



Per-Cervical Uterine Artery Tourniquet Versus Rectal Misoprostol in Reducing Blood Loss During Abdominal Myomectomy: A Randomized Controlled Clinical Trial

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Received: 📅 December 20, 2019

Published: 📅 January 21, 2020

Abstract

Introduction: Uterine myomas are smooth muscle tumor and uterine connective tissues. Myomas occur in women of reproductive age who may represent menorrhagia, abdominal weight, effects of stress and infertility. Myomas symptoms may be affected by the tumor's size, number, and site. Myomectomy is known as a significant option for women with symptomatic leiomyomas and want potential pregnancy. Myomectomy is the removal of myoma(s) from the womb. Often intraoperative bleeding is often an issue in this procedure, suggesting blood transfusion in up to 20 percent of women and conversion to hysterectomy in 2 percent of women. Therefore, during abdominal myomectomy, several approaches are used to minimize blood loss. One of these is uterine artery interventions such as; peri cervical mechanical tourniquet, bilateral uterine ligation, embolization of the uterine artery, and hormonal tourniquets such as vasopressin. One of these methods is also uterotonic such as (misoprostol and oxytocin) and antifibrinolytic agents such as (tranexamic acid).

Objective: To compare the efficacy of peri cervical mechanical tourniquet with pre-operative rectal misoprostol in decreasing blood loss during abdominal myomectomy.

Materials and methods: Seventy-two women with symptomatic uterine leiomyomas and meeting the study inclusion criteria were scheduled to undergo abdominal myomectomy. Patients were randomly divided into two groups

Group A: Including 36 in which patients underwent peri cervical mechanical tourniquet in which an incision of about 1 cm was made in a clear space at the internal os bilaterally then a Foley's catheter was applied as tourniquet through the incisions.

Group B: Including 36 patients receiving 400 micrograms of rectal misoprostol 1 hour before the procedure.

Outcome measures: Primary outcome: Estimating blood loss intraoperation and blood transfusion need. There was a need for intraoperative blood transfusion when intraoperative blood loss exceeds 15 percent of the estimated blood volume of the patient, which is equal to the weight of the patient in (Kg) multiplied by 10. Secondary outcome: The need for myomectomy-to-hysterectomy transformation. Total operating time (measured from the beginning of the skin incision till closure. Difference between hemoglobin and hematocrit levels pre-and post-operative. (Measures for postoperative outcome: included. Venous blood samples of hemoglobin and hematocrit levels were taken from patients after 24 h to avoid false results due to hemodilution by intravenous fluids in the first 24 h). Hospital time (based on the well-being of the patient, lack of anemia, simple ambulation, bowel motility and clean wound.

Results: The difference in intraoperative blood loss between the two groups was 24.5 ml with more blood loss in the misoprostol band, yet there was no statistically significant difference in estimated intraoperative blood loss between the two groups. There was no statistically significant difference in the need for blood transfusion between 2 groups in this study, 48 patients (66.7%) had no complications, 8 patients (11.1%) needed post-operative blood transfusion and were all in the misoprostol group, and 16 patients (22.2%) had post-operative fever; while 12 patients were in the misoprostol group and 4 patients were in the uterine tourniquet group, there was no need for patients to convert from myomectomy to hysterectomy. between the two groups. There was a statistically significant difference in postoperative complications. There was no statistically significant difference in hospital stay and drain collection between the two groups.

Conclusion: Peri cervical mechanical tourniquet compared to preoperative rectal misoprostol is more effective in minimizing blood loss intraoperatively and postoperatively in addition to shortening operating time. However, the tourniquet may need additional professional surgical skills.

Keywords: Blood loss; Fibroid; Myomectomy; Uterine artery tourniquet; Rectal misoprostol

Introduction

Uterine fibroids are Benign smooth muscle hormone-sensitive tumors of the uterus and it is estimated to be 40% in women of child-bearing period and this percentage differ according to age. Fibroids in women of reproductive age are known to be the most common benign uterine tumors. It causes a wide variety of symptoms which include abnormal uterine bleeding, and dysmenorrhea along with micturition and defecation disorders. Submucosal and intramural fibroids that distort the endometrial cavity may impair fertility [1]. Treatment options for leiomyoma; usually, treatment approaches are individualized based on the: severity of the symptoms, the size and location of leiomyoma lesions, the age of the patient, their menopausal state, complications caused by excessive bleeding, lower abdominal pain and pressure on adjacent organs. The usual goal of therapy is the symptom relief. The treatment options range from the use of acupuncture (old Chinese method) to complete removal of the uterus and its contents of myoma (hysterectomy) [2]. The presence of leiomyomas in the uterus distorts normal vascular structure, which means that the arcuate arteries will travel in any direction, and not transversally. During myomectomy incision, whether vertical or transverse incisions, can transect these arteries and increase blood loss during the procedure [3]. There are many Interventions with uterine arteries such as: uterine embolization [4]. peri cervical mechanical tourniquet, vasopressin (natural or synthetic), bupivacaine vasoconstrictive solution plus epinephrine

and bilateral uterine ligation which can minimize blood loss during myomectomy [5]. One of the most effective procedures to minimize blood loss during abdominal myomectomy is the external occlusion of uterine blood supply by mechanical tourniquet [6]. Uterotonics: for example, oxytocin and misoprostol are used to minimize blood loss during myomectomy [7]. Pharmacological medication that manipulate coagulation cascade such as tranexamic acid and hemostatic sealant gelatin-thrombin are also used to minimize blood loss during myomectomy [8].

Patients & Methods

It was a Prospective randomized controlled interventional clinical trial the patients were recruited from the outpatient gynecology clinic at Zagazig University Hospital from March 2017 to November 2018. The study included 72 women with symptomatic leiomyomas, all of them underwent abdominal myomectomy.

The study population was divided into 2 groups whose means of intra- operative blood loss were compared.

Sample size calculation: the sample size was done according to data that was obtained from a previous related study [9]. 85 patients enrolled in this study 8 refused participation and 5 not came at the day of operation. The total sample of 72 subjects was calculated to achieve a statistical power of 80% at a 95% confidence interval. The total sample of 72 subjects was calculated to achieve a statistical power of 80% at a 95% confidence interval (Figure 1).

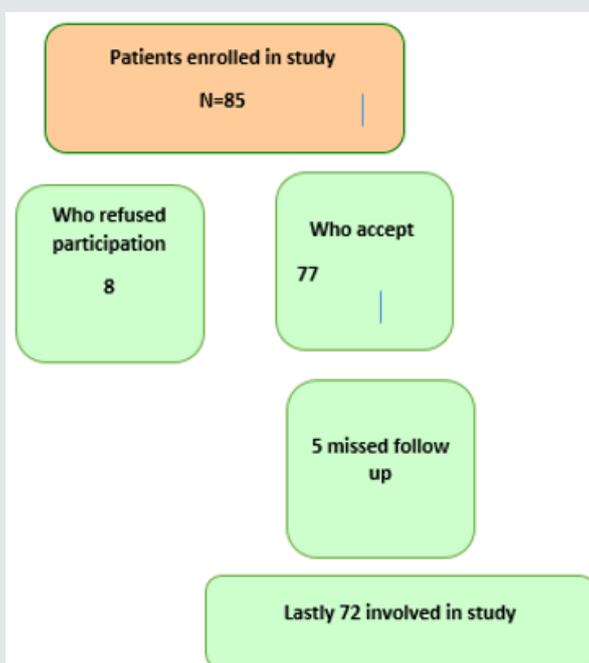


Figure 1: The total sample of 72 subjects was calculated to achieve a statistical power of 80% at a 95% confidence interval.

Inclusion criteria

A diagnosis of uterine leiomyoma and a decision for abdominal myomectomy.

Exclusion Criteria

- a) Patients with positive pregnancy test.
- b) Patient with previous myomectomy
- c) Patients who received pre-operative hormonal therapy such as a.
- d) Patients known to be allergic to misoprostol (prostaglandin preparations).

- e) Patients diagnosed as having cervical, paracervical, broad ligamentary and pedunculated leiomyomas.
- f) Patients presented by or with suspected malignant gynecological disease
- g) Any associated pelvic pathology other than uterine leiomyomas.

Randomization of patients

This study is a double blinded to ensure that every patient (who fulfilled the inclusion criteria) had the chance of participation. Researchers prepared the management protocol for each group and sealed one protocol per envelope with a computer-generated number assigned. Randomization was performed by picking the numbered study envelopes sequentially and managing the participant based on the enclosed protocol. Participants were identified with the randomization number until discharge from the hospital.

A total of 72 patients recruited to the study were randomly allocated into 2 groups:

- a) Group A: 36 cases underwent peri cervical uterine artery tourniquet.
- b) Group B: 36 cases received rectal 400 microgram of misoprostol.
- c) In group A: Peri cervical mechanical tourniquet:
- d) the broad ligament was palpated just above the level of the internal cervical os (to identify a space which is free of vessels and the ureter.
- e) An incision about 1 cm was made in this clear space bilaterally.
- f) A Foley's catheter size 18 was applied as tourniquet (or a latex-free tourniquet in a latex-allergic patient) through the incisions.
- g) The ends of the tourniquet were protruded anteriorly and pulled tightly and secured the ends with a clamp.
- h) The time of tourniquet administration was recorded, and it was released not later than 45 minutes after its application.
- i) For those requiring multiple applications, the tourniquet was reapplied after a period of at least 15 minutes.

In group B: Patients received 400 microgram Misoprostol (prostaglandin E2 analogue) 2 tablets of Misotac® (by SIGMA pharmaceutical industries, Alexandria, Egypt) were inserted in rectum, using a lubricant, 1 hour before the surgery [9]. And the patient was asked to stay in bed for 30min after insertion of the rectal misoprostol.

Ethical consideration

This research was done according to Helsinki declaration for research in human being, an informed written consent was taken from all participants before recruitment in the study, after

proper counseling and a very clear explanation of the purpose, possible risks and complications of different study procedures (e.g: possibility of blood transfusion and the possible need for hysterectomy).

History taking and Examination

Imaging: 2D Ultrasonography was carried out using abdominal and vaginal probe to confirm the exact size, site, and number of uterine myomas and to exclude any associated pelvic pathology.

Laboratory Investigations: For each patient, the following pre-operative investigations were done as a part of anesthetic workup:

- a. Venous blood sample for assessment of hemoglobin and hematocrit levels.
- b. Kidney functions.
- c. Liver functions.
- d. Coagulation profile (PT, PTT, INR).
- e. Viral markers (HBVs Ag and HCV antibody).

Intraoperative data collection

Anesthesia: The type of anesthesia either General or Regional and was decided by the Anesthesia team.

Surgical technique

Technique: Abdominal myomectomy.

- a) Pre-operative blood preparation: two units of blood were prepared for each patient.
- b) Pre-operative antibiotic: in the form of 2 grams of 3rd generation cephalosporin taken 30 to 60 minutes before skin incision.
- c) Positioning of the patient on the operative table followed by urinary catheterization (after anesthesia), surgical sterilization and taweling.
- d) The operations were performed by three experienced surgeons via the standard technique through transverse lower abdominal incision (P fannensteil incision) or midline vertical incision.
- e) Surgical techniques which reduce intra-operative blood loss were applied as much as possible.
- f) In group A mechanical tourniquet was applied as mentioned before.

Blood loss during the operation was calculated as following

- a) Surgical towels used in the operation were weighed (in grams) before the procedure.
- b) After the operation, the towels that were used in drying blood from the operative field were re-weighed using the same balance, and the difference in weight between dry and soaked

linen towels was calculated. (one-gram difference = one ml of blood)

- c) Blood collected in the suction bottle was measured at the end of the operation; the blood loss was equal to the difference between clean empty and full suction bottle container.
- d) Peritoneal irrigation with warm saline during or after the operation or the use of saline wet towels was avoided so as not to change in the weight of the used towels.
- e) Difference in weight of towels (in grams) (A). (weight of soaked towels – weight of dry towels).
- f) Difference between clean empty and full suction bottle containers (in grams) (B).

So; blood loss during operation = (A+B).

Outcome Measures

Primary outcome

It was about estimating the intra operative blood loss and the need for blood transfusion. The need for

intra-operative blood transfusion was indicated when intra-operative blood loss exceeds 15% of the

patient's estimated blood volume, that is equal to the patient's weight in (Kg) multiplied by 10 and [10].

Secondary outcome

Intra-operative or post- operative complications

i. The need for conversion from myomectomy to hysterectomy; It was indicated when there was uncontrolled intra-operative hemorrhage affecting the patient's vital signs and not responsive to conservative measures, or when it was impossible to reconstruct the uterus because of the many defects left by the removal of multiple myomas.

ii. Post-operative fever; temperature >38 °C within 24 hours after surgery.

iii. Total operative time was measured (in minutes) since the start of skin incision till the skin closure (included enucleation time of all fibroids, time of suturing of the defect of myoma bed and need for intraoperative hysterectomy if present)

Difference between pre and post- operative hemoglobin and hematocrit levels (Post-operative hemoglobin

and hematocrit levels were measured via a venous blood sample 24 hours after the operation).

Post-operative care

- a) All the patients received one ampoule of non-steroidal anti- inflammatory drugs immediately post-operative then one ampoule 12 hours post-operative.
- b) IV fluids and nothing by mouth till restoration of intestinal sounds.

c) Full observational chart including blood pressure, pulse, temperature, fluids, urine output and any case with temperature more than 38 C° measured orally, considered to have febrile morbidity.

d) Observation of any symptoms as regards excessive vomiting, rigors, colic and extra need of analgesics.

e) Recording any case having intraoperative or postoperative blood transfusion and mention the transfused units.

f) The Foley's catheter was removed once the patient starts to ambulate (usually during the first postoperative day).

g) The patient was discharged from hospital according to the decision of the surgeon (who performed the operation) based on resuming normal bowel function, easy ambulation, absence of fever, absence of anemia clinically and by measuring hemoglobin level and presence of clean and dry wound, and the period of hospitalization are recorded.

Elimination of bias

a) Laboratory samples were done in the same laboratory pre-operative and post-operative.

b) All the towels used in the operation were similar in material, and almost of same size and weight.

c) All suction bottles used in the operation were of the same trademark and their containers were equal in weight.

Statistical analysis

a) Data were analyzed using Statistical Program for Social Science (SPSS) version 25.0 for windows (SPSS Inc., Chicago, IL, USA).

b) Quantitative data were expressed as mean ± standard deviation (SD). Median and inter-quartile range (IQR) were also calculated for quantitative data. Qualitative data were expressed as frequency and percentage.

c) Probability (p-value): p-value <0.05 was considered significant (S), p-value <0.001 was considered as highly significant and p-value >0.05 was considered insignificant (NS).

Result

A. The present study included 72 women who attended the gynecology clinic, seeking for treatment of the symptomatic uterine leiomyomas. The participants were randomly categorized into two groups; group A (n=36) which represented the uterine artery tourniquet group and groupB (n=36) which represented the misoprostol group.

B. In the current study, The mean age of study population was 32.1 years ,with range (27–36), 18 patients (25%) (NG) didn't conceive before while 18 patients (25%) conceived once before and 36 patients (50%) conceived more than one before, 32 patients (44.4%) didn't been aborted before while 34patients (47.3%) aborted once before and 6 patients (8.3%)

aborted more than one and 58 patients (80.6%) didn't use COC as hormonal contraception and 14 patients (19.4%) were COC users. there was no statistically significant difference between

both groups regarding the patients' age, the use of COC as hormonal contraception, previous abortion and parity (Table 1).

Table 1: Comparison between the studied groups regarding the demographic and obstetric history.

Demographic and Obstetric History	Misoprostol	Uterine Tourniquet	Test	P-value (Sig.)
Count	36	36		
Age (years)				
Mean ± SD	33.4 ± 6.3	30.8 ± 5.8	1.329 *	0.193 (NS)
Parity				
Nulliparous	12 (33.3%)	6 (16.7%)	2.000 ‡	0.368 (NS)
P1	6 (16.7%)	12 (33.3%)		
More than P1	18 (50%)	18 (50%)		
Previous abortion				
Never	12(33.3%)	20 (55.6%)	1.863 ‡	0.394 (NS)
Once	20 (55.6%)	14 (38.8%)		
Twice or more	4 (11.1%)	2 (5.6%)		
COC as contraception				
No	30 (83.3%)	28 (77.8%)	‡F	1.000 (NS)
Yes	6 (16.7%)	8 (22.4%)		

C. In the present study, the most common presenting symptom among study population was heavy menstrual bleeding in [58]. patients (80%), yet there was no statistically significant difference between both groups regarding the main presenting symptoms. Regarding the myoma site, there

was significant difference between the both group there was no statistically significant difference between both groups regarding change in pre-operative HB and HCT level and post-operative HB and HCT (Tables 2 & 3).

Table 2: Comparison between the studied groups regarding the presenting symptoms.

Presenting symptoms	Misoprostol	Uterine tourniquet	Test	P-value(Sig.)
Count	36	36		
Symptom				
Heavy menstrual bleeding	26 (72.2%)	32 (88.6%)	‡F	0.402 (NS)
Abdominal pain	28 (77.8 %)	16 (44.4%)	4.208 ‡	0.060 (NS)
Infertility	18 (50%)	8 (22.2%)	3.010 ‡	0.083 (NS)
Pressure symptoms	8 (22.2%)	6 (16.7%)	‡F	1.000 (NS)

Table 3: Comparison between the studied groups regarding the pre-operative data.

Pre-Operative Data	Misoprostol	Uterine Tourniquet	Test	P-value (Sig.)
Count	36	36		
Hb (gm/dL)				
Mean ± SD	12.3 ± 1.2	11.9 ± 1.1	0.991*	0.329 (NS)
HCT (%)				
Mean ± SD	38.0 ± 5.2	36.2 ± 3.2	1.301*	0.202 (NS)

Table 4: Comparison between the studied groups regarding the operative data.

Operative Data	Misoprostol	Uterine Artery Tourniquet	Test	P-value (Sig.)
Count	36	36		
Myoma site				
Interstitial	16 (44.4%)	12 (33.3%)	10.286 ‡	0.016 (S)
Subserous	8 (22.2%)	0 (0%)		
Submucous	0 (0%)	12 (33.3%)		

Mixed	12(33.3%)	12 (33.3%)		
Myoma number	5-Feb	4-Feb	0.217	0.788(NS)
Operative time (min)				
Mean ± SD	98.1 ± 13.3	96.9 ± 12.5	0.258 *	0.798 (NS)
Intra-operative blood loss (ml)				
Mean ± SD	493.9 ± 125.2	469.4 ± 104.5	0.636 *	0.529 (NS)
Need for blood transfusion				
No	14 (38.9%)	18 (50%)	0.450 ‡	0.502 (NS)
Yes	22 (61.1%)	18 (50%)		
Operative data	Misoprostol	Uterine artery tourniquet	Test	P-value

D. In the present study the mean difference in the intraoperative blood loss between both groups was 24.5ml with more blood loss in misoprostol group, yet there was no statistically significant difference between both groups regarding estimated intraoperative blood loss. Forty patients needed blood transfusion (55.6%); 18 patients were in the uterine artery tourniquet and 22 patients were in misoprostol group, yet there was no statistically significant difference between both groups regarding the need for blood transfusion. the mean difference in operative time in both groups was 1.2 min with no statistically significant difference between both groups (Table 4).

E. In the current study 48 patients (66.7%) had no complications, 8 patients (11.1%) needed post-operative blood transfusion and were all in misoprostol group, and 16 patients (22.2%) had post-operative fever; whereas 12 patients were in misoprostol group and 4 patients were in uterine tourniquet group, no patients needed conversion from myomectomy to hysterectomy. There was statistically significant difference between both groups regarding postoperative complications. In the current study, there was no statistically significant difference between both groups regarding hospital stay and drain collection (Table 5).

Table 5: Comparison between the studied groups regarding the post-operative data.

Post-Operative data	Misoprostol	Uterine Tourniquet	Test	P-value (Sig.)
Count	36	36		
Hb (gm/dL)				
Mean ± SD	11.5 ± 1.0	11.6 ± 0.8	-0.388 *	0.701 (NS)
HCT (%)				
Mean ± SD	33.3 ± 2.9	34.9 ± 2.6	-1.777 *	0.085 (NS)
Post-operative complications				
No complication	16 (44.4%)	32 (88.9%)	8.667 ‡	0.013 (S)
Fever	12 (33.3%)	4 (11.1%)		
Blood transfusion	8 (22.2%)	0 (0%)		
In-hospital data	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	36	36		
Hospital stay (days)				
Median (IQR)	4 (2.75 - 4.25)	3 (2 - 4)	-0.291	0.323 (NS)
Drain (ml)				
Median (IQR)	150 (100 - 212.5)	150 (100 - 212.5)	-0.737	0.743 (NS)

F. As regard misoprostol side effect only one patient complaining of diarrhea and no other complication detected.

Discussion

I. The objective of this study was to compare the effect of uterine artery tourniquet (surgical techniques) with pre-operative rectal misoprostol (medical techniques) on their efficacy in minimizing blood loss during abdominal myomectomy.

II. The mean age of the study population in the current study was (32.1± 6.1) years, ranging (27-36). There was no statistical

significance. The present study coincides with the results of a study (Day Baird et al., 2003) that showed that the incidence of uterine leiomyomas at 35 years of age was 60 percent among African American women and Caucasian women at 35 years of age showed an incidence of 40 percent. Other studies reported the same findings. Patients in the current study (58) did not use combined oral contraceptives as hormonal contraception (80.6%) and 14 patients used COC as hormonal contraception (19.4%). There was no statistically significant difference in the use of hormonal contraception (COC) by the patient between the two types. In (Wise et al., 2004) research, the risk of leiomyoma

was not affected either by oral contraceptive ingredients, its hormonal strength nor duration of use [11-14].

III. 18 patients (NG) (25%) were nulliparous, 18 patients conceived once before (25%) and 36 patients (50%) conceived more than once in the present study. 32 patients (44.4%) had not previously aborted, 34 patients (47.3%) had previous abortions and 6 patients (8.3%) had more than one abortion. There was no statistically significant difference in the parity of the patient between the two groups.

IV. In the current study, 34 patients had interstitial uterine fibroid (38.9%), 8 patients had uterine subserous fibroid (11.1%) and 12 patients had submucous fibroid (16.7%) and 24 patients had mixed uterine fibroids (33.3%). There was a statistically significant difference in myoma site between both groups.

V. This result did not match the results documented by [15]. who reported (70%) intramural, (20%) submucous and (10%) submucous position frequencies, and this is in line with the present study.

VI. Certain findings were recorded in a study by Wallach and Vlahos (2004), who found that most fibroids are intramural (85.4%), followed by submucous (53.4%) and submucous (32%) [16]. Heavy menstrual bleeding in 58 patients (80.6 percent), abdominal pain in 44 patients (61.1 percent), pressure symptoms in 14 patients (19.4 percent) and primary or secondary infertility in 26 patients (36.1 percent) were the most common presenting symptoms in this study. There was no statistically significant difference in the main symptom between the two groups. The most common complaint of women with uterine leiomyoma in a study by Ragab et al. [3] was severe and persistent bleedings that suit the results of this study. In addition, diagnosed women more frequently reported spontaneous and irregular bleedings, often defined as repeated cycles that occur more frequently than every 24 days or bleedings between periods.

VII. Most women with uterine myomas are asymptomatic and remain largely undiagnosed in a study by Aamir et al. [17]. These results are not in agreement with the present study because the study excluded asymptomatic patients.

VIII. Nonetheless, in a study conducted by Ezeama et al. [18], abdominal mass was the primary symptom presenting (67 percent) of the study population, which is not consistent with the results of this study. This may be due to the research that took place in Nnewi, southeastern Nigeria, where traditional African patients presented late and more serious.

IX. The results of this study were to compare intraoperative blood loss in two classes, the need for intraoperative blood transfusion, the need for hysterectomy transfer, operating time (in minutes), intraoperative and postoperative Studies comparing the peri cervical mechanical tourniquet during abdominal myomectomy versus uterine artery ligation [4]. and peri cervical mechanical tourniquet versus perivascular

vasopressin plus rectal misoprostol to minimize blood loss during abdominal myomectomy [19]. and research comparing rectal misoprostol versus placebo [5]. vaginal misoprostol versus placebo [20] and single dose versus double dose of misoprostol [3]. The mean blood loss in the peri cervical mechanical tourniquet group was (469± 104.5ml) in the present study and was higher among participants with perioperative rectal misoprostol (493± 125.2ml). Although the two groups were not statistically significant.

X. In study of Alptekin & Efe [21] which had a comparison between the use of tourniquet and the use of no-tourniquet use and recorded significant reduction in blood loss in the tourniquet group (21). The estimated blood loss from the tourniquet group in the study of Ikechebelu et al. [22] was (515.7 ± 292.81ml) and this was higher than in the current study.

XI. The results of this study vary from studies conducted by Fletcher et al. [23] and Helal et al. [4] in which the use of mechanical tourniquet resulted in higher blood loss compared to other hemostatic techniques such as (vasopressin or The Tourniquet category increased significantly preliminary uterine ligation).

XII. Another study by EL Sharkawy et al. [19] in which (104) women with symptomatic uterine leiomyomas wishing to retain their uterus and needing surgical intervention, (52) patients randomly assigned to receive 400µg rectal misoprostol plus perivascular vasopressin in combination, and (52) patients assigned to peri cervical tourniquet [19]. Tourniquet group increased significantly in blood loss compared to rectal misoprostol plus perivascular vasopressin group (375.7± 292.3ml) vs. (254.1 ± 185.4ml) subsequently (P= 0.03) and disagreed with the current study. In a study 103 patients undergoing myomectomy were distributed randomly in which (51) patients underwent peri cervical mechanical tourniquet and (52) patients underwent preliminary uterine artery ligation. Intraoperative blood loss was significantly higher with peri cervical tourniquet compared to uterine artery ligation (823.23 ± 237.33mL) vs. (433.80 ± 285.21mL), (P 0.001) (4). This result agrees with other study of Cheng et al. [24] that have reported the benefit of uterine artery ligation in decreasing blood loss during myomectomy [24].

XIII. In a study undergoing abdominal myomectomy by Christos et al. [20], (284 patients), where 142 patients received 400 micrograms of misoprostol vaginally and the other 142 patients received a placebo tablet vaginally. The mean blood loss in the misoprostol group was (347.5ml), while it was (539.3ml) in the placebo group (20). Other studies reported similar findings [3,25].

XIV. Another study in which 67 women undergo laparoscopic myomectomy by (Kalogiannis et al. 2011). Patients received preoperative misoprostol and 33 patients received placebo tablets, with slightly lower total blood loss in the misoprostol group vs. placebo group (126± 41ml) vs. (217± 74ml). Because

of the laparoscopic approach of the procedure, the blood loss was much lower in both the study and control group than the current study [26].

XV. In this study, 40 patients needed blood transfusion (55.6%); the intraoperative blood transfusion rate was higher among participants who had 22 patients with preoperative rectal misoprostol (61.1%) compared to those who had 18 patients with peri cervical mechanical tourniquet (50%) 18 patients.

XVI. The intra-operation blood transfusion rate of (55.6%) in current study was higher than in previous study of (Celik H et al. [10] of (15.3%) and (24%) in Adel-Hafeez et al. [5,10].

XVII. There was no statistically significant difference in pre-operative and post-operative hemoglobin and hematocrit rates between the two groups in the present study.

XVIII. In the present study, the mean operating time in the group of mechanical peri cervical tourniquet was (96.9min) and in the group of misoprostol was (98.1min). So, there was no statistically significant difference between both groups regarding operative time. There was no statistically significant difference between the use of vaginal misoprostol and vaginal placebo tablet (20) in a report by Christos et al. [20].

XIX. In the present study, 48 had no complications (66.7%), 16 patients had postoperative fever (22.2%); 4 patients were in peri cervical tourniquet and 12 patients in misoprostol group. There was statistically significant difference between both groups regarding postoperative and fever.

XX. The current study disagrees with the findings of Abdel-Hafeez et al. [5] in which there was no significant difference between misoprostol group and placebo group with regard to postoperative febrile morbidity and other side effects of misoprostol (e.g. diarrhea, nausea and vomiting), this may be attributed to the use of daily paracetamol IV in the first 24h after surgery [5].

XXI. No patient had postoperative wound infection in the current study, no patients had urinary bladder injury, no patients had wide hematoma of the ligament, no patients needed hysterectomy conversion. There was no significant difference in postoperative complications between both groups.

Conclusion

In comparison with pre-operative rectal misoprostol, peri cervical mechanical tourniquet is a more effective method in reducing both intraoperative and postoperative blood loss and shortening operating time during abdominal myomectomy, but this requires skilled operating technique. Nonetheless, in reducing blood loss in abdominal myomectomy, a single pre-operative dose of 400 micrograms of rectal misoprostol is as active as peri cervical tourniquet. The choice between peri cervical tourniquet and preoperative rectal misoprostol is therefore left to the surgical preference and capabilities of the surgeon.

Strength and Limitations

The strength of the current study is the comparison of peri cervical mechanical tourniquet with a. preoperative rectal misoprostol (which is uncommon in the literature), randomized design, and objective blood loss measurement.

There were some limitations to the present study

- a) First, only one misoprostol route (rectal route) has been created.
- b) Second, the operating period in some patients was extended incorrectly due to the measurement from the beginning of the skin incision to the skin closure, which was not the actual operating time, since some patients with adhesions would need more time to enter the abdomen; the operating time should have been measured after entering the peritoneal cavity.
- c) Third, the range of variations in the number, size and site of leiomyoma should have been narrowed as the results of operating time and blood loss have been significantly affected.

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DOI: [10.32474/IGWHC.2020.04.000179](https://doi.org/10.32474/IGWHC.2020.04.000179)



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