	-6.20.3		0.6–2.1
P-value [Times]		<0.001*	<0.001*		

DISCUSSION

Available information on the comparison between uterine artery ligation and misoprostol for reducing blood loss during myomectomy is limited and inconclusive. However, there have been studies that examined the efficacy of vaginal misoprostol versus a placebo ^[12, 13], rectal misoprostol versus a placebo ^[14], single versus double dose of misoprostol ^[15], uterine artery ligation during abdominal myomectomy versus traditional myomectomy [without uterine artery ligation or occlusion] ^[16], as well as uterine artery ligation versus peri-cervical mechanical tourniquet

In the current study, the Uterine Artery Ligation group demonstrated significantly shorter operation durations and considerably reduced blood loss in comparison to the misoprostol group. In contrast to our results, **Abdel-Fattah** *et al.*^[17] conducted a prospective randomized controlled trial to compare the effectiveness of preoperative vaginal misoprostol and bilateral uterine artery ligation in reducing blood loss during trans-abdominal myomectomy. Their findings showed no significant difference between the two groups in terms of blood loss, operative time, and postoperative hospital stay.

The variation in results can be attributed to several factors. One possible explanation is differences in the methodology and sample size between the two studies. Moreover, variations in patient characteristics and the severity of myomas could also contribute to the disparity in results. Different patient populations with varying degrees of uterine fibroid burden may respond differently to interventions, which could explain why one study reported a significant reduction in blood loss with uterine artery ligation, whereas the other study did not find a notable difference. Further research is warranted to explore these discrepancies and provide a comprehensive understanding of the factors influencing blood loss during myomectomy. Larger sample sizes, standardized methodologies, and rigorous study designs can help elucidate the effectiveness of different interventions and minimize confounding factors, ultimately ensuring more accurate and reliable results.

Regarding the use of preoperative misoprostol to reduce blood loss associated with myomectomy, a recent meta-analysis, which included moderateand high-quality studies, demonstrated that the use of misoprostol during open myomectomy resulted in a significant decrease in blood loss without an increased risk of febrile complications. Furthermore, the analysis revealed that the misoprostol group experienced reduced blood transfusions and shorter operative times compared to the control group. Although the absolute reduction in blood loss and hemoglobin levels may appear modest [170 ml and 0.48 g/dl, respectively], the importance lies in the decreased need for blood transfusions among those who received misoprostol. These findings are relevant to all women with a BMI lower than 30 who are undergoing open myomectomy without comorbidities or a history of previous laparotomy^[18].

Meanwhile, there was a variation in the results when comparing misoprostol with other methods of reducing blood loss during open myomectomy.

Misoprostol has shown efficacy in reducing blood loss during myomectomy, particularly when compared to a placebo. Its effectiveness has been reported in cases involving excessive pelvic adhesions, leiomyoma located in the broad ligament, uterine isthmus, or cervix ^[14].

Ali *et al.* ^[19] revealed that peri-cervical mechanical tourniquet is more effective method in comparison with pre-operative vaginal misoprostol in shortening of operative time during trans-abdominal myomectomy. In addition, they revealed that peri-cervical mechanical tourniquet is more effective method in comparison with pre-operative vaginal misoprostol in reducing both intra-operative and post-operative blood loss with no needed blood transfusions. On the other hand, a larger randomized controlled trial [RCT] discovered that there was no significant disparity in blood loss when comparing misoprostol to mechanical artery

compression. The study involved 80 participants and compared the use of 400 μ g misoprostol to a peri-cervical tourniquet. The conclusion drawn from the study was that misoprostol and mechanical artery occlusion were equally effective in minimizing blood loss.

Mostafa-Gharabaghi *et al.* ^[20] conducted a randomized controlled trial [RCT] involving 70 participants. The study compared the effectiveness of using a 400- μ g dose of misoprostol versus a 30-unit oxytocin infusion during an open myomectomy procedure. The results showed that misoprostol was more effective in reducing blood loss, shortening the operative time, and decreasing the need for blood transfusion.

In a prospective comparative study conducted by **Shafqat** *et al.* ^[21], involving 50 women who underwent open myomectomy to remove a single intramural fibroid, it was discovered that administering 400 μ g of misoprostol 60 minutes before surgery significantly reduced blood loss by 171 ml compared to the use of intraoperative intravenous tranexamic acid. However, there was no significant difference observed regarding the requirement for blood transfusion.

Despite the current study showing that uterine artery ligation was more effective than preoperative misoprostol, the latter still has a number of advantages. These include its acceptable side effect profile, affordability, and easy accessibility. Therefore, it may be beneficial to consider routinely using misoprostol before surgery in women who do not have any contraindications ^[18].

Alternatively, there were several studies that reported efficacy of uterine artery tourniquet or ligation over other methods of reducing blood loss. In a meta-analysis of 25 studies involving 2.871 women, it was found that uterine artery ligation [UAL] during myomectomy had significant benefits. These included a notable decrease in estimated blood loss, reduced risk of blood transfusion, and less change in postoperative hemoglobin levels compared to control groups. These advantages were observed for both laparoscopic and open myomectomy procedures. UAL also resulted in a shorter hospital stay and lower risk of fibroid recurrence compared to controls. The only trade-off was a slightly longer surgical time, but there was no increased risk of complications associated with UAL^[22].

Mehdizadehkashi *et al.* ^[23] discovered that using a tourniquet resulted in a reduced surgical duration compared to the control group, regardless of the additional time needed for securing and removing the tourniquet. This observation implies that performing myomectomy without a tourniquet can lead to complications, particularly increased blood loss ^[24].

According to **Sanyal** *et al.* ^[24], the utilization of a tourniquet through Foley's catheter demonstrated effective results in minimizing bleeding during abdominal myomectomy.

On the other hand, **Fanny** *et al.* ^[25] conducted a study that contradicted these findings. According to their research, the utilization of a mechanical tourniquet led to increased blood loss when contrasted with alternative hemostatic methods like vasopressin. Specifically, they observed significantly greater intra-operative blood loss with the peri-cervical tourniquet. This could potentially be attributed to the presence of significant pelvic adhesions, the need for adhesiolysis and pelvic dissections, as well as the presence of leiomyoma in the broad ligament, uterine isthmus, or cervix.

physiology behind surgical UAL The involves reducing arterial pulse pressure and uterine perfusion. which helps promote hemostasis and decrease blood loss. The presence of extensive collateral circulation within the pelvis prevents uterine ischemia. One advantage of this procedure is its affordability and suitability for low-resource settings. Experienced surgeons can complete the procedure in 10 to 20 minutes. However, it is important to carefully consider the benefits of UAL in relation to its risks, which primarily depend on the surgeon's experience and technique. Inexperienced surgeons may take longer to perform the procedure and face a higher risk of injuring neighboring uterine veins or the ureter ^[22].

This study's notable strengths include its prospective study design, ensuring the collection of data over a specific period, and the absence of any patients lost to follow-up throughout the study. Moreover, it is the pioneering study to directly compare perioperative misoprostol with uterine artery ligation, a comparison that is infrequently explored in existing literature.

The limitations of the study include a small sample size, being a single center study and

limited generalizability as the study only include women with specific criteria.

In conclusion, in this comparative study, intraoperative cervical hemostatic uterine artery ligation demonstrated superior efficacy in reducing blood loss during myomectomy procedures compared to preoperative misoprostol administration. The results suggest that this technique could be a valuable approach for improving surgical outcomes, minimizing blood loss, and potentially reducing the need for blood transfusion in patients undergoing myomectomy. Further research and long-term follow-up studies are warranted to validate these findings and determine the clinical significance of this approach.

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