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Uterine Artery Tourniquet Versus Vaginal Misoprostol to Decrease Blood Loss during Transabdominal Myomectomy

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ABSTRACT

Background: Uterine fibroids are tumor of the smooth muscles and the connective tissue of the uterus. They are considered to be the most common benign tumor of the pelvis. Conservative surgery remains the main approach for management of uterine myomas. Myomectomy is considered to be an important option for women who desire future childbearing or simply want to preserve their uterus.

Objective: The aim of the study was to compare between the effect of pericervical uterine artery tourniquet (surgical) and perioperative vaginal misoprostol (medical) regarding their efficacy to decrease blood loss during trans- abdominal myomectomy.

Methods: Prospective randomized controlled clinical trial. The study was approved by the Ethical Research Committee. The study was conducted in Obstetrics and Gynecology Department, Zagazig University Hospital. The study included 36 women with symptomatic myomas randomized into Group A included 18 patients who underwent uterine artery tourniquet and Group B included 18 patients who received single dose of 400 μg vaginal misoprostol one-hour before surgery.

Results: The present study showed that there was statistically significant difference between both groups regarding intra-operative blood loss, operative time, the need for blood transfusion and amount of fluid within the post-operative drain.

Conclusion: Pericervical mechanical tourniquet in comparison with pre-operative vaginal misoprostol is more effective method in; reducing both intra-operative and post-operative blood loss, and shortening of operative time during transa-bdominal myomectomy.

Keywords: Uterine Artery Tourniquet, Vaginal, Misoprostol, Blood Loss, Transabdominal Myomectomy.

INTRODUCTION

Uterine fibroids are hormone-sensitive tumors in smooth muscles. Serum tumors are the most common uterine tumors in women in the reproductive age group. There are associated symptoms; dysmenorrhea and menstrual bleeding leading to anemia, lower abdominal pain and pressure on neighboring organs. Submucosal and intramural fibroids, which distort the endometrial cavity are considered to impair fertility [(1)].

Treatment of fibroids should be individualized, and the associated symptoms may be an important factor in whether myoma is removed or not. Myomectomy still remains the gold standard for treatment for patients who wish to preserve their uterus and desire future pregnancy. The procedure can be accomplished by either laparoscopy or laparotomy [(2)].

Treatment options for myomas are typically individualized based on the severity of the symptoms, the size and location of the fibroid lesions, the patient's age, their chronological proximity to menopause and the patient's desire for future pregnancy. The usual goal of therapy is to relief the symptoms. The treatment options range from the use of ancient Chinese method (acupuncture) to hysterectomy (total removal of the uterus and its leiomyoma contents) [(3)].

The presence of fibroids in the uterus distorts normal vascular architecture. So, the arcuate arteries may change their axis, rather than transversely, so, either vertical or transverse incisions during myomectomy may transect these vessels and increase blood loss during the myomectomy [(4)].

Many interventions have been performed to decrease blood loss during myomectomy: Interventions on uterine arteries: as pericervical mechanical tourniquet (physical occlusion of the uterine blood supply by mechanical tourniquet is one of the most effective interventions to decrease blood loss during transabdominal myomecyomy [(5)], uterine artery embolization [(6,7)], bilateral uterine artery ligation, vasopressin (synthetic or natural), a vasoconstrictive solution of bupivacaine plus epinephrine, utero-tonics (such as oxytocin and misoprostol) [(9)] and antifibrinolytic agents such as tranexamic acid and gelatin-thrombin haemostatic sealant [(10)].

PATIENTS AND METHODS

I- Technical Design

Study Design:

The study was conducted in Zagazig University Hospital. The patients were recruited from the Outpatient Gynecology Clinic. The study included 36 women with symptomatic leiomyomas, all of them underwent transabdominal myomectomy.

Type of the study:

Prospective randomized controlled interventional clinical trial.

Sample Size:

The study population was allocated into 2 groups

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whose means of intra-operative blood loss were compared. The total sample of 36 subjects was calculated to achieve a statistical power of 80% at a 95% confidence interval.

Inclusion criteria:

- Age (20 – 40).
- A total number of ≤ five symptomatic uterine myomas, presented with either:
  - Abnormal uterine bleeding (menorrhagia and/or metrorrhagia).
  - Pressure symptoms (dyspareunia, dysuria, dyschazia and backache).
  - Pain (dysmenorrhea and dull aching lower abdominal pain).
  - Progressive enlargement of the abdomen.
- All fibroids were classified as subserous or intramural by ultrasound, whereas the maximum diameter of the largest fibroid was > 4 cm and < 10 cm.

Exclusion Criteria:

- Virgins.
- Patients who have positive pregnancy test.
- Patients who received pre-operative hormonal therapy as GnRH analogue.
- Patients who have allergic reaction to prostaglandin preparations (misoprostol).
- Patients diagnosed as having broad ligamentray, cervical, supracervical, and pedunculated fibroids.
- Patients presented with suspected malignant gynecological disease
- Any associated pelvic pathology other than uterine fibroids.

Randomization of patients:

This study is a double blinded to ensure that every patient (who fulfilled the inclusion criteria) had the chance of participation. A total of 36 patients recruited to the study were randomly divided into 2 groups:

- **Group A:** 18 cases underwent pericervical uterine artery tourniquet.
- **Group B:** 18 cases received vaginal 400 microgram of misoprostol.
- **In group A:** Pericervical mechanical tourniquet:

  - The broad ligament was palpated above the level of the internal cervical os (to identify a space, which is free of vessels and the ureter).
  - An incision about 1 cm was made bilaterally in this clear space.
  - A Foley's catheter was applied as tourniquet (or a latex-free tourniquet in a latex-allergic patient) through the incisions.
  - The ends of the tourniquet were protruded anteriorly and pulled tightly and secured the ends with a clamp.

In group B: patients received 400 microgram misoprostol (prostaglandin E2 analogue) (2 tablets of Misotac® in posterior vaginal fornix), using a lubricant 1 hour before the surgery and the patient was asked to stay in bed for 30 min after insertion of the vaginal misoprostol.

Before the surgery selective cases were subjected to the following:

All patients will be subjected to the following:

History taking , examination (general and local), imaging (trans-abdominal and trans-vaginal 2D ultrasonography and laboratory investigations (venous blood sample for the assessment of hemoglobin (Hb), hematocrit value, kidney functions (serum creatinine level), liver functions (ALT), coagulation profile (PT, PTT, INR) and viral markers; HBVs Ag and HCV antibody).

Intraoperative data collection:

Anaesthesia

- The type of anaesthesia either general or regional was decided by the anaesthesia team.

Surgical technique:

- Technique: Abdominal myomectomy.
- Pre-operative blood preparation: two units of blood were prepared for each patient.
- Pre-operative antibiotic: in the form of 2 grams of 3rd generation cephalosporin taken 30 to 60 minutes before skin incision.
- Positioning of the patient on the operative table followed by urinary catheterization (after anaesthesia), surgical sterilization and toweling.
- The operations were performed by three experienced surgeons via the standard technique through transverse lower abdominal incision (Pfannensteil incision) or midline vertical incision.
- Surgical techniques which reduce intra-operative blood loss were applied as much as possible.

  - In **group A** mechanical tourniquet was applied as mentioned before (pericervical tourniquet).

Blood loss during the operation was calculated as following:

- Surgical towels used in the operation were weighed (in grams) before the procedure.
- 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.
- 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.
- Avoiding peritoneal irrigation with warm saline during or after the operation to prevent changing in the weight of the used towels.
- Difference in weight of towels (in grams). **(A)** Weight of soaked towels – weight of dry towels.
- Difference between empty and full suction bottle containers **(B)**.

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

Ethical approval and written informed consent:

An approval of the study was obtained from Zagazig University Academic and Ethical committee. Every patient signed an informed written consent for acceptance of the operation 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).

Elimination of bias:

- Laboratory samples were done in the same laboratory pre operative and post operative.
- All the towels used in the operation were almost of same size and weight.

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples t-test of significance was used when comparing between two means.
- Chi-square (x^2) test of significance was used in order to compare proportions between two qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. The p-value was considered significant as the following:
- Probability (P-value)
- P-value <0.05 was considered significant.
- P-value <0.001 was considered as highly significant.
- P-value >0.05 was considered insignificant.

RESULTS

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	18	18		
Age (years)				
Mean ± SD	33.4 ± 6.3	30.8 ± 5.8	1.329 *	0.193 (NS)
Parity				
Nulliparous	6 (33.3%)	3 (16.7%)	2.000 ‡	0.368 (NS)
P1	3 (16.7%)	6 (33.3%)		
More than P1	9 (50%)	9 (50%)		
Previous abortion				
Never	6 (33.3%)	10 (55.6%)	1.863 ‡	0.394 (NS)
Once	10 (55.6%)	7 (38.8%)		
Twice or more	2 (11.1%)	1 (5.6%)		
COC as contraception				
No	15 (83.3%)	14 (77.8%)	‡F	1.000 (NS)
Yes	3 (16.7%)	4 (22.4%)		

* Independent samples Student's t-test.
‡ Chi-square test.
‡F Fisher's Exact test.
p < 0.05 is significant.
Sig.: significance.

Table (2): Comparison between the studied groups regarding the presenting symptoms

Presenting symptoms	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	18	18		
Symptom				
Heavy menstrual bleeding	13 (72.2%)	16 (88.6%)	‡F	0.402 (NS)
Abdominal pain	14 (77.8%)	10 (55.6%)	2.000 ‡	0.157 (NS)
Infertility	9 (50%)	4 (22.2%)	3.010 ‡	0.083 (NS)
Pressure symptoms	4 (22.2%)	3 (16.7%)	‡F	1.000 (NS)

‡ Chi-square test.
‡F Fisher's Exact test.
p < 0.05 is significant.

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

Pre-operative data	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	18	18		
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)

* Independent samples Student's t-test.
p < 0.05 is significant.

Table (4): Comparison between the studied groups regarding the operative data

Operative data	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	18	18		
Myoma character				
Single < 5 cm	10 (55.6%)	6 (33.3%)	2.091 ‡	0.352 (NS)
Single > 5 cm	5 (27.7%)	6 (33.3%)		
Multiple	3 (16.7%)	6 (33.3%)		
Operative time (min)				
Mean ± SD	98.1 ± 13.3	88.9 ± 10.8	2.271 *	0.030 (S)
Intra-operative blood loss (ml)				
Mean ± SD	493.9 ± 125.2	408.3 ± 94.3	2.315 *	0.027 (S)
Need for blood transfusion				
No	11 (61.1%)	17 (94.4%)	‡F	0.041 (S)
Yes	7 (38.9%)	1 (5.6%)		

* Independent samples Student's t-test.
‡ Chi-square test.
‡F Fisher's Exact test.
p < 0.05 is significant.
Sig.: significance.

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

Post-operative data	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	18	18		
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				
Fever	3 (16.7%)	1 (5.6%)	‡F	0.603 (NS)
Blood transfusion	4 (22.2%)	0 (0%)	8.667 ‡	0.013 (S)

* Independent samples Student's t-test.
‡F Fisher's Exact test. p < 0.05 is significant. Sig.: significance.

Table (6): Comparison between the studied groups regarding the in-hospital data.

In-hospital data	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	18	18		
Hospital stay (days)				
Mean ± SD	3.8 ± 0.1	3.3 ± 0.1	1.055 *	0.299 (NS)
Drain (ml)				
Mean ± SD	187.5 ± 81.5	129.4 ± 54.8	2.509 *	0.017 (S)

* Independent samples Student's t-test. p < 0.05 is significant. Sig.: significance.

DISCUSSION

The present study agrees with the results of a study carried out by **Day Baird *et al.*** [11] which showed that the incidence of fibroids by age of 35 years was 60% among African-American women and Caucasian women showed an incidence of 40% by the age of 35 years. The same results were reported in other studies [12]. The results of the current study agree with the study performed by **Wise *et al.*** [13] which showed absence of association between the use of COCs and risk of occurrence of myomas. Leiomyoma risk was neither affected by the ingredients of oral contraceptive, its hormonal strength nor duration of use.

Other studies disagree with the present study as **Qin *et al.*** [14] who concluded that the effect of oral contraceptives on risk of development of uterine leiomyoma was reduced by 17% in women who used COCs for 5 years or more. Similar results were reported by **Brenda *et al.*** [15]. Also another study was in contrast to the current study where **Marshall *et al.*** [16] included more than 3000 patients with myomas and found a positive correlation between the early use of COCs and the incidence of myomas, that doesn't match with the results of the current study. Moreover, **Okolo** [17]***;* Terry *et al.*** [18] **and Wise *et al.*** [13] disagree with the current study. They reported that increased parity decreases the incidence of clinically apparent fibroids.

In a study by **Ragab *et al.*** [4]**,** the most common complaint of the women with uterine leiomyoma was heavy and prolonged bleedings which matches the results of the present study. In a study by **Aamir *et al.*** [19], they reported that most women with uterine myomas are asymptomatic and mainly remain undiagnosed. These results disagree with the present study because asymptomatic patients were excluded from the study. However, in a study by **Ezeama *et al.*** [20] abdominal mass was the most presenting symptom representing 67% of the study population, which is not consistent with the results of the present study.

There are studies comparing the pericervical mechanical tourniquet during abdominal myomectomy versus uterine artery ligation and pericervical mechanical tourniquet versus perivascular vasopressin plus rectal misoprostol to reduce blood loss during abdominal myomectomy. Besides, there are other studies comparing use of rectal misoprostol versus placebo, vaginal misoprostil versus placebo and single dose versus double dose of misoprostol [4].

In the present study, the mean of intra-operative blood loss in the pericervical mechanical tourniquet group was 408.3 ± 94.3 ml and it was higher among participants who had perioperative vaginal misoprostol group (493 ± 125.2 ml). There was statistically significant difference between both groups regarding the intra-operative blood loss. The estimated blood loss from the tourniquet group in the study of **Ikechebelu *et al.*** [21] was 515.7 ± 292.81ml and this was higher than in the current study. The current study agrees with the studies by **Ikechebelu *et al.*** [21] **and Alptekin & Efe,** [22]**,** which reported that applying tourniquet by Foley's catheter had proved to be an effective technique for reducing bleeding at time of abdominal myomectomy. The results of the present study differ from studies by **Fletcher *et al.*** [23] in which the use of mechanical tourniquet produced higher blood loss when compared to other hemostatic techniques as (vasopressin or preliminary uterine artery ligation) in which the intra-operative blood loss was significantly higher with pericervical tourniquet compared to uterine artery ligation (823.23 ± 237.33 mL vs 433.80 ± 285.21 mL respectively)(P = 0.001) and this result agrees with other studies of **Holub *et al.*** [24]***;* Liu *et al.*** [25] **and Cheng *et al.*** [26] that have reported the benefit of uterine artery ligation in decreasing blood loss during myomectomy. Another study by **Kalogiannidis *et al.*** [27] in which 67 women underwent laparoscopic myomectomy. Patients received pre-operative misoprostol and 33 patients received placebo tablets, the average blood loss was significantly less with misoprostol group vs placebo group (126 ± 41 ml vs 217 ± 74 ml respectively). As the approach of the procedure was laparoscopic, the blood loss was lower in both the study and control group of **Kalogiannidis *et al.*** than in the current study.

The intra-operation blood transfusion rate in current study (22.2%) was lower than in previous study of **Adel-Hafeez *et al.*** [8] (24%), while there was no blood transfusion in other study [4].

In the current study the mean difference in operative time in both groups was 9.2 min with statistically significant difference between both groups. The present study disagrees with a study of **Iavazzo *et al.*** [9], in which there was no statistically significant difference according to operative time between the use of vaginal misoprostol and vaginal placebo tablet.

In the current study, there was no statistically significant difference between both groups according to hospital stay. This result matches with the study of **Abdel-Hafeez *et al.*** [8] where there was no statistically significant difference between the misoprostol group and the placebo group regarding postoperative hospital stay (3.33 ± 0.49 in both groups).

CONCLUSION

Pericervical mechanical tourniquet in comparison with pre-operative vaginal misoprostol is more effective method in; decreasing both intraoperative and postoperative blood loss and shortening of operative time during transabdominal myomectomy.

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